

**The OPTIMAL study: A randomized
controlled trial and process
evaluation of an occupational therapy
led self-management support
programme for people with
multimorbidity in primary care**

A thesis submitted to The University of Dublin,
Trinity College for the degree of Doctor of
Philosophy

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Medicine

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Declaration

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Author's contributions to the development and evaluation of the OPTIMAL programme

This section declares the author's contributions and specific roles in relation to the development and evaluation of the OPTIMAL programme in accordance to the phases of the Medical Research Council (MRC) Framework for the development and evaluation of complex interventions.

Phase 1: Development

- The author's (LOT) research supervisors (DC, SS, FB) were involved in developing and piloting occupational therapy complex interventions for those with multimorbidity.
- The first pilot study evaluated individual home-based occupational therapy assessment and intervention (Wallace, 2011). Based on this study's findings the development of a group-based occupational therapy intervention for those with multimorbidity was recommended
- The author as part of an MSc (by research) developed and piloted a group-based self-management support programme for those with multimorbidity in primary care. This programme was subsequently coined the OPTIMAL programme. In terms of development the author:
 - Conducted a detailed literature review to identify key intervention dimensions and components. This was also informed by the research supervisor's (SS) Cochrane review which was underway but not yet published at this time.
 - Consulted with the research supervisors (DC, SS) and other professionals including a pharmacist and physiotherapist.
 - Developed programme materials and session plans in collaboration with the research supervisors (DC, SS).

Phase II: Feasibility & piloting

- Following this developmental work, the author conducted a mixed methodology pilot study of the OPTIMAL programme (also part of the MSc by research). This study included a quasi-experimental pre-test-post-test design and focus groups with intervention participants. The author:
 - Developed and delivered the OPTIMAL programme as part of this study.
 - Collected and analysed quantitative and qualitative data.

- Published the findings of this study in a paper (O' Toole et al., 2013) and presented at national and international conferences.
 - Provided recommendations for future studies of the OPTIMAL programme
- Based on these recommendations, a pilot RCT of the OPTIMAL programme was undertaken as part of an MSc by research by Jess Garvey with the research supervisors (DC; SS; FB). While the author (LOT) was not involved directly in the pilot RCT, the study was informed by the authors' previous MSc research.
- Findings from the pilot RCT were published (Garvey et al., 2015). It was recommended to conduct an RCT and process evaluation of the OPTIMAL programme as per stage III of the MRC framework. This study is the focus of the author's PhD thesis.

Phase III: Evaluation

- The author in fulfilment of the PhD thesis:
 - Developed the study protocol as part of the grant application for this PhD
 - Applied for and obtained required ethical and HSE approvals for the study
 - Contacted and recruited health professionals to deliver and refer participants to this study
 - Collected, analysed and reported both quantitative and qualitative data for this study.

Summary

Background: People with multiple chronic conditions or multimorbidity, are particularly vulnerable with poorer health outcomes, higher health service utilisation and costs. Despite the negative impact of multimorbidity on individuals and the healthcare system a recent updated Cochrane review concluded that there was limited research on interventions for those with multimorbidity. The review concluded that interventions were more likely to be effective if they focused either on risk factors common across co-morbid conditions or on generic outcomes such as daily functioning (S. M. Smith, Wallace, O'Dowd, & Fortin, 2016). The provision of function-oriented interventions appear to be in line with preferences and priorities of those with multimorbidity. Occupational therapy has been proposed as a profession suited to delivering interventions for those with multimorbidity due to the profession's generic focus on functioning. Despite this there is a paucity of high quality occupational therapy interventions for those with multimorbidity.

The Medical Research Council's (MRC) Framework (2008) for complex interventions was used to develop and pilot "OPTIMAL" an occupational therapy led self-management programme for those with multimorbidity. The OPTIMAL programme is a six-week group based programme focusing on topics of concern to those with multimorbidity including fatigue management, maintaining mental well-being, physical activity, managing medication and communication strategies. Following on from previous developmental and pilot work, the overall aim of this PhD study was to evaluate the effectiveness of the OPTIMAL programme as per Stage III of the MRC framework (Medical Research Council, 2008).

Methods: The study was conducted in HSE primary care teams (PCT) in the Dublin Mid-Leinster region. The approach selected was a pragmatic parallel randomised controlled trial. Participants with multimorbidity were recruited from primary care settings. Primary outcome measures were the EQ-VAS (health related quality of life measure) and Frenchay Activities Index (activity participation). Participants were randomly allocated to the intervention group, to attend the OPTIMAL programme, or to the wait list control group, to receive care as usual. Follow-up data collection took place immediately post-intervention. Intention to treat and per protocol analyses using multi-level linear regression models were performed. A concurrent mixed methods process evaluation was also used to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice. Quantitative process evaluation data were collected using study team recruitment logs, baseline

participant questionnaires, therapist log/fidelity tool and programme attendance records. Qualitative data were collected using focus groups with intervention participants and semi-structured interviews with the occupational therapists and other health professionals who referred to and delivered the programme. Qualitative data were transcribed verbatim and analysed using thematic analysis.

Results: In total 149 participants were recruited across eight HSE primary care team areas. At follow-up, immediately post-intervention there was a significant improvement in health-related quality of life for the intervention group (Adjusted mean difference (MD) in EQ-VAS = 7.86; 95% CI=0.92 to 14.80) in comparison to controls. No significant differences were found between the two groups in frequency of activity participation. Sub-group analyses found a significant difference in favour of the intervention group for participants aged <65 in both health-related quality of life (Adjusted EQ-VAS MD = 13.46; 95% CI = 1.48 to 25.45) and frequency of activity participation (Adjusted MD = 5.00; 95% CI = 1.29 to 8.72). Sub-group analyses also found a significant difference for intervention participants with four or more chronic conditions in frequency of activity participation (Adjusted MD = 2.86; 95% CI = 0.31 to 5.41).

Process evaluation results highlighted significant difficulties with recruitment and wide variation in referral sources by site with some sites unable to deliver the programme. The group-based nature and goal-setting components of the programme were perceived as being important mechanisms of change. Barriers and facilitators to implementation included managerial and collegial support, low participant numbers, resources and caseload demands. Overall the intervention content and delivery was well received by participants and health professionals, who perceived that the intervention improved participants' activity levels, emotional well-being and self-management skills.

Conclusion: This study found that the OPTIMAL programme was effective in improving health related quality of life but not frequency of activity participation at immediate follow-up. The results of ongoing research (6-month follow-up) will be important in determining the sustainability of these clinical effects over time and on other secondary outcomes. The process evaluation highlighted that the intervention was acceptable to health professionals and participants but enablers and barriers to the routine implementation of the OPTIMAL programme in primary care settings were identified. The study's findings can be used to inform the next phase of the MRC framework, Phase IV i.e. implementation.

Acknowledgement

First and foremost, thank you to the participants who kindly agreed to take part in this study and for their valuable contribution. I am sincerely grateful to the health care professionals who worked with me on this study and put significant effort into this research in the hope that it will contribute to the evidence base and improve care for those with multiple morbidities within primary care.

I wish to express my deep gratitude to my supervisors Dr. Deirdre Connolly, Prof. Susan Smith and Dr. Fiona Boland for their guidance, excellent advice and kindness which they have provided me with since my Masters studies. I appreciate their continuous patience, encouragement and support which made completion of this thesis possible.

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List of Planned Publications

Papers

O' Toole, L., Boland, F., Connolly, D., & Smith, S.M. Effectiveness of an occupational therapy led self-management support programme for those with multimorbidity in primary care: A parallel randomised controlled trial (OPTIMAL study). [In preparation. Aim to submit to The BMJ by June 2019]

O' Toole, L., Smith, S.M., Boland, F., & Connolly, D. A process evaluation of an occupational therapy led self-management programme for people with multimorbidity in primary care: The OPTIMAL study. *Trials* [In preparation. Aim to be submitted to *Trials* by Sept 2019]

O' Toole, L., Smith, S.M., Boland, F., & Connolly, D. Evaluation of goal-setting in the OPTIMAL programme: A self-management support programme for those with multimorbidity in primary care *The British Journal of Occupational Therapy* [Planned. Aim to submit by Dec 2019]

O' Toole, L., Boland, F., Connolly, D., & Smith, S.M. Health care professionals experience of primary care team working in Ireland. *Primary Health Care Research & Development* [Planned. Aim to submit by Spring 2020]

Presentations

O' Toole, L., Smith, S.M., Boland, F., & Connolly, D. The OPTIMAL study: Examining the impact and implementation of an OccuPaTlional therapy led self MAnagement support programme for people with muLtimorbidity in primary care. AOTI Primary Care Advisory Group Study Day, Dr. Steeven's Hospital, June 6th 2019 [In preparation]

O' Toole, L., Smith, S.M., Boland, F., & Connolly, D. The OPTIMAL study. A randomized controlled trial and process evaluation of an OccuPaTlional therapy led self MAnagement support programme for people with muLtimorbidity in primary care. Dissemination Exchange Event, Trinity Centre for St. James's Hospital, Sept 2019 [Planned]

Table of Contents

Declaration	i
Author's contributions to the development and evaluation of the OPTIMAL programme	ii
Summary	iv
Acknowledgement	vi
List of Planned Publications	vii
Table of Contents	viii
List of Tables	xiv
List of Figures	xvii
List of Abbreviations	xviii
Chapter 1 Introduction	1
1.1 Introduction	2
1.2 Definition of terms	2
1.3 Background	3
1.4 Development and evaluation of the OPTIMAL programme: The MRC framework	7
1.4.1 Phase I and II: Development, feasibility and piloting of the OPTIMAL intervention	8
1.4.2 Phase III: Evaluation	10
1.5 Aims and objectives	10
1.6 Brief overview of the OPTIMAL programme and methodology	11
1.6.1 The OPTIMAL programme	11
1.6.2 Randomised controlled trial	12
1.6.3 Process Evaluation	13
1.7 Phase IV: Implementation	13
1.8 Thesis outline	14
Chapter 2 Literature Review	15
2.1 Introduction	16
2.2 Literature search	16
2.2.1 Information source and search strategy	16
2.2.2 Study selection	17
2.2.3 Data extraction and analysis	17
2.3 Multimorbidity	17
2.3.1 Definitions of multimorbidity	17

2.3.2	Prevalence of multimorbidity	19
2.3.3	Risk factors for multimorbidity	25
2.3.4	Impact of multimorbidity	28
2.3.5	Irish primary care policy and implementation.....	39
2.3.6	Recommended care delivery and management of multimorbidity in primary care	41
2.4	Evidence of effectiveness of interventions for multimorbidity	44
2.4.1	Chronic disease self-management interventions	48
2.4.2	Occupational therapy interventions for multimorbidity in primary care	57
2.4.3	Occupational therapy led self-management interventions for multimorbidity in primary care	59
2.5	Current practice of occupational therapists in primary care	61
2.6	Summary.....	63
Chapter 3	OPTIMAL randomised controlled trial study design	67
3.1	Introduction	68
3.2	Approaches to the development of complex interventions: The Medical Research Council Framework.....	68
3.3	Application of the MRC framework to the OPTIMAL intervention and study ..	70
3.3.1	Phase 1: Development of the OPTIMAL intervention	72
3.3.2	Phase 2: Feasibility and piloting	73
3.3.3	Theoretical underpinning of OPTIMAL: Self-efficacy theory	77
3.3.4	OPTIMAL programme development through feasibility and piloting	79
3.4	Phase 3: Pragmatic parallel randomised controlled trial	81
3.4.1	Study aim, objectives and hypothesis.....	81
3.4.2	Specific objectives.....	82
3.4.3	Justification for research design	82
3.5	The OPTIMAL programme	84
3.5.1	Group component	85
3.5.2	Facilitators.....	85
3.5.3	Programme duration and content.....	86
3.5.4	Individual goal-setting	89
3.5.5	Programme resources.....	91
3.6	Study population	92
3.7	Recruitment.....	93
3.7.1	Primary care occupational therapy teams engagement.....	93
3.7.2	Primary care clinicians engagement.....	93
3.7.3	General practitioners' engagement	94

3.7.4	Recruitment of participants.....	94
3.8	Allocation concealment and randomisation	95
3.9	Outcome measures.....	96
3.9.1	Demographic Questionnaire and Referral Form	97
3.9.2	Primary outcome measures.....	98
3.9.3	Secondary outcome measures.....	102
3.10	Sample size calculation.....	111
3.11	Data collection.....	112
3.12	Blinding	113
3.13	Data analysis.....	113
3.14	Ethical approval.....	116
3.14.1	Ethical considerations	117
3.15	Trial Governance Arrangements	118
3.16	Funding.....	118
3.17	Phase IV: Implementation	119
3.18	Conclusion	124
Chapter 4	Process evaluation methodology.....	125
4.1	Introduction	126
4.2	Process evaluation aims and objectives	126
4.3	Process evaluation.....	126
4.3.1	Process evaluation study design	127
4.3.2	Study population	129
4.3.3	Data collection methods	129
4.4	Intervention fidelity	132
4.4.1	Study and treatment design.....	133
4.4.2	Training.....	137
4.4.3	Treatment delivery	141
4.4.4	Treatment receipt	143
4.4.5	Enactment of treatment skills	143
4.5	Process evaluation: Qualitative component.....	145
4.5.1	Qualitative approach	145
4.5.2	Qualitative data collection	146
4.6	Process evaluation data analysis	151
4.6.1	Quantitative data analysis	151
4.6.2	Qualitative data analysis	151
4.6.3	Rigour of qualitative data.....	152
4.7	Conclusion	158

Chapter 5	Trial Results	159
5.1	Introduction	160
5.2	Recruitment, attrition and attendance	160
5.3	Participants' baseline demographic characteristics	163
5.3.1	Primary outcomes at baseline	163
5.3.2	Baseline profile of attenders and non-attenders	165
5.3.3	Baseline profile of responders and non-responders at study completion 166	
5.4	Secondary outcomes at baseline	168
5.4.1	Baseline Hospital Anxiety and Depression Scale scores	169
5.5	Immediate post-intervention results: Analyses of primary outcomes.....	170
5.5.1	Primary outcome: EQ-VAS.....	171
5.5.2	Primary outcome: FAI total score	178
5.5.3	Description of FAI subscale scores	181
5.6	Conclusion	182
Chapter 6	Process Evaluation	184
6.1	Introduction	185
6.2	Part one: Quantitative process evaluation results.....	186
6.2.1	Recruitment.....	186
6.2.2	Fidelity	193
6.2.3	Attendance (dose received)	195
6.3	Part two: Qualitative process evaluation results	198
6.3.1	Qualitative data sets.....	199
6.4	Themes related to implementation of the OPTIMAL programme	202
6.4.1	Perceptions of training and facilitator manual	202
6.4.2	Recruitment.....	205
6.4.3	Reasons for low referrals and uptake	205
6.4.4	Appropriateness of recruited participants	207
6.4.5	Recommended OPTIMAL recruitment strategies	209
6.4.6	OPTIMAL programme content and delivery.....	212
6.4.7	Perceptions of programme organisation	213
6.4.8	Perceptions of programme content	216
6.4.9	Useful programme resources	220
6.4.10	Intervention recommendations	223
6.5	Themes related to mechanisms of impact	227
6.5.1	Benefits of group-based interventions	228
6.5.2	Benefits of goal-setting.....	231

6.5.3	Challenges in goal-setting	234
6.6	Themes related to context	237
6.6.1	Enablers to implementation	237
6.6.2	Barriers to implementation	240
6.7	Themes related to outcomes	245
6.7.1	Programme benefits	245
6.7.2	No benefits	251
6.8	Summary of process evaluation results	251
Chapter 7	Discussion	254
7.1	Introduction	255
7.2	Summary of main findings	256
7.3	OPTIMAL RCT results in the context of the current evidence	258
7.3.1	Health related quality of life	259
7.3.2	Frequency of activity participation	265
7.4	Process evaluation results in the context of the current literature	267
7.4.1	Implementation	267
7.4.2	Mechanisms of impact	283
7.4.3	Enablers and barriers to implementation	287
7.5	Strengths and limitations	291
7.6	External validity	293
7.7	Assessment of RCT risk of bias	294
7.7.1	Selection bias	294
7.7.2	Performance bias	295
7.7.3	Detection bias	296
7.7.4	Attrition bias	296
7.7.5	Reporting bias	296
7.7.6	Other biases: Risk of contamination	297
7.7.7	Summary of risk of bias	298
7.8	Impact of findings	299
7.8.1	Research related impacts	299
7.8.2	Policy related impacts	300
7.8.3	Service related impacts	302
7.8.4	Societal related impacts	303
7.9	Phase IV: Implementation	303
7.10	Implementation of the OPTIMAL programme in primary care: Normalisation process theory	304
7.11	Recommendations for implementation	310

7.11.1	Recruitment and retention	310
7.11.2	Training.....	311
7.11.3	OPTIMAL programme elements.....	312
7.11.4	Recommendations for future research	313
7.11.5	Public and patient involvement (PPI).....	314
7.12	Conclusion	314
	References.....	316
	Appendix 1 Consort Guidelines for Parallel RCTs	347
	Appendix 2 Literature Review Search Strategies.....	350
	Appendix 3 OPTIMAL session plans	351
	Appendix 4 Goal Attainment Scaling Form	370
	Appendix 5 OPTIMAL Weekly goal-setting and review sheets	372
	Appendix 6 Original sample size calculation.....	374
	Appendix 7 Information Packs for GPs and Primary Care Professionals	375
	Appendix 8 OPTIMAL Referral form for GPs and Primary Care Professionals	378
	Appendix 9 OPTIMAL Poster	379
	Appendix 10 Participant Information Leaflet and Consent Form	380
	Appendix 11 Baseline Participant Questionnaires	383
	Appendix 12 Immediate Follow-Up Questionnaires	394
	Appendix 13 Ethical Approval Letter.....	397
	Appendix 14 Fidelity Tool	398
	Appendix 15 Participant Focus Group Topic Guide	410
	Appendix 16 Interview Guide Occupational Therapists.....	412
	Appendix 17 Interview Guide Physiotherapists.....	414
	Appendix 18 Interview Guide Pharmacists	415
	Appendix 19 Interview Guide GPs.....	416
	Appendix 20 Healthcare Professionals Invitation Letter, Information Leaflet and Consent Form for Interview	417
	Appendix 21 Case studies of cancelled and deferred primary care study areas	420

List of Tables

Table 2-1 International prevalence studies of multimorbidity	21
Table 2-2 International prevalence studies of multimorbidity (cont.)	22
Table 2-3 Prevalence studies of multimorbidity in Ireland	24
Table 2-4 Identification of interventions in Cochrane review for multimorbidity interventions according to EPOC.....	45
Table 2-5 Generic chronic disease self-management programmes	52
Table 2-6 Evidence of clinical and cost effectiveness of self-management interventions in HIQA HTA	55
Table 2-7 Summary of literature according to PICO	66
Table 3-1 Application of the MRC framework to the OPTIMAL study.....	71
Table 3-2 Overview of Phase I and Phase II of the MRC framework	76
Table 3-3 Sources of self-efficacy and application to OPTIMAL programme	78
Table 3-4 OPTIMAL intervention development	79
Table 3-5 OPTIMAL intervention development (cont.)	80
Table 3-6 Finalised OPTIMAL intervention	84
Table 3-7 Summary of trial outcome measures	97
Table 3-8 Interpretation of GAS T-Scores.....	110
Table 3-9 Interpreting results of ITT and PP analyses	116
Table 3-10 NPT constructs and sub-constructs: Coherence.....	120
Table 3-11 NPT constructs and sub-constructs: Cognitive participation	121
Table 3-12 NPT constructs and sub-constructs: Collective action	122
Table 3-13 NPT constructs and sub-constructs: Reflexive monitoring	123
Table 4-1 Process evaluation data collection methods in line with the MRC process evaluation functions.....	130
Table 4-2 Assessment of treatment fidelity and strategies: Study and treatment design (adapted from Borelli, 2011)	136
Table 4-3 Assessment of treatment fidelity and strategies: Training (adapted from Borelli, 2011).....	140
Table 4-4 Assessment of treatment fidelity and strategies: Treatment delivery (adapted from Borelli, 2011)	142
Table 4-5 Assessment of treatment fidelity and strategies: Treatment receipt and enactment (adapted from Borelli, 2011).....	144
Table 4-6 Methods to ensure rigour in qualitative research	153

Table 5-1 Participant baseline characteristics.....	164
Table 5-2 Baseline characteristics of attenders and non-attenders.....	165
Table 5-3 Baseline characteristics of responders and non-responders for primary outcomes	167
Table 5-4 Participant baseline secondary outcome measures	169
Table 5-5 Categorisation of baseline HADS scores	170
Table 5-6 Linear Regression Analyses of EQ-VAS (ITT and PP).....	173
Table 5-7 Analyses of EQ-5D-3L index score.....	175
Table 5-8 Descriptive analysis of EQ-5D index at baseline and immediate follow-up	177
Table 5-9 Linear Regression Analysis of FAI total (ITT and PP).....	180
Table 5-10 Frequency and percentage of participants in each group who improved, stayed the same or dis-improved for EQ-VAS and FAI Total	181
Table 5-11 Descriptive analysis of FAI subscales at baseline and immediate follow-up	181
Table 6-1 Programme delivery sites and timing	187
Table 6-2 Recruitment by PCTs and GP practices	189
Table 6-3 Participant numbers by referral sources	190
Table 6-4 Withdrawn and deferred areas	192
Table 6-5 Results self-report fidelity tool.....	194
Table 6-6 Number of sessions attended by area	196
Table 6-7 Weekly attendance by area	197
Table 6-8 Themes according to MRC process evaluation functions	198
Table 6-9 Profile of participant focus groups.....	199
Table 6-10 Profile of interview participants: Occupational therapist facilitators	200
Table 6-11 Profile of interview participants: Other health professionals	201
Table 6-12 Themes and sub-themes related to training and facilitator manual	202
Table 6-13 Themes and sub-themes related to participant recruitment	205
Table 6-14 Themes and sub-themes relevant to OPTIMAL programme content and delivery.....	212
Table 6-15 Themes and sub-themes related to mechanisms of impact	227
Table 6-16 Themes and sub-themes related to context.....	237
Table 6-17 Themes and sub-themes related to programme outcomes	245
Table 7-1 Comparison of EQ-5D index scores with recent intervention trials.....	264
Table 7-2 Assessment of risk of bias in the OPTIMAL RCT.....	298
Table 7-3 Research Impact Framework.....	299
Table 7-4 Findings according to NPT framework: Coherence.....	306
Table 7-5 Findings according to NPT framework: Cognitive participation	307

Table 7-6 NPT constructs and sub-constructs: Collective action	308
Table 7-7 NPT constructs and sub-constructs: Reflexive monitoring	309

List of Figures

Figure 1-1 MRC framework for development and evaluation of complex interventions and application to the OPTIMAL study (adapted from MRC, 2008)	7
Figure 3-1 MRC framework for development and evaluation of complex interventions (adapted from MRC, 2008).....	70
Figure 4-1 Key functions of process evaluation and relations among them according to the MRC framework on process evaluations (adapted from Moore et al., 2014).....	128
Figure 5-1 Consort flow diagram	162
Figure 6-1 OPTIMAL process evaluation findings (adapted from Moore et al., 2014)	253

List of Abbreviations

ADLs	Activities of Daily Living
AOTI	Association of Occupational Therapists of Ireland
BADLS	Basic Activities of Daily Living
BDI	Beck Depression Inventory
CARDI	Centre for Ageing Research and Development in Ireland
CCM	Chronic Care Model
CCM	Chronic Care Model
CDSMP	Stanford Chronic Disease Self-Management Programme
CHO	Community Healthcare Organisation
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CIRS	Cumulative Illness Rating Scale
CONSORT	Consolidated Standards of Reporting Trials
COPD	Chronic Obstructive Pulmonary Disease
COPM	Canadian Occupational Performance Measure
COPM-P	Canadian Occupational Performance Measure: Performance
COPM-S	Canadian Occupational Performance Measure: Satisfaction
CSO	Central Statistics Office
DC	Dr. Deirdre Connolly (Research Supervisor)
DSN	Diabetic Specialist Nurse
DT	Dietician
EBSCO	Elton B. Stephens CO (company) database
EMA	European Medicines Agency
EMBASE	Excerpta Medica dataBASE
EPP	Expert Patient Programme
EQ-5D-3L	The European Quality of Life 3 Level measure
EQ-5D-5L	The European Quality of Life 5 Level measure
EQ-VAS	The European Quality of Life Visual Analogue Scale
FAI	Frenchay Activity Index
FB	Dr. Fiona Boland (Research Supervisor)
GAS	Goal Attainment Scaling
GMS	General Medical Services
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale

HADS-A	Hospital Anxiety and Depression Scale- Anxiety Subscale
HADS-D	Hospital Anxiety and Depression Scale- Depression Subscale
HBA1c	Haemoglobin A1c
HCP	Health Care Professional
HCU	Health Care Utilisation
HeiQ	The Health Education Impact Questionnaire
HIQA	Health Information and Quality Authority
HRQoL	Health Related Quality of Life
HSE	Health Service Executive
HTA	Health Technology Assessment
IADLS	Instrumental Activities of Daily Living
ICARE4EU	Innovating Care for People with Multiple Chronic Conditions in Europe
ICC	Intraclass Correlation Coefficient
ICD-9	9th revision of the International Statistical Classification of Diseases and Related Health Problems
ICP	Integrated Care Programmes
IQR	Interquartile Range
ITT	Intention To Treat
MCID	Minimally Clinically Important Difference
MD	Mean Difference
MECC	Making Every Contact Count
MeSH	Medical Subject Heading
MRC	Medical Research Council
NCP	National Clinical Programme
NEADL	Nottingham Extended Activities of Daily Living
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NPT	Normalisation Process Theory
OPTIMAL	OccuPaTlional therapy led self-MAnagement support programme for people with muLtimorbidity
OT	Occupational Therapy
PCC	Primary Care Centre
PCRS	Primary Care Reimbursement Scheme
PCT	Primary Care Team
PHARM	Pharmacist
PHN	Public Health Nurse

PHQ-9	Patient Health Questionnaire
PIL	Participant Information Leaflet
PN	Practice Nurse
PP	Per Protocol
PRISMS	Practical Reviews of Self-Management Support
PT	Physiotherapist
PubMed	MEDLINE database
QoL	Quality of Life
RCT	Randomised Controlled Trial
SCT	Social Cognitive Theory
SD	Standard Deviation
SEMCD	Stanford Chronic Disease Self-Efficacy 6-item Scale;
SES	Socio-Economic Status
SLT	Speech and Language Therapist
SMART	Specific, Measurable, Achievable, Realistic, Timed
SR	Self-referral
SS	Prof. Susan Smith (Research Supervisor)
TEDSS	Taxonomy of Everyday Self-management Strategies
TILDA	The Irish Longitudinal study on Ageing
WHO	World Health Organisation

Chapter 1 Introduction

1.1 Introduction

This thesis presents the findings of a parallel randomised controlled trial (RCT) of the OPTIMAL programme, an occupational therapy led self-management support programme for individuals with multimorbidity in primary care, as per Stage III of the Medical Research Council (MRC) framework (Medical Research Council, 2008). A process evaluation was also conducted to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice. The MRC framework for the development and evaluation of complex interventions was used to guide the development and evaluation of the OPTIMAL programme (Medical Research Council, 2008). This framework was used in previous studies to develop and pilot the intervention and to direct the current study which is a definitive trial and process evaluation of the OPTIMAL programme. This chapter begins by outlining the need and evidence for multimorbidity interventions. The findings of the previous development and pilot studies which led to this RCT and process evaluation are also discussed. The aims and objectives of the research are then presented. Following this, a brief overview of the OPTIMAL programme will be described, including self-efficacy theory which underpins the intervention, the programme content and structure. Additionally, a very brief overview of the methodology employed to address these aims and objectives is summarised, and finally the chapter concludes with an outline of the thesis structure.

1.2 Definition of terms

Multimorbidity is the co-existence of two or more chronic conditions in the same individual (S. M. Smith et al., 2016; Xu, Mishra, & Jones, 2017). For the purposes of this study this definition was used as it is most common, easily understood and reflective of the generalist approach of primary care. The World Health Organisation definition of chronic diseases is health problems which require ongoing management over a period of years or decades (World Health Organisation, 2002). Participants were also required to be on four or more repeat medications to ensure targeting of those with well-established multimorbidity. Participants were also required to be aged 40 years or over, this criterion was selected as multimorbidity is relatively uncommon in individuals younger than this and it facilitated targeted recruitment.

Self-management is generally described as a holistic intervention, aimed at maximising physical and psychosocial functioning by providing individuals with skills to manage symptoms, treatments and the psychosocial consequences of living with a chronic condition (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002; Davies, 2010; Richard & Shea, 2011; Schulman-Green et al., 2012).

Occupational therapy is a client-centred health profession focused on promoting health and well-being through occupation (World Federation of Occupational Therapists, 2010). Occupations are purposeful and meaningful daily activities to occupy time and are typically classified as self-care, productive or leisure (Reitz & Scaffa, 2013). Occupational therapists promote health and well-being by working with people and communities to enhance their ability to participate in valued occupations and/or by modifying the occupation or the environment to better support their occupational engagement (World Federation of Occupational Therapists, 2010).

Health related quality of life (HRQoL) is a subjective concept encompassing multifaceted dimensions of physical, emotional and social functioning (Fortin, Dubois, Hudon, Soubhi, & Almirall, 2007; Fortin et al., 2004).

Activity participation refers to an individual's involvement or engagement in self-care, productive or leisure activities that are desired and/or necessary to one's health and well-being (Kielhofner, 2008; Law, 2002). The presence of disability or functional decline leads to participation that is less diverse, is located more in the home, involves fewer social relationships, and includes less active recreation (Law, 2002).

Self-efficacy is described as an individual's belief in their ability to execute necessary actions in response to specific situations (Bandura, 1986b, 2004). Self-efficacy theory is one theory which underlies some self-management interventions and has been suggested to influence occupational performance and self-management behaviours (Gage & Polatajko, 1994; Lorig & Holman, 2003).

1.3 Background

Multimorbidity can be defined as the co-existence of two or more chronic conditions in the same individual (S. M. Smith et al., 2016; Xu et al., 2017). It is clear from international and national research that multimorbidity is increasing and represents the norm in

primary care practice (Fortin, Stewart, Poitras, Almirall, & Maddocks, 2012). A recent study of prevalence within Irish primary care practices suggested that 66.2% of patients aged over 50 years of age have multimorbidity (Glynn et al., 2011). It is likely that the prevalence of multimorbidity will continue to increase due to the ageing population and increased life expectancy worldwide. It is worthwhile noting that while multimorbidity has been seen as a problem predominantly effecting older people, in absolute terms there are more middle-aged adults living with multimorbidity (Barnett et al., 2012; Fortin et al., 2012).

Multimorbidity is associated with increased health care utilisation and cost, increased numbers of medications and increased risk of death (Marengoni et al., 2011). Multimorbidity is associated with poor physical functioning, psychological well-being and quality of life (QoL) (Kanesarajah, Waller, Whitty, & Mishra, 2018; Marengoni et al., 2011; Aine Ryan, Wallace, O'Hara, & Smith, 2015; Vancampfort, Koyanagi, Hallgren, Probst, & Stubbs, 2017). Those with multimorbidity highlight difficulty with functioning including maintaining social roles, work and leisure activities, a positive identity, well-being, relationships and managing medications (Lindsay, 2009; Noel, Frueh, Larme, & Pugh, 2005). Furthermore, those with multimorbidity have identified priorities in maintaining function in order to be able to participate in valued activities and roles (Bratzke et al., 2015; Cheraghi-Sohi et al., 2013). Noel et al. (2005) found that those with multimorbidity are more concerned with functioning and the impact of their conditions on daily routines rather than symptoms per se.

There is a growing recognition of the impact of multimorbidity on individuals and health care systems and the importance of improving outcomes for individuals affected and the healthcare system alike (National Institute for Clinical Excellence, 2016; S. M. Smith et al., 2016). Despite the documented impact of multimorbidity, chronic disease care continues to emphasise management of chronic conditions based on single disease management, which is unsuited to those with multimorbidity (National Institute for Clinical Excellence, 2016; World Health Organisation, 2016). Poor integration between primary and secondary care services means that patients with multimorbidity are overwhelmed and over-burdened not just by multimorbidity but an increased burden of treatment, involving management, monitoring, appointments, and passing information between multiple healthcare providers (May, Montori, & Mair, 2009). General Practitioners (GPs) describe feeling overwhelmed by the range of problems that need to be addressed and challenges regarding care coordination, prioritization of patient's needs and medicines management of patients with multimorbidity (Sinnott, Mc Hugh, Browne, & Bradley,

2013). At present, no health policy has been developed in Ireland specifically addressing management of those with multimorbidity. Despite this, there is recognition that primary care is the optimal place in which to address multimorbidity and primary care teams (PCTs) are ideally placed to provide and coordinate care for people with multimorbidity who require multidisciplinary support for complex physical and psychosocial problems (Health Service Executive, 2017; Smyth et al., 2017). It is therefore imperative that health policy and systems be designed to provide for effective prevention and management of multimorbidity.

A recent updated Cochrane review concluded that there was limited research to date on interventions for those with multimorbidity (S. M. Smith et al., 2016). In existing studies, there was a tendency to focus on co-morbid conditions or multimorbidity in older patients. The review highlighted many challenges in multimorbidity research including identifying patients within the broad multimorbidity spectrum at increased risk of poor health outcomes and the targeting of interventions. The review concluded that interventions were more likely to be effective if they focused either on risk factors common across co-morbid conditions or on generic outcomes such as daily functioning (S. M. Smith et al., 2016). The provision of function-oriented interventions appear to be in line with preferences and priorities of those with multimorbidity (Bratzke et al., 2015; Cheraghi-Sohi et al., 2013; Noel et al., 2005).

Self-management interventions for chronic disease have become one of the most commonly researched interventions for chronic disease management in primary care (Reynolds et al., 2018). Self-management is a term attached to many patient education programmes (Lorig & Holman, 2003). Self-management has been described as the actions taken by individuals to lead a healthy lifestyle, meet their needs and care for one or more chronic conditions by managing the role, emotional and medical aspects of their conditions (Health Service Executive, 2017; Lorig & Holman, 2003). Self-management interventions are generally described as a holistic intervention, aimed at maximising physical and psychosocial functioning by providing individuals with skills to manage symptoms, treatments and the psychosocial consequences of living with a chronic condition (Barlow et al., 2002; Davies, 2010; Richard & Shea, 2011; Schulman-Green et al., 2012). Many self-management programmes are targeted towards single and common chronic conditions. Of the eighteen studies included in the Cochrane review of multimorbidity interventions, there were two studies of group-based self-management support interventions specifically targeting those with multimorbidity in primary care (S. M. Smith et al., 2016). Previous studies of self-management interventions have not

reported outcomes for those with multimorbidity or reported sub-group analysis only (Health Information and Quality Authority, 2015; S. M. Smith et al., 2016). This is despite the fact that many participants attending both generic and disease-specific self-management interventions are likely to have multimorbidity (Health Information and Quality Authority, 2015). Currently there is insufficient evidence to recommend self-management programmes for those with multimorbidity. Furthermore, despite self-management interventions aiming to improve role and emotional management, studies tend to focus on outcomes pertaining to medical management rather than outcomes associated with function and participation which are priorities for those with multimorbidity (Augustine, Roberts, & Packer, 2011; S. M. Smith et al., 2016). In Ireland there has been a growing recognition of the need to provide self-management support to individuals with chronic diseases, with the HSE recently publishing the “National Framework and Implementation Plan for Self-management Support for Chronic Conditions: Chronic Obstructive Pulmonary Disease (COPD), Asthma, Diabetes and Cardiovascular Disease” (Health Service Executive, 2017).

Occupational therapy has been proposed as a profession suited to provide interventions for individuals with multimorbidity. Occupational therapy focuses on identifying barriers to activity engagement due to physical and mental health difficulties, using either individual or group-based interventions to remediate or compensate for these barriers (American Association of Occupational Therapy, 2014). The potential role of occupational therapy in self-management programmes, for a wide range of chronic conditions including those with multimorbidity, is being considered internationally with a recommendation for increased attention to occupational participation and quality of life measures in programme evaluations (Hand, Law, & McColl, 2011; Hand, Letts, & von Zweck, 2011; Leland, Fogelberg, Halle, & Mroz, 2017; Packer, 2011, 2013). Occupational therapy may be suited to enabling individuals with multimorbidity incorporate chronic disease management strategies into daily routines and occupational engagement to maintain function (Hand, Letts, et al., 2011; Leland et al., 2017; Mercer, Smith, Wyke, O'Dowd, & Watt, 2009). However it remains that the role of occupational therapy in relation to chronic disease and multimorbidity is poorly defined and researched (Hand, Law, et al., 2011; Hand, Letts, et al., 2011; Leland et al., 2017). In Ireland primary care based OTs have tended to provide home-based interventions mainly with vulnerable elderly patients in need of assistive devices and home adaptations (Flannery & Barry, 2003; Tinnelly & Byrne, 2016).

Based on the gaps identified in the literature an occupational therapy led group-based self-management support intervention for those with multimorbidity in primary care, named OPTIMAL, was developed and evaluated using the MRC framework for development and evaluation of complex interventions (Garvey, Connolly, Boland, & Smith, 2015; O' Toole, Connolly, & Smith, 2013). The following section describes the previous development and pilot studies which led to the current study i.e. an RCT and process evaluation of the OPTIMAL programme.

1.4 Development and evaluation of the OPTIMAL programme: The MRC framework

The UK Medical Research Council (MRC) Framework for the design and evaluation of complex multi-component interventions was used to develop and evaluate the feasibility of the intervention (Medical Research Council, 2008). The application of the MRC framework to the OPTIMAL programme is presented briefly in the Section 1.4.1.

Figure 1.1 summarises the framework's stages and the key elements and activities at each stage. The arrows indicate the main interactions between the phases. It is important to note that the stages do not necessarily follow a linear or cyclical sequence. Reporting is viewed as an important element at each stage in the process.

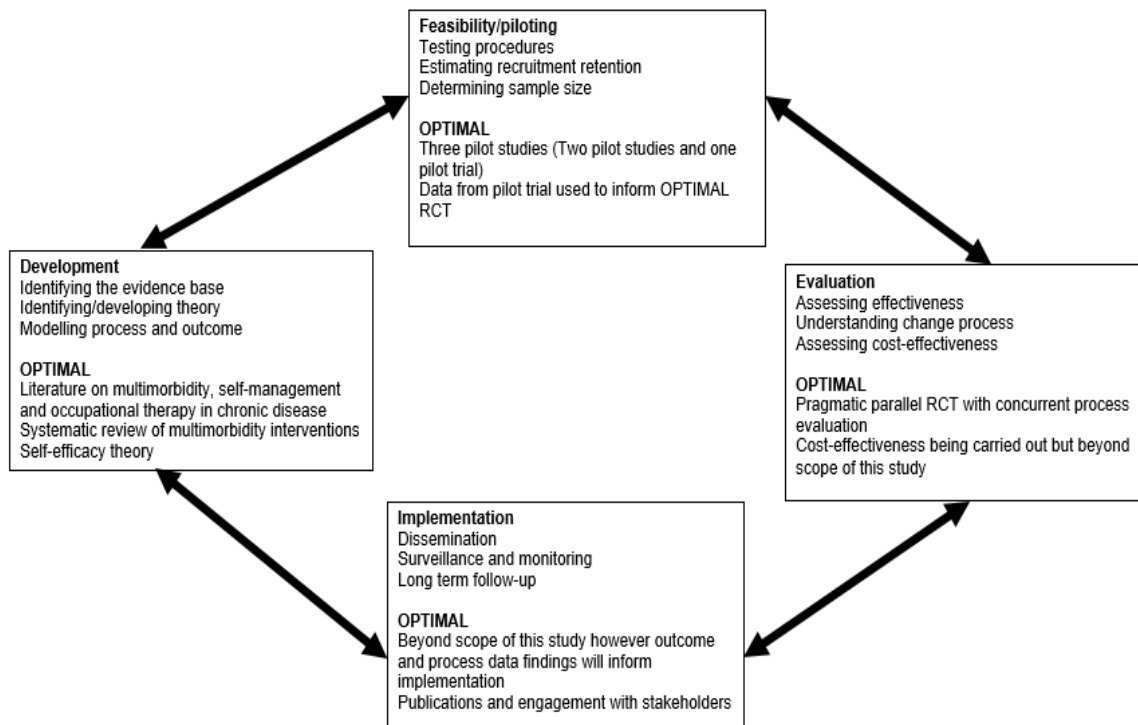


Figure 1-1 MRC framework for development and evaluation of complex interventions and application to the OPTIMAL study (adapted from MRC, 2008)

1.4.1 Phase I and II: Development, feasibility and piloting of the OPTIMAL intervention

The MRC Framework was used to develop the intervention. An extensive literature review and findings from the Cochrane review of interventions for those with multimorbidity in primary care informed intervention development. After two initial pilot studies, the intervention was refined to a six-week occupational therapy led self-management programme, OPTIMAL, specifically designed to target individuals with multimorbidity. This intervention was underpinned by self-efficacy theory. This intervention was then further tested in an exploratory RCT. Since the publication of the exploratory RCT (Garvey et al., 2015) a framework for defining pilot and feasibility studies has been developed (Eldridge et al., 2016). According to this framework the exploratory RCT would be categorised as a pilot RCT. Feasibility and pilot studies are not mutually exclusive with pilot studies being considered a subset of feasibility studies. A feasibility study considers whether something can be done, if it should be proceeded with and how to proceed. A pilot study, while considering the same questions as feasibility studies, includes a specific design feature whereby a future study, or part of a future study, is conducted on a smaller scale (Eldridge et al., 2016). The exploratory trial will be described as a pilot RCT in this thesis.

The previous piloting work which led to this study, the definitive trial of the OPTIMAL programme, is summarised below and described in further detail in Chapter 3, Section 3.3.

1.4.1.1 Study One: Wallace (2011)

The first study used a quasi-experimental pre-test post-test design to explore the feasibility of individual home-based occupational therapy assessment and intervention for community dwelling adults with multimorbidity (Wallace, Connolly, & Smith, 2011). GPs in two practices identified eligible patients, i.e. those with a chronic respiratory diagnosis and with two or more co-occurring conditions, from practice registers and invited patients based on their clinical knowledge of who may benefit from occupational therapy intervention. A home-based occupational therapy assessment was conducted with identified patients who agreed to participate (n=18) and based on this assessment eight patients were identified as requiring occupational therapy intervention. The intervention consisted of home visits and the provision of interventions in individually

identified problems (environmental modifications, fatigue, lifestyle and anxiety management). While the intervention seemed promising, it was resource intensive with a range of 2-11 home visits required per patient. Wallace et al. (2011) recommended the pilot of a group intervention, with provision of individual sessions, which would serve to increase social interaction and promote active transfer of skills. The study also recommended the inclusion of other health professionals in interventions to meet the populations' complex needs.

1.4.1.2 Study 2: O' Toole et al., (2013)

This led to a follow-on study conducted by the researcher as part of an MSc by research. This study developed, delivered and examined the acceptability and impact of an occupational therapy led, six week group-based intervention for individuals with multimorbidity in primary care (O' Toole et al., 2013). The programme was named OPTIMAL (OccuPaTional therapy led self-MAnagement support programme for people with muLtimorbidity). Section 1.6.1 briefly describes content/delivery. The study was conducted with 19 individuals with multimorbidity who were recruited via general practitioners (GPs). The study used a convergent-parallel mixed methods design including a quasi-experimental pre-test post-test design and participant focus groups. Findings were promising in terms of feasibility. Statistically significant improvements at 8-week follow-up were found in activity participation ($p=0.008$), self-perceptions of occupational performance ($p=0.017$) and satisfaction with same ($p=0.023$) and self-efficacy ($p=0.050$), however these findings were limited given the small quasi-experimental nature of the study and as the focus of the pilot study is not to assess effectiveness (or efficacy) (Eldridge et al., 2016). In the qualitative evaluation, participants reported improvements in the targeted behaviours and being more positive about their general health. Participants valued the group-based nature of the intervention and the weekly goal-setting and review element of the programme (O' Toole et al., 2013).

1.4.1.3 Study 3: Garvey et al., (2015)

These promising findings led to a pilot pragmatic parallel randomised controlled trial (RCT) of OPTIMAL delivered by HSE primary care occupational therapists in three Dublin-based primary care teams (Garvey et al., 2015). Participants were recruited from primary care settings. The intervention group received OPTIMAL, while the control group

received care as usual. The results showed a significant improvement in the intervention group compared to the control group at two-week follow-up in frequency levels of activity participation ($p=0.003$), perceptions of occupational performance ($p<0.001$) and satisfaction with same ($p<0.001$), self-efficacy ($p<0.001$), perception of independence in daily activities ($p<0.001$), health-related quality of life ($p=0.001$) and positive and active engagement in life ($p=0.002$). The intervention group demonstrated high levels of goal achievement, between baseline and follow-up scores ($p<0.001$). No significant differences were found in anxiety, depression or healthcare utilisation. In light of these findings an RCT to test the effectiveness of the OPTIMAL programme over a longer time period and across a wider range of primary care settings was recommended.

1.4.2 Phase III: Evaluation

As a result of this development and pilot work it was decided to conduct an RCT and process evaluation of the OPTIMAL programme as per stage III of the MRC framework. This study is the focus of the PhD thesis.

1.5 Aims and objectives

The overall aim of this study was to evaluate the effectiveness of the OPTIMAL programme, an occupational therapy led chronic disease self-management programme for individuals with multimorbidity in primary care, as per Stage III of the MRC framework (Medical Research Council, 2008).

Null hypothesis

An occupational therapy led chronic disease self-management programme has no effect on activity participation and quality of life in intervention participants compared to controls.

Alternative hypothesis

An occupational therapy led chronic disease self-management programme has an effect on activity participation and quality of life in intervention participants compared to controls.

A secondary aim of this study was to conduct a process evaluation to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice. The objectives to achieve this aim were:

- To describe the recruitment process including sampling of sites and recruitment sources.
- To analyse the extent to which the OPTIMAL programme was delivered as intended and how and why it varied, i.e. to explore intervention fidelity.
- To quantify the dose received by OPTIMAL programme participants i.e. programme attendance.
- To explore OPTIMAL facilitators' perceptions of the impact, delivery and acceptability of the OPTIMAL programme.
- To explore participants' perceptions of the impact, delivery and acceptability of the OPTIMAL programme.

Additional project aims planned as part of the wider OPTIMAL study include evaluating the effectiveness and sustainability of the OPTIMAL programme at six-month follow-up and a cost-effectiveness analysis of the OPTIMAL programme. However these aims are beyond the scope of the thesis.

1.6 Brief overview of the OPTIMAL programme and methodology

1.6.1 The OPTIMAL programme

The OPTIMAL programme is an occupational therapy led group-based self-management programme delivered over six consecutive weekly sessions of two and a half hours duration. Section 3.5 in Chapter 3, provides a detailed overview of the programme. Each weekly session comprises an educational component and individual weekly goal-setting and review. The programme covers a variety of topics including activity and health, fatigue management, healthy eating, maintaining mental well-being, maintaining physical activity and communication with health care professionals. While the programme is occupational therapy led, one of the sessions incorporates education on physical activity delivered by a physiotherapist and another incorporates medicines management, delivered by a pharmacist. The OPTIMAL programme is underpinned by the theory of self-efficacy which informed the mode of delivery of the programme. Self-efficacy is one of the core concepts of social cognitive theory and focuses on increasing an individual's

confidence in their ability to carry out a certain task or behaviour, thereby empowering the individual to self-manage (Health Service Executive, 2017). Self-efficacy is theorised to be influenced by four sources of information: performance accomplishments, vicarious experience, persuasion and physiological state (Bandura, 1986b, 2004). Programme elements such as goal-setting, peer discussion, interaction, brainstorming, coaching, feedback, encouragement and information provision have been included in the programme in order to address these sources of self-efficacy. The theoretical underpinning of the intervention is explored in further detail in Chapter 3, Section 3.3.2.1.

1.6.2 Randomised controlled trial

A pragmatic parallel randomised controlled trial was selected to examine the effectiveness of the OPTIMAL programme. The trial was conducted in eight primary care team areas in the Dublin/Mid-Leinster region from 2016-2018. The study was designed in line with the CONSORT statement (See Appendix 1) (Schulz, Altman, Moher, & Consort Group, 2010).

Primary outcome measures were the EQ-VAS (health related quality of life measure) and Frenchay Activities Index (frequency of activity participation). Participants were randomly allocated to the intervention group, to attend the OPTIMAL programme, or to the wait list control group, to receive care as usual. Follow-up data collection took place immediately post-intervention. Six-month data were collected for primary and all secondary outcomes (Nottingham Extended Activities of Daily Living Scale (NEADL), Stanford Chronic Disease Self-Efficacy 6-item Scale (SEMCD); Hospital Anxiety and Depression Scale (HADS) and Canadian Occupational Performance Measure (COPM)), however the reporting of six-month follow-up data is beyond the scope of this thesis.

Data analysis and reporting was according to CONSORT guidelines for randomised controlled trials. Data was inputted and analysed using Stata version 15 (StataCorp, 2017). Data were analysed using intention-to-treat (ITT) comparisons between the two groups for the primary outcomes (EQ-VAS and FAI total). Models were adjusted as appropriate for gender, baseline scores, area, number of conditions and age. The analyses were replicated for participants who completed the trial as per protocol (PP), excluding those who were randomised to the intervention but attended less than three of the group sessions. Planned sub-group analyses evaluated the effects of age (< 65 and ≥ 65) and number of chronic conditions (< 4 and ≥4 conditions). All analyses used linear

regression models, with results presented as point estimates (difference in means), 95% confidence intervals (CI) and p-values.

1.6.3 Process Evaluation

The process evaluation used a mixed methods approach, combining both qualitative and quantitative data as recommended by the MRC guidance on process evaluations in complex interventions (Moore et al., 2014). The process evaluation in this study was based on examining the three key functions of process evaluations identified in the MRC guidance as follows: i) implementation (identifying what intervention was delivered and how was this done or achieved), ii) mechanisms of impact (which factors contributed to the delivered intervention producing or not producing change) and iii) context (contextual factors external to the intervention which affected implementation, intervention mechanisms, outcomes and vice versa).

Quantitative process evaluation data collection sources included demographic forms, recruitment logs, research logs and fidelity tools. Data from these sources were inputted into Stata version 15 and summarised using descriptive statistics (StataCorp, 2017). Qualitative process evaluation data were collected immediately post-intervention. Focus groups were held with intervention participants. Semi-structured interviews were used to collect qualitative data from occupational therapists and a sample of physiotherapists, pharmacists and GPs involved in delivering the intervention or referring participants to the programme. A qualitative descriptive approach was employed for the qualitative element of the process evaluation. Qualitative description aims to stay close to the data in both the analytical process and data presentation by producing a rich, straight description of an experience or an event (Sandelowski, 2000). Qualitative description is a suitable method for studies focusing on health intervention development and evaluation (Sandelowski, 2000, 2010). Qualitative data were inputted into the Nvivo qualitative software package and thematic analysis was used to identify, analyse and report patterns (themes) (Braun & Clarke, 2006; Clarke & Braun, 2013).

1.7 Phase IV: Implementation

Phase IV of the MRC framework, whilst beyond the scope of this study, will be informed by the findings of this study. Outcomes will be disseminated to key stakeholders and

used to inform levers and barriers to the implementation of the OPTIMAL programme within Irish primary care settings. Implementation, based on the RCT and process evaluation results, are discussed using Normalisation Process Theory (NPT) in Chapter 7, Section 7.8. NPT provides a framework to describe, assess and enhance implementation through identification of factors that promote or inhibit the routine integration of complex intervention into everyday practice (May & Finch, 2009).

1.8 Thesis outline

This thesis is presented in eight chapters. Chapter 2 will discuss in detail the literature pertaining to multimorbidity, multimorbidity intervention research, self-management interventions and the role of occupational therapy in primary care to provide background to the need for the current study. Chapter 3 describes the methodology of the OPTIMAL RCT. Chapter 4 outlines the methodology employed to conduct the process evaluation. Chapter 5 will present the results from the OPTIMAL RCT while the results of the process evaluation are presented in Chapter 6. Chapter 7 summarises the findings of both the RCT and process evaluation and discusses the results in the context of existing literature. The clinical, research and policy implications of this thesis are then examined alongside barriers and enablers to implementation using NPT.

Chapter 2 Literature Review

2.1 Introduction

This chapter summarises the existing literature relevant to the development and evaluation of the OPTIMAL programme, an occupational therapy led self-management programme for people with multimorbidity in primary care. The chapter begins by providing an overview of the literature search methods. Literature pertaining to definitions, measurement of multimorbidity and the prevalence of multimorbidity is discussed. Evidence regarding the consequences of multimorbidity particularly in relation to function, psychological well-being, quality of life and health care utilisation are examined. Irish health policy relevant to the management of multimorbidity in primary care is described. Finally, the literature for interventions for multimorbidity is summarised and evaluated with a specific focus on self-management and occupational therapy interventions. The context of current primary care occupational therapy practice is also described. The chapter concludes by identifying the gaps in the existing literature.

2.2 Literature search

The aim of this literature review was to identify literature related to the prevalence, impact and interventions for multimorbidity with a particular focus on identifying self-management interventions and occupational therapy interventions for multimorbidity in primary care.

2.2.1 Information source and search strategy

The search was conducted on the following online databases: PubMed, CINAHL, the Cochrane Database of Systematic Reviews, ProQuest and PsychINFO. The search engine Google Scholar was also utilised. Grey literature was searched using Lenus and RIAN. Additional publications were identified by a manual search of the reference lists of relevant studies and review articles. A combination of search terms and MeSH terms, where available, were used in the literature search. Publications were reviewed and reference lists searched for further publications. Key search terms included multimorbidity, chronic conditions, self-management, occupational therapy, primary care, community, function, activity and participation. Further details of the search terms used are available in Appendix 2.

2.2.2 Study selection

No time period was applied but efforts were made to ensure up to date literature was identified with the latest searches being conducted in August 2018. The search was limited to English language studies.

2.2.3 Data extraction and analysis

The results of the searches were downloaded into an Endnote file and reviewed for relevancy based on the article title and abstract. Articles which were not relevant and duplicates were deleted. The full-text of relevant articles were sourced from the online library, library or via direct contact with the authors. Articles were reviewed and summarised narratively as presented in the proceeding sections.

2.3 Multimorbidity

2.3.1 Definitions of multimorbidity

Multimorbidity is often described as the co-existence of two or more chronic conditions in the same individual (Almirall & Fortin, 2013; Lefèvre et al., 2014; World Health Organisation, 2015, 2016). There is no consensus on terminology to describe the presence of multiple concurrent conditions (Almirall & Fortin, 2013). A variety of terms have been used to describe the presence of multiple co-occurring diseases including multimorbidity, co-morbidity, polymorbidity, polypathology, pluripathology, multipathology and multicondition. Different definitions of multimorbidity have specified varying numbers of morbidities, the number and severity of morbidities, and the number and severity of morbidities together with concurrent limitations in functional status or frailty (Almirall & Fortin, 2013; Lefèvre et al., 2014; Xu et al., 2017). Some definitions of multimorbidity have specified medical conditions whereas others include unlimited numbers and types of medical conditions, chronic conditions, or both acute and chronic conditions, physical conditions only, or physical and psychiatric conditions (Almirall & Fortin, 2013; Lefèvre et al., 2014; Ording & Sørensen, 2013). A recently published National Institute of Clinical Excellence (NICE) guideline on the assessment and management of multimorbidity has emphasised that multimorbidity can include two or more of the following conditions: physical conditions, mental health conditions, learning

disability, symptom complexes (e.g. frailty or chronic pain), sensory impairment, alcohol and substance misuse (National Institute for Clinical Excellence, 2016). While all the different definitions of multimorbidity refer to multiple diseases and have different strengths and limitations the precise meaning varies (Almirall & Fortin, 2013; Xu et al., 2017). This lack of consensus has considerable implications for both practice and research in terms of finding relevant and comparable evidence (Almirall & Fortin, 2013).

Efforts have been made to distinguish clearly between the terms co-morbidity and multimorbidity which have been used interchangeably in the past (S. M. Smith et al., 2016). The term “co-morbidity” is used to describe the existence or occurrence of any distinct additional entity that occurs during the clinical course of a patient who has the index disease under study (Feinstein (1970) as cited in van den Akker, Buntinx, & Knottnerus, 1996). ‘Comorbidity’ implies that there is an index disease to which co-existent diseases relate and may share an aetiology and potential solutions (S. M. Smith & O’Dowd, 2007). Individuals with comorbidity can have multimorbidity but the reverse does not always apply (S. M. Smith et al., 2016).

It has been argued that a holistic definition of multimorbidity is required, incorporating, chronic disease labels, emotional and psychological distress, spiritual and existential distress and disease severity (Mercer et al., 2009). The need to incorporate disease severity recognises that many people living with multimorbidity are managing well and do not require additional intervention (Mercer et al., 2009). The recognition that some individuals with multimorbidity manage well and the need to account for and differentiate severity has resulted in the development of the concept of complex multimorbidity (C. Harrison, Britt, Miller, & Henderson, 2014). Complex multimorbidity has been defined as the co-occurrence of three or more chronic conditions affecting three or more different body systems within one person without defining an index chronic condition (C. Harrison et al., 2014; C. Harrison, Henderson, Miller, & Britt, 2017). This definition provides greater specificity than the definition of multimorbidity as two or more chronic conditions and may be useful in identifying high-need individuals (C. Harrison et al., 2014). The number of regular or repeat medications an individual with multimorbidity takes has also been recommended as a means to identify complex patients with multimorbidity. The recently published NICE guideline for multimorbidity recommends identifying those patients who are prescribed 15 or more regular medications as they are at particular risk of adverse events and drugs interaction (National Institute for Clinical Excellence, 2016).

A recent overview of systematic reviews examining definitions and measurements of multimorbidity recommended that multimorbidity studies should be explicit about the definition and measurement used. This review recommended that a cut-off of two or more conditions be widely adopted (M. C. Johnston, Crilly, Black, Prescott, & Mercer, 2018). For the purposes of this study the most commonly used definition of multimorbidity has been used i.e. that multimorbidity is the co-existence of two or more chronic conditions in the same individual (S. M. Smith et al., 2016; Xu et al., 2017). The WHO define chronic diseases as health problems which require ongoing management over a period of years or decades (World Health Organisation, 2002). This definition was used in the current study and selected as it simple and reflective of the generalist approach of primary care. The primary care approach recognises that care should be patient-centred as opposed to focused on specific conditions which may impact individuals differently over time (Valderas, Mercer, & Fortin, 2011; Xu et al., 2017).

2.3.2 Prevalence of multimorbidity

Prevalence estimates of multimorbidity are important from an epidemiological perspective and in informing health policy and resource allocation (Naughton, Bennett, & Feely, 2006). Tables 2.1 and 2.2 provide an overview of international prevalence studies and systematic reviews. It is clear from the studies reviewed that there is a wide disparity in prevalence estimates of multimorbidity. The wide variation is attributable to differences in study designs, multimorbidity definitions and included conditions, assessment methods and the variety of sources being used to calculate estimates including self-report, practice databases and administrative databases of pharmacy claims databases (Marengoni et al., 2011; Schram et al., 2008; Violan et al., 2014). Estimates also contrasted sharply based on the study population and setting. Despite the heterogeneity of studies reviewed many studies found multimorbidity to be associated with age, lower socioeconomic status, female gender and higher prevalence of anxiety and depression (Garin et al., 2016; Marengoni et al., 2011; A. W. Taylor et al., 2010; Violan et al., 2014).

While the studies reviewed highlighted that multimorbidity increases with age it is clear from the literature that multimorbidity is also prevalent in younger age groups, particularly in areas of social deprivation (Barnett et al., 2012; Fortin, Bravo, Hudon, Vanasse, & Lapointe, 2005; Fortin et al., 2012; A. W. Taylor et al., 2010). Of particular concern were the results of a large practice based study in Scotland which found that the onset of

multimorbidity was 10-15 years earlier in people living in the most deprived areas compared to the most affluent, with socioeconomic deprivation particularly associated with multimorbidity including a mental health condition (Barnett et al., 2012). A systematic review of prevalence studies has shown the presence of an S-shaped curve, with low estimates of multimorbidity before 40 years of age, followed by a sharp increase thereafter which plateaus at 70 years of age (Fortin et al., 2012). The existing evidence indicates that the problem of multimorbidity is not solely confined to older adults and that multimorbidity is an issue for individuals across the age spectrum.

Table 2-1 International prevalence studies of multimorbidity

Author and Year	Setting	Type of study	N	Definition of multimorbidity	Prevalence/Findings
Violan et al. (2014)	Primary care	Systematic review	n=70,057,611 patients in 44 studies included; Only primary care settings of adults aged ≥ 18 years and older	Simultaneous presence of more than one health condition in the same individual	12.9% in participants >18 years of age to 95.1% in a population >65 years of age
Fortin et al., (2012)	Primary care and general population	Systematic review	21 studies: 8 primary care, 12 in the general population, and 1 in both primary care and general practice	Definitions of multimorbidity varied in included studies	Wide variety of prevalence estimates but studies demonstrate presence of s-shaped curve in relation to age
Marengoni et al. (2011)	Institutionalised and non-institutionalised settings	Systematic review	12 studies on prevalence (41 studies in review in total); Older adults ≥ 65 years of age	Co-occurrence of multiple diseases Varied ascertainment and definition of multimorbidity across studies	20-30% general population 55-98% older adults only
Garin et al. (2016)	General population	Data from COURAGE and SAGE studies	n= 41,909; Non institutionalised adults ≥ 50 years of age	Presence of 2 or more chronic conditions from a pre-specified list of 12 conditions	45.1% (China) to 71.9% (Russia)
Barnett et al. (2012)	Primary care	Cross-sectional	n=1,751,841; Adults aged ≥ 16 years and older	Presence of 2 or more chronic conditions from a pre-specified list 40 morbidities	23.1%

Table 2-2 International prevalence studies of multimorbidity (cont.)

Author and Year	Setting	Type of study	N	Definition of multimorbidity	Prevalence/Findings
Agborsangaya et al. (2012)	General population	Cross-sectional	n= 5,010; Adults aged ≥ 18 years	Presence of 2 or more chronic conditions from a pre-specified list of 16 conditions	19.0%
Taylor et al. (2010)	General population	Biomedical Cohort	n=3,206; Adults aged ≥ 20 years of age	Presence of 2 or more chronic conditions from a pre-specified list of 7 conditions	4.4%: 20-39 years; 15.0%: 40-59 years 39.2% 60 years of age; Total: 17.1%
Schram et al. (2008)	Data from three population based studies; two general practitioner registries; one hospital discharge register; nursing homes	Cross-sectional	n= 11,275 (General population) n= 8,505 (General practice) n= 1,058,234 (Hospital discharge) n= 1,274 (nursing homes) Adults aged ≥ 55 years of age	Presence of 2 or more chronic conditions; Use of ICD-9 (International Classification of Diseases) codes to identify chronic conditions	Difference in prevalence between settings Nursing homes: 82%; General population: 56%; General practitioner registries: 72%; Hospital setting: 22%.
Fortin et al. (2005)	Primary care	Cross-sectional	n=980: Adults aged ≥ 18 years	Presence of 2 or more chronic conditions	68%: 18- to 44-years 95%: 45- to 64-years 99%: 65 years and older Overall total: 89.3%

Research examining the prevalence of multimorbidity in Ireland have faced similar issues to international research owing to the lack of consensus on the definition and measurement of multimorbidity and the population studied. Irish estimates of the prevalence of multimorbidity have ranged from 11% to 66.2%. Table 2.3 summarises studies examining the prevalence of multimorbidity in Ireland. One study used the HSE Primary Care Reimbursement Pharmacy database to estimate the prevalence of chronic disease of all individuals aged over 70 years who were dispensed with three or more items over a 12 month period (Naughton et al., 2006). This database contains dispensing records of medicines prescribed to patients in primary care by their general practitioners. A high level of multimorbidity was present, with 27% having two or more chronic diseases, 19% having three or more conditions and 14% having four or more conditions. However, the reliability of the results are limited given the lack of definitive diagnoses information.

A prevalence study conducted by Centre for Ageing Research and Development in Ireland (CARDI) examined multimorbidity on the island of Ireland (CARDI, 2011). For the purposes of this literature review the study results pertaining to the Republic of Ireland will be focused on. Multimorbidity was defined as the presence of two or more chronic conditions from a list of eight chronic conditions. A multimorbidity prevalence rate of 11% in the population over 50 in Ireland was found based on the conditions included in this study. In line with previous international studies the prevalence of multimorbidity is associated with increased age, lower socio-economic status and is more common in those who are single or widowed (CARDI, 2011). It is likely that multimorbidity prevalence was underestimated in this study, given the use of a small pre-specified list of chronic conditions. Of note no mental health conditions were included in the pre-determined list. Furthermore the data were obtained through postal surveys, with no confirmation of diagnoses via medical records. A criticism of using population based data for multimorbidity prevalence estimates is that it tends to underestimate multimorbidity in comparison with general practice samples. Glynn et al. (2011) examined the prevalence of multimorbidity using a patient record review of 3,309 patients aged over 50 years of age across three general practices in the West of Ireland. The definition of multimorbidity used in the study was the presence of two or more chronic conditions occurring simultaneously in the same individual, using the WHO definition of chronic conditions. This definition was broader than that used in the CARDI (2011) study. Results indicated that multimorbidity appeared to be very common, with 66.2% of patients aged over 50 years of age having multimorbidity. Consistent with other studies, increasing age and lower-socio economic status had a significant effect on the prevalence of multimorbidity.

It is clear from both international and national research that there is a wide disparity in prevalence estimates of multimorbidity with comparisons being limited by the lack of a standardised definition, assessment method of multimorbidity and the variety of sources being used to calculate estimates (Marengoni et al., 2011; Schram et al., 2008; Violan et al., 2014). Despite these limitations it is acknowledged that the prevalence of multimorbidity is rising and multimorbidity is now the norm as opposed to the exception in primary care (Barnett et al., 2012; Fortin et al., 2005). It is likely that the prevalence of multimorbidity will continue to increase due to the ageing population and increased life expectancy worldwide. Well-established determinants of multimorbidity consistently detected in prevalence studies in spite of their heterogeneity include increasing age, female gender and low socio-economic status (Marengoni et al., 2011; Violan et al., 2014). Violan et al. (2014) advocated for future prevalence studies to consider unrestricted eligibility of conditions, diagnoses confirmed by health professionals and reporting of results stratified by age and gender. Setting and registry characteristics affect multimorbidity prevalence estimates with research indicating that estimates are 10% higher in primary care practices than those found in general population samples (Mokraoui, Haggerty, Almirall, & Fortin, 2016). Prevalence estimates from primary care practices may be more informative to policy and decision-makers in determining resource allocation as it reflects complexity within this setting (Fortin, Hudon, Haggerty, van den Akker, & Almirall, 2010; Mokraoui et al., 2016; Schram et al., 2008).

Table 2-3 Prevalence studies of multimorbidity in Ireland

Author and Year	Setting	Number of participants	Definition of multimorbidity	Prevalence
CARDI (2011)	Population based	n=4,255	≥2 chronic conditions from a pre-specified list of eight conditions	11%
Glynn et al. (2011)	General practice based	n=3,309	≥2 chronic conditions	66.2%
Naughton et al. (2006)	Population based	n=271,518	≥2 chronic conditions identified by dispensed items associated with a specific chronic condition	27%

2.3.2.1 Patterns of multimorbidity

Despite the prevalence of multimorbidity, health care delivery and clinical guidelines are currently focused towards single chronic diseases which does not cater for or address the complex needs of those with multimorbidity (World Health Organisation, 2016). Clinical guidelines based on single morbidities are potentially contradictory when applied to those with multimorbidity (National Institute for Clinical Excellence, 2016). It has been suggested that examining patterns, combinations and common conditions of multimorbidity will assist in generating an evidence base for clinical guidelines, management and interventions (Xu et al., 2017). However much of the research examining multimorbidity patterns has experienced similar difficulties to prevalence studies due to the heterogeneity of studies in terms of multimorbidity definitions, selection criteria (eligible conditions considered), patterns and analyses techniques (Prados-Torres, Calderón-Larrañaga, Hanco-Saavedra, Poblador-Plou, & van den Akker, 2014; Violan et al., 2014). Two systematic reviews examined multimorbidity patterns using a definition of multimorbidity as two or more chronic conditions. Three particular patterns were found in both reviews despite the heterogeneity in studies as follows: i) cardiovascular and metabolic conditions, ii) mental health related problems and iii) musculoskeletal disorders (Prados-Torres et al., 2014; Violan et al., 2014). However as with prevalence studies, formal consensus on the best methods for studying multimorbidity patterns needs to be developed (Violan et al., 2014).

2.3.3 Risk factors for multimorbidity

While there is extensive literature on risk factors for the development of specific single chronic diseases, limited research has been conducted into risk factors for development of multimorbidity such as genetics, biomarkers, lifestyle factors or environmental factors (N. N. Dhalwani et al., 2016; Fortin et al., 2014; Gallacher et al., 2018; Marengoni et al., 2011; Violan et al., 2014). Xu et al. (2017) categorises risk factors for multimorbidity as follows; biomedical and individual factors, health behaviours, socioeconomic characteristics and social and environmental factors. Results from some studies have suggested a dose-response relationship with a number of these risk factors and subsequent multimorbidity (Fortin et al., 2014; Katikireddi, Skivington, Leyland, Hunt, & Mercer, 2017).

With regards to biomedical and individual factors, systematic reviews of prevalence studies, as previously discussed, have indicated that increased age and female gender are associated with multimorbidity (Marengoni et al., 2011; Violan et al., 2014; Xu et al., 2017). Other individual factors which may increase risk of multimorbidity but which warrant further research include negative life events (Tomasdottir et al., 2015; van den Akker, Vos, & Knottnerus, 2006), cognitive impairment, depressive symptoms and mental health conditions (Barnett et al., 2012; Melis, Marengoni, Angleman, & Fratiglioni, 2014).

In recent years more attention has been centred on identification of lifestyle factors and health behaviours predisposing individuals to multimorbidity with inconsistent findings emerging. A population-based study in Finland of 25-64 years olds found that smoking, obesity and physical inactivity were risk factors for multimorbidity among initially disease-free individuals. However this study only focused on a limited list of chronic conditions (Wikström, Lindström, Harald, Peltonen, & Laatikainen, 2015). N. N. Dhalwani et al. (2016) examined lifestyle factors and the incidence of multimorbidity in an older English population and found that physical inactivity in combination with obesity or smoking increased the risk of multimorbidity by two to three times and more than four times when combined with both smoking and obesity (N. N. Dhalwani et al., 2016). A further study also demonstrated an inverse-dose relationship between multimorbidity and physical activity, whereby the odds of multimorbidity in individuals engaging in vigorous, moderate and light physical activity was 55%, 39% and 16% lower than those who were inactive (Nafeesa N. Dhalwani et al., 2016). Fortin et al. (2014) investigated the relationship between lifestyle factors and occurrence of multimorbidity in participants aged 45 years and older. Multimorbidity was defined as three or more conditions using a pre-defined list of chronic conditions. Consistent with N. N. Dhalwani et al. (2016) individual lifestyle factors including a low or high BMI and having a present or past smoking habit increased the likelihood of the presence of multimorbidity (Fortin et al., 2014). However in contrast to other studies physical inactivity was not associated with multimorbidity. A recently published population-based cohort study using data from The Irish Longitudinal study on Ageing (TILDA) examined the impact of physical activity and physical function on the development and worsening of multimorbidity over time (A. Ryan, Murphy, Boland, Galvin, & Smith, 2018). This study also found that while physical function (i.e. gait speed and reduced grip strength) impacted the risk of developing chronic conditions over time in both those with and without established multimorbidity, physical activity did not. Differences in ages in the population samples, definitions of multimorbidity, chronic

conditions and physical activity measures between studies may account for these differences.

Research examining the impact of diet and alcohol intake as determinants of multimorbidity have been inconsistent. Two studies found no association between not eating a recommended amount of fruit and vegetables or alcohol consumption and a higher likelihood of multimorbidity (Fortin et al., 2014; Nagel et al., 2008). Whereas others have found a link between excess alcohol consumption, low consumption of fruit and vegetables and increased risk of developing multimorbidity (N. N. Dhalwani et al., 2016; Katikireddi et al., 2017; Ruel et al., 2014; Wikström et al., 2015).

The association between the prevalence of multimorbidity and low socio-economic status has been consistently established (Lefèvre et al., 2014; Marengoni et al., 2011; Violan et al., 2014; Xu et al., 2017). However measurements of socio-economic status have varied between deprivation indices, education, income levels and health insurance coverage (Violan et al., 2014). A recent systematic review and meta-analysis found that low education and higher area-based deprivation was consistently associated with increased odds of multimorbidity, however findings about income level were less conclusive (Pathirana & Jackson, 2018). Future studies examining the relationship between socio-economic status and multimorbidity should adjust for these factors in order to develop a deeper understanding of the impact of inequalities on multimorbidity (Pathirana & Jackson, 2018). This is particularly true when considering the concept of ecological fallacy i.e. assuming that the statistical correlation between two variables at the aggregated level is equal to the correlation between the corresponding variables at the individual level i.e. that area deprivation applies to all those residing within that area at the individual level (Sedgwick, 2015). Complex mechanisms may underlie the association between low socioeconomic status and multimorbidity including factors such as lifestyle, access and use of healthcare and community resources and services and local context. One such mechanism may be the enduring effects of deprivation and adverse childhood experiences on later life physical and mental health. Recent research suggests that multimorbidity is independently associated with a history of adverse childhood events (Sinnott, Mc Hugh, Fitzgerald, Bradley, & Kearney, 2015). A cross-sectional study of 7,305 participants aged ≥ 50 years in the US found that childhood financial hardship and lifetime earnings are associated with multimorbidity (Tucker-Seeley, Li, Sorensen, & Subramanian, 2011). Perceived stress levels are associated with multimorbidity and higher utilisation of primary care services (Prior, Vestergaard, Larsen, & Fenger-Grøn, 2018; K. C. Roberts, Rao, Bennett, Loukine, & Jayaraman,

2015; Stubbs et al., 2018; Vancampfort, Koyanagi, Ward, et al., 2017). The presence of risk factors such as stress, unemployment, income inequality and substance abuse are preventable risk factors that require multi-sectoral policies and intervention in order to tackle multimorbidity. Such results demonstrate the psychosocial complexity associated with multimorbidity.

Similarly to prevalence studies there is heterogeneity in studies examining determinants of multimorbidity due to variances in definitions, measurement, populations studied (including age and setting) and measurements of risk factors. While more research is warranted, existing literature suggests predisposing risk factors for multimorbidity exist such as age, female gender, low socio-economic status and lifestyle factors such as obesity and physical inactivity (N. N. Dhalwani et al., 2016; Wikström et al., 2015). Addressing multimorbidity involves more than the development of interventions for existing multimorbidity. It is important that efforts are also focused on identifying high risk groups and targeted primary and secondary prevention through health promotion campaigns and interventions.

2.3.4 Impact of multimorbidity

2.3.4.1 Functional decline

Functional decline is often defined and measured by a reduction in ability to perform activities of daily living (ADL) because of a decrement in physical and/or mental functioning (Abdulaziz et al., 2016). ADL tasks have been classified into basic activities of daily living (BADL) that a person normally performs on a daily basis, such as personal care, and instrumental activities of daily living (IADL) that allow an individual to live independently in a community, such as grocery shopping (Abdulaziz et al., 2016). The term functioning refers to body functions, activities and participation, while disability is similarly an umbrella term for impairments, activity limitations and participation restrictions (World Health Organisation, 2001). The presence of disability or functional decline leads to participation that is less diverse, is located more in the home, involves fewer social relationships, and includes less active recreation (Law, 2002). Activity participation refers to an individual's involvement or engagement in self-care, productive or leisure activities that are desired and/or necessary to one's health and well-being (Kielhofner, 2008; Law, 2002).

Two systematic reviews have assessed the association between multimorbidity and disability or functional decline (Marengoni et al., 2011; Aine Ryan et al., 2015). Marengoni et al. (2011) only included studies of individuals with multimorbidity aged over 65 years, five studies were identified, three of which were cross-sectional and two of which were longitudinal. Four of the five studies found a significant impact of multimorbidity on functional decline and disability, with increasing numbers of conditions increasing odds or risk for disability. This review included studies of individuals with multimorbidity in hospitals and institutional settings. In contrast Aine Ryan et al. (2015) included studies of community-dwelling adults aged over 18 years. A total of 37 studies (28 cross sectional and 9 cohort studies) were identified, the majority of which were high quality with a low risk of bias. The majority of cross-sectional studies found an association between multimorbidity and functional decline. Similarly to Marengoni et al. (2011), the majority of cross-sectional studies found an association with increasing numbers of conditions and deteriorating functional decline. Findings from the majority of cohort studies indicated that multimorbidity predicted functional decline, with increasing numbers and severity of conditions being indicative of more marked decline (Aine Ryan et al., 2015). As with other studies of multimorbidity prevalence and epidemiology, these systematic reviews are somewhat limited as included studies varied in terms of multimorbidity definitions (number and conditions included) age of participants, follow-up duration and outcome measures. Cross-sectional and cohort studies focusing on the association between multimorbidity and function in the “oldest old” have found that disability and geriatric conditions are associated with, and predictive of, mortality more so than increased morbidity (Landi et al., 2010; Lu, Chang, & Wu, 2016; Marengoni, Von Strauss, Rizzuto, Winblad, & Fratiglioni, 2009; Woo & Leung, 2014). These findings highlight the importance of clinicians taking a function-oriented rather than disease-oriented approach to early identification and targeting of elderly patients with multimorbidity for intervention.

Many of the studies which have examined the impact of multimorbidity on function and disability have tended to focus on physical performance components (e.g. grip strength), single-item measures of disability or activity scales which are focused on basic or personal activities of daily living (BADLs) (de Carvalho Yokota et al., 2016; Landi et al., 2010; Aine Ryan et al., 2015). Such measures do not provide information on the impact of multimorbidity on instrumental ADLs (IADLS) which can be defined as activities needed to support daily life in the home and community, such as housework, meal preparation, shopping, and transport, which require more complex interactions than

BADLs (American Association of Occupational Therapy, 2014). Exploring the impact of multimorbidity on IADLs may be more relevant in primary care settings and younger individuals with multimorbidity who have not progressed to significant functional disability. A small number of studies which have focused on the effect of multimorbidity on IADLs have found that increasing numbers of chronic conditions are associated with disability in IADLs (den Ouden, Schuurmans, Mueller-Schotte, Brand, & van der Schouw, 2013; Marengoni et al., 2009; Su et al., 2016). These findings are similar to other studies of increasing numbers of conditions being associated with disability in BADLs.

A recent study examining predictors of participation in social leisure activities (defined as leisure activities that are social in nature) in older adults with and without multimorbidity found that while overall participation levels were high, those with multimorbidity participated at a lower level (Galenkamp et al., 2016). There appears to be very little research on the impact of multimorbidity on other elements of participation such as satisfaction with activity levels and performance (Anaby, Miller, Eng, Jarus, & Noreau, 2011; Anaby, Miller, Eng, Jarus, & Noreau, 2009). One study which examined the contribution of different elements of participation to well-being for those with multiple chronic conditions found that satisfaction with participation had a unique contribution to well-being more so than performance or activity accomplishment (Anaby et al., 2011).

2.3.4.2 Psychological impact

A number of studies have examined the relationship between multimorbidity and outcomes related to psychological well-being and mental health with many studies finding a significant negative effect of multimorbidity on such outcomes. Psychological distress is one such outcome. Psychological distress refers to subjective general emotional distress and is correlated with stress and overall mental health. It does not refer to a specific clinical entity or mental health disorder such as major depressive or anxiety disorders (Fortin et al., 2006; Fortin, Hudon, Bayliss, Soubhi, & Lapointe, 2007). A study evaluating the relationship between multimorbidity and psychological distress in primary care settings found that psychological distress increased with multimorbidity and severity of disease burden (Fortin et al., 2006). Similarly, a cross-sectional study of working Australians supported these findings with results indicating that number of morbidities was strongly associated with psychological distress (Holden, Scuffham, Hilton, Vecchio, & Whiteford, 2010).

A large cross-sectional study involving 245,404 participants from 60 countries found that nearly a quarter of participants with multimorbidity had depression in addition to their chronic physical conditions and that these participants had the worst health states in comparison to those with depression alone, any chronic disease alone or any combination of chronic diseases (Moussavi et al., 2007).

Results from a number of cross-sectional studies in general population and primary care settings demonstrate that multimorbidity is associated with depression and depressive symptoms (Gunn et al., 2012; Jani et al., 2013; D. J. Smith et al., 2014; Spangenberg, Forkmann, Brähler, & Glaesmer, 2011). Gunn et al. (2012) in a cross-sectional postal survey of 7,620 patients from 30 general practices in Australia found a clear-dose response relationship between number of chronic physical health conditions and depressive symptoms. The dose-response relationship was reduced when function and self-rated health were taken into account suggesting these factors mediate this relationship. Similarly to Gunn et al. (2012), a study examining the effects of routine depression screening in family practices in Scotland found that positive screens ranged from 17-21% for those with a single chronic condition to 26% for those with multimorbidity (Jani et al., 2013). Of particular interest in this study was that females, those from socioeconomically deprived backgrounds and younger multimorbid individuals (18-44 years of age) were more at risk of depression. A large cross-sectional study involving primary care practices in Scotland concluded that depression in primary care is associated with 32 chronic physical conditions and those with depression were more likely to have multimorbidity (D. J. Smith et al., 2014). One study found that increasing numbers of physical conditions are associated with loneliness after adjustment for socio-demographic factors (Stickley & Koyanagi, 2018). The association was particularly strong in the younger multimorbid group (16-44 years). The relationship between multimorbidity and loneliness was mediated by stressful life events, anxiety and depression (Stickley & Koyanagi, 2018).

A recent large cross-sectional general population study across 42 countries examined the association between chronic physical conditions and anxiety and found that increasing numbers of chronic physical conditions are associated with higher odds for anxiety (Vancampfort, Koyanagi, Hallgren, et al., 2017). Consistent with this Gould, O'Hara, Goldstein, and Beaudreau (2016) examined whether number of medical conditions were associated with increased occurrence of anxiety in retired adults aged 65 and over and found that higher numbers of medical conditions were associated with

elevated anxiety. Limitations of both of these studies were the general population setting of the study and the self-report nature of medical conditions.

Multimorbidity has also been found to be related to depressive symptoms, anxiety symptoms, more negative affect, less positive affect and activity limitations (Jones, Amtmann, & Gell, 2016). The negative impact of depression and other mental health symptoms on activity participation and function in those with multimorbidity has been supported in other studies (Quiñones, Markwardt, & Botoseneanu, 2016; Scott et al., 2009). Scott et al. (2009) in a large cross-sectional study involving 17 countries found that those with mental health conditions were more likely to be severely disabled than those with chronic physical conditions and those with both a mental health and physical condition were more likely to be severely disabled than those with either condition alone. Depression is associated with lower social leisure activities in older adults with multimorbidity, this reduced participation may relate to feelings of isolation and loneliness (Galenkamp et al., 2016; Stickley & Koyanagi, 2018).

The prevalence of depression and anxiety in the multimorbid population has significant resource implications for primary care settings. Multimorbid patients with depression are associated with significantly higher health care utilisation and costs than multimorbid patients without depression after adjustment for comorbidity and functional status (Bock et al., 2014). Increased costs relate to inpatient care, outpatient care, medical supplies, prescriptions, informal and formal care (Bock et al., 2014; Diminic-Lisica et al., 2010; Jani et al., 2013). These additional costs cannot be attributed to mental health service use (Bock et al., 2014).

It is clear from the research above that multimorbidity is associated with psychological issues including psychological distress, depressive symptoms and anxiety. The cross-sectional nature of the majority of these studies means that the causality of the relationship between multimorbidity and mental health symptoms and disorders cannot be determined, however it is likely to be bi-directional (Jones et al., 2016). This is supported by research which indicates, as previously discussed, that stress and adverse life events are risk factors for multimorbidity (Prior et al., 2018; K. C. Roberts et al., 2015; Stubbs et al., 2018; Vancampfort, Koyanagi, Ward, et al., 2017). Regardless the overlap between multiple chronic physical conditions and mental health conditions and symptoms necessitates a holistic approach to multimorbidity beyond disease or symptom specific interventions given the impact on functioning and quality of life. It is vital that policy makers and health care professionals should be aware of the complex

interactions between physical and psychological conditions and factors (Martin Fortin et al., 2007). Overall, recognition of and intervention for psychological issues that those with multimorbidity experience may have the potential to improve functioning, quality of life and decrease health resource utilisation.

2.3.4.3 Healthcare utilisation and costs

There is a growing body of literature which highlights the negative impact multimorbidity has on healthcare utilisation and costs. A number of systematic reviews have summarised research on the impact of multimorbidity on healthcare utilisation and costs (France et al., 2012; Lehnert et al., 2011; Marengoni et al., 2011). Two of these systematic reviews focused on healthcare utilisation in older adults with multimorbidity (Lehnert et al., 2011; Marengoni et al., 2011). Both of these reviews found that the number of chronic conditions was significantly associated with increased prescriptions, referrals, GP visits, hospital admissions and expenditures. Consistent with these findings France et al. (2012) conducted a systematic review of prospective cohort studies of those with multimorbidity in primary care settings and found that multimorbidity predicted increased health service use and costs.

However it is difficult to generalise these findings to Ireland given the variety of countries involved in included studies and acknowledging that the impact of multimorbidity on healthcare utilisation and costs is likely to vary according to healthcare systems (S. M. McPhail, 2016). Many of the studies examining healthcare utilisation and costs have been conducted in America. A recent study highlighted the differences between health care systems in terms of the relationship between multimorbidity, income levels and hospital admissions in three different countries, Scotland, Hong Kong and China (H. H. X. Wang et al., 2015). While multimorbidity increased the odds of admission in the three countries consistent with other international literature, the impact of income on this relationship varied. In Scotland and Hong Kong, which have systems with universal coverage, individuals on lower incomes with multimorbidity were more likely to be admitted than those with higher incomes. On the other hand in China, which does not provide universal coverage, those with lower incomes had reduced odds of hospital admissions (H. H. X. Wang et al., 2015).

Research from European and Irish health systems are consistent with other international research with multimorbidity being associated with increased utilisation and costs

despite variation in healthcare systems. A large cross-sectional study using data from 18 European countries found that increasing numbers of chronic conditions were associated with increased healthcare utilisation in both primary and secondary care settings (Palladino, Lee, Ashworth, Triassi, & Millett, 2016). Similarly two small studies examining the association of healthcare utilisation and multimorbidity in Irish primary care settings found that multimorbidity was associated with increased numbers of GP visits, hospital admissions, outpatient visits, prescriptions and overall cost (Glynn et al., 2011; Susan M. Smith, Ferede, & O'Dowd, 2008).

More research is needed to determine person-specific factors in those with multimorbidity, such as age and social deprivation, associated with higher health care utilisation. Such information would assist in directing resources and targeting interventions to improve quality of care and reduce utilisation. It is important that further research is carried out into the healthcare utilisation of those with multimorbidity who are younger, with mental health conditions and those living in socially deprived areas given the high prevalence of multimorbidity in these groups and the resultant impact on functioning and quality of life. For example one recent large retrospective cohort study of individuals with multimorbidity in general practices in Scotland demonstrated the particularly adverse impact such individual factors have on healthcare utilisation (Payne, Abel, Guthrie, & Mercer, 2013). This study examined the association between unplanned admissions to hospital and physical multimorbidity as well as any additional effect of mental health morbidity and socioeconomic deprivation. The study found that the individuals most likely to be admitted were those with mental illness in addition to high levels of physical multimorbidity and living in deprived areas (Payne et al., 2013).

2.3.4.4 Experience of healthcare utilisation and quality

Those with multimorbidity face challenges in relation to the healthcare they receive in terms of coordination and burden. Given the traditional disease specific approach to managing chronic conditions those with multimorbidity are likely to receive care from a higher number of providers with expertise in different chronic conditions. The fragmentation of the system means that coordination of care is difficult to achieve and that patients find it difficult to understand, reconcile and implement instructions from these various providers (Vogeli et al., 2007). The NICE guideline on clinical assessment and management of patients with multimorbidity specifically caution against healthcare providers applying clinical guidelines for specific conditions to those with multimorbidity

and advocates for continuity and a coordinated approach to care (National Institute for Clinical Excellence, 2016). The quality of care which individuals with multimorbidity receive has been examined with some contradictory results. While some research suggests that increasing numbers of conditions is associated with better quality of preventive care in primary care settings (Bae & Rosenthal, 2008; Higashi et al., 2007; Min et al., 2007), others identified quality of care deficiencies in those with multimorbidity particularly when patients have unrelated chronic conditions (Schjøtz et al., 2017). Barriers to quality of care for those with multimorbidity have been identified as short consultation times in general practice and outpatient clinics, lack of care coordinators, and lack of shared IT systems providing an overview of treatments (Schjøtz et al., 2017). Differences in studies may be attributed to the definitions of multimorbidity and measures used to assess quality of care. For example in previous studies quality of healthcare has been measured based on condition specific indicators of processes of care and/or intermediate outcomes, or on patient reported information of patient-centred care (Ricci-Cabello, Violán, Foguet-Boreu, Mounce, & Valderas, 2015). Adequately defining and measuring what constitutes quality of care for those with multimorbidity is the key issue. For example some studies have found that increasing morbidity and severity may be associated with better quality of healthcare when measured using condition specific processes or intermediate outcome indicators but with worse quality when patient-centred measures are used (Ricci-Cabello et al., 2015). It is not clear what constitutes quality of care in those with multimorbidity but the recent NICE guideline recommends taking an approach to care to those with multimorbidity which is person-centred, provides continuity of care, improves coordination of care and reduces treatment burden (National Institute for Clinical Excellence, 2016).

Treatment burden for individuals with multimorbidity is being increasingly recognised as a concern. Treatment burden refers to a patient's perception of the aggregate weight of the actions and resources they devote to their health care, including difficulty, time, and out-of-pocket costs dedicated to health care tasks such as adhering to medications, dietary recommendations, and self-monitoring (Boyd et al., 2014). It has been suggested that patients with multimorbidity experiencing an excessive burden of treatment might not adhere to prescribed medical treatment (Rosbach & Andersen, 2017). Qualitative research consistently highlights the difficulties perceived by those with multimorbidity in accessing and using healthcare. Such challenges include managing multiple medications, poor continuity of care, difficulty accessing non-urgent care, referral waiting lists, juggling medical appointments and provision of conflicting advice from providers (Noel et al., 2005; Rosbach & Andersen, 2017). The fragmentation of care results in

those with multimorbidity feeling confused and overwhelmed by the system (Bayliss, Edwards, Steiner, & Main, 2008). Those with multimorbidity in both qualitative and cross-sectional research have communicated clearly a desire for convenient access to providers, clear communication of care plans and support from a single coordinator of care, preferably their GP, to prioritize and coordinate care and for continuity of relationships (Bayliss et al., 2008; Gulliford, Cowie, & Morgan, 2011; Noel et al., 2005; O'Malley & Cunningham, 2009; Rosbach & Andersen, 2017). Individuals with multimorbidity have also expressed a desire for providers to listen to and acknowledge their individual needs and have a caring attitude (Gulliford et al., 2011; Noel et al., 2005). A recent systematic review of qualitative studies on patients with multimorbidity experience of treatment burden concluded that burden of treatment was a complex concept associated with the workload demands of multimorbidity (number of conditions, number of medications and health status), patients' capacity to manage the demands (cognitive, physical and financial resources, educational level, cultural background, age, gender and employment conditions) and the context (structure of healthcare and social support) (Rosbach & Andersen, 2017).

Primary care has been espoused in the literature and health policy as the appropriate context for the management and coordination of care of those with multimorbidity. GPs in primary care are faced with the daunting task of ensuring risk factors are managed and coordinating care for those with multimorbidity while struggling with an increased workload associated with these patients (S. M. Smith, O'Kelly, & O'Dowd, 2010). A systematic review of qualitative research on GPs' perspective on the management of multimorbidity acknowledged four main areas of difficulty experienced by GPs in this task (Sinnott et al., 2013). These areas included the disorganisation and fragmentation of healthcare, the inadequacy of guidelines and evidence-based medicine for multimorbidity, challenges in delivering patient-centred care and barriers to shared decision-making (Sinnott et al., 2013). The cumulative burden of multimorbidity treatments has resulted in calls for a minimally disruptive medicine approach which can be described as a patient-centred approach to care that focuses on achieving an individual's goals for life and health while imposing the smallest possible treatment burden on their lives (Leppin, Montori, & Gionfriddo, 2015; May et al., 2009; Trevena, 2018). The NICE guideline on assessment and management of those with multimorbidity specifically recommends that treatment burden should be assessed by discussing with people how their health problems and treatments affect their day-to-day life (National Institute for Clinical Excellence, 2016). Such an approach is in line with patients' desire for collaborative care guided by patient priorities particularly as research suggests

patients are more concerned with functioning and quality of life than symptoms per se (Noel et al., 2005; Noël et al., 2007).

2.3.4.5 Mortality

A recent systematic review and meta-analyses investigated the association between multimorbidity and mortality in older adults aged over 60 years of age (Nunes, Flores, Mielke, Thume, & Facchini, 2016). Results demonstrated that despite heterogeneity of studies and irrespective of the operationalisation of multimorbidity used in studies, there was a positive association between multimorbidity and mortality. Interestingly, disabilities appear to mediate the effect of multimorbidity on mortality again suggesting that identification of those with multimorbidity experiencing functional disability may be an appropriate means to target interventions.

2.3.4.6 Quality of life

Health related quality of life (HRQoL) is a subjective concept encompassing multi-faceted dimensions of physical, emotional and social functioning (Fortin et al., 2004). A number of systematic reviews have examined the impact of multimorbidity on HRQoL in different settings and have consistently found that multimorbidity is associated with poorer QoL. A systematic review on multimorbidity, QoL and HRQoL in primary care settings found inverse relationships between number of chronic conditions and quality of life, particularly in physical dimensions of QoL (M. Fortin et al., 2007; Fortin et al., 2004). There were less clear findings about the impact of multimorbidity in relation to social and psychological domains of QoL (Fortin et al., 2004). Marengoni et al. (2011) focused on the consequences of multimorbidity in the elderly population and identified that across six studies multimorbidity was associated with decreased QoL even after adjustment for confounders. A recent systematic review focused on multimorbidity and HRQoL at mid-life due to the paucity of research about consequences of multimorbidity in this age group (Kanesarajah et al., 2018). This review found consistent findings across eight studies that multimorbidity was associated with poorer HRQoL at mid-life. Two of the cross-sectional studies included in the review found that HRQoL was poorer at early mid-life years in comparison to late mid-life years (Juul et al., 2014; L. Wang, Palmer, Cocker, & Sanderson, 2017). Results from some studies included in the review suggested that particular disease clusters have a more detrimental impact on HRQoL than others. It has

been suggested that clusters which include mental health conditions have poorer HRQoL than those with cardiovascular conditions (Kanesarajah et al., 2018). This finding merits particular consideration given that many multimorbidity studies exclude those with co-morbid mental health conditions despite the association and burden of mental health conditions with multimorbidity (Kanesarajah et al., 2018). A more recent cross-sectional study not included in the Kanesarajah et al. (2018) review, reported similar findings with younger multimorbid adults having worse HRQoL than older adults (N'Goran et al., 2017). Mediators of this relationship should be explored and it should be considered whether those with multimorbidity adjust and develop coping strategies as they age over time.

There is limited research on determinants and factors that may mediate the relationship of multimorbidity with HRQoL (Lawson et al., 2013; Mavaddat, Valderas, van der Linde, Khaw, & Kinmonth, 2014). A longitudinal cohort study examined predictors of HRQoL in those with multimorbidity and found that the impact of multimorbidity on daily activities was the most significant predictor of HRQoL outcomes (Tyack et al., 2016). Other predictors included the impact of chronic back pain on daily activities, increased morbidity, general health functioning and psychological distress (Tyack et al., 2016). A study which investigated the association between multimorbidity and HRQoL and how this varies by deprivation and age, found that multimorbidity was associated with reduced HRQoL (Lawson et al., 2013). The largest reduction in HRQoL was found in those living in the most deprived areas and the deprivation effect was most marked in younger multimorbid adults (Lawson et al., 2013). As previously discussed research indicates that those with multimorbidity in deprived areas experience higher levels of stress and adverse life events and circumstances which may explain this relationship (Barnett et al., 2012).

There was heterogeneity in relation to measures used, definitions of multimorbidity and use of clinical records and self-report to collect data on multimorbidity in reviews and studies of HRQoL and further research is required on predictors and mediators of poor HRQoL in those with multimorbidity. Despite these issues with the current literature, it is clear that multimorbidity negatively impacts QoL.

2.3.5 Irish primary care policy and implementation

In line with international developments Ireland has sought to reform its primary health care system (Phillips & Bazemore, 2010; Van Lerberghe, 2008). The 2001 Irish Health Strategy “Quality and Fairness: A Health System for You” established primary care as the central focus of the delivery of health and personal social services in Ireland and proposed to radically reform and strengthen the primary care system (Department of Health and Children, 2001b). The full details of this proposed reform was published in 2001 in a document entitled “Primary Care: A New Direction” (Department of Health and Children, 2001a). This strategy sought to address issues within the health system including service fragmentation, the sole emphasis on diagnosis and treatment, the poorly developed primary care infrastructure and capacity, the provision of services in secondary care more appropriate in primary care and professional isolation and limited teamwork (Department of Health and Children, 2001a). Primary care was to be the first and continuing point of contact and the appropriate setting for the delivery of 90-95% of health and personal social services. The proposed model of primary care was the development of interdisciplinary primary care teams (PCT) with each team tasked to meet the health and social care needs of specific populations. The strategy also proposed that PCT members should ideally be located on the same site or in very close proximity (Department of Health and Children, 2001a).

Unfortunately, 16 years after the publication of this foundational policy, the primary care system remains fragmented and underdeveloped (Kelly, Garvey, & Palcic, 2016). The strategy originally proposed that approximately 600-1,000 PCTs would be required nationally, based on a population of 3.8 million and would be implemented on a phased basis (Department of Health and Children, 2001a). A target of two-thirds implementation i.e. 400-600 PCTs by the end of 2011 was established. Data regarding the exact number of PCTs that have been established is unclear however it is generally accepted that the targets set for implementation of PCTs have been missed (Kelly et al., 2016; Tierney, O’Sullivan, et al., 2016). There are currently 120 primary care centres operational throughout the country, 12 of which opened in 2018. A further seven are expected to open before the end of the year while another 65 centres are either being developed or in the planning process (Houses of the Oireachtas, 2018). Health policies and strategies published since the 2001 primary care strategy remain committed to the need to reform and develop primary care services as part of wider health system reform in Ireland (Department of Health, 2012; Smyth et al., 2017).

The failure to fully implement the policy has been attributed to a number of issues. The economic crisis of 2008 had a severe impact on the provision of health services in Ireland (Kelly et al., 2016). Notwithstanding the negative impact of the economic recession, implementation appeared to be constrained due to a disconnect between those involved in policy formation and implementation, lack of consideration to the feasibility and practicalities of implementation particularly in relation to the commitment of resources and the power of political actors and organisations including challenges posed by mixed funding models and remuneration (Kelly et al., 2016; O'Reilly et al., 2017). Irish research findings indicate that there has been limited implementation of the interdisciplinary PCTs despite primary care professionals being supportive of interdisciplinary working (N. Kennedy, Armstrong, Woodward, & Cullen, 2015; O'Reilly et al., 2017; Tierney, O'Sullivan, et al., 2016). Factors considered important by primary care professionals to implement interdisciplinary working include increasing resources for primary care, the revision of GP and practice nurse contracts to support involvement in PCTs, increased staffing, interdisciplinary team training, PCT infrastructure including physical space and rooms for intervention delivery, administrative support and improved communication from HSE management to staff (N. Kennedy et al., 2015; O'Reilly et al., 2017; O'Sullivan, Cullen, & MacFarlane, 2015; Tierney, O'Sullivan, et al., 2016).

In 2017 a cross-party committee on the future of healthcare published the "Sláintecare Report" (Oireachtas Committee on the Future of Healthcare, 2017). This report details a vision for a new health service in Ireland and a health reform plan for the next ten years and recommends a universal health system in Ireland. This report marks the first time there has been political consensus and cross party support on a healthcare reform plan. The report provided specific costings for the expansion of entitlements and system development and timelines for implementation and recommended the establishment of an Implementation Office to drive the reform (Oireachtas Committee on the Future of Healthcare, 2017). In terms of primary care the report specifically recommended the continued expansion and reorientation of the healthcare system towards primary care services. It also recommended that GP contracts, due for re-negotiation in 2017, should provide for GP leadership roles with PCTs, facilitate and incentivise new ways of working so that GPs carry out disease prevention and chronic disease management for those with multimorbidities (Oireachtas Committee on the Future of Healthcare, 2017). In August 2018, the Department of Health published the implementation plan for Sláintecare with the overarching goals and strategic actions to guide reform. An executive director and a chair of an advisory council were appointed to guide this reform (Department of Health, 2018). However there has been criticism that the implementation

plan does not contain accurate costings for the individual actions or for the overall proposals (Bardon, 2018).

2.3.6 Recommended care delivery and management of multimorbidity in primary care

The WHO has recommended changes at policy level including taking a systems-based patient-centred approach and universal primary care coverage to meet the needs of those with multimorbidity (World Health Organisation, 2016). A policy brief prepared for the European Union (EU) by the Innovating care for people with multiple chronic conditions in Europe (ICARE4EU) project identified that European health systems do not meet the needs of those with multimorbidity due to their disease-oriented focus and the fragmented nature of healthcare (Rijken et al., 2016). Consistent with the WHO recommendations, the ICARE4EU brief recommended patient-centred and integrated care with specific recommendations for multidisciplinary and self-management support (Rijken et al., 2016). Self-management refers to the care taken by individuals towards their own health and well-being, comprising the actions taken to lead a healthy lifestyle; to meet their social, emotional, psychological and physical needs; to care for their long-term condition; and to prevent further illness (Clark et al., 1991).

The WHO has recommended the Chronic Care Model (CCM) to guide healthcare system reform worldwide (World Health Organisation, 2002). The CCM was developed in recognition of the increasing prevalence, costs, and impact of chronic conditions. It recognises that the health systems' traditionally reactive and curative approach and the fragmentation of care is inappropriate to address the needs of those with chronic conditions (Wagner et al., 2001). The CCM is an internationally recognised evidence-based model which identifies the essential elements of a healthcare system that supports the provision of high quality care for chronic illness in primary care (Darker, Whiston, & O'Shea, 2015; O'Shea, Darker, & O'Kelly, 2013). These elements include: i) healthcare system organisation (i.e. policies, goals and structures of healthcare systems including leadership to secure resources and remove barriers to care), ii) self-management supports (i.e. information and supports to empower patients to manage their care), iii) delivery system design (i.e. coordinating care processes to proactively determine and address individual health needs), iv) decision supports (i.e. healthcare provider access to evidence-based processes and clinical expertise and experience), v) clinical information systems (tracking progress by report data and outcomes to patients and

populations) and vi) community resources and policy (i.e. sustaining care by using community resources and public policy to facilitate care outside of the clinical setting) (Darker et al., 2015). These elements are purported to create more effective health care delivery systems moving from systems which are acute and episodic to those which focus on promotion, prevention, early intervention and chronic care (Darker et al., 2015). A systematic review of the effectiveness of chronic care models internationally concluded that the majority of studies tended to focus on CCMs for common individual chronic diseases (Davy et al., 2015). The most commonly implemented and researched element of the CCM was self-management support. Due to considerable variation between studies in terms of the type and implementation of CCM elements it was impossible to identify which CCM elements resulted in improvements (Davy et al., 2015).

2.3.6.1 Irish health policy on management of chronic diseases

A number of policy documents in Ireland have focused on the management of chronic diseases, however no policy has specifically targeted multimorbidity. In 2008, the Department of Health and Children published “Tackling Chronic Disease: A Policy Framework for the Management of Chronic Disease” which recommended the management of chronic diseases through the re-orientation towards primary care and the provision of integrated health services (Department of Health and Children, 2008). The policy also specifically recommended the development of self-care or self-management programmes for major chronic diseases in order to support patients to actively participate in the management of their condition (Department of Health and Children, 2008). Self-management programmes are any interventions that help patients to manage portions of their chronic disease or diseases through education, training and support (Health Service Executive, 2017).

The development of Integrated Care Programmes (ICPs) and National Clinical Programmes (NCPs) is a major element of the health reform agenda identified in “Future Health: A Strategic Framework for Reform of the Health Service 2012–2015” and “Planning for Health” (Department of Health, 2012; Smyth et al., 2017). ICPs aim to design integrated models of care to treat patients at the lowest level of complexity in a safe, timely and efficient manner in close proximity to their home while NCPs provide the clinical services. An ICP is being developed for the prevention and management of chronic diseases. Both the ICPs and NCPs are focused on single common chronic

diseases rather than multimorbidity (Health Service Executive, 2015a). No specific policy or programme has been developed to address multimorbidity in Ireland.

'Healthy Ireland' is the national policy framework to improve the future health and well-being of the Irish people (Department of Health, 2013). The HSE implementation plan for 'Healthy Ireland' details how this framework will be implemented within Irish health services (Health Service Executive, 2015b). The plan identified three strategic priorities including health service reform, reducing the burden of chronic disease and improving staff health and well-being. Six key actions were identified to reduce the burden of chronic disease as follows: i) reducing modifiable risk factors using a life course perspective, ii) training health professionals to incorporate prevention and support for behaviour change as part of routine healthcare delivery, iii) building capacity for self-care and self-management of chronic diseases, iv) raising standards of health literacy, v) ensuring patient quality and safety and vi) conducting research and applying evidence.

In accordance with these priorities and actions the HSE published the "Making Every Contact Count" (MECC) framework and "The National Self-management Support Framework for Chronic Conditions: COPD, Asthma, Diabetes and Cardiovascular disease" in 2016 (Health Service Executive, 2016, 2017). The MECC framework is focused on chronic disease prevention and envisions that health behaviour change interventions will be part of routine practice delivered by all health professionals in the HSE (Health Service Executive, 2016). The framework presents a tiered model of chronic disease prevention supports readily available within the health service from brief advice to specialised intervention. The four main risk factors to be targeted initially are smoking, alcohol and drug use, unhealthy eating and physical inactivity. A key part of the implementation of this framework is the training of all existing health care professionals and students in undergraduate health professional programmes to carry out a brief intervention with patients or service users.

Strongly linked to the MECC framework is the National Self-Management Support framework which also seeks to enact the HSE implementation plan for Healthy Ireland (Health Service Executive, 2017). This framework provides an overview for the rationale for self-management support; and sets out how the HSE will implement self-management support for four major chronic conditions: COPD, asthma, diabetes and cardiovascular disease. It specifically recommends the development and provision of disease specific and generic self-management supports, training for healthcare professionals and at undergraduate level, developing materials to engage patients in

managing their conditions and organisational level supports including specific governance structures, financial and managerial supports to ensure implementation.

2.4 Evidence of effectiveness of interventions for multimorbidity

Given the high prevalence of multimorbidity in primary care and the negative consequences of multimorbidity on individuals and health care systems it is important that effective interventions are developed for this population. The 2016 updated Cochrane review of interventions for improving outcomes in patients with multimorbidity in primary care and community settings found limited evidence to support multimorbidity management (S. M. Smith et al., 2016). The review examined a range of intervention types using the Effective Practice and Organisation of Care (EPOC) taxonomy (Effective Practice and Organisation of Care, 2015). This taxonomy categorises interventions as follows: i) professional interventions, ii) financial interventions, iii) organisational interventions, iv) patient-oriented interventions and v) regulatory interventions. Table 2.4 defines these type of interventions and reports the number of studies identified in the Cochrane review according to EPOC. In total 18 RCTs were identified in the review all with a low risk of bias. Twelve of the studies were focused on organisation of care delivery with a focus on case management, care coordination or enhancing the skill mix in multidisciplinary teams. The remaining six studies were patient-oriented predominantly focused on self-management interventions delivered directly to patients. Two of the six patient-oriented intervention studies included intervention delivery by occupational therapists and targeted functional difficulties (Garvey et al., 2015; Gitlin et al., 2006). Both of these studies are discussed in detail in Section 2.4.2.

Overall there was mixed results in terms of outcomes for interventions studies with a variety of outcomes examined. Limited effects were found in patient-reported outcomes such as HRQoL and outcomes relating to health service utilisation. Mixed effects were reported on hospital admission rates and outcomes relating to medication use and adherence (S. M. Smith et al., 2016). Five of the included studies examined patient health behaviour outcomes and found these to be improved particularly in those with comorbid conditions. The majority of studies which examined self-efficacy, i.e. an individual's belief or confidence in their ability to carry out a certain task or behaviour, found no improvement post-intervention. Generic self-efficacy is not condition specific and thus as an outcome is applicable to examine in those with multimorbidity. Previous studies that have reported on self-efficacy have involved co-morbidity rather than

multimorbidity. The review also concluded that it was not possible to compare cost-effectiveness across studies with only a small number of studies presenting costs and a smaller number again conducting cost-effectiveness analyses. Existing studies continue to focus on co-morbid conditions and the elderly population which negates the complexity of multimorbidity in primary care settings and the prevalence in younger populations. The review highlighted challenges in multimorbidity research including identifying patients within the broad multimorbidity spectrum at increased risk of poor health outcomes and the targeting of interventions. The review concluded that interventions were more likely to be effective if they focused either on risk factors common across co-morbid conditions or on generic outcomes such as daily functioning. The review recommended future RCTs of interventions for those with multimorbidity in primary care to involve individuals across the age range (S. M. Smith et al., 2016).

Table 2-4 Identification of interventions in Cochrane review for multimorbidity interventions according to EPOC

Intervention Type	Focus and examples	No. of studies identified
Professional interventions	Training healthcare providers to improve their competencies and knowledge related to patients with multimorbidities; needs and patient-centred care e.g. providing training to healthcare professionals on managing multimorbidity to change behaviour of clinicians.	0
Financial interventions	Financial incentives to providers to reach treatment targets for those with multimorbidity e.g. incentivising health service delivery and extending consultation length for those with multimorbidity.	0
Organisation interventions	Organisational changes delivered through practitioners or directly to patients with multimorbidity e.g. supporting or providing case/care management, decision, team working or addition of new team members or healthcare workers.	12
Patient oriented interventions	Interventions directed primarily at individuals with multimorbidity e.g. patient education or support for self-management.	6
Regulatory interventions	Interventions directed at regulatory changes to facilitate and enable funding of care for those with multimorbidity e.g. changes to local or national regulations designed to alter care delivery to improve outcomes.	0

The results of the Cochrane review were similar to those reported by the NICE guidance on multimorbidity which reviewed evidence of interventions (National Guideline Centre, 2016). The purpose of the NICE guidance was to inform patient and clinical decision-making and models of care (interventions) for those with multimorbidity and was conducted by a multidisciplinary expert group of key stakeholders in multimorbidity. The

NICE review included 20 studies of complex interventions which usually comprised a variety of intervention components. There was a wide variety of interventions examined including multidisciplinary care, holistic assessment, care planning, care co-ordination, telephone follow-up, home follow-up, self-management and medication management. The NICE review concluded that the evidence of interventions currently available demonstrates limited clinical benefit in critical outcomes compared to usual care. Given that many models of care comprised multiple components it was impossible to ascertain which components produced effects when detected. No individual model of care provided a consistent high quality evidence base in comparison to usual care. The majority of the evidence was either of low or very low quality. This review also highlighted that the majority of studies were carried out with an older adult population. The review group, given these aforementioned limitations, felt it was not possible to make any recommendations on specific models of care for those with multimorbidity (National Guideline Centre, 2016).

An exploratory cluster RCT, the CARE plus study, was ongoing at the time of the updated Cochrane review but has since been published (Mercer et al., 2016). This study examined the impact of a general practice intervention in highly deprived communities comprised of structured longer consultations, relationship continuity, practitioner support, and self-management support materials. Results indicated a significant difference in HRQoL as measured by the EQ-5D-5L at 6 month follow-up and a reduction in negative well-being relative to controls (usual care). Energy and well-being were not significantly influenced by the intervention at 6 or 12 months. A definitive cluster trial was recommended based on the feasibility of the exploratory trial with the suggestion that enhancing primary care through a whole-system approach may be a cost-effective way to increase quality of life for multimorbid patients in deprived areas (Mercer et al., 2016).

Since the publication of the updated Cochrane review and the NICE review of evidence, the largest trial of an intervention to improve management of multimorbidity in primary care, the 3D intervention, has been published (Salisbury et al., 2018). This study was a pragmatic cluster RCT in general practices in England and Scotland. In total 1,546 patients with three or more chronic conditions were recruited from 33 practices. Intervention participants received the 3D intervention whilst control participants received care as usual. The intervention was based on international guidelines theorised to improve patient management of multimorbidity in primary care. Intervention participants received two six-monthly holistic patient-centred multidisciplinary reviews with a nurse and a GP, and medication review by a pharmacist, which specifically considered the

three dimensions of health, drugs and depression. The intervention also aimed to improve continuity, coordination and efficiency of care with intervention participants assigned a named GP. At 15-month follow-up while measures of patient-centred care showed significant differences in favour of the intervention group there was no evidence of a difference between intervention and controls on the primary outcome of HRQoL as measured by the EQ-5D-5L. Furthermore there were no differences between groups on secondary outcome measures including self-rated health, anxiety, depression, the effect of illness on life, patient-reported treatment burden, numbers of drugs prescribed or improved medication adherence. Intervention participants had significantly more GP and nurse visits than control participants. The study results suggest that while the intervention improved patients' perception of quality of care, it did not improve QoL. While improving patient experience is one of the triple aims of health care (alongside improving the health of populations and reducing costs) (Berwick, Nolan, & Whittington, 2008), it needs to be considered whether this is sufficient justification for provision of the 3D intervention (Salisbury et al., 2018). The results of the health economics analyses from this study, which will be published separately will be important in determining this. The 3D research team conducted an updated review and meta-analysis to include trials published since the updated Cochrane review by S. M. Smith et al. (2016) and included the results of the 3D study. The findings showed that, although different studies used a range of strategies to improve care, it is unlikely that current interventions for multimorbidity have a meaningful effect on patients' quality of life (Salisbury et al., 2018).

In summary, there is limited evidence on the effectiveness of interventions for multimorbidity. There is a need for high quality RCTs, with large samples and comparable study methods. There is also a need to identify those at increased risk of poor health outcomes who should be targeted for intervention. Previous studies of multimorbidity interventions have tended to focus on co-morbid conditions or multimorbidity in older adults (National Guideline Centre, 2016; S. M. Smith et al., 2016). It has been suggested that interventions are more likely to be effective if they focus either on risk factors common across co-morbid conditions or on generic outcomes such as daily functioning (S. M. Smith et al., 2016). This is in line with the preference of those with multimorbidity who report concerns with functioning and the impact of their conditions on daily routines (Bratzke et al., 2015; Noel et al., 2005; Noël et al., 2007).

Self-management interventions has been proposed as a potentially suitable intervention for those with multimorbidity (Liddy, Blazkho, & Mill, 2014; Xu et al., 2017). Some of the studies included in the Cochrane review were self-management interventions. The

background and evidence for self-management interventions for multimorbidity are discussed in the following sections. This is followed by a discussion of the role and evidence for occupational therapy interventions for those with chronic disease and multimorbidity in primary care.

2.4.1 Chronic disease self-management interventions

The Chronic Care Model has established self-management interventions as a necessary component of good care for persons with chronic disease (Davy et al., 2015; Wagner et al., 2001). Self-management interventions for chronic disease have become one of the most commonly researched interventions for chronic disease management in primary care (Reynolds et al., 2018). Self-management is a term attached to many health promotion and patient education programmes (Lorig & Holman, 2003). While no universally accepted definition of self-management exists such interventions are characterised by individuals being actively involved and taking responsibility for their care (Newman, Steed, & Mulligan, 2004). Self-management is generally described as a holistic intervention, aimed at maximising physical and psychosocial functioning by providing individuals with skills to manage symptoms, treatments and the psychosocial consequences of living with a chronic condition (Barlow et al., 2002; Davies, 2010; Richard & Shea, 2011; Schulman-Green et al., 2012).

Corbin and Strauss (1988) are credited with identifying three tasks involved in successfully managing chronic conditions as follows: role, emotional and medical management. Role management involves maintaining, adapting and/or adopting lifestyle behaviours and roles. Emotional management involves dealing with difficult emotions arising from living with a long-term condition. Medical management refers to taking medications and attending medical appointments. Lorig and Holman (2003) propose five core self-management skills needed to manage the aforementioned tasks including problem-solving, decision-making, resource utilisation, forming relationships with healthcare providers and taking action.

Self-management interventions have been distinguished from traditional patient education programmes in a number of ways (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Lorig & Holman, 2003). Traditional patient education defines problems based on inadequate control of conditions. Patient education programmes focus on information provision and technical skills targeting specific conditions with the underlying assumption

being that this information will improve behaviour, compliance and outcomes. In contrast self-management programmes enable participants to define their issues and aim to develop individuals' skills in problem-solving and action planning. It is theorised that this in turn will result in improved self-efficacy and behaviours in managing chronic conditions (Bodenheimer et al., 2002). Both disease-specific and generic chronic disease self-management programmes are available. Generic self-management programmes are targeted at any individual with one or more chronic diseases and are not tailored to support management of a specific chronic disease (Newman et al., 2004; Nolte & Osborne, 2013). Content covered in self-management interventions vary widely and differ in their intensity and duration (Health Information and Quality Authority, 2015).

Self-management programmes are delivered in groups, on an individual basis or a combination of both. Group-based self-management interventions are purported to offer benefits in terms of the value of the group process for participants and reduced costs. Individual interventions provide the opportunity to tailor interventions and are easier to integrate into clinical practice (Newman et al., 2004). In recent years, remote approaches to self-management interventions, such as the internet and telephone, have been developed in order to target groups such as those in full-time employment and in remote and rural areas. However there is limited evidence comparing these different modes of delivery of self-management programmes. Findings from one systematic review and a separate meta-analysis suggest that self-management interventions associated with face to face contact were associated with better outcomes (Newman et al., 2004; Warsi, Wang, LaValley, Avorn, & Solomon, 2004). In contrast to these results, Chodosh, Morton, Mojica, Maglione, and et al. (2005) in a meta-analysis of chronic disease self-management programmes for older adults, were unable to distinguish whether certain self-management programme components contribute to effectiveness. Self-management interventions have been facilitated by healthcare professionals and by lay led leaders. There has been debates about the merits of using lay leaders or health professionals as facilitators. It has been suggested that the advantage of lay leaders is they can act as role models and are less costly than using health professionals, on the other hand health-care professionals with their knowledge and skills can act as powerful models and are more able to address factual issues related to an illness (Coleman et al., 2012; Newman et al., 2004). Modelling for behaviour change has been argued to be constrained in lay led programmes because of the limited knowledge of lay leaders (Coleman et al., 2012). Presently limited evidence exists to determine which components of self-management programmes are more effective in terms of generic versus disease specific programmes, group versus individual interventions or those delivered by lay

leaders in comparison to health professionals (Health Information and Quality Authority, 2015; Newman et al., 2004; Warsi et al., 2004).

2.4.1.1 Effectiveness of generic chronic disease self-management programmes

Generic self-management programmes, developed to address the self-management needs of those with a range of chronic conditions, have been suggested as suitable for those with multimorbidity as disease specific programmes result in provision of confusing and conflicting information (Bodenheimer et al., 2002; Lorig & Holman, 2003). Some of the most common examples of generic self-management programmes include the Flinders programme, the Stanford Chronic Disease Self-Management programme (CDSMP) and the Expert Patients Programme (EPP). These programmes and the evidence for their effectiveness are presented in Table 2.5. In summary there is inconclusive and limited evidence of the clinical and cost-effectiveness of these self-management programmes.

Trials of the CDSMP and EPP has been criticised for carefully selecting participants based on specific chronic conditions with the majority of participants being older adults, of a higher socio-economic status, white and female (Greenhalgh, 2009; Horrell & Kneipp, 2017). This is despite research indicating that younger patients and those with poorer health and self-efficacy are most likely to benefit (Reeves et al., 2008). Difficulties have been encountered in recruiting participants from diverse backgrounds, from lower socio-economic groups and with low health literacy (Paone, 2014). The majority of trials have recruited using self-referral and social marketing which raises questions whether self-management programmes are recruiting more motivated individuals in better health (Bodenheimer et al., 2002; Bury & Pink, 2005; Greenhalgh, 2009). Studies have failed to examine non-attenders of programmes in any great detail (Bury & Pink, 2005). Such difficulties raise concerns that self-management interventions may not be accessible and acceptable to those at risk of poorer outcomes and most needing intervention. Other criticisms levelled at the CDSMP and EPP include a preoccupation with enhancing self-efficacy at the expense of provision of adequate supports and addressing social inequalities in management of chronic conditions (Greenhalgh, 2009; Lindsay & Vrijhoef, 2009; Rogers, 2009; Wilson, Kendall, & Brooks, 2007). The need to address the complex and fragmented nature of the health care service has also been ignored and needs to be acknowledged in self-management programmes (Bury & Pink, 2005). Furthermore,

the importance placed on peer-led self-management support is not supported by evidence and may neglect the value and need of support provided by healthcare professionals (Chodosh et al., 2005; Rogers, 2009).

Table 2-5 Generic chronic disease self-management programmes

Programme	Aim	Delivery and components	Evidence on effectiveness
Flinders Chronic Condition Management Programme	<p>To provide self-management support in any chronic condition, tailored to the bio-psychosocial needs of patients.</p> <p>To provide a link between the individual with chronic conditions and, disease specific and lay-led education groups</p>	<p>Delivered by trained health professionals. Care-planning approach using standardised forms and tools:</p> <ul style="list-style-type: none"> • Patient self-assessment of self-management capacity • Motivational interview • SMART (specific, measurable, achievable, realistic, timed) goals • Self-management care plan • Link to self-management support programmes 	<p>RCT: Statistically significant improvements in physical health components of HRQOL at six-months.</p> <p>No differences in self-management competencies, self-efficacy, energy and health distress.</p> <p>Evidence of poor links between healthcare providers and community resources (Battersby, Harris, Smith, Reed, & Woodman, 2015)</p>
Stanford Chronic Disease Self-Management Programme (CDSMP)	<p>To improve individual's management of medication, maintenance of life roles and management of negative emotions by increasing knowledge, skill and confidence (self-efficacy) to deal with disease-related problems</p>	<p>Based on self-efficacy theory. Group-based programme delivered by trained lay leaders; Six weekly sessions; 2.5 hours per session</p> <p>Teaches generic skills and topics including problem-solving and goal-setting</p> <p>Topics include exercise, cognitive symptom management techniques, medication management, managing exercises, dealing with emotions, communication, problem-solving and decision-making</p>	<p>RCT; Statistically significant improvements in self-efficacy, self-management behaviours and health care utilisation at 6-month follow-up (Lorig et al., 1999)</p> <p>RCT: Reduced emergency room visits, outpatient visits, health distress and improved self-efficacy at 2 years (Lorig et al., 2001)</p> <p>Systematic review and meta-analysis: Moderate improvements in self-efficacy and small-moderate improvements in psychological health and some health behaviours. Inconsistent findings in health status and health care utilisation (Brady et al., 2013; Nolte & Osborne, 2013)</p>
Expert Patients Programme (EPP)	<p>To deliver self-management support and improve the quality of life of people with long-term conditions by developing generic self-management skills and improving people's confidence and motivation to take more effective control over their lives and illnesses.</p>	<p>Same format as the CDSMP delivered within the National Health Service (NHS) by trained lay volunteers</p>	<p>RCT: Significant improvements in self-efficacy, energy levels and likely to be cost-effective (Rogers et al., 2008).</p> <p>No reductions in health care utilisation. Difficulties with recruitment in recruiting disadvantaged groups and engaging health professionals and integrating into NHS (Vadiee, 2012)</p>

2.4.1.2 Delivering self-management programmes in healthcare systems

Of particular concern are the difficulties encountered in pragmatic trials and other studies in integrating these programmes successfully into the health care system. Barriers to integration identified include difficulty recruiting sufficient numbers of patients, a low profile of self-management programmes within the health system and broader community, uncertainty among health professionals of the evidence of programme benefits, lack of engagement of GPs and healthcare professionals, lack of a multidisciplinary approach and fragmented health service delivery (Jordan & Osborne, 2007). While both GPs and other health professionals are commonly used as a source of recruitment, both have been found to be low sources of referrals for self-management programmes in primary care settings (Horrell & Kneipp, 2017; A. Kennedy, Rogers, & Gately, 2005; Packer et al., 2012). Some have argued that using health professionals as a source of referrals makes patients feel obliged and coerced to participate (Wilson et al., 2007). Problems encountered with referrals from health care professionals have been attributed to lack of awareness, time constraints, work practices, lack of training about self-management and organizational structures whereby there is poor communication and links within the PCT and other services (A. Kennedy et al., 2007; Packer et al., 2012). Strategies proposed to promote engagement of health professionals include provision of self-management training, education and dissemination across the care continuum and standardised referral pathways. It has also been recommended that programmes should be delivered at a local level to encourage community ownership and sustainability (Jordan & Osborne, 2007).

2.4.1.3 Evidence for chronic disease self-management programmes in multimorbidity

In 2014 the National Institute for Health Research in the UK published the PRISMS (Practical systematic Review of Self-Management Support for long-term conditions) study, a systematic review of self-management support for long term conditions (S. J. C. Taylor et al., 2014). This review aimed to inform health-care commissioners and providers about what works, for whom, and in what contexts. The review included 30 qualitative systematic reviews, 102 quantitative systematic reviews (including 969 RCTs), and 61 individual RCTs. The findings of this review concluded that effective self-management support interventions have multiple components, are flexible and tailored to the individual and their culture, beliefs, specific long-term conditions and position on the disease trajectory (S. J. C. Taylor et al., 2014). Such interventions require

a whole systems approach and should be underpinned by good collaborative relationships between the patient and a trusted health-care professional all within a healthcare organisation that actively promotes self-management (S. J. C. Taylor et al., 2014).

In Ireland in 2015, the Health Information Quality Authority of Ireland (HIQA) published a health technology assessment (HTA) of disease-specific and generic chronic disease self-management support interventions in order to inform the development of a chronic disease self-management support framework by the HSE, i.e. The National Self-management Support Framework for Chronic Conditions: COPD, Asthma, Diabetes and Cardiovascular disease (Health Information and Quality Authority, 2015; Health Service Executive, 2017). This HTA adopted the methodology of the earlier PRISMS review and updated and completed additional literature searches. The HIQA report includes the results of the updated search as well as the original PRISMS findings. Table 2.6 contains a summary of the evidence for clinical and cost-effectiveness based on this review. Over 2,000 RCTs across 160 systematic reviews examining clinical effectiveness of interventions were included in this review. Cost-effectiveness of these interventions was considered based on 180 studies. Overall evidence of the clinical and cost effectiveness of disease specific self-management interventions are unclear but there is some evidence that self-management programmes can improve health outcomes in specific individual conditions. A wide range of self-management interventions exist which impacts on the ability to determine which self-management interventions and intervention components are most effective. Existing RCTs were limited by the heterogeneous nature of interventions and studies, small sample sizes and short duration of follow-up which limits the applicability and validity of the findings and raises concerns about the sustainability of any benefits reported (Health Information and Quality Authority, 2015).

Table 2-6 Evidence of clinical and cost effectiveness of self-management interventions in HIQA HTA

Condition	Evidence on effectiveness
Multimorbidity	<ul style="list-style-type: none"> Effectiveness of self-management programme for those with multimorbidity have not been considered despite likelihood of many studies including those with multimorbidity.
Generic self-management programmes	
Any chronic condition	<ul style="list-style-type: none"> Majority of studies focus on Stanford CDSMP (See Table 2.5). CDSMP programmes: Evidence of low to very low quality. Some evidence of short-term improvements in self-efficacy, exercise, pain, disability, fatigue, and depression. No evidence of improvement in healthcare utilisation. No long-term follow-up. Some evidence of reduced health care utilisation, diet adherence, patient engagement, and self-reported health status in other self-management programmes.
Disease specific self-management programmes	
Asthma	<ul style="list-style-type: none"> Good evidence of improved QoL and reduced hospital admissions Limited evidence of cost-effectiveness
COPD	<ul style="list-style-type: none"> Good evidence of improved HRQoL Limited evidence of reduced health care utilisation and cost-effectiveness
Diabetes	<ul style="list-style-type: none"> Some evidence of short-term improvements in blood glucose Some evidence of cost-effectiveness
Cardiovascular disease (stroke, hypertension, coronary heart disease, heart failure)	<ul style="list-style-type: none"> Coronary heart disease/hypertension: Some evidence of smoking cessation and reduced blood pressure and limited evidence of cost-effectiveness Stroke/heart failure: Limited evidence of clinical or cost-effectiveness

Both the PRISMS and HIQA HTA highlighted in particular that it was not possible to specifically consider the effectiveness of self-management interventions for those with multimorbidity as it was not discussed in any detail in any of the included systematic reviews. This may be due to multimorbidity only recently becoming an area of particular concern to health services and research. Both reports stated that it was inevitable that most of the adult participants included within the systematic reviews would have more than one chronic condition.

The NICE Multimorbidity Guidance review group also conducted an evidence review of self-management support programmes for individuals with multimorbidity as part of their guidelines on multimorbidity (National Guideline Centre, 2016). In total, 13 RCTs were included in the review. The majority of the studies did not target multimorbidity specifically in terms of population but rather included co-morbid conditions or older adults. Intervention settings

included hospital clinics, nursing homes and community. Interventions varied widely in terms of duration (from 6 to 22 months), delivery method (group-based, individual or remotely), facilitator (health professional or lay leader) and key components (combinations of problem-solving, therapy, goal-setting, psychological and emotional strategies, skills for communicating with health care professionals, exercise, healthy eating, medication management, fatigue management, peer support, coordinating care, disease-specific education and coaching). Outcomes examined included HRQoL, function, self-efficacy, emergency department use, physical activity levels and treatment burden. The guidance review group concluded that there was insufficient evidence to recommend self-management programmes for those with multimorbidity. The group also highlighted concerns about the ability of the elderly, those who are frail and those with cognitive impairment being able to participate and access such interventions.

The Cochrane systematic review included two studies of chronic disease self-management support programmes which included participants with multimorbidity in primary care settings (S. M. Smith et al., 2016). As previously outlined in Table 2.5, Lorig et al. (1999) developed the Stanford generic chronic disease self-management programme, this programme is synonymous with self-management. The first RCT of this programme involved 952 participants with a sub-group of 536 participants being described as having two or more of the following conditions: heart disease, stroke, arthritis, lung disease. The programme included weekly group meetings for seven weeks delivered by trained lay leaders in community settings. Results from this study found statistically significant improvements at 6 months in exercise levels, frequency of cognitive symptom management, communication with physicians, self-reported health, health distress, fatigue, disability, and social/role activities limitations. There was also evidence of reduced hospitalisations and days in hospital. No differences were found in pain/physical discomfort, shortness of breath, or psychological well-being. It was unclear how many chronic conditions participants had. Furthermore, while follow-up for the overall study was described as adequate specific details pertaining to follow-up for the multimorbidity group was not provided.

The other included study, a pilot RCT, evaluated the effectiveness of OPTIMAL, a six-week occupational therapy led self-management support group programme for patients with multimorbidity in primary care settings (Garvey et al., 2015). While the RCT found significant improvements in frequency of activity participation, perceptions of activity performance and satisfaction, self-efficacy, independence in daily activities and quality of life, these results should be interpreted with caution as it was a pilot RCT with immediate follow-up data only (Garvey et al., 2015). The development and evaluation of the OPTIMAL programme is

discussed in detail in Chapter 3, Section 3.3. The current PhD thesis is an RCT and process evaluation of the OPTIMAL programme.

In summary the Cochrane review, PRISMS, HIQA HTA and NICE multimorbidity guidance review group, were unable to draw conclusions on the effectiveness of self-management programmes for those with multimorbidity and recommended further research to develop and evaluate self-management programmes specifically targeted and developed for those with multimorbidity.

Section 2.4.2 begins with an examination of occupational therapy interventions for multimorbidity in primary care and occupational therapy self-management interventions for multimorbidity and concludes with a review of the role of occupational therapy in primary care.

2.4.2 Occupational therapy interventions for multimorbidity in primary care

As previously discussed, the literature demonstrates the negative impact of multimorbidity on function, psychological well-being, quality of life and healthcare utilisation. A number of studies have reported that concerns regarding functioning take precedence over symptom management for those with multimorbidity (Bratzke et al., 2015; Cheraghi-Sohi et al., 2013; Noel et al., 2005). A shift from a disease-oriented approach to a function-oriented approach for the management of multimorbidity in primary care has been advocated for. The updated Cochrane review highlighted the lack of evidence for effective interventions for multimorbidity in primary care settings and recommended that interventions targeting specific risk factors or with a focus on functioning are more likely to be effective (S. M. Smith et al., 2016). In line with these priorities and recommendations occupational therapy has been identified as a profession potentially suited to providing interventions to those with multimorbidity in research agendas for multimorbidity and occupational therapy for chronic disease (Hand, Law, et al., 2011; Hand, Letts, et al., 2011; Leland et al., 2017; Mercer et al., 2009). Occupational therapy's focus on function and quality of life transcends specific diagnoses and enables OTs to address daily issues and complexities encountered by individuals with multimorbidity (Donnelly, Brenchley, Crawford, & Letts, 2014). However there is limited high quality research of occupational therapy interventions for those with multimorbidity in primary care with existing research of occupational therapy interventions for chronic disease tending to focus on single conditions and not reporting the presence of multimorbidity within populations studied. However there is a small number of occupational therapy interventions which have specially targeted those with multimorbidity.

As previously reported in Section 2.4, in the S. M. Smith et al. (2016) updated Cochrane review two of the included patient-oriented intervention studies involved intervention delivery by occupational therapists and targeted functional difficulties (Garvey et al., 2015; Gitlin et al., 2009). One of the studies was an RCT examining the effectiveness of a home-based occupational therapy intervention for older adults with multimorbidity (Gitlin et al., 2009; Gitlin et al., 2006). The other study was a pilot RCT of the OPTIMAL programme, an occupational therapy led self-management support programme for those with multimorbidity (Garvey et al., 2015). Gitlin et al. (2009) examined the effectiveness of a home-based and telephone intervention for urban community-dwelling older adults aged 70 years and older with multimorbidity and functional difficulties. Participants had a broad range of chronic conditions and a high level of multimorbidity with a mean number of seven chronic conditions. The intervention comprised occupational therapy and physical therapy sessions involving home modifications, problem-solving, and training in energy conservation, safe performance, balance, muscle strength, and fall recovery techniques. Those in the intervention group received four home visits with an occupational therapist and one visit from a physical therapist over a six month period. Over the following six months, three follow-up phone calls to reinforce strategies and a home visit at 10 months were provided by the occupational therapist. Those in the control group received no intervention. Findings suggested statistically significant improvements in functional performance in both basic activities of daily living (BADLS) and instrumental activities of daily living (IADLS) in intervention in comparison to control group participants. Improvements tended to be larger in BADLS than IADLS which may be suggestive of participants with greater functional disability. Statistically significant improvements were also found in functional self-efficacy (confidence in managing activities of daily living). Those in the intervention group had fewer home hazards and more use of adaptive strategies (Gitlin et al., 2006). Additionally intervention participants were found to have a statistically significant reduced risk of mortality, 1% risk of mortality, compared to a 10% risk in the control group indicating that the intervention may have reduced mortality risk (Gitlin et al., 2009). The differences between the intervention and control outcomes can be described as small to modest and the measures used were not well validated. In addition this study specifically targeted older adults which negates younger adults with multimorbidity. The other study, Garvey et al. (2015) examined an occupational therapy led-self management intervention was briefly outlined in Section 2.4.1 and is discussed in further detail in the proceeding section.

2.4.3 Occupational therapy led self-management interventions for multimorbidity in primary care

As highlighted there is a lack of evidence to support the effectiveness of self-management interventions for those with multimorbidity with recommendations made for further research to develop and evaluate self-management programmes specifically for the multimorbidity population. The client-centred nature of occupational therapy and the profession's focus on understanding the relationship between illness and disability, function, personhood and the environment has been suggested to make occupational therapists suited to providing multifaceted self-management support (Townsend, 2011). Occupational therapists are skilled in assisting individuals to incorporate self-management strategies into daily activities and routines using their expertise in enabling occupation (Pyatak et al., 2018; Raymond, Levasseur, Chouinard, Mathieu, & Gagnon, 2016).

Despite assertions that occupational therapists are suited to delivering self-management interventions for multimorbidity there is limited high quality research to support the effectiveness of such interventions for either single or multiple chronic diseases (Leland et al., 2017; Packer, 2011, 2013). A systematic scoping review (Richardson et al., 2014) of existing research of occupational therapy self-management programmes suggested that programmes have been targeted at specific chronic diseases such as visual impairment, diabetes, arthritis, cancer and neurological conditions such as stroke, multiple sclerosis and Parkinson's (Ghahari & Packer, 2012; Kos et al., 2016; Loh, Packer, Chinna, & Quek, 2013; Pyatak et al., 2018; Raymond et al., 2016). The content, format and duration of such interventions varies widely and focus on some but not all self-management tasks. The heterogeneity of studies, interventions and outcome measures make it difficult to draw conclusions on the effectiveness of occupational therapy led self-management interventions. There is a paucity of high quality studies, such as RCTs, for occupational therapy interventions for chronic conditions including self-management interventions (Hand, Law, et al., 2011; Hand, Letts, et al., 2011). The disease and symptom specific nature of many of the occupational therapy led self-management interventions means it is not possible to generalise these programmes to those with multimorbidity. It remains that the role of occupational therapy in relation to multimorbidity is poorly defined and researched. In the literature search no studies of occupational therapy self-management interventions specifically for those with multimorbidity in primary care were identified. The need for occupational therapists to develop and evaluate self-management programmes for multimorbidity has been identified in occupational therapy position papers

and research agendas (Hand, Law, et al., 2011; Hand, Letts, et al., 2011; Leland et al., 2017; Pyatak, 2011).

The paucity of evidence supporting the effectiveness of self-management interventions for those with multimorbidity, recommendations that multimorbidity interventions should be function-oriented and that occupational therapists are potentially suited to delivering such interventions, resulted in the development of OPTIMAL, an occupational therapy led self-management support programme for individuals with multimorbidity for delivery in primary care. The development and evaluation of OPTIMAL was guided using the Medical Research Council framework for development and evaluation of complex interventions (Medical Research Council, 2008). OPTIMAL was developed and evaluated in two previous pilot studies of occupational therapy interventions for multimorbidity prior to the pilot RCT by Garvey et al. (2015) (Section 3.3, Chapter 3 describes the development and piloting of OPTIMAL). The first pilot study examined individual home-based occupational therapy assessment and intervention (Wallace et al., 2011). This study indicated that while the individual OT interventions seemed promising they were resource intensive with a range of 2-11 home visits required per patient (Wallace et al., 2011). Development and testing of a group based programme was therefore recommended. This led to a pilot study developing and examining the acceptability and impact of the OPTIMAL programme (O' Toole et al., 2013). The OPTIMAL programme was a six-week group-based programme, comprising an educational and individual goal-setting component. Topics included in the programme were fatigue management, healthy eating; maintaining mental health, maintaining physical activity, managing medications and effective communication strategies. One of the weekly sessions incorporated education on physical activity delivered by a physiotherapist and another incorporated medicines management, delivered by a pharmacist. Findings were promising with statistically significant improvements at 8-week follow-up in activity participation, self-perceptions of occupational performance and satisfaction with same and self-efficacy. Qualitative findings showed that participants perceived improvements in the targeted behaviours and their general health. The weekly goal-setting and review element of the programme helped them focus and commit to achieving their weekly goals (O' Toole et al., 2013).

These promising findings led to a pilot RCT of the OPTIMAL programme conducted in three HSE primary care team areas in Dublin. The study included adults with multimorbidity (defined as two or more chronic conditions) and a minimum of 4 repeat prescriptions (polypharmacy) with 50 participants ultimately being recruited. Intervention participants received the OPTIMAL

programme while controls were allocated to a waiting list to receive care as usual. Participants' median number of chronic conditions was 4.5.

The study demonstrated significant improvements in activity participation and performance, self-efficacy and HRQoL at immediate follow-up. No differences were found in anxiety, depression, self-management scores or healthcare utilisation. A limitation of this study included low attendance among participants and a lack of blinding of outcome assessors which may have led to bias in the results. It was recommended that a RCT of the OPTIMAL programme, as per Stage III of the MRC framework, be undertaken to test the sustainability of these effects over time, across a wider range of primary care settings.

This RCT forms the current PhD thesis which aims to examine the effectiveness of the OPTIMAL programme in increasing frequency of activity participation and HRQoL. The programme was delivered by occupational therapists across a number of HSE primary care areas. Alongside an RCT of the OPTIMAL programme examining its effectiveness in improving outcomes, the PhD study included a concurrent process evaluation, to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice.

2.5 Current practice of occupational therapists in primary care

A number of studies, using cross-sectional surveys, qualitative and case study designs, have explored the scope of practice of primary care occupational therapists (Flannery & Barry, 2003; Quick, Harman, Morgan, & Stagnitti, 2010; Scriven & Atwal, 2004; Wood, Fortune, & McKinstry, 2013). Findings across international studies indicate that many primary care occupational therapists are still most commonly involved in providing individual assessment and intervention in the home environment to older adults and those with chronic conditions (Donnelly et al., 2014; Donnelly, Leclair, Wener, Hand, & Letts, 2016; Quick et al., 2010; Scriven & Atwal, 2004). Primary care occupational therapists tend to work on an urgent short-term basis and focus on home safety and functional independence for high-risk clients (Turcotte, Carrier, Desrosiers, & Levasseur, 2015). Concerns were expressed by some occupational therapists that there was a lack of understanding by some of their primary care colleagues about the scope of occupational therapy practice in primary care but this is perhaps unsurprising given the prioritisation of these home-based interventions (Wood et al., 2013). Occupational therapists generally perceived roles in intervening with individuals and groups at an earlier stage in their illness trajectory as aligned with primary care philosophy and practice. However, primary care occupational therapists reported limited involvement in such

interventions with frequently reported barriers including insufficient knowledge, high demand for services, limited funding and time spent on administrative tasks (Donnelly, Brenchley, Crawford, & Letts, 2013; Donnelly et al., 2014; Donnelly et al., 2016; Halle, Mroz, Fogelberg, & Leland, 2018; Quick et al., 2010; Tinnelly & Byrne, 2016).

In line with international research, primary care occupational therapists in Ireland also appear to experience difficulties in providing a broad scope practice as envisioned in Irish primary care policy (Department of Health and Children, 2001a). Two studies, published ten years apart, conducted in Irish primary care settings regarding the role of occupational therapy in primary care, highlighted the lack of progress during this timeframe (Flannery & Barry, 2003; Tinnelly & Byrne, 2016). While occupational therapists believe Irish primary care policy has expanded their role, practice remains in the development phase and continues to be associated with traditional community-based practice. In terms of the current scope of practice, primary care occupational therapists identified that they tended to work primarily with an elderly population with a focus on interventions including equipment provision, functional assessment and environmental adaptations for those experiencing significant disability. Over 66% of occupational therapists in Ireland reported limited or no involvement in group interventions targeting individuals (Tinnelly & Byrne, 2016). Based on these findings it appears that primary care occupational therapists in Ireland do not commonly provide group-based interventions in areas such as self-management. Barriers to involvement in these type of interventions were attributed to high referral rates for individual interventions, lengthy waiting times for service users, unrealistic caseloads and inadequate resources. These barriers resulted in occupational therapists experiencing pressure to reduce waiting lists. Occupational therapists also reported covering more than one primary care team and wide variation in terms of primary care team members, team functioning and facilities depending on location (Tinnelly & Byrne, 2016). Figures from May 2017 indicated that 1,546 patients aged 18 years and over were waiting over a year for an initial consultation with a primary care occupational therapist (Brennan, 2017). The role satisfaction for primary care occupational therapists in Ireland (Tinnelly & Byrne, 2016) appears to be lower than that reported in studies elsewhere (Quick et al., 2010). However occupational therapists in Ireland did identify supports in developing their role in primary care and other areas of practice from their occupational therapy manager, occupational therapy and multidisciplinary colleagues (Tinnelly & Byrne, 2016). This is in contrast to one study in Australia of primary care occupational therapists who when endeavouring to engage in interventions beyond individual home-based occupational therapy interventions identified challenges related to unsupportive occupational therapy managers and colleagues (Wood et al., 2013).

Recommendations were provided by a number of authors regarding strategies to enhance and broaden the scope of current primary care occupational therapy practice. Some authors have advocated for increased attention to be paid to primary care practice in occupational therapy undergraduate and postgraduate curricula (Halle et al., 2018; Quick et al., 2010; Wood et al., 2013). Receiving support from occupational therapy professional organisations through position statements on primary care practice has been recommended in order to advocate for a broader role and scope of practice in primary care occupational therapy than that currently in action (Wood et al., 2013). While position papers on primary care occupational therapy have been developed internationally and support a broad scope of practice in primary care, no such position statement has been developed by the Association of Occupational Therapists in Ireland (AOTI). Such a statement may assist in articulating the role within Irish primary care contexts. Turcotte et al. (2015) argued that although the needs of urgent and high risk clients must be addressed first, follow-ups could allow occupational therapists to intervene on less urgent but nonetheless important needs for meaningful activity and participation. In order to broaden the scope of primary care practice, primary care services must make early interventions for those who are currently functioning but at risk of decline, including group-based interventions, an operational priority (Turcotte et al., 2015). A more contentious suggestion is that a separate role for occupational therapists should be established within primary care to deliver such interventions rather than expanding the existing roles of primary care occupational therapists (Turcotte et al., 2015).

2.6 Summary

This literature review has presented the available research related to the extent and impact of multimorbidity, multimorbidity interventions, self-management interventions and occupational therapy interventions for multimorbidity in primary care settings. The findings from the literature review are summarised below in relation to how they informed the current study i.e. a Phase III study of the OPTMAL programme. The key findings from the literature review are presented in accordance to PICO (Population, Intervention, Comparison, Outcomes) and summarised in Table 2.7.

While no single definition of multimorbidity is accepted, multimorbidity is commonly defined as the presence of two or more chronic conditions. This definition was adopted for the current study given it is commonly used, easily understood and reflective of the generalist approach of primary care. Multimorbidity negatively impacts functioning and quality of life for the individual with resultant increased healthcare utilisation and cost (Marengoni et al., 2011; Xu

et al., 2017). Those with multimorbidity identify priorities around functioning rather than symptoms per se (Noel et al., 2005).

Primary care is recognised as the most appropriate place for the management and coordination of care for those with multimorbidity. Despite this, there is a lack of effective interventions for those with multimorbidity in primary care (S. M. Smith et al., 2016). Patient-oriented interventions focusing on function and risk factors common across co-morbid conditions are more likely to be effective than those focused on changing the organisation of care. An example of a patient-oriented intervention is self-management programmes (S. M. Smith et al., 2016). These programmes have been increasingly recommended as an intervention for those with single and multiple morbidities despite limited evidence for the effectiveness of such interventions for those with multimorbidity (Health Information and Quality Authority, 2015). One of the most commonly researched self-management interventions is the Stanford Chronic Disease Self-Management Programme (CDSMP), a group-based generic programme. However, existing evidence suggests that the CDSMP has modest effects particularly in settings outside of the USA with limited evidence of effectiveness for those with multimorbidity.

Existing interventions for multimorbidity do not target functioning and quality of life despite these outcomes being prioritised by those with multimorbidity (S. M. Smith et al., 2016). Occupational therapy has been proposed as suited to delivering interventions to those with multimorbidity given the profession's focus on such outcomes. There is limited evidence of effective occupational therapy interventions for multimorbidity (Hand, Letts, et al., 2011; Leland et al., 2017).

The gaps in the literature led to the development and evaluation of occupational therapy complex interventions for those with multimorbidity in primary care by the research supervisors and the PhD candidate alongside other occupational therapy researchers across a number of pilot studies. These studies were conducted using the Medical Research Council framework for development and evaluation of complex interventions (Medical Research Council, 2008). These studies led to the development and evaluation of the OPTIMAL programme, which is an occupational therapy led self-management support programme for those with multimorbidity. The programme was based on the CDSMP with the key adaptations being an occupational therapy focus, groups being professionally led and a clear focus on the specific challenges of multimorbidity identified from the qualitative literature in this area (Garvey et al., 2015; O'Toole, Connolly, & Smith, 2013; Wallace et al., 2015).

The overall aim of the current study, as per Stage III of the MRC framework, was to evaluate the effectiveness of the OPTIMAL programme in a RCT (Medical Research Council, 2008). The programme was delivered within Irish primary care settings. The literature suggests that primary care services in Ireland remain fragmented and underdeveloped with poor primary care team functioning. Primary care occupational therapists mainly deliver home-based interventions to those with urgent safety needs and significant functional disability. However, recent Irish health policy have advocated for the need for health behaviour change and self-management interventions. Given these service constraints and recent policy initiatives an important aspect of the trial of the OPTIMAL programme was to evaluate its implementation within existing primary care services in Ireland

The following two chapters outline in detail the study's methodology. Chapter 3 describes the development of the OPTIMAL programme and the methodology of the RCT to examine its effectiveness. Chapter 4 presents in detail the methods of the process evaluation of this trial.

Table 2-7 Summary of literature according to PICO

PICO element	Study component	Key literature informing PICO
Population	Multimorbidity	<ul style="list-style-type: none"> Lack of effective interventions for those with multimorbidity despite the negative impact on individuals in terms of functioning and quality of life and healthcare system in terms of utilisation and cost
	Two or more long-term chronic conditions	<ul style="list-style-type: none"> No single definition of multimorbidity accepted Definition of multimorbidity is commonly used, easily understood and reflective of the generalist approach of primary care
	4 or more repeat medications	<ul style="list-style-type: none"> Need to target those at risk of poorer outcomes for intervention Those with multimorbidity with higher numbers of medications at risk of poorer outcomes Polypharmacy defined as four or more repeat medications
	Aged 40 years	<ul style="list-style-type: none"> Existing interventions for those with multimorbidity target older adults. Need to target those multimorbidity across the age spectrum. A cut-off of 40 years chosen as multimorbidity is relatively uncommon in patients younger than and it facilitates targeted recruitment
	Self- management programme	<ul style="list-style-type: none"> Self-management programmes are designed to support patients to manage the consequences of living with chronic conditions
Intervention	Occupational therapy led	<ul style="list-style-type: none"> Cochrane review identified that interventions focusing on difficulties patients experience with daily functioning may be more effective than those focused on changing the organisation of care. Those with multimorbidity have identified priorities around functioning as opposed to the actual symptoms of their conditions. Lack of effective occupational therapy interventions for those with multimorbidity despite profession being proposed as suited to delivery of same due to focus on functioning Harness elements of other effective professionally led programmes in cardiac and pulmonary rehabilitation
	6 week group-based programme including education and goal-setting	<ul style="list-style-type: none"> Based on similar self-management programmes and effective cardiac/pulmonary rehabilitation programmes. Pilot study of individual occupational therapy intervention for multimorbidity recommended group-based programme to increase skill transfer and social interaction Topics based on challenges of multimorbidity identified in qualitative literature
Control	Usual primary care services	<ul style="list-style-type: none"> Primary care is an appropriate place for management of multimorbidity, lack of effective interventions for those with multimorbidity in primary care
Outcome	Quality of life Frequency of activity participation	<ul style="list-style-type: none"> Existing interventions for multimorbidity do not target functioning and quality of life despite these outcomes being core outcomes and prioritised by those with multimorbidity

**Chapter 3 OPTIMAL
randomised controlled trial
study design**

3.1 Introduction

The overall aim of this study was to evaluate the effectiveness of the OPTIMAL programme, an occupational therapy led chronic disease self-management programme for individuals with multimorbidity in primary care, as per Stage III of the Medical Research Council (MRC) framework (Medical Research Council, 2008). The development and evaluation of the OPTIMAL programme has been guided by the MRC framework for the development and evaluation of complex interventions as initially presented in Chapter 1. This chapter outlines the development of the OPTIMAL programme including a summary of the preceding pilot studies which led to the current study i.e. a RCT of the OPTIMAL programme. It presents the design of the pragmatic parallel randomised controlled trial to test the effectiveness of the intervention. The process evaluation methodology is presented in detail in Chapter 4.

3.2 Approaches to the development of complex interventions: The Medical Research Council Framework

Complex interventions have been defined as interventions comprising of several interacting components, which may act independently or interdependently, but all of which seem essential to the proper functioning of the intervention (Craig et al., 2008). While few interventions are truly simple, the number of components and range of outcomes vary widely. A number of characteristics distinguish complex interventions including: i) the number of interacting intervention components, ii) the number and difficulty of behaviours required by both those delivering the intervention and those who receive it, iii) the number of groups or organisational levels targeted by the intervention, iv) number and variability of outcomes and v) the amount of flexibility or tailoring of the intervention permitted (Craig et al., 2008). Challenges exist in standardising the design and delivery of interventions, their sensitivity to features of the local context, the organisational and logistical difficulty of applying experimental methods to service or policy change, and the length and complexity of the causal chains linking intervention to outcome (Craig et al., 2008).

As a result of the methodological challenges posed by the development and evaluation of complex interventions, the MRC published a framework in 2000 to assist researchers in improving the design and evaluation of complex interventions (Medical Research Council, 2008). The framework was updated in 2008 with a less linear model and

inclusion of non-experimental studies due to criticisms that the original framework characterised development and evaluation of complex interventions in terms of phases of drug development (Craig et al., 2008). The updated MRC framework comprises four phases as follows i) development, ii) feasibility and piloting, iii) evaluation and iv) implementation (Medical Research Council, 2008). Figure 3.1 summarises the framework's stages and the key elements and activities at each stage. Development involves developing the intervention to the point where it can be expected to have a reasonable effect prior to conducting a substantial evaluation. This involves identifying the existing evidence base for the intervention (ideally by undertaking or having access to a systematic review). It is vital to identify and develop a theoretical understanding of the likely processes of change at the outset using existing theory, evidence and if necessary primary research (Craig et al., 2008).

Modelling involves developing an understanding of the intervention, its' possible effects and how its' components might interact with each other and within the setting in which it is to be implemented. Modelling can provide important information about both the design and intervention and it is necessary to model both the process and outcomes of a complex intervention (Byrne et al., 2006). The feasibility/piloting stage includes testing procedures such as the intervention and data collection methods for their acceptability prior to embarking on a full-scale evaluation or RCT. This phase also estimates recruitment and retention, and the calculation of appropriate sample sizes. A mixture of qualitative and quantitative methods is recommended to understand barriers to participation and estimate response rates. The evaluation phase involves assessing the effectiveness of the intervention in a RCT or other appropriate design, understanding change processes and assessing cost-effectiveness (Medical Research Council, 2008). The implementation phase is the final phase involving the long-term dissemination, surveillance, monitoring and application of the intervention in real life contexts. The arrows indicate the main interactions between the phases. It is important to note that the stages do not necessarily follow a linear or cyclical sequence. Reporting is viewed as an important element at each stage in the process.

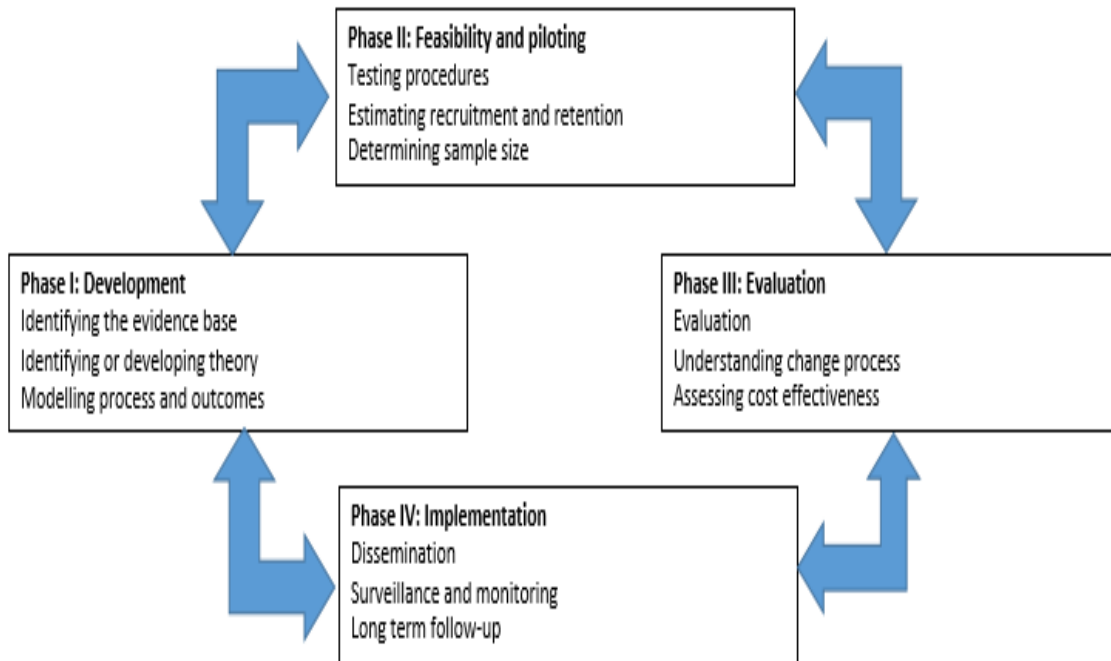


Figure 3-1 MRC framework for development and evaluation of complex interventions (adapted from MRC, 2008)

3.3 Application of the MRC framework to the OPTIMAL intervention and study

The updated MRC framework was used as a guide to develop and evaluate the OPTIMAL programme. The application of the MRC to the development, feasibility and piloting of the programme is presented in this section of the chapter. As previously stated the focus of this study is Phase III. Table 3.1 summarises the application of the framework to the OPTIMAL study, which is presented in more detail below.

Table 3-1 Application of the MRC framework to the OPTIMAL study

MRC phrase	Element	Application to OPTIMAL
Phase I: Development	Identifying evidence base by reviewing published literature and existing systematic reviews	Literature review identified evidence from self-management studies, occupational therapy interventions for chronic diseases and qualitative research on the needs of those with multimorbidity. Systematic review of multimorbidity interventions (Smith et al., 2016): Limited evidence but interventions should focus on risk factors common across co-morbid conditions or on generic outcomes such as daily functioning.
	Identifying and developing appropriate theory	Literature review identified self-efficacy has been used to guide other self-management programmes. Underlying theory guiding OPTIMAL is that of self-efficacy developed from Social Cognitive Theory (SCT) (Bandura, 1986a).
	Modelling process and outcomes	Used self-efficacy theory and literature review to link structure and content of OPTIMAL programme to desired outcomes in terms of HRQoL and functioning.
Phase II: Feasibility and piloting	Testing procedures for acceptability, compliance, and intervention delivery	OPTIMAL programme developed and tested over number of studies for feasibility and acceptability. Intervention tested within primary care in pilot RCT.
	Estimating recruitment and retention	Data from pilot RCT informed strategies for recruitment and retention in Phase III.
	Determining sample size	Data from pilot RCT used to calculate sample size.
Phase III: Evaluation*	Assessing effectiveness	Parallel RCT in primary care.
	Understanding change processes	Concurrent mixed method process evaluation.
	Cost-effectiveness	Separate cost-effectiveness study beyond the scope of this thesis being carried out.
Phase IV: Implementation	Dissemination	Publications and engagement with key stakeholders.
	Surveillance, monitoring and long term follow-up	If OPTIMAL effective, process and outcome data could inform national implementation study

*Note Phase III: Evaluation is the focus of the PhD thesis

3.3.1 Phase 1: Development of the OPTIMAL intervention

The development phase involved using existing evidence, identifying theories underpinning potential mechanisms of change and modelling processes and outcomes.

3.3.1.1 *The evidence base*

The existing evidence when developing a new intervention should ideally be identified in a systematic review. At the time of the initial development and piloting of the OPTIMAL programme, a systematic review to determine the effectiveness of interventions for patients with multimorbidity in primary care was underway but had not yet been completed (S. M. Smith et al., 2016). An extensive literature review was conducted to identify the existing evidence base and develop an understanding of how an occupational therapy led group-based chronic disease self-management programme would bring about change in those with multimorbidity. This literature review identified a gap in intervention studies and highlighted the need for generalist type interventions that would be effective across a range of different conditions (Mercer et al., 2009). It also highlighted the priorities of those with multimorbidity concerned functioning and the impact of their conditions on daily routines (Marengoni et al., 2011; Noel et al., 2005; Noël et al., 2007). Occupational therapy was identified as a profession potentially suited to providing interventions for those with multimorbidity due to its' generalist approach with a focus on functioning and quality of life (Mercer et al., 2009). However there was limited evidence of effective occupational therapy interventions for those with multimorbidity.

This published systematic review further informed the pilot RCT and the current OPTIMAL trial. The review concluded that there was limited research to date on interventions for those with multimorbidity. In existing studies, there was a tendency to focus on co-morbid conditions or multimorbidity in older patients. The review highlighted many challenges in multimorbidity research including identifying patients within the broad multimorbidity spectrum at increased risk of poor health outcomes and the targeting of interventions (S. M. Smith et al., 2016). The review concluded that interventions were more likely to be effective if they focused either on risk factors common across co-morbid conditions or on generic outcomes such as daily functioning. These findings further supported taking a function-oriented approach to interventions for those with multimorbidity.

3.3.2 Phase 2: Feasibility and piloting

The feasibility/piloting stage consisted of three pilot studies which are summarised in Table 3.2 below. Two of the studies were pilot studies involving preliminary work to develop an occupational therapy complex intervention for multimorbidity in primary care (O' Toole et al., 2013; Wallace et al., 2011). One study was a pilot RCT (Garvey et al., 2015). These studies allowed for the testing of procedures including the intervention and data collection methods for their acceptability prior to embarking on the current study i.e. a full-scale RCT. This phase also allowed for the estimation of recruitment and retention, and the calculation of appropriate sample sizes for the OPTIMAL trial.

Wallace et al. (2011) was the first study to develop and evaluate an occupational therapy led intervention for those with multimorbidity in primary care. A quasi-experimental pre-test post-test design was used to explore the impact and feasibility of individual home-based occupational therapy assessment and intervention for community-dwelling adults with a chronic respiratory diagnosis and with two or more co-occurring conditions. Patients meeting the eligibility criteria were identified through patient registers in two general practices. Of a register of 92 patients, 53 patients were identified as potentially suitable for occupational therapy intervention with 18 participants ultimately consenting to participate. A home-based occupational therapy assessment was completed with these participants, with eight of the 18 patients identified as requiring occupational therapy intervention. Individual home-based interventions based on participant goals were provided including environmental modifications, fatigue, lifestyle and anxiety management. This study found significant increases immediately post-intervention in frequency of activity participation, and perceived performance and satisfaction with occupations (activities). However the intervention was found to be resource intensive with a range of 2-11 home visits required per participant which was deemed not feasible in Irish primary care settings. Difficulties were noted with the recruitment method and a prospective recruitment method was recommended for future research whereby GP's would select study participants based on current issues. Wallace et al. (2011) recommended the piloting of a group-based intervention, with provision of individual sessions to increase social interaction and promote active transfer of skills. The study also recommended the inclusion of other health professionals in interventions to meet the populations' complex needs.

This led to a follow-on study conducted by the researcher as an MSc research study based on Wallace et al. (2011) recommendations to develop and pilot a group-based

intervention for those with multimorbidity. The study developed, delivered and examined the acceptability and impact of an occupational therapy led, six week group-based intervention for individuals with multimorbidity in primary care (O' Toole et al., 2013). The programme was named OPTIMAL (OccuPaTional therapy led self-MANagement support programme for patients with muLtimorbidity). Section 3.5 describes the OPTIMAL programme. The programme was based on the Stanford Chronic Disease Self-Management Programme (CDSMP), adapted to an occupational therapy focus, an emphasis on addressing difficulties experienced by those with multimorbidity identified in the qualitative literature and programme delivery by professionals. This programme was adapted based on the need to develop effective interventions for individuals with multimorbidity as existing evidence suggests that the CDSMP has modest effects when delivered outside the USA (Griffiths, Foster, Ramsay, Eldridge, & Taylor, 2007; A. Kennedy et al., 2013; Lorig et al., 1999). The delivery of the programme by professionals aimed to harness effective elements of other successful professional-led interventions such as cardiac and pulmonary rehabilitations (Griffiths et al., 2007). The theoretical underpinning for the OPTIMAL Intervention is Bandura's theory of self-efficacy (Bandura, 1986a, 1986b) (See Section 3.3.3 for an overview of self-efficacy theory and its' application in the OPTIMAL programme).

The study was conducted with 19 patients with multimorbidity who were recruited via general practitioners. The study used a convergent-parallel mixed methods design. A quasi-experimental pre-test post-test design was used to collect data at immediate and eight week follow-up. Focus groups explored participants' perceptions of the programme. Participants attended the OPTIMAL programme with some participants who required individual advice on assistive equipment or anxiety management receiving up to two individual sessions. Findings were promising with statistically significant improvements at 8-week follow-up in activity participation, self-perceptions of occupational (activity) performance and satisfaction and self-efficacy. In the qualitative evaluation, participants reported improvements in the targeted behaviours and being more positive about their general health. Recommendations were made to maintain the programme content, structure and session duration as delivered. The weekly goal-setting and review components helped participants to focus and facilitated health behaviour change. The results suggested that the study should move to the next phase, Phase II, of the MRC framework i.e. a pilot randomised controlled trial of the OPTIMAL programme in primary care (O' Toole et al., 2013).

A pilot pragmatic randomised controlled trial (RCT) of OPTIMAL was then conducted (Garvey et al., 2015). OPTIMAL was delivered by primary care OTs in three different primary care teams in Dublin. Participants were recruited from primary care settings with all general practices and PCT members in the areas advised of the study taking place. In total 50 participants were recruited and randomised to the intervention group (n=26) or to a waiting list control group (n=24). The intervention group received OPTIMAL, while the control group received care as usual. Prior to programme delivery OPTIMAL facilitators received a training session from the study team and a facilitator manual to standardise programme delivery. Forty-four participants provided follow-up data. Results showed a significant improvement in the intervention group compared to the control group at two-week follow-up in frequency levels of activity participation, self-perceptions of occupational (activity) performance and satisfaction, self-efficacy, perception of independence in daily activities, health-related quality of life and positive and active engagement in life. The intervention group demonstrated high levels of goal achievement, between baseline and follow-up scores. No significant differences were found in anxiety, depression or healthcare utilisation. The study provided preliminary evidence that OPTIMAL may be effective in improving outcomes for those with multimorbidity. It was recommended that a randomised controlled trial with a longer follow-up period across a large number of primary care areas be conducted, as per Stage III of the MRC framework.

Table 3-2 Overview of Phase I and Phase II of the MRC framework

Author & Year	Study design	N	Participants and setting	Intervention	Key findings	Recommendations
Wallace et al. (2011)	Quasi-experimental pre-test post-test design	n=8	Participants aged 45 to 75 years of age, with a chronic respiratory diagnosis and with ≥ 2 co-occurring conditions	Individual home-based occupational therapy assessment and intervention	At immediate follow-up: FAI p=0.043; COPM-P p=0.018; COPM-S p=0.018	Individual OT interventions promising but resource intensive with a range of 2-11 home visits required per patient Pilot group intervention, include other professionals with provision of individual sessions to increase social interaction, active transfer of skills and meet complex needs
O' Toole et al. (2013)	Convergent-parallel mixed methods study design: Quasi-experimental pre-test post-test design with immediate and 8-week follow-up. Qualitative descriptive (participant focus groups).	n=16	Participants aged ≥ 18 years with ≥ 2 chronic conditions.	OPTIMAL programme: Group-based occupational therapy led chronic disease self-management support programme for individuals with multimorbidity Up to two individual sessions were provided to those who needed advice around assistive equipment or anxiety management strategies.	At 8-week follow-up: FAI total p = 0.018; COPM-P p = 0.010; COPM-S p = 0.008; SEMCD p = 0.050 Focus group findings; Participants reported benefits and valued the interactive nature of the group based intervention for peer support and learning.	Pilot RCT with ITT analysis Exclude individual sessions in pilot RCT as impact not evaluated and require additional resources
Garvey, Connolly, Boland, and Smith (2015)	Pilot RCT with 2 week follow-up	n=50	Participants aged ≥ 18 years with ≥ 2 chronic conditions and ≥ four or more repeat medications	OPTIMAL programme: Group-based occupational therapy led chronic disease self-management support programme for individuals with multimorbidity	At two-week follow-up: FAI total p=0.003 (primary outcome); COPM-P p<0.001; COPM-S p<0.001; SEMCD p<0.001; NEADL p<0.001; EQ-VAS p=0.001; HeiQ p=0.002; GAS p<0.001.	A RCT to test effectiveness of the OPTIMAL programme over a longer time period and across a wider range of primary care settings.

FAI=Frenchay Activity Index (frequency of activity participation); COPM-P=Canadian Occupational Performance Measure Performance scale COPM-S=Canadian Occupational Performance Measure Satisfaction scale; SEMCD (6-item)=Stanford Chronic Disease Self-Efficacy 6-item Scale (self-efficacy); NEADL= Nottingham Extended Activities of Daily Living (self-reported independence in ADLs); HADS=Hospital Anxiety and Depression Scale (anxiety and depression); the EQ-5D (HRQoL); HeiQ= Health Education Impact Questionnaire; GAS= Goal attainment scaling

3.3.3 Theoretical underpinning of OPTIMAL: Self-efficacy theory

The underlying theory guiding the OPTIMAL self-management programme is that of self-efficacy, a concept which developed from Social Cognitive Theory (SCT) by Bandura (Bandura, 1986a). The OPTIMAL programme structure has been guided by its constructs (Garvey et al., 2015; O' Toole et al., 2013). SCT and self-efficacy have been used to guide a number of other health behaviour interventions and specifically self-management programmes (Bandura, 2004; Newman et al., 2004).

SCT differs from previous models of health behaviour by addressing the sociocultural determinants of health as well as the personal (Bandura, 1986a, 2004). SCT posits that behaviour is the result of a dynamic ongoing process in which personal factors, environmental factors and human behaviour influence each other (Bandura, 1986b). The core determinants influencing health behaviour are as follows: i) knowledge (knowledge of the benefits and risks of health behaviours), ii) perceived self-efficacy (confidence in one's ability to succeed in specific situations or accomplish a task) and iii) outcome expectations (anticipated outcomes of health behaviour engagement) (Bandura, 2004).

Self-efficacy is one of the core concepts of SCT and focuses on increasing an individual's confidence in their ability to carry out a certain task or behaviour, thereby empowering the individual to self-manage (Bandura, 1986a; Lorig & Holman, 2003). Self-efficacy theory suggests that unless an individual has the belief in their power to produce desired change by their actions, their will to act or persevere when faced with difficulties will be negatively impacted (Bandura, 1998, 2004). Self-efficacy is developed through an ongoing dynamic process involving evaluation of success and failure with each task people participate in (Bandura, 1986a, 2004). Self-efficacy develops through successful experiences that create high efficacy expectations and failure experiences that lower efficacy expectations. Those with higher self-efficacy set higher goals and have a stronger commitment to such goals, whilst those with lower self-efficacy expect their efforts to result in poor outcomes (Bandura, 2004). Self-efficacy has been proposed as a pre-requisite to achievement of self-management goals and maintenance of health behaviours. Self-efficacy is influenced by four sources of information: performance accomplishments, vicarious experience, social and verbal persuasion and physiological state (Bandura, 1998). A RCT of the Stanford CDSMP found that changes in participants' self-efficacy at six months was associated with health status and reduced health care utilisation at one year (Lorig et al., 1999). However, other evaluations of the Expert

Patient Programme (EPP) have found that increases in self-efficacy failed to produce changes in self-management and did not reduce healthcare utilisation as reported in Lorig et al. (1999). It has been suggested that this may relate to the integration between the EPP and the NHS (Vadiee, 2012). It has also been indicated that those with higher levels of self-efficacy have been shown to practice more self-management behaviours (Curtin et al., 2008; Du & Yuan, 2010). Self-efficacy has also been related to increased activity participation in those with multimorbidity (Perkins, Multhaup, Perkins, & Barton, 2008). Self-efficacy has been identified as a moderator or mediator of self-management interventions and was selected as a suitable theory to guide the content and structure of the OPTIMAL programme. Opportunities for each of these four sources of self-efficacy are incorporated into the format and content of the OPTIMAL programme as outlined in Table 3.3.

Table 3-3 Sources of self-efficacy and application to OPTIMAL programme

Sources of self-efficacy	Focus	OPTIMAL programme components
Performance accomplishments	Successes and failures in terms of an individual's past experiences, skills mastery and goal-setting can positively or negatively influence self-efficacy. Most influential source of self-efficacy.	Weekly goal-setting and review Trialling self-management strategies
Vicarious experience (Modelling)	Learning from others by observing a 'similar other' successfully perform the behaviour and appraising one's own performance against the performance of that similar other.	Group interactions and discussions Observation of peers
Social and verbal persuasion	Encouragement and discouragement pertaining to an individual's performance or ability to perform. Least influential source of self-efficacy.	Provision of self-management information Coaching and feedback from facilitators and participants
Reinterpretation of physiological and emotional states	Reducing negative emotional states and correcting misinterpretations of bodily states.	Information and alternative explanations for symptoms to encourage trial of new self-management behaviours

3.3.4 OPTIMAL programme development through feasibility and piloting

Tables 3.4 and 3.5 below provides an overview of the development of the OPTIMAL programme through Phase I and Phase II of the MRC framework. The intervention as evaluated in the RCT, as per Stage III of the MRC framework, is presented in Section 3.5.

Table 3-4 OPTIMAL intervention development

Intervention Component	Stage 1: Development	Stage 2: Pilot-testing the preliminary intervention (O' Toole et al., 2013; Garvey et al., 2015)	Stage 3: Definitive Intervention
Occupational therapy led with input from physiotherapist and pharmacist	<p>OT generic skills to address difficulties of those with multimorbidity (Mercer et al., 2009).</p> <p>Wallace et al., (2011) recommended inclusion of other health professionals to meet populations' complex needs.</p>	<p>Programme delivered by two occupational therapists with input from physiotherapist and pharmacist with participants reporting benefits of same.</p> <p>Training and facilitator manual developed following O' Toole (2013) study for Garvey et al. (2015) study.</p>	<p>Two HSE primary care occupational therapists as facilitators with input from primary care physiotherapist and local pharmacist. Sessional physiotherapist and pharmacist if required in some areas.</p> <p>Further development of facilitator manual and training following Garvey et. al (2015) study. Provision of training session and facilitator manual for OT facilitators.</p>
Group-based	<p>Group intervention to increase social engagement and promote active transfer of skills (Wallace, 2011).</p> <p>Less resource intensive than individual sessions.</p> <p>Group-based chronic disease self-management programmes provides some evidence of positive impact.</p>	<p>Participant focus groups in both pilot studies found that participants valued the interactive nature of the group based intervention for peer support and learning.</p> <p>Value of individual sessions not evaluated in O' Toole et al., (2013) and require additional resources/time commitments. Individual sessions not provided in Garvey et al., (2015).</p>	<p>Group-based programme aiming to recruit 8-15 participants per programme.</p> <p>No individual sessions provided.</p>

Table 3-5 OPTIMAL intervention development (cont.)

Intervention Component	Stage 1: Development	Stage 2: Pilot-testing the preliminary intervention	Stage 3: Definitive Intervention
Programme duration and timing	Systematic review of self-management programmes indicated duration and timing of effective programmes.	6 consecutive weekly sessions of 2½ hours duration with tea/coffee break.	6 consecutive weekly sessions of 2½ hours duration with tea/coffee break.
Programme content	Mindful of need for programme to be of sufficient duration to allow active practice of skills to enable behaviour change but cognisant of resource implications for HSE primary care. Topics based on: i) difficulties identified in qualitative research with those with multimorbidity, ii) difficulties identified in previous pilot, iii) topics covered in other self-management programmes.	Participant feedback on programme and session duration was favourable/acceptable. Participants reported on the importance of tea/coffee break for social interaction. Educational content as follows: i) introduction to self-management and activity and health, ii) fatigue management and healthy eating, iii) mental well-being, iv) physical activity, v) medication management and vi) communication with health professionals. Educational content reported by participants to be relevant and applicable to their needs. Some participants reported need for condition specific information particularly in relation to diet.	Minor revisions to content due to high baseline scores and no changes in mental-health outcomes in pilot studies (O' Toole et al., 2013; Garvey et al.,2015): i) More emphasis/integration of relationship between mental health and symptom management strategies throughout programme content ii) Relaxation CD provided Additional educational resources from HSE and disease support organisations provided for participants.
Goal-setting	Previous self-management programmes indicate that goal-setting is key to enhancing self-efficacy. Previous pilot recommended promotion of skills mastery in trial of group intervention (Wallace, 2011).	Participants reported that goal-setting assisted in making behaviour changes. Recommendation following O' Toole (2013) study for inclusion of a generic goal-setting tool to guide overall programme goal-setting. GAS-light used successfully by Garvey et al (2015).	Overall individual programme goal-setting guided by COPM and use of GAS-light. Continued use of weekly goal-setting format and sheets.
Participant booklet	Information may be helpful in improving outcomes in addition to verbal advice. Booklet provided in effective self-management programmes.	Participant booklet developed based on programme content. Participants reported mixed use of same but recommended continued provision.	Participant booklet provided to all participants.

3.4 Phase 3: Pragmatic parallel randomised controlled trial

The current study is a pragmatic parallel randomised controlled trial of the OPTIMAL programme to determine the effectiveness based on the recommendations from previous development and piloting work. The trial was conducted in eight primary care team areas in the Dublin/Mid-Leinster region from 2016-2018. The trial was registered with the ISRCTN register, a simple numeric system used for the unique identification of RCTs worldwide. The trial number is ISRCTN67235963. The study was designed in line with the CONSORT (Consolidated Standards of Reporting Trials) statement (Schulz et al., 2010).

3.4.1 Study aim, objectives and hypothesis

The overall aim of this study was to evaluate the effectiveness of the OPTIMAL programme, an occupational therapy led chronic disease self-management programme for individuals with multimorbidity in primary care, as per Stage III of the MRC framework (Medical Research Council, 2008).

Null hypothesis

An occupational therapy led chronic disease self-management programme has no effect on activity participation and quality of life in individuals with multimorbidity.

Alternative hypothesis

An occupational therapy led chronic disease self-management programme has an effect on activity participation and quality of life in individuals with multimorbidity.

As previously stated, a secondary aim of this study was to conduct a process evaluation to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice. However the process evaluation aim and objectives are discussed in detail in Chapter 4.

3.4.2 Specific objectives

The primary objective of this study was to evaluate the effectiveness of the OPTIMAL programme in improving activity participation and quality of life in individuals with multimorbidity in primary care in Ireland.

The secondary objectives were to examine the effectiveness of the OPTIMAL programme in improving participant outcomes in terms of:

- Self-perceptions of occupational (activity) performance and satisfaction,
- Self-efficacy,
- Mood,
- Goal attainment and
- Health care utilisation (secondary outcomes).

While the OPTIMAL study included secondary outcomes of self-perceptions of occupational performance and satisfaction, self-efficacy, mood, goal attainment and health care utilisation, the analysis is not included in this thesis due to the timing of the data collection points. The data from secondary outcomes will be collected and analysed as part of the wider OPTIMAL trial at six-month follow-up. This thesis presents immediate post-intervention data for the primary outcome measures of frequency of activity participation (FAI) and health related quality of life (EQ-VAS). Baseline data from secondary outcomes are reported.

3.4.3 Justification for research design

Randomised controlled trials when appropriately designed, conducted, and reported, represent the gold standard in evaluating the effectiveness of healthcare interventions (Akobeng, 2005; Schulz et al., 2010). A randomised controlled trial is a study in which a number of similar people are randomly allocated (randomised) to two (or more) groups to test a specific drug, treatment or intervention (Jadad, 1998). One group, the experimental group, receives the intervention being tested, while the other (the comparison or control group) receives an alternative intervention, a dummy intervention (placebo) or no intervention at all (Jadad, 1998). The distinguishing feature of the RCT is randomisation or random allocation which is the process of assigning study participants to experimental or control groups at random meaning that each participant

has an equal probability of being assigned to any given group (Akobeng, 2005). At study conclusion, the groups are analysed in terms of outcomes defined at the outset. As the groups are treated identically apart from the intervention received, any differences in outcomes can be attributed more confidently to an intervention effect as opposed to the influence of confounders (Akobeng, 2005; Jadad, 1998).

Choosing the right RCT design is vitally important to produce results that can be translated into practice (Spieth et al., 2016). This study used a two-arm pragmatic parallel trial in which participants were randomised into the intervention (OPTIMAL programme) or waiting list control group (care as usual). A pragmatic trial was selected for this study as the most appropriate design to assess the effectiveness of an intervention, i.e. the benefit the treatment produces in real clinical practice (Jadad, 1998). The benefit of such trials is that if the intervention produces a significant beneficial effect it demonstrates that not only does the intervention work, but it also works in real life (Godwin et al., 2003). This trial was conducted in primary care settings in Ireland in such a manner as to replicate how the intervention would be delivered as part of routine practice.

A cluster randomised controlled trial design was considered and may have been appropriate. Advantages of cluster RCTs include reduced risk of contamination and increased study participant compliance, however a parallel design was selected for various reasons (Donner & Klar, 2004). While cluster randomisation is frequently used to overcome the risk of contamination between treatment groups the risk of contamination using individual randomisation in this study is considered to be low (Murphy, Esterman, & Pilotto, 2006). It is unlikely that contamination will occur given the nature of and number of intervention components involved in the OPTIMAL programme. The OPTIMAL programme is not routinely offered in primary care and not all participants recruited to the study were receiving primary care occupational therapy services making it unlikely that those randomly allocated to the control group would receive the programme. There was limited funding available to conduct this study and cluster trials are generally more expensive to conduct due to the increased number of participants required to be recruited and the complexity in their design, conduct and analyses (Murphy et al., 2006). Balance between arms is more likely to be achieved using individual randomisation given the differences in socioeconomic status in different primary care team areas (Torgerson, 2001). This can be challenging to achieve with cluster randomisation as simple randomisation of clusters, even with relatively large numbers, can still result in an imbalance (Torgerson, 2001).

3.5 The OPTIMAL programme

Based on the findings from the development process and the pilot studies, the intervention was refined and finalised for the RCT. Table 3.5 previously outlined intervention development and refinement using the MRC framework. A complex intervention, however ‘complicated’, should strive to be reproducible. This requires a full description of the intervention and an understanding of its components, in order for the intervention to be delivered faithfully during the trial, allowing for any planned variation and for future implementation (Medical Research Council, 2008). Table 3.6 summarises the OPTIMAL programme as evaluated in this RCT. Appendix 3 contains weekly session plans. Each of the intervention components is described in detail below.

Table 3-6 Finalised OPTIMAL intervention

Intervention component	OPTIMAL programme
Theory	Self-efficacy theory incorporating influencers including: performance accomplishments, vicarious learning, social/verbal persuasion reinterpretation of physiological and emotional states (See Table 3.3)
Format	Group-based programme Delivered over 6 consecutive weeks; 2.5 hour session with tea/coffee break
Location	Primary care centres or community resource centres
Mode of delivery	Educational (includes participant interaction and discussion) and goal-setting components
Facilitators	HSE primary care occupational therapists with input from physiotherapist and pharmacist
Educational component	Week 1: Introduction to self-management, activity and health and goal-setting Week 2: Fatigue management and health eating Week 3: Maintaining physical activity Week 4: Maintaining mental well-being Week 5: Managing medications Week 6: Communication and programme review
Goal-setting component	Overall programme goals set in Week 1 Weekly goal-setting and review
Resources	Participant booklet, Relaxation CD, Information on local resources, HSE health promotional resources e.g. exercise booklets, get active your way, healthy eating, information on generics, mental health.

3.5.1 Group component

The OPTIMAL programme is a group-based intervention. A group-based programme was initially developed based on Wallace et al. (2011) recommendations for the piloting of a standard group intervention to increase social engagement and promote active transfer of skills. It was also hypothesised that a group-based self-management programme may be a cost-effective and efficient way of providing intervention to participants with multimorbidity in primary care. The previous pilot studies of the OPTIMAL programme supported this mode of delivery as effective with participants reporting on the positive benefits and security provided by the group including opportunities for peer support, learning, modelling and social interaction (O' Toole et al., 2013).

It was planned that the maximum number of participants for any programme would be 15 participants. This was to keep the numbers at a manageable number for facilitators to foster a positive group dynamic, have sufficient time to attend to individual group members as required and provide opportunities to incorporate programme mechanisms theorised to enhance self-efficacy i.e. exploration of past experiences, skills mastery, goal-setting, modelling and reinterpretation of symptoms.

3.5.2 Facilitators

Two HSE primary care occupational therapists co-facilitated each group. The facilitation style of the occupational therapists was guided by the intervention's underlying theoretical framework i.e. self-efficacy theory and the difference between traditional patient education approaches and self-management interventions (Lorig & Holman, 2003; McGowan, 2012).

As previously stated, self-efficacy relates to an individual's belief in their ability to execute necessary actions in response to specific situations (Bandura, 1986a, 2004). Those with higher self-efficacy, have belief in their ability to engage in behaviours and use the skills needed to manage their conditions on a daily basis (Lorig & Holman, 2003). There are four main mechanisms to enhance self-efficacy which should be included in self-management interventions i.e. performance mastery, modelling, interpretation of symptoms and social persuasion (Lorig & Holman, 2003). These elements have been previously discussed and applied to the OPTIMAL programme in Section 3.3.2.1. The

occupational therapist facilitators' role therefore was to foster a positive and collaborative group dynamic. Information giving involved a collaborative approach whereby participants were both provided with and shared their own knowledge and information. Participants had opportunities to discuss strategies and problem-solve issues. Opportunities for peer learning were in all sessions. A major aspect of the occupational therapists' role was to facilitate participants to set and review realistic individual weekly goals. This facilitation approach differs with that of traditional patient education programmes whereby facilitators act as educators, addressing common disease-specific skills and problems through information provision to ensure compliance with this advice (McGowan, 2012).

One week of the OPTIMAL programme focused on maintaining physical activity and was co-facilitated by a physiotherapist. One week focused on managing medications and was co-facilitated by a pharmacist. The occupational therapists were encouraged to approach these facilitators from within their own primary care team and local area. If these facilitators were not available the researcher organised and funded external physiotherapist and pharmacist facilitators.

Prior to the programme session the occupational therapists provided the physiotherapist and pharmacist with a session plan and notes. The occupational therapists also advised these guest speakers about the demographics of the intervention participants in terms of age, common conditions and functional status. The respective session guidelines highlighted the importance of the interactive components and activities in the session more so than the general information provision. The occupational therapist facilitators were present for these sessions in order to provide assistance and reinforce and incorporate key messages from these sessions as appropriate over the remainder of the programme.

3.5.3 Programme duration and content

The programme was facilitated over six consecutive weeks. Each session lasted two and a half hours with a tea break in the middle. No programmes were held on weekends.

Sessions were divided between an educational component in the first half and goal-setting in the second half (described in detail in Section 3.5.4). These educational components were not merely passive information provision but were designed to

incorporate opportunities for peer learning, modelling, social persuasion, reinterpretation of symptoms and goal-setting as these elements have previously been identified as key to enhancing self-efficacy. Each weekly educational component included opportunities for group interaction and problem-solving used group discussion, worksheets, flip charts and formal presentations. Sessions involved participants sharing difficulties and identifying ways of applying self-management strategies to their own lives. Efforts were made to ensure that written material presented on flip charts and projectors were easily readable. Session plans are provided in Appendix 3. A brief overview of weekly sessions is provided below.

3.5.3.1 Week One: Introduction to Self-Management

The main purpose of this session was to introduce participants to each other, the principles of self-management and explain the concept and process of goal-setting. The session began with introducing the participants to each other and establishing group rules. Time was spent exploring the relationship between activity and health. A tea break then occurred and following this participants were provided with their programme booklets. The facilitators introduced goal-setting and then assisted participants in establishing overall programme goals using a modified goal attainment scale, the GAS-light (Turner-Stokes, 2009) (See Appendix 4). This scale is described in more detail in Section 3.9.3.

3.5.3.2 Week Two: Fatigue Management and Healthy Eating

This session focused on applying fatigue management strategies to daily activities and routines and examining the principles of healthy eating and strategies for maintaining a healthy diet. This session began with the facilitators explaining fatigue management principles. Participants then analysed their own fatigue levels during their daily routines using a worksheet and discussed strategies to improve their fatigue levels. After a tea break, participants then explored principles of healthy eating, the food pyramid and had a group discussion on barriers to healthy eating and simple changes that can be made to their diet. Participants then established a goal for the week which can be based on their overall programme goals or an issue which they wish to address based on the session's content.

3.5.3.3 Week Three: Maintaining Physical Activity

A physiotherapist co-facilitated the educational component of this session. This session began with examining the benefits of physical activity and participants analysed their own exercise levels using a worksheet in relation to recommended levels. Types of exercise and how to start exercising were discussed and simple exercises which can be done at home were demonstrated and practiced with participants. After tea break participants then reviewed their previous weeks' goal and set an individual goal for the week ahead.

3.5.3.4 Week Four: Maintaining Mental Well-Being

This session began with a group discussion on identifying triggers and signs which indicate stress or low mood and explored how this impacts on participants' daily life and activities. Participants completed a worksheet and discussed previous coping strategies when faced with anxiety and low mood and alternative coping strategies where appropriate. Facilitators provided information on coping strategies including different relaxation techniques and sleep hygiene. After tea break, the facilitators led participants through a guided visualisation. Participants then reviewed their previous weeks' goal and set an individual goal for the week ahead.

3.5.3.5 Week Five: Managing Multiple Medications

The overall focus of this session was to increase participants' understanding of why they take medications and how to effectively manage their medication regime with an emphasis on managing multiple medications. A pharmacist co-facilitated this educational component on medication management. The pharmacist provided information on the need for medication, side effects and how to communicate effectively with doctors and pharmacists about medication. There was a group discussion about their thoughts and common concerns about their medication and barriers to medication management. The pharmacist also demonstrated products which can assist with medication management and advised on services commonly available in community pharmacies. There was also an opportunity for participants to ask questions about their medication. After a tea break

participants then reviewed their previous weeks' goal and set an individual goal for the week ahead.

3.5.3.6 Week Six: Communication with Health Professionals and Programme Review

The focus of this session was to examine effective communication strategies with health professionals and friends and review the programme overall in terms of key messages with participants. The facilitators began by providing information on useful strategies to communicate effectively with healthcare providers. There was a group discussion on situations where participants had difficulty communicating with a health professional in order to problem-solve strategies which may have improved communication. The session also explored methods for participants to communicate effectively with family and friends about their health and support needs. The facilitators then reviewed the programme overall with participants and identified future plans and available community resources. The session concluded with participants reviewing their previous weeks' goal and their progress with their overall programme goals which they established for themselves in Week One.

3.5.4 Individual goal-setting

Goal-setting is a core component of the OPTIMAL programme and facilitates a client-centred and tailored approach to the group-based programme. Individual weekly goal-setting and review has been identified as a key component of the programme in previous research (Garvey et al., 2015; O' Toole et al., 2013). The purpose of goal-setting is to address individual needs, facilitate behavioural change, problem-solving and skills mastery. Weekly goal review provides an opportunity for peer learning and modelling.

3.5.4.1 Overall programme goals

Prior to the delivery of the OPTIMAL programme, at baseline assessment, the researcher used a measure called the Canadian Occupational Performance Measure (COPM) (described in detail in Section 3.9.3), which is used by occupational therapists to facilitate client-centred goal-setting and evaluate goal achievement in accordance with

participant's perception of their occupational (activity) performance and satisfaction (Doig, Fleming, Kuipers, & Cornwell, 2010; Law et al., 2015). Occupational performance refers to the act of doing and accomplishing a selected activity or occupation (Law et al., 2015). Participants were given a copy of the goals identified in the COPM to act as a prompt or guide for overall programme goals they may wish to set.

Setting overall individual programme goals takes place in the second half of the first OPTIMAL session. Participants identified their overall programme goals using goal attainment scaling (GAS-light) (Turner-Stokes, 2009) (See Appendix 4). At this stage of the session, participants had explored the concept of self-management with facilitators, been provided with an overview of the programme and facilitators had explained and provided examples of weekly goal-setting. Participants identified between one and six overall programme goals. These goals could be either occupation focused or related to the principles of the OPTIMAL weekly content in more general areas of lifestyle change e.g. improving diet, fatigue management or medication management.

The occupational therapists assisted participants in setting overall programme goals using SMART (specific, measurable, achievable, realistic, timed) principles (Bovend'Eerd, Botell, & Wade, 2009). For each of the programme goals established, the facilitators asked participants to rate whether they had some function (able to do/manage some aspect at present) or no function (as bad as they could be) in relation to the goal.

3.5.4.2 Weekly goal-setting

From Week Two onwards participants set individual weekly goals. The majority of the second half of each weekly session was dedicated to individual weekly goal-setting and review. The goal-setting part of the session began with participants reviewing and sharing their progress on their previous week's goal and then setting a new goal for the following week.

Weekly goal-setting followed a similar format to that in the Stanford CDSMP (Lorig & Holman, 2003). Participants were required to identify specific and realistic goals each week, steps required to achieve the goal and enablers and barriers to achievement of this goal. Weekly goal-setting and review sheets were included in participants' booklets and participants completed this information with the assistance of the facilitators and then shared their goal with the group (Appendix 5). Facilitators were advised during

training to be mindful of literacy issues in relation to completing goal-setting sheets and be cognisant of participants who may require additional time and assistance. Goal-setting sheets were intended to act as guide and it was not compulsory to complete the sheets.

Participants were encouraged to review their COPM goals and the overall programme goals they established to guide their weekly goal-setting. However, participants were free to set goals around other issues in weekly goal-setting if they felt these were more pertinent to address. An individualised flexible approach was used around the focus or target of weekly goal-setting as it was reasoned that this would ensure a client-centred programme and empower participants to address and problem-solve around their own self-defined issues in a tailored way.

During weekly goal review each participant was encouraged to share with the group their progress in terms of achieving the goal, any difficulties encountered and any strategies that assisted with achieving the goal or that would help in the future.

3.5.5 Programme resources

A programme booklet was provided to each participant in the first programme session. This booklet reflected the educational topics covered in the OPTIMAL programme. The booklet contained each session's PowerPoint notes, worksheets, additional information on the topics covered in the programme and information and contacts for useful organisations such as disease support organisations. The booklet also had an individual goal-setting section where participants could set overall programme and weekly goals.

The aim of the provision of this booklet was to provide participants with an understandable resource which they could review over the course of the programme and to keep track of their weekly goals. The programme booklet also served as a resource for the future which they could consult after programme completion.

Intervention participants were also provided with a relaxation CD developed by the researcher. This CD contained four different relaxation exercises including two guided relaxation exercises, progressive muscle relaxation exercises and a quick relaxation exercise.

Additional resources from the HSE health promotion office were also provided each week according to the weekly sessions focus e.g. healthy eating, physical activity (including a chair exercise booklet), and understanding generic medicines.

3.6 Study population

Inclusion Criteria:

Participants were eligible for this study if they met the following criteria:

- Multimorbidity, defined as two or more discrete conditions. This is the internationally accepted definition and encompasses a broad range of patients.
- Age > 40 years. This limit was chosen as multimorbidity is relatively uncommon in people younger than this and it facilitated targeted recruitment (Barnett et al., 2012; Glynn et al., 2011). There was no upper age limit.
- Polypharmacy, defined as four or more repeat medications (Rankin et al., 2018). This criterion was added in order to identify a group within the broader multimorbidity population that is at increased risk of poor health outcomes and therefore more likely to benefit from an intervention. These criteria proved very effective in the pilot RCT as the participants had a median number of four conditions (range 2-9) and 9 medications (range 4 – 21), indicating higher burden of disease within the multimorbidity spectrum (Garvey et al., 2015).
- Ability to attend a local community healthcare centre to participate in data collection and the intervention groups.

Exclusion Criteria:

Participants were not eligible for this study if any of the following criteria applied:

- Psychiatric/psychological morbidity (such as psychosis) or cognitive impairment sufficient to impair participation in the intervention.
- Terminal illness likely to lead to death or major disability during the study follow-up period.
- Inability to attend intervention sessions held outside the home.
- Participated in the previous pilot studies or pilot trial.

3.7 Recruitment

It was originally planned to undertake participant recruitment, data collection and intervention delivery as per the original sample size calculation (Appendix 6) in three sequential blocks, i.e., 67 participants approximately per block, which is approximately three intervention and three control groups per block delivered in three separate primary care team areas. This was planned in order to avoid simultaneous intervention delivery for all groups and to allow for sufficient time for recruitment and data collection to be completed. It was aimed to recruit between 20-24 participants per primary care team area. It was planned to allow four months per block for recruitment of eligible participants. This would mean that in total, nine different primary care teams would be involved in the trial with an intervention group and waiting list control group in each primary care team area. However difficulties and delays were encountered with recruitment and some primary care team areas which agreed to participate in the trial withdrew or deferred their participation. This resulted in recruitment occurring in four blocks, with two intervention and two control groups per block in two separate primary care team areas. Information regarding trial recruitment and attrition are presented in detail as part of process evaluation results in Chapter 6.

3.7.1 Primary care occupational therapy teams engagement

The researcher provided information and a presentation on the logistics of the study at a meeting of HSE occupational therapy primary care managers to invite occupational therapy teams in the Dublin/Mid-Leinster region to participate in the study in October 2015. These teams were based in a mixture of urban, suburban and rural areas. The researcher contacted these managers subsequent to this meeting and asked if they were interested in participating in the study and delivering the intervention. If they agreed to participate the researcher presented to the occupational therapy teams about the programme and study.

3.7.2 Primary care clinicians engagement

Primary care team members were advised by the occupational therapy manager and occupational therapy colleagues that the programme and study was taking place in the area and provided with information packs containing study and programme information

and participant packs. In addition to this, the primary care occupational therapists organised for the researcher to present at the primary care team meeting on the background, logistics of the study and the programme itself. Publicity materials (information leaflets and posters) were also provided to be displayed in patient waiting areas in the primary care centres to promote the programme and study and to ask a PCT member if they were eligible to participate.

3.7.3 General practitioners' engagement

In each primary care team area the researcher and occupational therapists developed a list of general practices in the area. The OTs highlighted those who were actively engaged with the primary care team and who referred to occupational therapy. All identified practices were invited to participate via letter or email (when an email address was available) and sent an information pack which contained information on the referral procedure, programme, study and participant information materials (See Appendix 7-10). The researcher followed up these letters with a phone call to confirm if the practice wished to participate. The researcher also offered to present at practice meetings on the background, logistics of the study and the programme. The researcher also provided posters and information leaflets for the patient waiting room.

3.7.4 Recruitment of participants

General practitioners (GPs) and other primary care clinicians identified suitable potential participants meeting the inclusion criteria in a number of ways. Participants were identified by their General Practitioner and other primary care clinicians opportunistically during routine encounters or by reviewing their caseloads. Once identified potential participants were informed of what would be involved by participating in the research and those who expressed interest were provided with a participant pack containing a participant information leaflet and consent form (See Appendix 10). A referral form was then forwarded by the clinician to the gatekeeper in the primary care team area (See Appendix 8). Eligible participants were not required to make a formal decision about participating in the study at this stage. The gatekeepers were either the occupational therapy secretary or in areas where administrative support was not available, another nominated member of the primary care occupational therapy department not involved in OPTIMAL programme delivery and study. A follow-up phone call was made by the

gatekeeper at least 7-10 days after the initial referral to confirm if the eligible patient was interested in participating. If the patient agreed, arrangements were made to obtain informed consent and conduct baseline assessments in the local primary care centre.

Referrals were also made via self-referral. Posters were displayed in patient waiting areas in the primary care centres and in community venues where the programme was to be delivered (e.g. local community resource centres if there was no suitable primary care centre in the area). These posters contained the eligibility criteria for the study and contact details for the area gatekeeper (See Appendix 9). On contact with the gatekeeper, eligibility criteria was confirmed and a participant information leaflet and consent form was forwarded to the potential participant to consider. Eligible participants were not required to make a formal decision about participating in the study at this stage and were asked to consider participation for seven days. A follow-up phone call was then made by the gatekeeper after this period to confirm if they still wished to participate. Arrangements were made to obtain informed consent and conduct baseline assessments in the local primary care centre for those who wished to take part.

Both the researcher and the occupational therapists in each study site, who had completed OPTIMAL training, carried out the baseline assessments and obtained informed consent. Occupational therapists received training in informed consent procedures as part of the OPTIMAL training programme. The consent form was read to participants prior to data collection which provided an opportunity for participants to ask any questions. Participants were asked to sign the consent form (Appendix 10) and a copy of same was provided to participants with the researcher's contact details highlighted for the participants to contact if they had any further queries.

3.8 Allocation concealment and randomisation

Individual participants were randomised into the intervention or control group after collection of baseline data for each group to avoid any recruitment bias relating to participant preference or researcher influence (Medical Research Council, 2008; Schulz et al., 2010). Sequence generation and allocation for each primary care team area was carried out remotely by an independent statistician using a computer-generated sequence. This minimised the risk of selection bias as known and unknown confounders were most likely balanced between groups (Lambert, 2011; Moher et al., 2010). Without proper randomisation, treatment comparisons can be prejudiced consciously or not, by

selection of a particular kind of participant to receive a particular intervention (Moher et al., 2010).

Randomisation was stratified by gender. In some groups, couples were recruited. In such instances couples were randomised as a unit and minimisation was used to ensure an even distribution of couples between intervention and control. It was decided to randomise couples as a unit as there were concerns that if the couple were not allocated together this may increase attrition or influence programme attendance rates and increase the risk of contamination. A sensitivity analysis was used in final data analysis to test the effect of the involvement of couples in the trial.

3.9 Outcome measures

The outcome measures used in the study are patient reported outcome measures (Appendices 11-12). These measures have been specifically chosen to reflect the potential effects of the intervention and the theoretical underpinning of self-efficacy and self-management support. All outcome measures selected in the study were used in the previous pilot and pilot trial and were found to be feasible for use with this population and sensitive to change (Garvey et al., 2015; O' Toole et al., 2013). They also reflect the key finding of the related Cochrane review that interventions should target functional difficulties experienced by individuals with multimorbidity (S. M. Smith et al., 2016). The outcome measures are also reflective of the consensus-based set of core outcomes developed specifically for studies in multimorbidity (S. M. Smith et al., 2018). Table 3.7 below presents an overview of outcome measures, the methods of collection of these outcome measures and at which data follow-up periods the outcome measures were collected. Following this a description of the outcome measures is provided.

Table 3-7 Summary of trial outcome measures

Outcome measures	Completed by	T1	T2^a	T3^b
Demographic and referral information	Intervention and Control Group	x		
Primary outcome measures				
Health-related QoL (EQ-VAS)	Intervention and Control Group	x	x	x
Frequency of activity participation (FAI)	Intervention and Control Group	x	x	x
Secondary outcome measures				
Self-perception of ability to perform daily activities (NEADL)	Intervention and Control Group	x		x
Self-efficacy in management of chronic conditions	Intervention and Control Group	x		x
Anxiety and depression levels (HADS)	Intervention and Control Group	x		x
Self-perception of occupational performance and satisfaction with same (COPM)	Intervention and Control Group	x		x
Health care utilisation (number of GP visits, accident and emergency visits and hospital admissions)	Intervention and Control Group	x		x
Goal achievement (GAS)	Intervention Group	x	x	

^aT2 Immediate follow-up: Data was collected via postal questionnaire

^bT3 Six-month follow-up: Data currently being collected

3.9.1 Demographic Questionnaire and Referral Form

A demographic questionnaire (See Appendix 11) was designed by the researcher which gathered information on age, gender, marital status, living situation, educational attainment and employment status. Questions regarding self-reported health care utilisation were also included in order to inform a cost-effective analysis paper which is an additional planned activity within the OPTIMAL trial but is beyond the scope of this thesis. Further information on conditions and medication numbers were gleaned from patient OPTIMAL referral forms and participant self-report in the case of self-referrals.

3.9.2 Primary outcome measures

Primary outcome measures were collected at baseline, immediate follow-up and six month follow-up. The primary outcome measures are the EQ-VAS and FAI, these were the only outcome measures completed immediately post-intervention.

3.9.2.1 EQ-VAS

The EQ-VAS was a primary outcome, with sample size calculation based on this. The EQ-VAS was used to measure health-related quality of life. The EQ-VAS is part of the EQ-5D-3L which is a standardised measure of quality of life, developed by the EuroQoL Group in 1990. The EQ-5D-3L provides a simple, generic measure of health for clinical and economic appraisal (Brooks, 1996; EuroQoL, 1990; van Reenen & Oppe, 2015a). The EQ-5D-3L consists of two parts, the descriptive system and a visual analogue scale (EQ-VAS) (van Reenen & Oppe, 2015a). Both parts of the EQ-5D-3L were collected at baseline and immediate follow-up. The EuroQoL group recommends presenting descriptive analysis of the EQ-5D descriptive system and hypothesis testing using the EQ-VAS scores (Szende, Janssen, & Cabases, 2014). An index score can also be calculated based on the descriptive system for cost utility analysis. This is described in further detail below.

The EQ-5D-3L, including both the descriptive system and EQ-VAS, has been used in the previous pilot study and pilot trial (Garvey et al., 2015; O' Toole et al., 2013). Health-related quality of life (HRQoL) outcome measures are included in the core outcome set developed specifically for studies in multimorbidity (S. M. Smith et al., 2018). The measure is designed for self-completion and is brief, taking only a few minutes to complete. It can be administered in a variety of modalities including postal surveys, via telephone and in face-to-face interviews (van Reenen & Oppe, 2015a). Whilst an economic evaluation is beyond the scope of this thesis, it is planned as part of the wider OPTIMAL trial, the EQ-5D has been identified by the UK's National Institute for Health and Clinical Excellence (NICE) as the preferred generic instrument for the purpose of economic evaluation (National Institute for Health and Clinical Excellence, 2017).

As previously discussed, the EQ-5D-3L consists of two parts, the descriptive system and a visual analogue scale (EQ-VAS) (van Reenen & Oppe, 2015a). The descriptive system has five dimensions (mobility, self-care, usual activities, pain/discomfort and

anxiety/depression). Each dimension has three levels or responses (no problems, some problems or extreme problems). A unique health state is defined by combining 1 level from each of the 5 dimensions. A total of 243 possible health states is defined in this way. Each state is referred to in terms of a 5 digit code. The Visual Analogue Scale (EQ-VAS) allows participants to report their perceived health status on a vertical visual analogue scale ranging from 0 (worst imaginable health) to 100 (best imaginable health).

Data from the EQ-5D-3L can be presented in three ways (van Reenen & Oppe, 2015a):

- I. The results from the descriptive system can be presented as a health profile whereby the frequency and percentages of reported problems are outlined or a health state is presented.
- II. The results of the EQ-VAS can be presented as a measure of overall self-rated health status. In this instance a measure of central tendency and dispersion should be reported.
- III. EQ-5D health states, defined by the EQ-5D descriptive system, can be converted into a single summary index by applying a formula that essentially attaches values or weights to each of the levels in each dimension. This information is useful in calculating quality-adjusted life years (QALYs) for cost utility analysis. The index can be calculated by deducting the appropriate weights from 1, the value for full health (i.e. state 11111).

Data from the EQ-5D-3L was presented in the three ways. However, as previously discussed the EQ-VAS was the primary outcome measure, with hypothesis testing conducted using the EQ-VAS. However additional analyses of EQ-5D descriptive data and index scores were conducted as the recent 3D study (Section 2.5) analysed index scores and this enabled a comparison of our data to this study.

There is an extensive body of literature supporting the validity and reliability of the EQ-5D-3L in many conditions and populations (Janssen et al., 2013). The EQ-5D-3L has been found to be responsive and feasible for use with those with multimorbidity with low missing values (Agborsangaya, Lahtinen, Cooke, & Johnson, 2014; Agborsangaya, Lau, Lahtinen, Cooke, & Johnson, 2013). The EQ-5D-3L has been found to have good test-retest reliability, inter-rater reliability, good construct validity, convergent validity, and discriminatory power (Janssen, Birnie, Haagsma, & Bonsel, 2008; Janssen et al., 2013). The EQ-5D-3L is suitable and acceptable for self-completion and use in postal surveys (Devlin & Brooks, 2017).

A five-level EQ-5D version (EQ-5D-5L) was developed in 2009 by the EuroQoL group in order to improve the measure's sensitivity and reduce ceiling effects, as compared to the EQ-5D-3L (Herdman et al., 2011). Some research indicates that the EQ-5D-5L improves upon the measurement properties of the EQ-5D-3L by reducing the ceiling effect while improving discriminatory power, convergent and known-groups validity (Herdman et al., 2011; Janssen et al., 2008; Janssen et al., 2013). It has been suggested that 5L version is particularly useful for describing mild health problems and monitoring population health (Janssen et al., 2008). As previously discussed, the EQ-5D-3L has been chosen in this research based on the NICE recommendations of its continued use and the previous research conducted on the OPTIMAL programme using this instrument which found it to be acceptable (Garvey et al., 2015; National Institute for Health and Clinical Excellence, 2017; O' Toole et al., 2013).

While no significant differences in EQ-VAS scores were found in the feasibility study (O' Toole et al., 2013), the pilot trial demonstrated significant improvements in EQ-VAS scores in the intervention group in comparison to the control group (Garvey et al., 2015; O' Toole et al., 2013). Sample size calculation was based the EQ-VAS which is described in detail in Section 3.10.

3.9.2.2 Frenchay Activity Index

The Frenchay Activities Index (FAI) was also used to measure frequency of activity participation and was used in the previous pilot trial. Activities of daily living outcome measures are included in the core outcome set developed specifically for studies in multimorbidity (S. M. Smith et al., 2018). The FAI was originally developed by Holbrook and Skilbeck (1983) to measure participation in social and instrumental activities of daily living in stroke populations. The FAI was developed to assess abilities in more complex activities requiring higher levels of function in the home and community (Lin, Chen, Wu, Yu, & Ouyang, 2012).

The FAI comprises 15 activities which are divided into three subscales; domestic chores, leisure/work and outdoor activities with five items in each (Holbrook & Skilbeck, 1983). Wade, Legh-Smith, and Langton Hewer (1985) introduced a modified scoring system, which is used in this study whereby each item is scored on a 4-point scale (0-3) to yield a total score ranging from 0 (inactive) to 45 (active). Each subscale's scores ranges from 0-15. Scoring is based on the frequency with which the activities are carried out during

the last 3 to 6 months. The higher the score in the total and subscale score, the higher the frequency of activity participation (Wade et al., 1985).

The FAI is quick and easy to complete. The FAI was originally designed to be administered as a face-to-face interview but it has been found to be acceptable to be administered as a postal questionnaire and via telephone, although further validation studies of both these methods is required (J. Carter, Mant, Mant, Wade, & Winner, 1997; S. McPhail et al., 2009; Teale & Young, 2010).

Whilst originally developed and validated for stroke populations, it has also been used with other chronic conditions including multiple sclerosis, lower limb amputation, older adults and the general population (Einarsson, Gottberg, Fredrikson, von Koch, & Holmqvist, 2006; Miller, Deathe, & Harris, 2004; Turnbull et al., 2000). The FAI has been found to be a valid measure with good construct validity particularly in middle aged and elderly people (Han, Lee, & Kohzuki, 2009; Han et al., 2006; Turnbull et al., 2000). It has been found to have excellent concurrent validity with other measures of activity participation and disability including the Nottingham Extended Activities of Daily Living Scale (Sarker, Rudd, Douiri, & Wolfe, 2012; Wu, Chuang, Lin, & Horng, 2011).

The FAI has excellent test-retest reliability in the general population (Pearson's correlation coefficient, $r = 0.96$) (Turnbull et al., 2000) and those with lower limb amputations (intra-class coefficient (ICC)= 0.79) (Miller et al., 2004). The inter-rater reliability of the FAI when administered by occupational therapists with stroke patients has been found to be good for the total score of the FAI (0.90; 95% CI 0.82-0.94), however at the item-level reliability was found to be good ($\kappa > 0.60$) for only 11 out of 15 items (Post & Witte, 2003).

The findings from the pilot study and the pilot trial showed significant improvements in FAI scores (Garvey et al., 2015; O' Toole et al., 2013). The pilot trial found significant differences in the FAI total score (MD = 4.22; 95% CI = 1.59 to 6.85; $p < 0.01$) and domestic subscale score (MD = 2.77; 95% CI = 0.70 to 3.31; $p < 0.01$) (Garvey et al., 2015). Both studies supported the acceptability and responsiveness of the FAI for use in this study.

3.9.3 Secondary outcome measures

Secondary outcome measures were collected at baseline and six-month follow-up. Six-month follow-up data is not reported in this thesis however baseline data for secondary outcome measures are reported. Secondary outcome measures included the Nottingham Extended Activity of Daily Living scale (NEADL), the six-item Self-efficacy to Manage Chronic Disease Scale (SEMCD), The Hospital Anxiety and Depression Scale (HADS), the Canadian Occupational Performance Measure (COPM), Health Care Utilisation (HCU) and Goal Attainment Scaling (GAS).

3.9.3.1 Nottingham Extended Activity of Daily Living Scale

The Nottingham Extended Activities of Daily Living Scale (NEADL) was originally developed by Nouri and Lincoln (1987) to assess stroke patients' self-reported independence in activities of daily living. The NEADL was selected as a secondary outcome measure and had been used in the previous pilot study and pilot trial of the OPTIMAL programme (Garvey et al., 2015; O' Toole et al., 2013). The NEADL was included in the study as a measure in order to assess outcomes in many dimensions of activity participation, i.e. perceived independence in instrumental ADLs. As previously stated activities of daily living outcome measures are part of the core outcome set developed for multimorbidity (S. M. Smith et al., 2018).

The NEADL consists of 22 items divided into four sections as follows: mobility (six items), kitchen (five items), domestic (five items) and leisure (six items) activities. Each item is scored on a four point scale as follows; no (0), with help (1), on my own with difficulty (2) and on my own (3). Unfortunately there are no guidelines for assigning scores (DeLisa, 2005). Higher scores indicate greater function or independence. Summative subscale and total scores can be calculated. The maximum score for the mobility section is 18, the kitchen section is 15, the domestic section is 15 and the leisure section is 18, with a maximum total score of 66.

The NEADL is brief, easy to understand, score and interpret. The NEADL can be administered via post, telephone or face to face administration (Sutton et al., 2013). The NEADL has been found to be reliable and valid for use with community dwelling older adults and with those with chronic disabling conditions including pulmonary problems, hip replacements and multiple sclerosis (Harwood & Ebrahim, 2002; Nicholl, Lincoln, &

Playford, 2002; Yohannes, Roomi, Waters, & Connolly, 1998). The NEADL has been found to have good internal consistency, as measured by Cronbach's α in relation to patients undergoing hip replacement (0.90 for the total score; subscales ranging from 0.64-0.87) and those with multiple sclerosis (0.94 for the total score; subscales ranging from 0.72–0.92) (Nicholl et al., 2002). Test–retest reliability, concurrent and good construct validity has been demonstrated with stroke patients, patients undergoing hip replacements and those with multiple sclerosis (Harwood & Ebrahim, 2002; Nicholl et al., 2002; Sarker et al., 2012). However, there has been some criticism of the NEADL. The results of a Rasch analysis supported the psychometric properties of the four subscales of the NEADL but the use of the total scale as a general measure of ADL was not supported. The scale was found not to be unidimensional, however further research is needed to validate these findings (das Nair, Moreton, & Lincoln, 2011). There have also been suggestions that the NEADL is insensitive to change and is unsuitable for evaluating interventions outside of stroke populations (Harwood & Ebrahim, 2000, 2002).

While O' Toole et al. (2013) found a ceiling effect with the NEADL and no difference over follow-up, a significant difference was found in self-perceived independence of daily activities as measured by the NEADL ($p < 0.001$) in the pilot trial (Garvey et al., 2015).

3.9.3.2 The six-item Self-Efficacy to Manage Chronic Disease Scale

The six-item Self-Efficacy to Manage Chronic Disease Scale (SEMCD) measures self-reported self-efficacy related to tasks of managing chronic conditions (Ritter & Lorig, 2014). Measures pertaining to self-efficacy are included in the core set of outcome measures for multimorbidity research (S. M. Smith et al., 2018). This SEMCD was developed from a longer self-efficacy scale for managing chronic conditions which was used to evaluate the impact of the Stanford Chronic Disease Self-Management Programme (Ritter & Lorig, 2014). This longer scale comprised 10 subscales and consisted of a total of 32 items. The shorter 6-item scale was developed as it was considered less burdensome for participants and has been used in numerous evaluations of chronic disease self-management programmes. The SEMCD covers several domains that are common across many chronic diseases (Lorig, Ritter, & Gonzalez, 2003; Lorig et al., 1999). The SEMCD includes four items relating to confidence in keeping fatigue, pain, emotional distress and other symptoms from interfering with activities the person wants to do. One item relates to confidence in managing tasks and activities to manage the condition and one item relates to engaging

in tasks other than taking medication to decrease the effects of the condition on the person's daily life (Dal Bello-Haas, Klassen, Sheppard, & Metcalfe, 2011). Confidence levels for each of the 6 items are rated on a scale from 1 (not at all confident) to 10 (totally confident). The score for the scale is the mean of the six items. Higher scores indicate higher self-efficacy (Lorig et al., 2001). Changes of 0.5 in this score have been reported as being of clinical significance (Lorig et al., 2001). If more than two of the six items are missing, the scale is set to missing (Lorig et al., 2001; Ritter & Lorig, 2014). The SEMCD is quick and easy to administer and was used successfully in the previous two studies of the OPTIMAL programme (Garvey et al., 2015; Lorig et al., 2001; O' Toole et al., 2013).

Secondary analyses of questionnaire data from six studies involving 2,856 patients with chronic disease was used to quantify and validate the SEMCD and found the SEMCD to have a one-dimensional structure, high internal consistency as measured by Cronbach's (α ranged from 0.88 to 0.91 across the studies) and sensitivity to change (Ritter & Lorig, 2014). A study which investigated the psychometric properties of the scale in individuals with Parkinson's disease also found the scale to have excellent internal consistency (Cronbach's $\alpha = 0.91$), and strong item consistency (Dal Bello-Haas et al., 2011). This study also indicated the scale to have moderate to good test re-test reliability (intra-class coefficient of 0.72) which would be considered adequate for group level comparisons (Dal Bello-Haas et al., 2011; Portney & Watkins, 2009). They also estimated the minimal detectable change for the SEMCD to be 2.55, however further study is required to confirm this finding (Dal Bello-Haas et al., 2011). Some support has also been provided for the construct validity of the measure, with SEMCD correlating highly with some measures of disability, health distress, activity limitations, depression and fatigue (Amtmann et al., 2012; Ritter & Lorig, 2014).

Previous research has provided evidence that baseline self-efficacy prior to participation in a chronic disease self-management programme was associated with improved outcomes including improvements in self-efficacy (Katch & Mead, 2010; Lorig, Ritter, & Jacquez, 2005; Lorig, Ritter, & Plant, 2005). The intervention programme in the current study aimed to improve confidence in managing multimorbidity, thus it was important to investigate if OPTIMAL would improve this outcome. The SEMCD was selected as a secondary outcome measure and had been used in the previous pilot and pilot trial. Significant differences in self-efficacy were found over the follow-up period in those who received the OPTIMAL programme in both the pilot study ($p = 0.05$) and pilot trial ($p = 0.02$) (Garvey et al., 2015; O' Toole et al., 2013).

3.9.3.3 Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS) was also selected as a secondary outcome to measure the presence of anxiety and depression (Zigmond & Snaith, 1983). Measures pertaining to mental health are included in the core outcome set for multimorbidity (S. M. Smith et al., 2018). The HADS was originally developed to identify and quantify anxiety and depression in general hospital patients aged 16 to 65 who may require further psychiatric evaluation and assistance (Bjelland, Dahl, Haug, & Neckelmann, 2002; Zigmond & Snaith, 1983). The HADS is a 14-item self-reporting scale consisting of two subscales, anxiety (HADS-A) and depression (HADS-D) with 7 items in each. The anxiety scale items focuses on general anxiety, with five items being close to generalised anxiety disorder and the depression scale items focuses on anhedonia, which is considered to be the most reliable clinical marker of depression (Snaith, 2003; Zigmond & Snaith, 1983). The HADS is quick and easy to administer, taking only 2 to 5 minutes to complete (Snaith, 2003).

Each item is rated on a four-point scale from 0 (no problem) to 3 (severe problem). Scores on these items are totalled giving maximum scores of 21 for both anxiety and depression. Scores of 11 or more on either subscale are considered to be a significant 'case' of psychological morbidity, while scores of 8–10 represent 'borderline' and 0–7 'normal' levels of anxiety and depression (Zigmond & Snaith, 1983). It has been proposed that a total score can be calculated, which can be regarded as a global measure of psychological distress, by adding the sum of HADS-A and HADS-D scale (M. Johnston, Pollard, & Hennessey, 2000; S. B. Roberts, Bonnici, Mackinnon, & Worcester, 2001).

The psychometric properties of the HADS are generally supported. The HADS has been found to have excellent internal consistency in general practice patients with Cronbach's α coefficients of 0.89 for HADS-A and 0.86 for HADS-D (Olsson, Mykletun, & Dahl, 2005). Other studies have supported the internal consistency of the HADS in general populations, older adults and in chronic conditions including stroke, COPD and heart disease (Aben, Verhey, Lousberg, Lodder, & Honig, 2002; Bjelland et al., 2002; Mykletun, Stordal, & Dahl, 2001; M. H. Roberts, Fletcher, & Merrick, 2014; S. B. Roberts et al., 2001) The HADS has been found to have adequate test-retest reliability (Herrmann, 1997; S. B. Roberts et al., 2001). The concurrent validity of the HADS with other commonly used measures of anxiety and depression, such as the Beck Depression

Inventory (BDI), Patient Health Questionnaire (PHQ-9) and the Montgomery Asberg-Depression Scale, is good (Bjelland et al., 2002; Bratås, Grønning, & Forbord, 2014; Cameron, Crawford, Lawton, & Reid, 2008). The HADS was also found to have good case finding abilities of anxiety and depression in non-psychiatric patients and general practice patients (Brennan, Worrall-Davies, McMillan, Gilbody, & House, 2010; Olsson et al., 2005).

There has been considerable debate over the factor structure of the HADS with two, three and four factors structures being achieved in different methodologies (Bjelland et al., 2002; Bratås et al., 2014; Caci et al., 2003; Gale et al., 2010; Mykletun et al., 2001; M. H. Roberts et al., 2014; S. B. Roberts et al., 2001). A recent meta-confirmatory analysis which addresses some of the methodological issues in previous research supported the two factor structure. However this study suggested that due to the presence of a strong general factor, the HADS is best used as a measure of general distress rather than as means to delineate between anxiety and depression (Norton, Cosco, Doyle, Done, & Sacker, 2013). Overall the HADS has been found to be a responsive measure, with good sensitivity and specificity which given its good psychometric properties is suitable to measure change over time through treatment (Bjelland et al., 2002; Cameron et al., 2008; Mykletun et al., 2001; M. H. Roberts et al., 2014)

While a stated aim of self-management programmes are to enable participants to manage the emotional consequences of living with chronic conditions, there has been contradictory evidence that such programmes achieve these aims (Barlow, Wright, Turner, & Bancroft, 2005; Griffiths et al., 2005; Turner et al., 2010). The HADS was selected as a secondary outcome measure and had been used in the previous studies of OPTIMAL. While no significant differences were found in the HADS in either the pilot or pilot trial, it was decided to continue to measure this outcome given the increased sample size, longer follow-up period and the need to evaluate the stated aim and content of the OPTIMAL programme (Garvey et al., 2015; O' Toole et al., 2013).

3.9.3.4 Canadian Occupational Performance Measure

The Canadian Occupational Performance Measure (COPM) is a client-centred individualised outcome measure which assesses change in self-reported occupational performance and satisfaction over time (Law et al., 2015). The COPM is a standardised

instrument which is administered as a semi-structured interview and usually takes between 15-30 minutes to administer.

The interview begins by the participant identifying the occupations (self-care, productivity and leisure activities) that they want to do, need to do or are expected to do in daily life and if there are any issues in their performance of these occupations. For each of the occupational performance issues identified, the therapist asks the participant to rate the importance of being able to do each of the identified occupational issues on a scale ranging from 1 to 10 with higher scores indicating higher importance. From this list, participants can identify up to five priority problems for occupational therapy intervention which forms the basis for goals. For each of these identified problems participants rate their performance from 1 to 10 with higher scores reflecting greater performance or satisfaction. Total COPM performance and satisfaction scores (out of 10) can be yielded by dividing the sum of performance or satisfaction scores by the number of goals with higher scores again indicating greater perceived occupational performance and satisfaction. At re-assessment participants rate again both their performance and satisfaction from 1-10 in the specific problem areas. Total performance and satisfaction scores are calculated by summing these values and dividing by the number of identified problems. Change in performance and satisfaction are calculated by subtracting Time 1 values from Time 2. A change score of 2 points or more represents a clinically significant change (Law et al., 2015).

The COPM has been found to be a reliable and valid measure for adults with a range of chronic diseases. Research examining the psychometric properties of the COPM in adults with varying chronic diseases (including COPD, stroke, ankylosing spondylitis) has found the test-retest reliability of the measure to be adequate with reliability coefficients ranging from $r=.67$ to $r=.92$ (Carswell et al., 2004; Cup, Scholte op Reimer, Thijssen, & van Kuyk-Minis, 2003; Eyssen, Beelen, Dedding, Cardol, & Dekker, 2005; Kjekken et al., 2005; Sewell & Singh, 2001). The COPM has also been found to have adequate content, criterion and construct validity in community-dwelling older adults and those with various chronic diseases (Eyssen et al., 2005; Tuntland, Aaslund, Langeland, Espehaug, & Kjekken, 2016). Research also indicates that COPM is responsive and sensitive to change in those with arthritis, chronic pain, depression, hip fracture, stroke, neurological conditions and with community dwelling older adults with a variety of chronic conditions (Carpenter, Baker, & Tyldesley, 2001; Edwards, Baptiste, Stratford, & Law, 2007; Eyssen et al., 2011; Macedo, Oakley, Panayi, & Kirkham, 2009; Tuntland et al., 2016; Wressle, Eeg-Olofsson, Marcusson, & Henriksson, 2002).

The findings from the OPTIMAL pilot study and the pilot trial showed significant improvements in both COPM performance and satisfaction subscale scores (Garvey et al., 2015; O' Toole et al., 2013). The pilot trial found significant differences in the COPM performance subscale score ($p=0.02$) and satisfaction subscale scores ($p=0.02$) (Garvey et al., 2015). Both studies support the acceptability and responsiveness of the COPM for use in this study.

3.9.3.5 Health Care Utilisation

Health care utilisation was collected for participants over a one-year period; six months prior to programme commencement and six months post programme commencement. Self-report information was collected on GP visits, the number of accident and emergency visits, number of hospital admissions, nights spent in hospital and number of outpatient appointments. These questions were adapted from The Irish Longitudinal Study on Ageing (TILDA) (Barrett et al., 2011). Information was also collected on use of other health professionals during these periods. It was decided to use self-report healthcare utilisation due to the logistical difficulties in accessing clinical records across multiple sites. Health care utilisation information would not be accessible on primary care team records and would be dependent on securing permission from each individual practice that participants attended. Challenges exist in the accuracy of self-reported health care utilisation (Bhandari & Wagner, 2006; Peersman, Pasteels, Cambier, De Maeseneer, & Willems, 2014). The most frequently reported difficulty in a systematic review of the accuracy of self-reported health care utilisation data was under-reporting and this is more likely as utilisation increases (Bhandari & Wagner, 2006; Ritter et al., 2001). This is a particular concern in the current study given that multimorbidity is associated with increased health care utilisation (Marengoni et al., 2011). Factors such as cognitive status can affect accuracy of self-reported data (Bhandari & Wagner, 2006). An optimal recall period for self-report surveys appears to be 6 months or less which is in line with the time period used in the current study (Ritter et al. 2001). While the limitations of the accuracy of self-reported health care utilisation data is acknowledged, this method was deemed the most suitable data collection method for this variable given the time and resource constraints involved.

3.9.3.6 Goal Attainment Scaling

Goal attainment scaling (GAS) is a method of scoring the extent to which a patient's individual goals are achieved in the course of an intervention (Turner-Stokes, 2009). Whilst originally developed for outcome assessment in mental health settings it has since been used in a wide variety of settings including rehabilitation, chronic pain and elderly care units (Gaasterland, Jansen-van der Weide, Weinreich, & van der Lee, 2016; Kiresuk & Sherman, 1968; Krasny-Pacini, Hiebel, Pauly, Godon, & Chevignard, 2013; Turner-Stokes, 2009). GAS has been described as a measure of the achievement of expectation rather than an outcome measure (Turner-Stokes, 2009). In GAS, "SMART" (specific, measurable, achievable, realistic, timed) goals are established with the patient, each goal is rated on a 3 point likert scale in terms of importance to the individual and anticipated difficulty in achieving it. Higher scores denote higher levels of importance and difficulty respectively. For each goal there is the "a priori" establishment of criteria for a successful outcome in that individual. Following intervention at follow-up patients rate the degree of attainment for each goal: If the patient achieves the expected level, this is scored at 0. If they achieve a better than expected outcome this is scored at: +1 (somewhat better) or +2 (much better). If they achieve a worse than expected outcome this is scored at: -1 (somewhat worse) or -2 (much worse).

For the purposes of this study, a type of GAS known as the "GAS-light" model was adopted. GAS-light was used successfully in the pilot trial (Garvey et al., 2015). GAS-light was only used with intervention participants to set overall programme goals. On the first programme session participants were asked to identify between one and six goals they would like to achieve by the end of the programme. In the GAS-light system only the expected level (0) of achievement is defined (Grant & Ponsford, 2014; Turner-Stokes, 2009). Goals are set to SMART principles meaning they are designed to be specific, measurable, achievable, realistic and timed. Participants rated each of these goals on a 3-point likert scale in terms of importance and difficulty with higher scores denoting higher perceived levels of importance and difficulty. Participants were also asked to rate their current level of performance or function in relation to each goal from "none" (as bad as can be) or "some" (some level of function). On the last programme session participants were asked to verbally rate each of the identified goals again in terms of goal achievement on a 6-point scale (got worse, no change, partially achieved, as expected, a little more, and a lot more). A computer program then converts the performances attained on this 6-point scale to the original GAS 5-point scale ranging from "-2" (much

less than expected) to “+2” (much more than expected). These attainment scores are then combined to calculate an overall GAS score or “T score” by applying the formula recommended by Kireush & Sherman, shown below, which accounts for the number of goal-sets, inter-correlation of goals and allocated weights.

$$\text{Overall GAS} = 50 + \frac{10 \sum(w_i x_i)}{\sqrt{(0.7 \sum w_i^2 + 0.3(\sum w_i)^2)}}$$

Where w_i is the weight assigned to the i^{th} goal and x_i is the score (ranging from -2 to +2) of the i^{th} goal

Effectively, the composite goal score (the sum of the attainment levels x the relative weights for each goal) is transformed into a standardized measure or T-score with a mean of 50 and standard deviation of 10 (Turner-Stokes, 2009). Lannin (2003) in a study of a home-based occupational therapy rehabilitation intervention for adults proposed cut-off scores for interpretation of GAS scores. Table 3.8 presents these cut-off scores. This method has was used in the pilot trial to interpret GAS scores.

Table 3-8 Interpretation of GAS T-Scores

GAS T-score	Performance level
<50	Reflects performance below the expected level.
50	Expected level of performance.
>50	Reflects performance above the expected level.

The GAS has been suggested as a useful measure to guide and measure change in community-based health promotion interventions (Becker, Stuifbergen, Rogers, & Timmerman, 2000; Kloseck, 2007; Kolip & Schaefer, 2013). The literature suggests that the GAS has good inter-rater validity, congruent content validity and excellent sensitivity to change however while some evidence existed to support the concurrent validity this was limited to physical and neurological settings and with an elderly population (Hurn, Kneebone, & Cropley, 2006; Krasny-Pacini et al., 2013). Furthermore, while the psychometric properties of GAS are supported, there does not appear to be literature examining the properties of the GAS-light.

The GAS-light method rather than the original GAS was selected for this study for a number of reasons. It was thought that setting a priori criteria for each participant’s goals

would be too time-consuming as overall programme goal-setting took place for intervention participants in the first session. It was decided to use the GAS-light as occupational therapists may not have had previous experience using the GAS so it was rationalised that the simplified version would be more accessible. The GAS-light was used successfully in the pilot trial of the OPTIMAL programme and found a significant difference ($p>0.001$) in participant goal achievement between baseline and follow-up for intervention participants (Garvey et al., 2015).

3.10 Sample size calculation

Sample size calculations in the original fellowship application were revised, in consultation with the Trial Steering Committee (TSC) (See Section 3.15 for Trial Governance arrangements), during the trial due to the challenges with recruitment rates (Chapter 6; Section 6.2.1). The original calculation is presented in Appendix 6. The revised sample size calculation used interim baseline data ($n=108$) as the original estimates were based on smaller numbers in the pilot RCT. The Trial Steering Committee also decided to reduce power to 80% to ensure that trial recruitment could be completed within the PhD timeframe. Retention at both immediate and six-month follow-up data collection had been higher than anticipated so a loss to follow up of 20% was anticipated. The revised sample size calculations for each of the primary outcome measures was as follows:

1. Frenchay Activity Index

The overall interim mean FAI baseline scores was 25.3 (SD 7.5) based on 108 participants. To improve a baseline FAI score by 4 points, with 80% power, a sample size of 114 in total ($n=57$ per group) was required.

Improvements of 4 points have been reported as clinically significant in older patients with stroke (Forster et al., 2009). To allow for a 20% loss to follow up of patients, 30 participants were added resulting in a total of 144 participants.

2. The overall interim mean EQ-VAS baseline scores were 59.1 (SD 20.3) based on 108 patients. Improvements of 8.7 points have been reported as a moderate effect size and changes of 14 points have been reported as representing a large effect size in clinically ill patients (as opposed to population norms) (Roset, Badia, & Mayo, 1999). To improve a baseline EQ-VAS score of 59.1 by 14 points, with 80% power, required a total sample size

of 68 (n=34 per group). To allow for a 20% loss to follow up, 27 patients are added resulting in a total sample of 95 participants.

Hence, the revised calculation, based on 80% power and 20% loss to follow up indicated that 144 participants were required in total to detect a clinically relevant change, as described above, in both primary outcomes measures.

3.11 Data collection

Participants with multimorbidity were assessed three times at baseline (primary and secondary outcome measures), immediately post-intervention (primary outcome measures only) and 6 months post-intervention (primary and secondary outcome measures) for both control and intervention groups. The researcher and the occupational therapists in each study site, who had completed OPTIMAL training, carried out the baseline assessments. The researcher is currently conducting all 6-month follow-up assessments.

At baseline and six-month follow-up, face to face interview-based assessments took place. At immediate post-intervention participants completed outcome measures by postal survey (within a 2-3 week period). Primary outcome measures (EQ-VAS and FAI) only were completed immediately post-intervention. Telephone follow-up was used for non-responders. This method was used immediately post-intervention as a pragmatic and cost-effective alternative to a face to face interview-based assessment and in order to minimise participant burden. A limitation of this is that in combining methods of outcome measure administration the psychometric properties of these outcome measures cannot be assumed to be equivalent across methods of administration (Teale & Young, 2010). However in the case of both the EQ-VAS and the FAI, previous research has indicated that postal administration of the FAI and EQ-VAS instruments is suitable (Devlin & Brooks, 2017; Szende et al., 2014; Turnbull et al., 2000; van Reenen & Oppe, 2015a).

A critique of interview-completed questionnaires is that they can be prone to observer and interview bias (Cook, 2010). Observer expectation bias occurs when observers erroneously record data to match expected and desired outcomes, similarly interview bias involves the tendency of the interviewer to subconsciously obtain answers that support preconceived notions (Cook, 2010). Therefore advantages of using self-report

postal questionnaires is that it may potentially minimise the risk of these biases. However the use of postal questionnaires rather than face to face interviews does not permit the clarification of questions for participants and increases the likelihood of measures being completed incorrectly and/or missing data (Bowling, 2005; Cook, 2010).

3.12 Blinding

While randomisation aims to minimise differences between the treatment arms at trial outset, it does not prevent differential treatment of the groups or assessment of outcomes during the trial which may result in biased estimates of intervention effects (Karanicolas, Farrokhyar, & Bhandari, 2010; Schulz & Grimes, 2002). Blinding assists in minimising the likelihood of differential treatment or outcome assessment (Karanicolas et al., 2010). Researchers should report who was blinded and how in order for readers to judge those efforts (Schulz & Grimes, 2002). While blinding should be employed whenever feasible, the difficulties of blinding in pragmatic randomised controlled trials of non-pharmacological interventions in primary care have been recognised (Boutron et al., 2007; N. Foster & Little, 2012; Nelson & Mathiowetz, 2004). It was not possible in this study to blind participants or intervention facilitators to allocation. The OPTIMAL programme is interactive in nature, involving ongoing engagement between facilitators and participants during the programme which provides an opportunity for both facilitators and participants to show bias for or against an intervention (Nelson & Mathiowetz, 2004). Participants were also advised in the participant information leaflet and consent form that they would be randomly allocated to an intervention group or wait list control. Another recommended strategy to minimise the risk of bias is to blind data collectors as it removes the relationship aspect between the assessor and participant. In this study the researcher conducted all six-month follow-up assessments and was blinded to participant allocation to intervention or waiting list control group. Even in carefully designed and blinded trials, assessors may become aware of allocation. The researcher, kept a record of when blinding was broken when administering the six-month follow-up assessments.

3.13 Data analysis

Data analysis and reporting was conducted according to CONSORT guidelines for randomised controlled trials, and conducted blinded to group status by the researcher

(Schulz et al., 2010). As previously discussed a record of when blinding was broken at six month follow-up was maintained. The statistical analysis plan was agreed prior to trial completion as described in the study protocol as part of the HRB grant application. This study aimed to evaluate the effectiveness of the OPTIMAL programme in improving activity participation and health-related quality of life in intervention participants compared to controls. While immediate post-intervention data was collected and six-month post-intervention data is being collected only primary outcome results at immediate follow-up were available, analysed and presented in this thesis. Baseline data for secondary outcomes are presented for intervention and control groups. All results were analysed using Stata statistical software, STATA version 15 (StataCorp, 2017). Statistical significance at $p < 0.05$ was assumed throughout.

The first stage of analysis was to use descriptive statistics to describe recruited individuals and to investigate comparability of the trial arms at baseline. Baseline characteristics are presented using descriptive statistics, including means (SD), frequencies and percentages.

The primary analyses involved 'intention-to-treat' comparisons between the two groups for the primary outcomes (EQ-VAS and FAI). An intention-to-treat (ITT) analysis includes all participants randomised in a trial in their treatment groups to which they were originally randomized, irrespective of any treatment that they subsequently received (D. Wang & Bakhai, 2006). ITT analysis minimises bias by assuming that rates of noncompliance or withdrawal are equal in both groups preserving the strengths of randomisation, providing appropriate randomisation has been completed (D. Wang & Bakhai, 2006). However, when there is missing data in any study it can result in larger standard errors and increase the likelihood of missing effects. That said, when there is no evidence of a pattern to the missing data, coefficients are unlikely to be biased. There can be missing covariate or outcome information. When there is missing covariate information there are three 'simple' techniques commonly used: complete case analysis (CCA), last observation carried forward (LOCF) and mean imputation. LOCF is criticised for being too conservative of an estimate and can make a treatment look worse or better. Mean imputation reduces the variance, artificially reducing standard errors and hence affecting the analysis. Finally, CCA can result in a loss of power (wider confidence intervals) but when data are missing completely at random it is considered a valid technique that will not lead to bias of results. A more complex technique is multiple imputation, but this can be time consuming and needs to be conducted with care. Appropriate variables must be chosen for the imputation model.

When there are missing outcome data, the complete case analysis has been argued as more appropriate since imputed outcome data can lead to misleading results (Jackobsen et al., 2017; Papageorgiou et al 2018). Imputation techniques can be used if there are variables that are highly correlated with the outcome and the probability that the outcome is missing. However, this will only help in reducing the loss in accuracy of the estimates. As recommended by Papageorgiou et al (2018) the complete case analysis should be regarded as the principle analysis in the case of missing outcome data. Given that there was only missing outcome data in this study and no evidence of a pattern to the missing data, based on the above recommendations, a complete case analysis was used for ITT.

Unadjusted and adjusted models were explored. Models were adjusted as appropriate for gender (stratification variable), baseline scores, area, number of conditions and age. The European Medicines Agency (EMA) recommends adjusting for stratification variables and variables known a priori to be related to outcome, including baseline values (European Medicines Agency, 2015). While a baseline imbalance was observed post hoc (marital status) between treatment allocation, the EMA suggests that these variables should not be considered as a covariate in the primary analysis (European Medicines Agency, 2015). However, conducting exploratory analyses including such variables when large baseline imbalances are observed might be helpful to assess the robustness of the primary analysis.

The analyses were replicated for participants who completed the trial 'as per protocol' (PP), excluding those who were randomised but did not receive the trial intervention (non-adherence was defined as attending less than three programme sessions). PP analysis, also known as efficacy analysis or analysis by treatment administered, excludes participants who were not fully compliant with the study protocol. By focusing only on the fully compliant participants, the maximal efficacy of a treatment can be determined (D. Wang & Bakhai, 2006). As stated, PP analysis in this trial, excluded those who were randomised to the intervention but attended less than three of the group sessions. The cut-off of less than three sessions was selected as this represented less than half of the intervention and previous RCTs of chronic disease self-management interventions had selected this limit for PP analysis (Griffiths et al., 2005).

Pre-planned sub-group analyses evaluated the effects of age (<65 and ≥65 years of age) and the number of chronic conditions present (<4 and ≥4). These sub-group analyses were selected as the literature recommends targeting of multimorbidity interventions across the age range and evidence suggests that those with higher levels of morbidity

are at risk of poorer outcomes (S. M. Smith et al., 2016). A sensitivity analysis was also conducted excluding any couples from the analyses.

All analyses used linear regression models, with results presented as point estimates (difference in means), 95% confidence intervals (CI) and p-values. The results of adjusted and unadjusted models are presented as recommended by CONOSRT guidelines (Yu, Chan, Hopewell, Deeks, & Altman, 2010).

Table 3.9, adapted from D. Wang and Bakhai (2006), outlines how the results of ITT and PP analyses can be interpreted. When both ITT and PP analyses are performed either or both can reach statistical significance. When both analyses reach the same conclusion, there can be more confidence in the study results.

Table 3-9 Interpreting results of ITT and PP analyses

Findings	Interpretation
ITT significant, PP slightly more significant	While some subjects were noncompliant, they were equally distributed between groups.
PP results much more significant than ITT results	High rate of noncompliance in the study Study was efficacious, not effective
ITT significant, PP not significant	May be confounding other than treatment differences
ITT not significant, PP significant	May be considerable proportion of participants switching treatments in one direction (e.g. from placebo to intervention)
ITT not significant, PP not significant	No evidence of effectiveness

3.14 Ethical approval

Ethical approval was sought and granted from the Trinity College Faculty of Health Sciences Research Ethics Committee (Ref: 150900; Appendix 13). Permission was also sought and gained from the Health Service Executive (HSE) National Primary Care Research Committee. This committee is not an ethics committee but reviews and

approves all research requests requiring engagement with HSE primary care services, staff and providers.

3.14.1 Ethical considerations

Particular consideration was given to ensuring that eligible participants who may be considered vulnerable did not feel obliged to participate if prospectively identified by PCT members. Participant information leaflets (PIL) and consent forms were written in lay language and emphasised that participation, non-participation or withdrawal in the study would not affect their current or future care in primary care services. All study participants were advised that they could withdraw at any stage from the research process and this was clearly stated in the PIL and consent forms.

A “cooling off” period of at least seven days was allowed between eligible participants expressing interest before a follow-up phone call was made by the gatekeeper to confirm interest and make arrangements to obtain informed consent and conduct baseline assessments.

All participant identities remained confidential through coding of identities and secure storage of study data. Participants’ identities on measures and in audio recordings were coded using numbers for collection of results. The key was stored separately to consent forms and data collected. The key was stored in a locked office, in a locked filing cabinet, to which only the researcher and one of the research supervisors (DC) had access. Data collected, both administered measures (hard-copy) and audio recordings from the qualitative process evaluation component (discussed in detail in Chapter 4), were also stored in a secure office in a locked filing cabinet. Electronic data inputted for the purpose of data analysis were coded and stored on a password protected laptop. All data will be stored for five years and then destroyed. Hardcopy records will be shredded and electronic records will be reformatted.

Maintenance of confidentiality is important when groups of participants meet, as was the case with this intervention. Special emphasis was placed on the importance of confidentiality to group members and made explicit in the participant information leaflets and consent procedures. This was reinforced throughout the intervention by the healthcare professionals delivering the intervention and establishment of group norms of which confidentiality was key.

There was no change to participants' routine care during the study with participants continuing to receive their usual primary care services. If any issues arose during assessment which caused any concern about safety this was managed using normal clinical pathways. For example, if the assessment indicated a safety concern and a need for an assistive device this was managed through the usual community pathways with the participant's permission. Participants were advised that they could be provided with a copy of their assessment results following completion of the study if they wished to share these with their GP or other healthcare professionals. If participants were distressed by any issues during research procedures (assessments, group discussions, focus groups) the participant was provided with initial support by the occupational therapists and researcher and if necessary advised of other available supports within primary care. All study participants were provided with contact numbers for emotional support groups.

3.15 Trial Governance Arrangements

As part of the original grant application, governance arrangements of a Trial Steering Committee (TSC) and Scientific Advisory Group (SAG) were put in place. The TSC committee consisted of the PhD author, supervisors, statistician, primary care general manager and occupational therapy manager. The TSC provided advice and support in recruiting patients and communication with the primary care teams involved in the study, reviewed and commented on project progress, advised on the scientific aspect and impact of the trial and discussed relevant data. A Scientific Collaborative Advisory Group (SAG) was also established in order to provide advice to the TSC and assist with planning for knowledge exchange and dissemination of results. This group consisted of the PhD author, supervisors, statistician, primary care general manager, occupational therapy managers and health economist.

3.16 Funding

This study was funded by the HRB (Health Research Board) Research Training Fellowship for Healthcare Professionals (Grant Ref: HPF 2015-972). The Health Research Board is the lead agency in Ireland supporting and funding health research. There was no conflict of interest between the funders and the aims and results

of the study. The funding awarded covered salary and related costs, student fees, running costs, dissemination and knowledge exchange costs, training costs and a travel grant to gain research experience abroad.

3.17 Phase IV: Implementation

Phase IV of the MRC framework is the final phase involving the long-term dissemination, surveillance, monitoring and application of the intervention in real life contexts (Medical Research Council, 2008). It aims to evaluate the implementation by healthcare services of research findings and the translation of interventions of proven efficacy in research settings into routine care (Pinnock, Epiphaniou, & Taylor, 2014). While Phase IV of the MRC framework is beyond the scope of this study, recommendations for this phase based on the RCT and process evaluation outcomes will be discussed in Chapter 7.

Normalisation Process Theory (NPT), a theoretical sociological model from the implementation science domain, provides a framework which was used to describe, assess and enhance implementation through identification of factors that promote or inhibit the routine integration of complex intervention into everyday practice (May & Finch, 2009). NPT examines all stages of implementation from early implementation to when an intervention becomes ingrained into routine practice and is “normalised.” NPT in this study was used to sensitise the research to the incorporation or rejection of the OPTIMAL programme from an organisational (HSE primary care), health professional and participant perspective. NPT comprises four main constructs, i.e. coherence, cognitive participation, collective action and reflexive monitoring, with each of these constructs having four sub-constructs. Tables 3.10 to 3.13 below define the constructs and sub-constructs of NPT and the questions which the study results aim to inform for the next phase of the MRC framework.

Table 3-10 NPT constructs and sub-constructs: Coherence

NPT Construct/sub-construct	Definition	Questions to consider
Coherence: Refers to the extent that a technology or health practice must make sense to targeted stakeholders		
1. Differentiation	Stakeholders understand and distinguish the intervention from current ways of working	Does the stakeholder recognise the OPTIMAL programme as different to existing ways of working? Is the OPTIMAL programme different to other interventions for those with multimorbidity?
2. Communal specification	Stakeholders collectively agree about the purpose and benefits of the intervention	Does the stakeholder agree about the purpose of the OPTIMAL programme?
3. Individual specification	Stakeholders individually understand what the intervention requires of them	Does the stakeholder identify their personal role and responsibilities with the OPTIMAL programme?
4. Internalization	Stakeholders construct potential value of the intervention for their work	Does the stakeholder view the OPTIMAL programme as fitting well with practice in primary care? What is the benefit of adopting OPTIMAL and to whom?

Table 3-11 NPT constructs and sub-constructs: Cognitive participation

NPT Construct/sub-construct	Definition	Questions to consider
Cognitive participation: Concerns the commitment and collective engagement of stakeholders		
5. Initiation	Key individuals work to drive the intervention forward.	Is the stakeholder a supporter and promoter of the OPTIMAL programme? Are they willing to engage others in implementation?
6. Enrolment	Stakeholders agree that the intervention is part of their work. This may involve organising or reorganising themselves and others in order to collectively contribute to the work involved in new practices.	Does the stakeholder view the OPTIMAL programme as part of their role? Do they get involved, make changes to their work to assist with implementation?
7. Legitimation	Stakeholders buy in to the intervention and make a contribution to it.	Does the stakeholder commit time and effort to deliver the OPTIMAL programme? Do they believe it is appropriate to be involved?
8. Activation	Stakeholders collectively continue to support the intervention once underway.	Does the stakeholder take steps to drive forward and sustain the OPTIMAL programme in the future?

Table 3-12 NPT constructs and sub-constructs: Collective action

NPT Construct/sub-construct	Definition	Questions to consider
Collective action: Refers to relationships and work required enabling a new intervention to be taken up in practice and identifying the barriers to implementation		
9. Interactional workability	Stakeholders perform the tasks required by the intervention.	What work was required of the stakeholder as part of the OPTIMAL programme? Does it fit with current work practices? What made it easier or difficult to be involved?
10. Relational integration	Stakeholders maintain their trust in each other's work and expertise through the intervention.	To what extent did stakeholders trust/have confidence in the OPTIMAL programme? Did stakeholders work together to deliver the programme?
11. Skill set workability	The work of the intervention is appropriately allocated to stakeholders.	Was the programme delivered appropriately? Did the programme fit with stakeholders' skill sets? Did the stakeholder receive the correct training?
12. Contextual integration	This refers to the resource work - managing a set of practices through the allocation of different kinds of resources and the execution of protocols, policies and procedures.	Does the integration of the OPTIMAL programme fit with the objectives of the stakeholder, resources and policies?

Table 3-13 NPT constructs and sub-constructs: Reflexive monitoring

NPT Construct/sub-construct	Definition	Questions to consider
Reflexive monitoring: This refers to appraisal work that stakeholders do to assess and understand the ways that a new set of practices affect them and others around them		
13. Systematisation	Stakeholders access information about the effects of the intervention to determine how effective and useful it is for them and for others.	Do stakeholders feel the OPTIMAL programme is an effective and useful way to provide intervention to participants with multimorbidity?
14. Communal appraisal	Stakeholders collectively assess the intervention as worthwhile both formally and informally	How will stakeholders collectively judge the effectiveness of OPTIMAL?
15. Individual appraisal	Stakeholders individually assess the intervention as worthwhile in terms of the personal effects on them and the context in which they operate	How do individual stakeholders judge the effectiveness of the OPTIMAL programme?
16. Reconfiguration	Stakeholders modify their work in response to their appraisal of the intervention	Will stakeholders be able to modify the OPTIMAL programme based on evaluation and experience?

3.18 Conclusion

The overall aim of this study was to evaluate the effectiveness of the OPTIMAL programme, an occupational therapy led chronic disease self-management programme for individuals with multimorbidity in primary care, as per Stage III of the MRC framework for the development and evaluation of complex interventions (Medical Research Council, 2008). This chapter outlined the approaches to the development of the OPTIMAL programme and the studies preceding the current trial as per Phase I and Phase II of the MRC framework. Recruitment, data collection and analysis used for this trial have been described in detail as per CONSORT guidelines. The proceeding chapter presents the OPTIMAL process evaluation design.

Chapter 4 Process evaluation methodology

4.1 Introduction

This chapter presents the methodology of the process evaluation which was conducted alongside the OPTIMAL RCT as a secondary aim of the overall OPTIMAL study. The chapter begins by outlining the aims and objectives of this process evaluation. The process evaluation study design, which used the MRC guidance on process evaluations to structure the evaluation, is presented. The data collection and analysis methods are described in detail. Methods selected to monitor, measure and assess intervention fidelity are discussed.

4.2 Process evaluation aims and objectives

The overall aim of this process evaluation was to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice. The objectives to achieve this aim were:

- To describe the recruitment process including sampling of sites and recruitment sources.
- To analyse the extent to which the OPTIMAL programme was delivered as intended and how and why it varied, i.e. to explore intervention fidelity.
- To quantify the dose received by OPTIMAL programme participants i.e. programme attendance.
- To explore OPTIMAL facilitators' perceptions of the impact, delivery and acceptability of the OPTIMAL programme.
- To explore participants' perceptions of the impact, delivery and acceptability of the OPTIMAL programme.

4.3 Process evaluation

Whilst RCTs are regarded as the gold standard for establishing intervention effectiveness, trial results on their own do not provide policy makers with information on how an intervention might be replicated or whether trial outcomes will be reproduced in their specific context (Moore et al., 2015). The MRC framework recommends incorporating process evaluations at each stage of developing and evaluating complex interventions (Medical Research Council, 2008). The focus of a process evaluation will

vary according to the stage at which it is conducted. The MRC guidance on process evaluations in complex interventions states that the emphasis of process evaluations in evaluating intervention effectiveness shifts towards providing greater confidence in conclusions about effectiveness (Moore et al., 2014). In line with the MRC guidance, a process evaluation was conducted alongside the OPTIMAL trial.

Process evaluations aim to understand the functioning of an intervention, by providing insight into why an intervention fails or has unexpected consequences or why a successful intervention works and how it can be optimised (Craig et al., 2008). Process evaluations also help to distinguish between interventions that are inherently faulty (failure of intervention concept or theory) and those that are badly delivered (implementation failure). Process evaluations therefore provide the more detailed understanding needed to inform policy and practice (Moore et al., 2015). The ultimate goal of a process evaluation is to illuminate the pathways linking what starts as a hypothetical intervention, and its underlying causal assumptions, to the outcomes produced. Process evaluations are particularly necessary in multi-site trials, such as the current study, where the "same" intervention may be implemented and received in different ways in different sites (Oakley et al., 2006). It is important to explicitly state causal assumptions about how an intervention will work to allow external scrutiny of its plausibility and help evaluators decide which aspects of the intervention or its context to prioritise for investigation. The principal aim of an outcome evaluation is to test the theory of the intervention, in terms of whether the selected course of action led to the desired change.

4.3.1 Process evaluation study design

The process evaluation used a mixed methods approach, combining both qualitative and quantitative data as recommended by the MRC guidance on process evaluations in complex interventions (Moore et al., 2014). This guidance states that a clear description of the intervention and its causal assumptions about how the intervention works to produce desired outcomes should be stated explicitly. This OPTIMAL programme and its underlying theoretical assumptions were previously outlined in Chapter 3. The process evaluation in this study was based on examining the three key functions of process evaluations as outlined in the MRC guidance on process evaluations of complex interventions (See Figure 4.1 below) (Moore et al., 2014):

- i. **Implementation:** Examining this factor involved analysing how the OPTIMAL programme was delivered (e.g. the training and resources necessary to achieve full implementation), the quantity and quality of what was delivered; the quality (fidelity) and quantity (dose) of what was implemented in practice, and the extent to which the intervention reached its intended audiences and how.
- ii. **Mechanisms of impact:** Examining this factor involved focusing on how the OPTIMAL programme did or did not produce change. This is vital in understanding how the effects of the intervention occurred and how these effects might be replicated.
- iii. **Context:** Exploring this factor involved understanding anything external to the OPTIMAL programme that acts as a barrier or facilitator to its implementation or effects and the circumstances under which ‘mechanisms’ were activated or suppressed. Implementation will often vary from one context or site to another and an intervention may have different effects in different contexts even if its implementation does not vary. Understanding context is therefore critical in interpreting the findings of a specific evaluation and generalising beyond it.

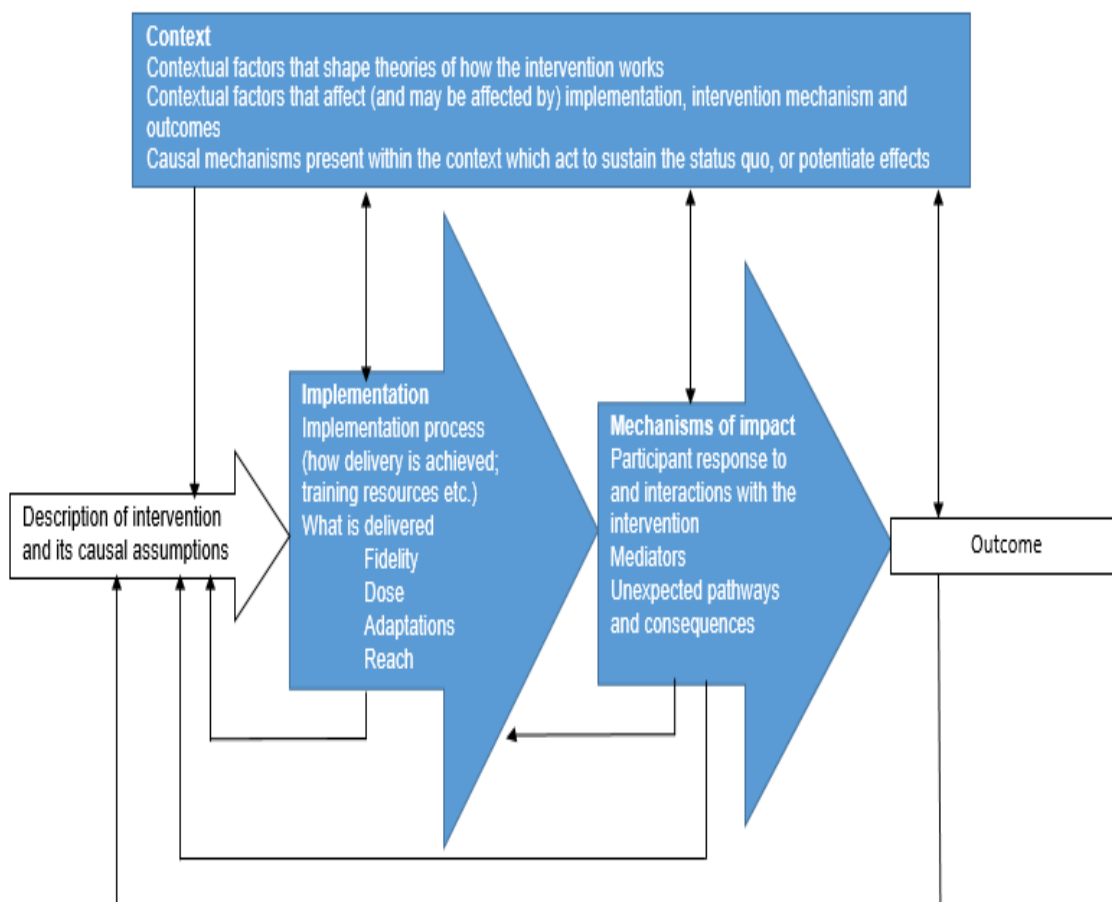


Figure 4-1 Key functions of process evaluation and relations among them according to the MRC framework on process evaluations (adapted from Moore et al., 2014)

4.3.2 Study population

Both participants in the OPTIMAL programme and healthcare professionals involved in delivering and referring participants to the programme were included in the process evaluation.

All participants who attended the final programme session at each site were invited to participate in a focus group. It was decided to conduct the focus group on the final programme session in order to minimise participant burden and maximise the numbers who would participate. It is acknowledged that this approach meant the views of those participants who did not attend the final programme session or those who dropped out of the programme were not captured and these participants may have had different perceptions.

All occupational therapists involved in intervention delivery were invited to participate in individual semi-structured interviews. Interviews were also conducted with a sample of GPs involved in referring to the programme. Interviews were also conducted with a sample physiotherapists and pharmacists involved in delivering the programme. The sample of health professionals were invited primarily from the final three blocks of recruitment. Given resource constraints it was not feasible to interview all healthcare professionals involved in referral and intervention delivery.

4.3.3 Data collection methods

Data collection involved both quantitative and qualitative methods. Table 4.1 below outlines the data collection and analysis methods used for the process evaluation in this study in line with the functions of process evaluations identified in the MRC guidance on process evaluations (Moore et al., 2015).

Table 4-1 Process evaluation data collection methods in line with the MRC process evaluation functions

Factor	Research Focus	Data source
Implementation	<ul style="list-style-type: none"> • How delivery is achieved (training, resources)? • What is delivered (fidelity, dose, adaptations, reach)? 	<ul style="list-style-type: none"> • Study team recruitment logs • Participant questionnaires and demographic information from baseline • Therapist log/Fidelity tool • Interviews with health professionals involved in programme delivery and referral • Focus group with participants • Attendance by the participants
Mechanisms of impact	<ul style="list-style-type: none"> • Participant responses to, and interactions with, the intervention • Mediators • Unanticipated pathways and consequences 	<ul style="list-style-type: none"> • Qualitative focus groups with OPTIMAL participants and individual interviews with professionals to explore causal mechanisms. • Quantitative mediators (Demographic information from referrals forms and participant questionnaires) collected by the trial.
Context	<ul style="list-style-type: none"> • Contextual factors which shape theories of how the intervention works • Contextual factors which affect implementation, intervention mechanisms, outcomes and vice versa • Causal mechanisms present within the context which sustain the status quo, or enhance effects 	<ul style="list-style-type: none"> • Study team research logs regarding context of delivery and decisions regarding study progression and intervention delivery in different contexts (area and centre delivery). • Qualitative focus groups with OPTIMAL participants and individual interviews with professionals to explore contextual variation in uptake and outcomes.

4.3.3.1 Demographic information

Summary demographic information was collected from participants as part of baseline demographic information. Demographic information was also collected on each of the sites in which the intervention was delivered. The 2016 Pobal HP Deprivation Index (Haase & Pratschke, 2017) was used to describe the relative affluence or disadvantage of each primary care team area in which the intervention was delivered. The Pobal HP Deprivation Index uses data compiled from the census for the purpose of this description.

4.3.3.2 Study recruitment logs

Recruitment activities for each site was recorded in terms of GPs contacted, responses received and primary care team meetings attended. A recruitment log was maintained whereby a record of the number of participants, reasons for attrition and the time period when this occurred was kept as much as possible.

4.3.3.3 Study team research logs

The study team maintained a research logbook of informal communication between the occupational therapists (OT), healthcare professionals (HCP) and the research team (calls, e-mails and visits/meetings with primary care teams and primary care occupational therapists/managers). The aim of the maintenance of such a log was to provide a more in-depth understanding of the context of each primary care site and how the occupational therapy primary care team (PCT) was implementing the intervention with the PCT.

4.3.3.4 Therapist log/fidelity tool

The occupational therapists were asked to complete a session log or fidelity tool at the end of each session (See Appendix 14). The tool was based on the content and delivery of the OPTIMAL programme as described in the facilitator manual provided and the training delivered to every therapist who delivered the programme. Therapists were

requested to record the following for each session: session duration, session attendance, structured questions (i.e. yes or no) regarding whether the specified content/activity for each session was delivered and facilitator manual were adhered to, open questions regarding comments/suggestions relating to session content/activity and reasons for deviating from facilitator manual. More detailed information regarding the facilitator training and manual and strategies used to maintain and monitor fidelity are described in Section 4.4.2.

4.4 Intervention fidelity

Treatment fidelity can be defined as “the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions” (Bellg et al., 2004, pp. 443). It is essential to monitor, measure and assess intervention or “treatment” fidelity as fidelity is a mediator of study outcomes and helps explain study results (Bellg et al., 2004; Mars et al., 2013; Spillane et al., 2007). Analysing treatment fidelity can help determine if an intervention is inherently faulty (failure of intervention concept or theory) or badly delivered (implementation failure). Given the multi-site nature of this trial, it is vital that adequate attention is paid to fidelity.

There is a need for interventions to have standardised features in all settings with adherence to such features achieving the best outcomes (Moore et al., 2014). However, Hawe, Shiell, and Riley (2004) contended that too much attention has been paid to rigidly standardising content and modes of intervention delivery, and allowing this to change across contexts may ensure greater fidelity to an intervention’s intended functions. This is easier to achieve if the key intervention components or “ingredients” are understood. Without understanding which components of an intervention are central to effectiveness, facilitators must implement with complete fidelity to increase the likelihood of positive outcomes (Bumbarger & Perkins, 2008). Bumbarger and Perkins (2008) emphasise the need for evaluators to distinguish between changes made in intervention delivery due to ‘innovation’ (skilled implementers actively attempting to make an intervention better fit their context, thus enhancing effectiveness) versus those which ‘drift’ (unintentional implementation failures due to limited acceptability or other barriers to implementation). This is vital in establishing the extent to which the outcomes evaluation represents a valid test of intervention theory (Steckler & Linnan, 2002).

In recent years there has been much debate on how best to conceive and measure fidelity with no consensus being made due to the multidimensional construct of fidelity (Mars et al., 2013). For the purposes of this study, fidelity was examined using the model developed by the Behavioural Change Consortium (BCC) which outlines five, mutually exclusive domains of treatment fidelity (Bellg et al., 2004). These five domains are as follows: i) study design, ii) provider training, iii) treatment delivery, iv) treatment receipt and v) enactment of treatment skills. The fidelity model and the accompanying measure developed by the BCC is not intended to be used as a series of rigid steps but rather as guidelines to assist researchers increase the likelihood of giving their interventions the fairest possible test. Bellg et al. (2004) advocate for maintaining high levels of treatment fidelity with flexible adaptation according to setting, provider, and participant. Each of these domains are explained and strategies used in this study to assess, monitor, and enhance treatment fidelity within each of the domains are discussed. Tables 4.2 to 4.5 outline the treatment fidelity strategies, adapted from Borrelli (2011) under these five domains.

4.4.1 Study and treatment design

Fidelity strategies related to study and treatment design ensure that a study adequately tests its hypotheses in relation to an intervention's underlying theoretical and clinical processes (Bellg et al., 2004; Borrelli et al., 2005) (Table 4.2). This means that the intervention is operationalised in such a way that its' hypothesised key components or ingredients are based on and delivered according to theory guiding the intervention. A printed treatment manual was provided to facilitators to ensure consistency of delivery and adherence to the key components of the OPTIMAL programme. While monitoring fidelity to intervention delivery is discussed in detail later, monitoring in relation to study design involves ensuring theoretical fidelity. This means that the intervention's underlying theory and key intervention components need to be made explicit from the outset in the intervention protocol, and in facilitator training and follow-up supervision of facilitators.

As previously discussed in Chapter 3, Section 3.5, self-efficacy theory has been identified and used as the theoretical model forming the basis of the OPTIMAL programme. The key intervention components included in each programme session as guided by this theory have been previously described (See Section 3.3.2.1). Borrelli (2011) recommended using piloting and feedback from participants to refine adherence

to the theoretical model and improve the acceptability, feasibility, and potential effectiveness of the intervention. The previous pilot studies of the OPTIMAL programme prior to this trial sought to achieve this aim (Garvey et al., 2015; O' Toole et al., 2013).

It was important to ensure that treatment receipt between intervention and control is monitored in order to prevent conclusions about the effectiveness of the OPTIMAL programme being affected. The number, length and frequency of contacts in the OPTIMAL programme were determined a priori as detailed in Chapter 3, Section 3.5, in line with Bellg et al. (2004) recommendations. Those in the control group were allocated to the waiting list and received their usual primary care service. Efforts were made to monitor the primary care services received by the control participants via self-report.

It is also recommended that adherence to the protocol be monitored over the course of the trial and that intervention delivery and assessment administration be monitored (Borrelli, 2011). Protocol deviations were recorded in terms of both dose and content both within and between groups. There are a number of methods which can be used in order to monitor treatment fidelity including audiotaping, videotaping, self-report checklists and questionnaires (Borrelli et al., 2005). While observation using audio and video-taping allows objective measurement of content and dosage, this method can be more obtrusive and was not possible to use in this study in an effort to maintain blinding of the researcher to participant allocation (Borrelli, 2011). A self-report monitoring checklist was completed by facilitators after each weekly session. The advantages of this method was that it may remind facilitators about the key components or ingredients to be delivered and encourage facilitators to implement with fidelity as they were aware that they were required to report on intervention delivery. The potential disadvantage of this method is that this can require more facilitator time to complete and there is a possibility that facilitators may rate themselves as more adherent than they really are (Borrelli, 2011). This checklist, in addition to qualitative data received from facilitators and participants, assisted in recording deviations across sites in relation to intervention dose and content. It also assisted monitoring in relation to adherence to the principles of OPTIMAL's underlying theory of self-efficacy and delivery of key intervention components underpinned by this theory. Weekly attendance was recorded for all participants to monitor dose and the weekly intervention checklist completed by facilitators also indicated the length of the session and the components delivered. The researcher also maintained regular contact with facilitators over the course of interventions in order to check in and answer any queries regarding programme delivery.

Assessment administration was also monitored. All occupational therapists administering baseline assessments were trained in assessment administration as part of the OPTIMAL training. They received written instructions on how to administer the assessments as part of this training to ensure consistency of measurement at baseline.

Implementation setbacks were planned for, particularly attrition of facilitators, as setbacks in study implementation could potentially confound study results. In each study site more than two facilitators were trained in OPTIMAL programme delivery and assessment administration. This is recommended as unanticipated facilitator dropout could lead to rushed attempts at training new facilitators, potentially resulting in performance differences between new and existing facilitators (Bellg et al., 2004; Borrelli, 2011).

Table 4-2 Assessment of treatment fidelity and strategies: Study and treatment design (adapted from Borelli, 2011)

Treatment fidelity strategy	Rate: Present, Not present and Not Applicable. If present, describe the strategy used for that component.	Strategy
Study and treatment design		
Provide information about the intervention condition	Present	Theory, content and delivery of OPTIMAL programme defined and provided in training and facilitator manual. Participant attendance and participation monitored in fidelity tool and participant focus groups.
Provide information about the control condition	Present	Participants received primary care as usual. Record of HCU overtime maintained at 6-month follow-up.
Specification of facilitator credentials needed	Present	Qualified HSE primary care occupational therapists.
Theoretical model upon which the intervention is based is clearly articulated	Present	Intervention developed through Phase I and II of MRC framework. Self-efficacy theoretical basis of OPTIMAL and key components of same identified and incorporated in intervention and training.
Potential confounders identified	Present	Treatment dose identified in terms of programme and session duration. Different approaches by different facilitators in site monitored.
Plan to address setbacks in implementation (backup systems or facilitators)	Present	Two OT facilitators required per intervention group but more trained in case of facilitator dropout.

4.4.2 Training

Facilitator training is an important element of treatment fidelity. Treatment fidelity involves ensuring that facilitators have been sufficiently trained to deliver the intervention to participants (see Table 4.3 below). This may require facilitators to gain new skills in addition to their existing clinical training and experience. Borrelli (2011) emphasised the importance of adequate facilitator training, emphasising that insignificant study results may be as a function of poorly trained facilitators rather than an ineffective intervention. Well-trained facilitators will possess increased competency to deliver the intervention and are less likely to deviate from the intervention's intended delivery. A number of different strategies were used to preserve fidelity in facilitator training.

OPTIMAL training was standardised. All facilitators were trained in the same manner in an effort to ensure programme delivery in a systematic manner across sites and prevent differential outcomes by different facilitators and sites (Bellg et al., 2004). Borrelli (2011) stated that perception of organisational support has been shown to be critical for motivating facilitators in intervention provision. It is important to note that prior to facilitator training, in each study site, managerial support and permission from the occupational therapy manager was sought and obtained. An information session was provided to managers and occupational therapists in each study site prior to commitment to the study where the study design, rationale and the intervention were explained. It was hoped that such information sessions would enhance buy-in from occupational therapist facilitators as they had a clear picture of the intervention and research commitment involved.

In order to standardise intervention training, it is recommended to use the same trainer, train all facilitators together and use standardized training materials (Bellg et al., 2004; Borrelli, 2011). The researcher provided all OPTIMAL training sessions, using the same standardised training materials. Therapists were provided with a training pack consisting of the training notes and programme outcome measures. The occupational therapists were provided with a facilitator manual which is described in detail below. All occupational therapist facilitators were qualified occupational therapists employed by the HSE. No specifications in relation to a facilitator's seniority or experience were made. The occupational therapist facilitators in each study site were trained together and provided with one training session in their primary care centre. It was not possible to train all occupational therapists across different sites at the same time due to phased recruitment and programme delivery.

As previously noted, more than two occupational therapists were trained in each area. This contingency was made in case of facilitator attrition. However, it was recommended that the same two therapists facilitate the OPTIMAL programme weekly in each area to ensure consistency. Training additional occupational therapists in the area permitted that in rare circumstances if one of the facilitators was unavailable (e.g. sick leave) one of the other trained occupational therapist facilitators could step in. In instances where this did occur this was recorded.

The training session was of 3 hours duration. The training covered the following content: impact and management of multimorbidity, self-management, self-efficacy theory, the development and features of the OPTIMAL programme and OPTIMAL weekly content (including physical activity and medication management session). Considerable time was spent on the concept of goal-setting and establishing overall and weekly programme goals. Informed consent and administration of baseline assessments was also instructed on. Training also explained the study design and rationale, the principles of RCTs and advice on preventing contamination. The training also emphasised the need to adhere to the intervention specified in the facilitator manual and to avoid the omission or addition of components not specified in the OPTIMAL programme. Given the varied experience among facilitators in terms of group facilitation and delivery of similar health promotion interventions, facilitators were provided with information on managing group member roles and group dynamics.

A limitation of the training provided is that the skill acquisition of the occupational therapist facilitators was not assessed. Training was delivered in a timely manner, close to when facilitators were due to deliver the intervention programme. It was hoped that this timing would prevent skill drift. All facilitators were also offered follow-up sessions and contact prior to and during intervention delivery.

4.4.2.1 Facilitator manual

All occupational therapists who attended training were provided with a facilitator manual to standardise and quality control programme delivery. The facilitator manual reflects the content covered in the training session but includes additional information and resources. The manual covers the following topics: Principles of self-management, research on self-management interventions, self-efficacy theory, the development and features of the

OPTIMAL programme, facilitation style and group preparation and management. The manual contains detailed information on weekly programme content and facilitation guidance. For each weekly session the manual contained: i) a session plan (outlining session aims, content, activities and recommended timing), ii) session PowerPoint and worksheets and iii) notes or script to guide the facilitators. There are instructions for the occupational therapist facilitators in order to prepare for the physical activity and medication management sessions. The weekly session content for these sessions are in the same format and are provided to the physiotherapist and pharmacist facilitators a number of weeks prior to the session.

Table 4-3 Assessment of treatment fidelity and strategies: Training (adapted from Borelli, 2011)

Treatment fidelity strategy	Rate: Present, Not present and Not Applicable. If present, describe the strategy used for that component.	Strategy
Training facilitators		
Description of how facilitators will be trained	Present	Received standardised 3 hours training and facilitator manual developed and delivered by researcher
Standardization of facilitators training (especially if multiple waves of training are needed for multiple groups of facilitators).	Present	Standardised 3 hours training developed and delivered by researcher
Assessment of facilitator skill acquisition.	Not present	Not formally assessed as part of training process. All facilitators qualified occupational therapists with skills in group intervention.
Assessment and monitoring of facilitator skill maintenance over time	Present	Monitored through completion of fidelity tool and facilitator interview post-intervention.
Characteristics being sought in a treatment facilitator are articulated a priori.	Present	Qualified HSE primary care occupational therapists who wished to participate after attendance at OPTIMAL information sessions to occupational therapy team.
At the hiring stage, assessment of whether or not there is a good fit between the facilitator and the intervention(e.g., ensure that facilitators find the intervention acceptable, credible and potentially efficacious)	Not present	Facilitators were qualified HSE primary care occupational therapists who wished to participate after attendance at OPTIMAL information sessions to occupational therapy team.
There is a training plan that takes into account trainees' different education and experience and learning styles.	Not present	Facilitators were qualified HSE primary care occupational therapists. Facilitator training and manuals standardised but ongoing communication/support from researcher offered to all facilitators.

4.4.3 Treatment delivery

Monitoring and assessing fidelity of treatment delivery involves treatment differentiation (whether the facilitators deliver the intended intervention and not other interventions), treatment competency (whether facilitators maintained the skill set gained in training), and treatment adherence (delivery of intervention components as intended). It is vital to implement strategies to maintain, monitor and assess fidelity in treatment delivery (Borrelli, 2011) (see Table 4.4 below). Even if facilitators are well-trained, it does not mean that a well-operationalised intervention and protocol will be delivered effectively to different participants across multiple sites (Borrelli et al., 2005).

A variety of strategies were used in an effort to enhance fidelity of treatment delivery as recommended by Borrelli (2011). Some efforts were made to monitor facilitator differences across multiple sites such as facilitator credibility and warmth through feedback from participant focus groups. The researcher endeavoured to create collaborative relationships with the occupational therapists delivering the OPTIMAL programme. It was hoped that fostering a supportive and cooperative relationship would increase facilitators comfort in reporting deviations in intervention delivery. The rationale for the self-monitoring fidelity checklist was explained to facilitators as well as the implications of lack of intervention delivery fidelity on study outcomes.

As previously discussed a facilitator intervention manual with a script was provided in order to increase fidelity in treatment delivery. There is some debate about the use of such manuals. While it is acknowledged that the use of manuals assist in standardising the intervention, manuals may inhibit creativity and flexibility which is required to meet individual participant needs (Borrelli et al., 2005). The researcher during training advised facilitators of the importance of adhering to the treatment manual in relation to key intervention components and content. However training also acknowledged facilitators using their own professional knowledge and skills and local contextual knowledge to meet participants' needs. Fidelity of OPTIMAL delivery was monitored through the participant focus groups, facilitator interviews and self-monitoring fidelity checklist as previously discussed. These multiple methods enabled adherence to intervention delivery in relation to dose, content and process to be explored. A limitation of the methods used to monitor intervention delivery was that no direct observation was used.

Table 4-4 Assessment of treatment fidelity and strategies: Treatment delivery (adapted from Borelli, 2011)

Treatment fidelity strategy	Rate: Present, Not present and Not Applicable. If present, describe the strategy used for that component.	Strategy
Delivery of treatment		
Method to ensure that the content of the intervention is delivered as specified.	Present	Fidelity tool monitoring session content delivery.
Method to ensure that the dose of the intervention is delivered as specified.	Present	Fidelity tool monitors dose in terms of number and duration of sessions. Attendance list monitoring individual participant attendance.
Mechanism to assess if the facilitator actually adhered to the intervention plan	Present	Fidelity tool, facilitator interviews and participant focus groups.
Assessment of non-specific treatment effects.	Present	Participant focus groups provided information regarding non-specific treatment effects (e.g. facilitator interaction/rapport).
Use of treatment manual	Present	All facilitators provided with standardised OPTIMAL facilitator manual.
There is a plan for the assessment of whether or not the active ingredients were delivered.	Present	Fidelity tool, facilitator interviews and participant focus groups.
There is a plan for the assessment of whether or not prescribed components were delivered. (e.g., components that are unnecessary or unhelpful)	Present	Fidelity tool, facilitator interviews and participant focus groups.
There is a plan for how will contamination between conditions be prevented.	N/A	Contamination unlikely between arms. OPTIMAL not part of routine practice and key components are hypothesised as interactive group components rather than information provision. Couples were randomised as a unit to prevent contamination.
There is an a priori specification of treatment fidelity (e.g. providers adhere to delivering >80% of components).	Not present	

4.4.4 Treatment receipt

Treatment receipt refers to whether the intervention that was delivered to the participant was actually “received” by the participant (Bellg et al., 2004; Borrelli, 2011) (see Table 4.5 below). It relates to whether participants understand and can perform the intervention skills and strategies provided during intervention delivery. The OPTIMAL programme seeks to increase self-efficacy and improve self-management skills. Receipt therefore means that participants demonstrate behaviour indicating increased self-efficacy and performance of self-management skills and strategies that have been presented to them. Monitoring treatment receipt is particularly important where participants may have low literacy levels, education, cognitive impairment or poor proficiency in English (Bellg et al., 2004; Borrelli, 2011). During OPTIMAL training the need to identify participants with such issues was highlighted. Other strategies to enhance fidelity in treatment receipt included provision and delivery of the intervention in an engaging manner, the use of programme materials with appropriate health literacy, using multiple formats of information provision (verbal, visual and written) and the use of interactive activities and goal-setting to promote skills and provide opportunities for coaching and feedback from facilitators and peers. Such activities also enable facilitators to assess participants’ understanding and confidence in performing self-management skills (Borrelli, 2011).

4.4.5 Enactment of treatment skills

Enactment focuses on whether the behavioural skills and strategies related to the intervention are implemented appropriately in real-life contexts, with the intended effect on clinical and research outcomes (Bellg et al., 2004; Borrelli, 2011) (See Table 4.5 below). Enactment focuses on what participants actually use as a result of an intervention in their daily lives and is distinct from what is actually taught (treatment delivery) and learned (treatment receipt) (Bellg et al., 2004). Suggested strategies to assess for enactment of skills include direct observation, self-report, and provider report. In this study both occupational therapist facilitator interviews and participant focus groups aimed to gather information about what strategies participants had learnt and were using.

Table 4-5 Assessment of treatment fidelity and strategies: Treatment receipt and enactment (adapted from Borelli, 2011)

Treatment fidelity strategy	Rate: Present, Not present and Not Applicable. If present, describe the strategy used for that component.	Strategy
Receipt of treatment		
There is an assessment of the degree to which participants understood the intervention.	Present	Participant focus groups, occupational therapist facilitator interviews and fidelity tool
There are specification of strategies that will be used to improve participant comprehension of the intervention.	Present	Strategies to assist participants with low literacy levels discussed during facilitator training and manual. Use of multiple modalities of information provision and interactive nature of programme emphasised in training. Participant booklet and materials literacy friendly.
The participants' ability to perform the intervention skills will be assessed during the intervention period.	Present	Participant focus groups and follow-up outcome measures may provide information on implementation of self-management strategies.
A strategy will be used to improve participant performance of intervention skills during the intervention period.	Present	Researcher available for support during OPTIMAL programme.
Multicultural factors considered in the development and delivery of the intervention	Not present	
Enactment of treatment skills		
Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied.	Present	Participant focus groups, occupational therapist facilitator interviews and specifically information about engagement in programme.
A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied.	N/A	Participant focus groups, occupational therapist facilitator interviews.

4.5 Process evaluation: Qualitative component

Qualitative methods in a process evaluation can provide in-depth understanding of mechanisms of impact including unanticipated or complex casual pathways, how context effects implementation, experiences of the intervention and why those delivering or receiving the intervention do or do not engage as planned (Moore et al., 2014).

4.5.1 Qualitative approach

A qualitative descriptive design was used for the qualitative component of this process evaluation. Qualitative description aims to stay close to the data in both the analytical process and data presentation by producing a rich, straight description of an experience or an event (Sandelowski, 2000, 2010). This is in contrast to other qualitative approaches which focus on aims such as thick description (ethnography), theory development (grounded theory) or interpretative meaning of an experience (phenomenology) (Kim, Sefcik, & Bradway, 2017).

While the final product of qualitative description is a description of participants' experiences in a language similar to their own, this does mean that no interpretation of data occurs (Sandelowski, 2000, 2010). A common misconception of qualitative description is that no interpretation of data takes place. Analysis and interpretation is always present and qualitative researchers are always required to "make something of their data" (Sandelowski, 2010, p. 79). The interpretation of data in a qualitative descriptive study can be explained as low inference or data near (Kim et al., 2017).

Qualitative description is a common method employed in qualitative studies of health care phenomena and interventions (Kim et al., 2017; Polit & Beck, 2010). Qualitative description has been suggested to be a compatible and useful method for mixed methods studies focusing on health intervention development or refinement because of its descriptive breadth which parallels and blends well with quantitative methods (Neergaard, Olesen, Andersen, & Sondergaard, 2009; Sullivan-Bolyai, Bova, & Harper, 2005). Qualitative description can be used to scrutinize and ensure that clinical interventions are acceptable and understandable to individuals to whom the intervention is targeted, tailored to their needs and takes account of factors promoting access and use of the intervention (Sullivan-Bolyai et al., 2005). Qualitative description also ensures

that interventions are acceptable and understandable to those clinicians who ultimately must translate findings into practice (Sullivan-Bolyai et al., 2005). Despite its popularity, there is limited supporting literature on how to design, implement, analyse, or report the results of a qualitative descriptive study (Kim et al., 2017).

4.5.2 Qualitative data collection

Qualitative data collection involved the use of two separate methods. Focus groups were carried out with intervention participants in each site immediately post-intervention. Semi-structured interviews were conducted with occupational therapists and other health care professionals involved in referring to or delivering components of the OPTIMAL programme.

4.5.2.1 Focus groups

Focus groups were used to collect qualitative data from intervention participants. Focus group interviews are a data collection method where participants express their views by interacting in a group discussion of the issues (Liamputtong, 2011). The collective context of focus groups creates a process which differs from individual interviews as the data is generated by the group's interactions (S. Carter & Henderson, 2005; Ritchie, Lewis, Nicholls, & Ormston, 2013). The purpose of the focus groups was to explore participants' perceptions of the programme design, content, key intervention components and delivery. It also sought to evaluate participants' perceptions of the programme impact, if any, and views on programme feasibility and recommendations.

Focus groups have been recommended as an appropriate method of data collection in process evaluations of health care interventions (Liamputtong, 2011). Utilising a focus group post-intervention may help explain trends and variances, elucidate quantitative findings, and consider processes of change, attitudes and opinions about the intervention (Sarantakos, 2012). A focus group therefore was indicated given that participants were already in a pre-existing group having attended the six-week OPTIMAL programme. Participants in the programme had shared experiences and focus groups are valuable in exploring these. As a result participants may feel more at ease with each other which can facilitate discussion and the ability to challenge each other. A further advantage of focus groups is their efficiency, allowing the collection of qualitative data

from both an individual and collective perspective (Liamputtong, 2011). Group interactions tend to focus on the most salient issues, allowing identification of a relatively consistent view among participants (Lysack, Luborsky, & Dillaway, 2017).

Conversely, using focus groups with pre-existing groups runs the risk of shared assumptions resulting in issues not being fully explored or elaborated on because meaning is assumed and group norms or particular members dominate or influence the discussion (Finch, Lewis, & Turley, 2013). Participants may be influenced by “social desirability” bias by providing responses which they believe are more socially desirable or acceptable to others (Lysack et al., 2017). Given the challenges in conducting focus group interviews, it is unsurprising that obtaining quality data from focus groups requires a skilled facilitator to enable all participants to contribute (Lysack et al., 2017). The facilitator has a dual role in progressing and assisting open discussion but also moderating the discussion to control the agenda, manage unexpected diversions and prevent dominance for certain participants (Finch et al., 2013). In this study, an independent facilitator conducted the focus groups in order to minimise the possibility of social desirability bias occurring. The focus group facilitator was an occupational therapist by background but was not involved directly in intervention delivery in this study. The focus group facilitator possessed theoretical and methodological knowledge of the study and, having been involved in previous group interventions and focus groups, was skilled in managing group dynamics (Davidson, Halcomb, & Gholizadeh, 2010).

The focus group interview guide was based on the research objectives to examine the impact, feasibility and acceptability of the programme and inform future recommendations (See Appendix 15). The interview guide was developed in consultation with the research supervisors. Focus groups were used in the previous research of the OPTIMAL programme which proved useful in providing previous experience of questions which “worked” and those which caused difficulties. Two general principles were followed when developing the guide, the first being that questions were ordered from the more general to the specific (Stewart & Shamdasani, 2015). This meant the interview began by asking questions about the group format and impact before progressing to more specific questions about intervention components. The second principle involved ordering questions in relation to relative importance in terms of the research aim, this meant exploring the acceptability and impact first before progressing to questions regarding programme materials (Stewart & Shamdasani, 2015). While the guide included questions on these objectives, the facilitator modified or asked additional

appropriate questions to address these objectives accordingly as the discussion progressed (Stewart & Shamdasani, 2015).

Eight focus groups were conducted with the size of the focus group ranging from three participants to nine participants. Focus group size of a minimum of four and a maximum of 12 participants has been previously recommended in the literature (Carlsen & Glenton, 2011). Each focus group lasted approximately 45 minutes to an hour. Focus groups were conducted in each site due to the understanding that implementation, context and mechanisms could have varied in each site.

4.5.2.2 *Semi-structured interviews*

Semi-structured interviews were used to collect qualitative data from occupational therapists, physiotherapists and pharmacists involved in delivering the intervention and GPs involved in referring participants. Interviews can be described as a purposeful conversation which is used to generate narrative accounts or descriptions and interpretations of phenomenon (Sarantakos, 2012; Yeo et al., 2013). Semi-structured interviews use a pre-established set of open-ended questions but permit flexibility in administration by allowing tailoring of questions and probes to obtain more in-depth and trustworthy information (R. R. Taylor & Kielhofner, 2006).

All occupational therapists who were involved in programme delivery were invited to take part in the qualitative process evaluation of the study after the intervention was completed in their area. The purpose of this interview was to explore the occupational therapists' perceptions of the impact of OPTIMAL and the appropriateness, acceptability and feasibility of implementing the intervention in a primary care setting. Given the amount of process evaluation data being collected, interviews were conducted with a small number of physiotherapists and pharmacists rather than all the pharmacists and physiotherapists involved in programmes. Interviews sought to examine their perceptions of the session content, delivery and feasibility of implementation of the programme in primary care. Telephone interviews were also conducted with a small number of GPs who referred as a means to explore facilitators and barriers to referrals and implementation of OPTIMAL in primary care.

It was decided to use individual interviews for a number of reasons. The health professionals have different roles and expertise in the delivery of the OPTIMAL

programme. It was decided that more personal and truthful responses may be elicited if professionals had the confidentiality provided in an individual interview given the different dynamics and working relationships that may exist in primary care teams. Furthermore the occupational therapist facilitators who facilitated the programme together were interviewed separately as individual therapists may have more experience or seniority which could influence the other therapist in their responses.

The researcher conducted the interviews as it was not feasible due to resource constraints to have an independent interviewer. There were both advantages and disadvantages to the researcher acting as interviewer. Interview participants would have been aware of the interviewer's role as developer of the OPTIMAL programme and as a researcher. This may have resulted in participant's providing socially desirable responses to questions posed. In order to address this challenge, the interviewer endeavoured to be neutral, receptive and interested in participants' responses (Sarantakos, 2012). The interviews were conducted either in person (in the clinical setting) or via telephone depending on participant preference.

The telephone interview has been criticised in qualitative research as producing lower quality data as it prohibits the assessment of visual cues and compromises contextual and nonverbal data, rapport building, probing, and interpretation of responses. However this criticism has been described by some as unfounded (Novick, 2008). Sturges and Hanrahan (2004) found that there was little difference in the data produced by face to face interviews in comparison to telephone interviews. Indeed telephone interviews have distinct advantages in terms of allowing interviewees to feel comfortable disclosing sensitive information and practical benefits such as decreased cost, access to participants in widely dispersed geographical areas, decreased space requirements and the ability to take notes unobtrusively (Novick, 2008; Opdenakker, 2006). In the context of this study the researcher was cognisant of the clinical demands on primary care health professionals and the potential challenge in securing face-to-face time.

Successful interviews are associated with positive and effective relationships where interviewer and interviewee are from a similar background. This similarity can help promote trust, understanding and cooperation (Sarantakos, 2012). The researcher was an occupational therapist by background. In the case of the occupational therapists, the interviewer had established a working relationship with the therapists through involvement in training, programme delivery, assisting with recruitment and liaising regularly with them regarding programme delivery and data collection follow-up.

The interview guide aimed to explore the perspectives of health professionals' who both referred to and delivered the OPTIMAL programme. A separate interview topic guide was developed for each profession interviewed (See Appendix 16-19). All healthcare professionals were questioned about their perceptions of the impact, delivery (in terms of both content and format) and acceptability of the OPTIMAL programme. Questions related to barriers and facilitators to implementation in primary care, including recruitment to the programme, were also included in the guides. Healthcare professionals directly involved in programme delivery (i.e. occupational therapists, physiotherapists and pharmacists) were asked about their views on the programme training, facilitator manual, resources and fidelity to the intervention protocol.

4.5.2.2.1 Recruitment and informed consent procedures

Participants allocated to the intervention in each site were invited to participate in the focus group which was held on the final session of the OPTIMAL programme. Participants were informed and consented to focus group participation as part of the informed consent procedure and baseline data collection outlined in Chapter 3, Section 3.7.4. It may have been beneficial to interview participants who declined participation in the study or who did not attend the intervention.

All healthcare professionals invited to participate in interviews were forwarded an information pack (containing an invitation letter, information leaflet and consent form) (See Appendix 20). Those who wished to participate were asked to contact the researcher directly. OTs who were involved in programme delivery were invited to take part in the qualitative process evaluation of the study after the intervention had been completed in their area. The information pack was forwarded by the OT manager to the OTs involved in intervention delivery. The researcher then made arrangements to interview the participant either face to face or via telephone. In the case of face to face interviews participants were asked to sign the consent form prior to interview commencement and in the case of telephone interview, participants were asked to return the signed informed consent form to the researcher prior to the arranged interview data.

Interviews were conducted with 15 occupational therapists out of possible 16 occupational therapists involved in delivering the programme in eight primary care areas. Ten GPs were invited to be interviewed with four consenting and participating in interviews. Four physiotherapists were invited to participate in interviews with three physiotherapists participating. Three pharmacists were invited to be interviewed with all three consenting and participating in interviews.

4.6 Process evaluation data analysis

Qualitative and quantitative components should assist interpretation of each other's findings. Methods should be combined in order to develop a greater understanding of how the intervention is delivered and works. Qualitative and quantitative components of a process evaluation should facilitate interpretation of one another's findings (Moore et al., 2015).

4.6.1 Quantitative data analysis

Quantitative data gathered from demographic forms, referral forms, recruitment logs, research logs and fidelity tools were inputted into Stata version 15 and summarised using descriptive statistics (StataCorp, 2017).

4.6.2 Qualitative data analysis

All focus groups and interviews were audiotaped and transcribed verbatim by a transcription service. Qualitative data were analysed using thematic analysis (Braun & Clarke, 2006). Thematic analysis is a method for identifying, analysing and reporting patterns (themes) across a dataset in relation to a research question (Braun & Clarke, 2006; Clarke & Braun, 2013).

Nvivo, an atheoretical qualitative data analysis package, was used to code data into themes. The systematic process of analysis recommended by Braun and Clarke (2006) for rigorous thematic analysis was used. Focus groups and interviews were analysed as a single data set. This process is recursive rather than linear and the phases are as follows:

1. Familiarising with data: The researcher familiarised herself with the data by reading and re-reading the data and noting any initial analytic observations.
2. Generating initial codes: Each transcript (focus group and interviews) was inputted into Nvivo. Coding is a term given to marking important sections or “chunks” in the data of relevance to the research question guiding the analysis (Braun & Clarke, 2013; Clarke & Braun, 2013). The researcher coded the data using the Nvivo package by progressing systematically through each transcript, coding as many “chunks” (sentences or groups of sentences with similar meaning) as possible. The researcher then collated all codes and relevant data extracts.
3. Searching for themes: A theme is a coherent and meaningful pattern in the data relevant to the research question (Braun & Clarke, 2013). The researcher searched for candidate themes and sub-themes, by considering how different codes combined and related by examining each code individually and comparing codes across the data set. This enabled the researcher to generate larger more encompassing themes. All coded data relevant to each theme was collated.
4. Reviewing themes: The researcher then refined the themes further by deciding if the candidate themes ‘worked’ in relation to both the coded extracts and the full data-set (Clarke & Braun, 2013). The nature of each theme and the relationship between themes was then defined. Themes were compared to each other, overlapping themes combined, sub-themes identified and some themes were discarded while other themes were re-developed again.
5. Defining and naming themes: Themes were further refined and defined by completing a detailed analysis of each theme in terms of what its core message or “essence” is and how it fitted in with the data overall and research questions.
6. Reporting: The final phase of thematic analysis involves the reporting of the finalised themes in a concise, coherent and logical way which is related back to the research questions and literature.

4.6.3 Rigour of qualitative data

Rigour in qualitative research means that researchers have followed procedures to ensure they have penetrated and comprehended accurately participants’ experiences (Holloway, 2008). Milne and Oberle (2005) described approaches to maintain rigour within a qualitative descriptive study. The strategies proposed are organized according to Whittemore, Chase, and Mandle (2001) framework of primary validity criteria in

qualitative research which are as follows: (i) authenticity i.e. attending to the voices of participants by ensuring the research accurately reflects the meanings and experiences lived by the participants, (ii) credibility which is confidence in the 'truth' of the findings or results, (iii) criticality or the need to critically appraise all decisions throughout the research process and iv) integrity, demonstrated by on-going reflection and self-criticality of the researcher. Milne and Oberle (2005) emphasized the inter-relatedness of these factors as the credibility of a study promotes authenticity by remaining true to the phenomenon under study. Integrity is a reflection of the study's criticality, or the attention paid to each and every research-related decision. The strategies used in this study to promote rigour will be discussed in pairs as follows: i) credibility and authenticity and ii) integrity and criticality. Table 4.6 summarizes the methods used to enhance rigour in this study.

Table 4-6 Methods to ensure rigour in qualitative research

Strategy to increase scientific rigour	Contributing factors	Methods to address factor	Use in this study
Credibility and authenticity	Ensuring freedom to speak	Purposeful sampling	✓
		Sample size	✓
		Ensuring participant driven data	✓
	Ensuring participants' voices are heard	Probing for clarification and depth	✓
		Focus groups to facilitate discussion	✓
	Ensuring participants' perceptions are accurately represented	Ensuring accurate transcription	✓
	Content analysis: Ensuring data-driven coding and categorizing	Ensuring attention to context	X
Integrity and criticality	Reflecting on researcher bias		✓
	Respondent validation		✓
	Peer review		✓

4.6.3.1 Credibility and authenticity

Promoting authenticity involves providing participants the freedom to speak, allowing their voices to be heard and ensuring their perceptions are accurately represented (Milne & Oberle, 2005). The methods which were used to promote credibility and authenticity in this study are discussed in the sections below.

4.6.3.1.1 Ensuring freedom to speak

In order to ensure that participants have the freedom to speak it is important to consider whose voices will be heard. This requires purposeful sampling, adequate sample size and participant driven data collection. As suggested purposeful sampling was used in this study by inviting all participants with multimorbidity who had participated in the OPTIMAL programme and health professionals who had delivered and referred to the programme.

In terms of sample size Milne and Oberle (2005) recommend qualitative data collection to continue until theoretical saturation for qualitative description is reached. Theoretical saturation means that qualitative sampling is adequate when additional data fails to generate new information. Debate exists regarding the concept of saturation which is consistent with a more positivist approach to qualitative data whereby data are collected to provide a complete and truthful picture (Braun & Clarke, 2013). This can be difficult to achieve in qualitative description given that this approach aims to explore individual participant experiences including commonalities and differences. In this study the researcher decided to conduct focus groups with participants and occupational therapy facilitators in each intervention programme to ensure attention to context. With regards to other health professionals, a small sample of health professionals involved in delivering and referring to the programme participated in interviews. This was due to pragmatic concerns regarding the the amount of qualitative data being collected and the overall focus of the study.

The final recommended method to ensure participants have freedom to speak is generating participant driven data. Using a flexible topic guide can enable participants to tell their own story (Milne & Oberle, 2005). Both the focus group and interview guides permitted flexibility, participants were allowed to expand into issues and topics which

were not explicitly addressed in the interview guides but bore relevance to the research aims and objectives.

4.6.3.1.2 Ensuring participants' voices are heard

The use of probing questions and focus groups were methods employed to ensure participants' voices were heard (Milne & Oberle, 2005). Participants in focus groups and interviews were probed as appropriate to clarify and elaborate responses providing rich data. Focus groups have also been identified as a suitable method to enable participants' voices to be heard as they provide a safe environment. The focus group environment provided a safe environment for OPTIMAL programme participants to respond to specific questions, in addition to the fact that participants also had developed relationships and rapport over the programme duration. Facilitators were mindful to encourage and enable all members to participate without singling out individual participants. In relation to interviews of health professionals it was rationalised that focus groups could potentially prohibit individual voices from being heard due to the influence of team dynamics and seniority as previous research indicates that differences in status among participants in focus groups can negatively influence communication (Tausch & Menold, 2016).

4.6.3.1.3 Ensuring participants' perceptions are accurately represented

Ensuring participants' perceptions are accurately represented begins with transcription of each focus group or interview (Milne & Oberle, 2005). As a transcription service was used to transcribe both focus group and interview data, the researcher read the transcripts while listening to the audio-recordings to ensure direct and accurate quotes were obtained.

4.6.3.1.4 Ensuring data-driven coding and integrity

Content analysis has been specifically recommended as suitable for qualitative description by Milne and Oberle (2005) as means to ensure data-driven coding and categorizing. As previously outlined, a thematic analysis was used in this study. Thematic analysis has also been identified as a suitable method of analysis for qualitative descriptive studies (Vaismoradi, Turunen, & Bondas, 2013). Thematic analysis was

specifically selected to produce a detailed and nuanced account of the data across the data set rather than content analysis which focuses on a purely descriptive approach reporting data trends both qualitatively and quantitatively in the data (Milne & Oberle, 2005; Vaismoradi et al., 2013). In line with a qualitative descriptive approach authenticity of data and analytical integrity was ensured by maintaining data-driven coding rather than super-imposing codes and themes pre-determined by the research question. This required ongoing critical review and appraisal of codes and emergent themes as analysis progressed.

Understanding the context of the interview as a whole also promotes authenticity and credibility. Thematic analysis permits the researcher to combine analysis of meaning within context. The researcher was cognisant of the need to include additional pieces of data to codes when necessary to provide context to the data “chunk” (Milne & Oberle, 2005). The researcher also listened to audio to note participant tone to provide additional meaning. Field notes were maintained by the independent focus group facilitators and by the researcher when conducting interviews to capture observations, impressions, and assumptions during and following a focus group or interview.

4.6.3.2 Criticality and Integrity

Criticality refers to critically appraising the research decisions made and is a key feature of a study’s overall integrity (Milne & Oberle, 2005). Methods proposed to promote the overall integrity of a qualitative descriptive study include consistent reflection on potential sources of bias, specifically on the researcher’s role, respondent validation, and peer review (Milne & Oberle, 2005). The methods were incorporated to promote criticality and integrity in this study and are discussed below.

4.6.3.2.1 Reflecting on researcher bias

A study’s integrity involves a researcher being able to reflect on his or her biases and the influence these may have on the research process. Previously discussed strategies aiming to promote participant-driven data and data-driven analysis were used in line with qualitative description and assisted in minimising interpretation of the data in line with the researcher’s lens (Milne & Oberle, 2005; Sullivan-Bolyai et al., 2005). Given the researcher’s involvement in the development, and previous research, of the OPTIMAL

programme, it was vital to employ strategies to manage any assumptions held by the researcher in order to gather relevant and truthful qualitative data. This was particularly important when conducting the interviews with the occupational therapy facilitators given the researcher's multiple roles as project manager, researcher and occupational therapist. While this in-depth knowledge allowed the researcher to ask and tailor questions relevant to individual contexts it was also vital to engage in continuing reflection about the researcher's multiple roles and if this was influencing the interviews. This allowed adjustments to be made as appropriate during and in subsequent interviews.

4.6.3.2.2 Respondent validation

Respondent validation was also used to ensure that participants' perceptions were represented for both focus group and interview data (Birt, Scott, Cavers, Campbell, & Walter, 2016). However it is important to note that member checking of transcripts was not used in this study rather member checking was an ongoing process involving probing and summarizing the main points of the focus groups and interviews during data collection in order to clarify what participants had said and to allow participants to confirm or disagree with the summary provided (Milne & Oberle, 2005).

4.6.3.2.3 Peer review

Peer review was also used to ensure that the researcher was remaining faithful to the goal of qualitative description by staying close to the data in terms of both the analysis and presentation of findings or themes (Milne & Oberle, 2005). Peer review was not used as a means to strengthen analytic claims or to find a single objective knowable truth (Braun & Clarke, 2013). Codes were reviewed with one of the supervisors (DC) during analysis to ensure they were data-driven and themes were also discussed to ensure logical progression from the data and explore alternative interpretations. While both latent and manifest codes were used, the majority of codes were manifest, reflecting the nature of qualitative description.

4.7 Conclusion

A process evaluation was conducted alongside the OPTIMAL RCT in order to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice. This chapter presented the process evaluation methodology which employed both quantitative and qualitative methods to address the process evaluation aim and objectives. The findings from the OPTIMAL trial and process evaluation will be presented in Chapter 5 and Chapter 6 respectively.

Chapter 5 Trial Results

5.1 Introduction

This chapter presents the trial results. The chapter begins by providing an overview of progress through the trial in terms of participant recruitment and attrition. Participant baseline characteristics, including both baseline primary and secondary outcome measures, are described. Analyses of primary outcome measures are then presented. The chapter concludes with a summary of the RCT results.

5.2 Recruitment, attrition and attendance

Eight OPTIMAL intervention programmes were delivered over four recruitment blocks, from April 2016 until March 2018. The progress of participants through the RCT is summarised in Figure 5.1. In total 149 participants were recruited for the study and completed baseline assessments. Following baseline assessment, 78 participants were randomly allocated to receive the OPTIMAL programme whilst 71 participants were randomly allocated to a waiting list control to receive care as usual. Of the participants allocated to the intervention, 11 participants did not attend any of the six intervention sessions. The reasons for non-attendance were as follows; unknown (n=3), not available/programme timing didn't suit (n=2), illness (n=4), not interested (n=1) and a busy schedule/other commitments (n=1). Detailed information regarding attendance is described in detail as part of the process evaluation results in Chapter 6.

As described in the methodology chapter, participants returned immediate follow-up postal questionnaires, those who did not return questionnaires were followed-up with a phone call and thereafter those who did not return questionnaires were classified as non-responders. As the primary data analysis was ITT all participants were asked to return immediate follow-up assessments regardless of the number of sessions attended. In total 18 participants (7 intervention and 11 control participants), did not return immediate follow-up questionnaires. An additional 14 participants returned incomplete questionnaires, (6 intervention participants and 8 control participants). Accounting for both non-responders and those who provided incomplete data, there was an overall attrition rate of 21.5%.

In terms of the EQ-VAS data, in total 124 participants (83.2%) were included in ITT analysis, 66 participants from the intervention and 58 participants from the control group.

Incomplete EQ-VAS data were received from 6 participants in total (5 intervention participants and 2 control participants), and were excluded from analysis.

In relation to FAI total scores, data for 121 participants (81.2%) were analysed, 68 intervention participants and 53 control participants provided complete FAI data respectively. Incomplete FAI data were received from 10 participants in total (3 intervention participants and 7 control participants), and were excluded from analysis.

In terms of per protocol analysis, 19 intervention participants attended less than 3 sessions and were excluded from analysis. A total of 52 intervention participants were included in per protocol analysis of the EQ-VAS. An additional 7 intervention participants who attended three or more intervention sessions either did not provide immediate follow up data or provided incomplete follow-up data with no data for the EQ-VAS. A total of 55 intervention participants were included in per protocol analysis of the FAI. Four intervention participants who attended three or more intervention sessions either did not provide immediate follow up data or provided incomplete follow-up data with no data for the EQ-VAS.

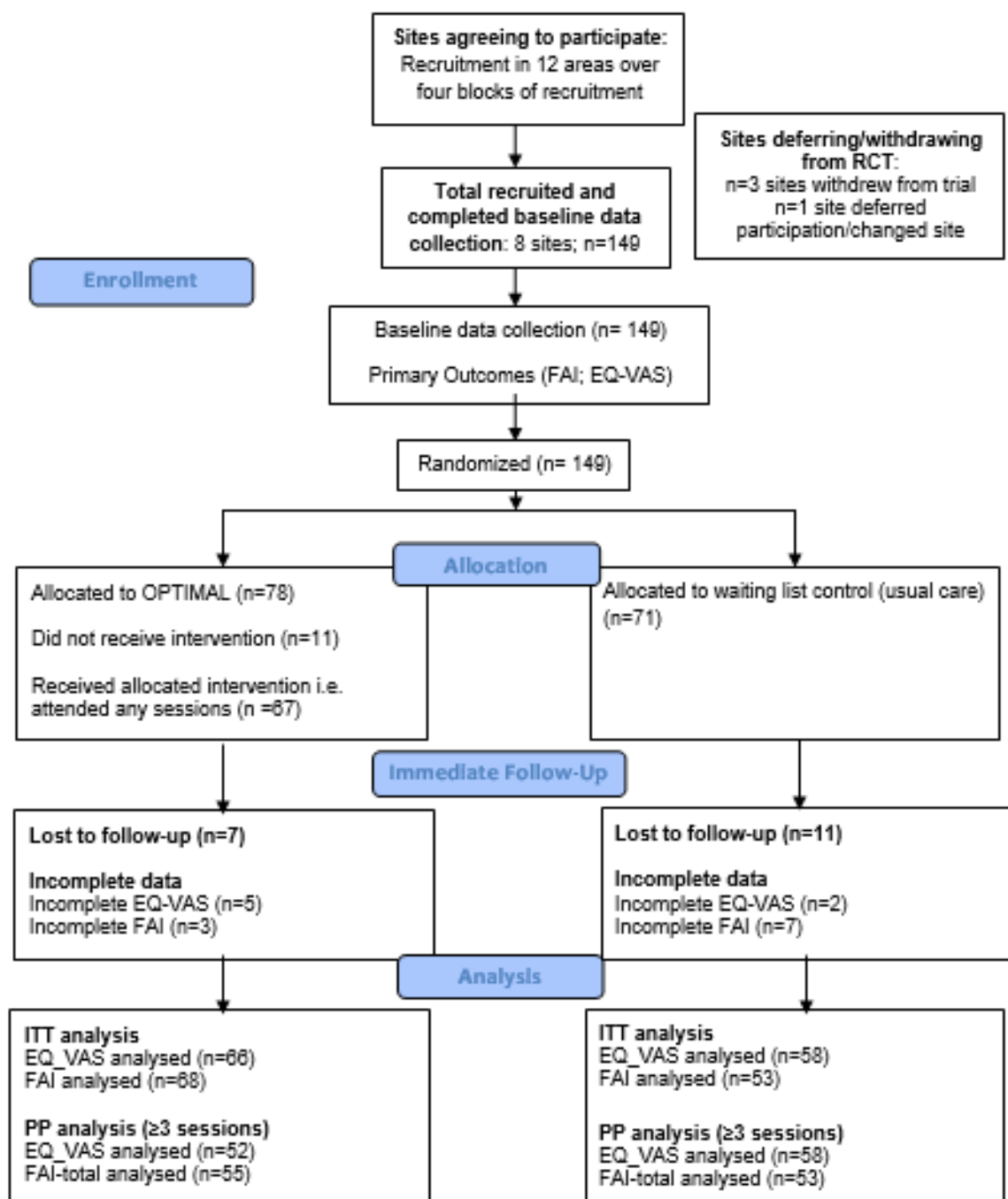


Figure 5-1 Consort flow diagram

5.3 Participants' baseline demographic characteristics

Consort guidelines recommends the reporting of baseline data for participants but advises that significance testing of baseline differences in randomized controlled trials should not be performed (Moher et al., 2010). Participant's characteristics at baseline are summarised in Table 5.1. There were 78 participants in the intervention group and 71 participants in the control group. Participants were well balanced in terms of mean age, 65.5 years in the intervention group and 65.9 years in the control group. Both average numbers of chronic conditions and number of medications varied little between groups. Intervention participants had a mean number of 4.4 conditions and control participants had 4.7 conditions. Average number of medications was 9.1 medications for intervention and 8.5 for control participants respectively. Participants were generally balanced in terms of gender, General Medical Services scheme (GMS) status, educational level and employment status. Overall the majority of participants had not completed secondary education and in terms of employment described themselves as either not working due to their conditions or retired. Slightly more intervention participants (33%) were living alone in comparison to control participants (25%). In terms of marital status a higher proportion of intervention participants were widowed (22%) in comparison to the control (10%). Additionally, a higher proportion of intervention participants were wheelchair users (8%) in comparison to control participants (1%).

5.3.1 Primary outcomes at baseline

Table 5.1 also presents baseline means and standard deviations for the two primary outcome measures the EQ-VAS and FAI total score. Intervention participants had a slightly higher average EQ-VAS score at baseline (60.6) in comparison to control participants (58.2). FAI total scores were similar with intervention participants having an average score of 25.7 and control participants average score was 25.1.

Table 5-1 Participant baseline characteristics

Characteristic	Intervention n=78		Control n=71		Total n=149	
	n (%)		n(%)		n (%)	
Gender						
Male	25 (32)		21 (30)		46 (31)	
Female	53 (68)		50 (70)		103 (69)	
GMS Card holder						
GMS	67 (86)		65 (92)		132 (89)	
Non-GMS	11 (14)		6 (8)		17 (11)	
Marital status						
Single	8 (10)		16 (22)		24 (16)	
Married	38 (49)		34 (48)		72 (48)	
Widowed	17 (22)		7 (10)		24 (16)	
Divorced/Separated	11 (14)		14 (20)		25 (17)	
In a relationship	4 (5)		0 (0)		4 (3)	
Educational level						
Primary	29 (37)		27 (38)		56 (38)	
Some secondary	19 (24)		20 (28)		39 (26)	
Complete secondary	14 (18)		11 (16)		25 (17)	
College/University	16 (21)		13 (18)		29 (19)	
Employment status						
Full-time employment	0 (0)		2 (3)		2 (1)	
Part-time employment	6 (8)		1 (1)		7 (5)	
Not working due to condition	17 (22)		23 (32)		40 (27)	
Unemployed	5 (6)		5 (7)		10 (7)	
Retired	46 (59)		37 (52)		83 (56)	
Carer	1 (1)		2 (3)		3 (2)	
Full-time Housewife	3 (4)		1 (1)		4 (3)	
Mobility Aid						
Independent	57 (73)		53 (75)		110 (74)	
With Aid	15 (19)		17 (24)		32 (21)	
Wheelchair user	6 (8)		1 (1)		7 (5)	
Living situation						
Living alone	26 (33)		18 (25)		44 (30)	
Living with family	49 (63)		53 (75)		102 (68)	
Living with others	3 (4)		0 (0)		3 (2)	
<hr/>						
Characteristic	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Age	65.5 (9.3)	66 (15)	65.9 (10.5)	66 (17)	65.7 (9.9)	66 (16)
Mean no. of conditions	4.4 (1.7)	4 (2)	4.7 (2.1)	4 (3)	4.5 (1.9)	4 (3)
Mean no. of repeat medications	9.1 (5.4)	7 (7)	8.5 (5.1)	7 (7)	8.8 (5.2)	7 (7)
<hr/>						
Baseline primary outcome measures	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
EQ-VAS	60.6 (19.9)	60 (15)	58.2 (21.3)	60 (35)	59.4 (20.6)	60 (25)
FAI total score	25.7 (8.1)	27 (12)	25.1 (7.2)	26 (11)	25.4 (7.6)	27 (11)

5.3.2 Baseline profile of attenders and non-attenders

Table 5.2 presents the characteristics of the intervention participants who attended any intervention sessions (n=67) and those who did not attend any intervention sessions (n=11). Characteristics between the two groups were similar, however it is worth noting that non-attenders had a slightly higher mean age than those who did attend and lower baseline mean EQ-VAS and FAI scores.

Table 5-2 Baseline characteristics of attenders and non-attenders

Characteristic	Attenders n=67		Non-attenders n=11	
	n	(%)	n	(%)
Gender				
Male	21	(31)	4	(36)
Female	46	(69)	7	(64)
GMS card holder				
GMS	57	(85)	10	(91)
Non-GMS	10	(15)	1	(9)
Marital status				
Single	7	(11)	1	(9)
Married	32	(48)	6	(55)
Widowed	15	(22)	2	(18)
Divorced/Separated	9	(13)	2	(18)
In a relationship	4	(6)	0	
Educational level				
Primary	21	(31)	8	(73)
Some secondary	18	(27)	1	(9)
Complete secondary	13	(20)	1	(9)
College/University	15	(22)	1	(9)
Employment status				
Full-time employment	0	(0)	0	(0)
Full-time housewife	3	(5)	0	(0)
Not working due to condition	17	(25)	0	(0)
Part-time employment	5	(7)	1	(9)
Unemployed	4	(6)	1	(9)
Retired	37	(55)	9	(82)
Carer	1	(2)	0	(0)
Mobility				
Independent	50	(75)	7	(64)
With Aid	12	(18)	3	(27)
Wheelchair user	5	(7)	1	(9)
Living situation				
Living alone	23	(34)	3	(27)
Living with family	41	(61)	8	(73)
Living with others	3	(5)	0	(0)
	Mean	Median	Mean	Median
	(SD)	(IQR)	(SD)	(IQR)
Age	65.2 (9.7)	66 (17)	67.5 (6.4)	67 (7)
No. of conditions	4.4 (1.7)	4 (3)	4.4 (1.7)	4 (3)
No. of repeat medications	8.5 (4.7)	7 (6)	12.9 (7.4)	12 (15)
Baseline primary outcome measures	Mean	Median	Mean	Median
	(SD)	(IQR)	(SD)	(IQR)
EQ-VAS	61.1(19.9)	65 (26)	57.2(21.0)	60 (20)
FAI total score	26.3 (7.8)	27 (11)	22.1 (9.1)	24 (11)

5.3.3 Baseline profile of responders and non-responders at study completion

As summarized in Figure 5.1, of the 149 participants recruited 124 participants provided immediate follow-up data for the EQ-VAS and 121 participants provided follow-up data for the FAI total score. Eighteen participants did not respond or provide immediate follow-up data while a further six participants provided incomplete follow-up data for the EQ-VAS and ten participants provided incomplete data for the FAI.

Table 5.3 summarizes the characteristics of the participants who did not respond or provide any immediate follow-up data (n=18) to those who provided either complete or incomplete follow-up data (n=131). The profiles of responders and non-responders were largely similar, however responders had higher mean baseline primary outcome measure scores. The majority of non-responder participants were female (72%), all were GMS card holders, married (39%) and had primary school education (39%). Non-responders mean age was 64.7, number of conditions was 4.8 and number of medications were 10.4.

Table 5-3 Baseline characteristics of responders and non-responders for primary outcomes

Characteristic	Responders n=131 n (%)		Non-responders n=18 n (%)	
Gender				
Male	41 (31)		5 (28)	
Female	90 (69)		13 (72)	
GMS card holder				
GMS	114 (87)		18 (100%)	
Non-GMS	17 (13)		0 (0%)	
Marital status				
Single	18 (14)		6 (33)	
Married	65 (50)		7 (39)	
Widowed	22 (17)		2 (11)	
Divorced/Separated	22 (17)		3 (17)	
In a relationship	4 (3)		0	
Educational level				
Primary	49 (37)		7 (39)	
Some secondary	33 (25)		6 (33)	
Complete secondary	24 (18)		1 (6)	
College/University	25 (19)		4 (22)	
Employment status				
Full-time employment	1 (1)		1 (6)	
Part-time employment	6 (5)		1 (6)	
Not working due to condition	32 (24)		8 (44)	
Unemployed	10 (8)		0 (0)	
Retired	75 (57)		8 (44)	
Carer	3 (2)		0 (0)	
Full-time Housewife	1 (1)		0 (0)	
Mobility				
Independent	98 (75)		12 (67)	
With Aid	28 (21)		4 (22)	
Wheelchair user	5 (4)		2 (11)	
Living situation				
Living alone	36 (28)		8 (44)	
Living with family	92 (70)		10 (56)	
Living with others	3 (2)		0 (0)	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Age	65.8 (10.1)	67 (16)	64.7 (8.4)	64 (8)
Mean no. of conditions	4.5 (1.8)	4 (7)	4.9 (2.2)	5 (3)
Mean no. of repeat medications	8.6 (4.9)	7 (6)	10.4 (6.7)	8.5 (7)
Baseline primary outcome measures				
EQ-VAS	60.4 (20.4)	60 (20)	52.4 (20.6)	54.5 (30)
FAI total score	25.7 (7.7)	27 (8)	23.2 (6.8)	24 (8)

5.4 Secondary outcomes at baseline

As previously explained in Chapter 3, this thesis presents immediate post-intervention data for the primary outcome measures i.e. EQ-VAS and FAI. Descriptive analyses of baseline data from secondary outcomes are reported. The data from secondary outcomes will be collected and analysed as part of the wider OPTIMAL trial. Table 5.4 presents a summary of participants' baseline data in relation to secondary outcome measures.

In terms of total NEADL scores, intervention participants tended to have slightly higher mean scores (49.2) than control participants (47.7). Both intervention and control participants average SEMCD scores were similar with a mean of 6.4 and 6.2 respectively. Intervention and control participants HADS scores were balanced but scores on the HADS-A subscale tended to be higher than those on the HADS-D subscale. The COPM is a client-centred occupational therapy measure whereby individuals identify and set goals regarding individual difficulties in occupational performance and satisfaction (Law et al., 2015). Five intervention participants did not identify any goals in the COPM while two control participants did not identify any goals. COPM performance and satisfaction were subscales similar for both intervention and control participants. COPM performance scores for both intervention and control participants were 4.9. COPM satisfaction scores for intervention participants were 4.4.

Table 5-4 Participant baseline secondary outcome measures

	Intervention	Control	Total
	n=78	n=71	n=149
Characteristic	Mean (SD)	Mean (SD)	Mean (SD)
NEADL			
Mobility	13.1 (4.4)	13.4 (3.9)	13.2 (4.1)
Kitchen	13.7 (2.4)	13.4 (2.6)	13.5 (2.5)
Domestic	11.1 (3.6)	10.2 (4.0)	10.7 (3.8)
Leisure	11.3 (3.9)	10.7 (4.0)	11.0 (3.9)
Total	49.2 (11.4)	47.7 (11.6)	48.4 (11.5)
SEMCD	6.4 (2.2)	6.2 (2.2)	6.3 (2.2)
HADS			
HADS-A	7.5 (4.5)	8.1 (4.9)	7.8 (4.7)
HADS-D	5.9 (3.9)	5.9 (3.9)	5.9 (3.9)
HADS- Total	13.4 (7.6)	14.0 (7.9)	13.7 (7.7)
	Intervention	Control	Total
	n=69	n=69	n=142
	Mean (SD)	Mean (SD)	Mean (SD)
COPM			
Performance	4.9 (2.1)	4.9 (2.1)	4.9 (2.1)
Satisfaction	4.4 (2.3)	4.4 (2.4)	4.4 (2.4)

5.4.1 Baseline Hospital Anxiety and Depression Scale scores

The HADS is used to identify and quantify anxiety and depression and has two subscale scores accordingly, HADS-A and HADS-D. Scores for both subscales can be categorised as indicating 'caseness', 'borderline' or 'normal' levels of anxiety and depression. Table 5.5 below presents HADS-A and HADS-D scores for the intervention group, control group and overall sample. In relation to HADS-A scores, the majority of both intervention (56%) and control participants (45%) were categorized as having normal levels of anxiety. Similarly 67% of intervention participants and 69% of control participants had HADS-D scores within the normal category. Generally, proportions of caseness levels of anxiety appeared to be higher than caseness levels of depression for both intervention and control group participants.

Table 5-5 Categorisation of baseline HADS scores

% of caseness	HADS-A			HADS-D		
	n=78	n=71	n=149	n=78	n=71	n=149
	Intervention n (%)	Control n (%)	Total n (%)	Intervention n (%)	Control n (%)	Total n (%)
Normal	44 (56)	32 (45)	76 (51)	52 (67)	49 (69)	101 (68)
Borderline	12 (16)	19 (27)	31 (21)	18 (23)	11 (15)	29 (19)
Caseness	22 (28)	20 (28)	42 (28)	8 (10)	11 (15)	19 (13)

5.5 Immediate post-intervention results: Analyses of primary outcomes

The primary analyses involved comparisons between the two groups for the primary outcomes (EQ-VAS and FAI total). Models were adjusted as appropriate for gender, baseline scores, area, number of conditions and age. The analyses were replicated for participants who completed the trial ‘per protocol’ (PP), excluding those who were randomised to the intervention but attended less than three of the group sessions. In the per protocol analysis 14 participants who provided immediate follow-up data but did not attend 3 or more intervention sessions were removed from the analysis.

As mentioned in Chapter 3, Section 3.13, all analyses used linear regression models, with results presented as point estimates (difference in means), 95% confidence intervals (CI) and p-values. The results of adjusted and unadjusted models are presented as recommended by CONSORT guidelines (Yu et al., 2010). The European Medicines Agency (EMA) recommends adjusting for stratification variables and variables known a priori to be related to outcome, including baseline values (European Medicines Agency, 2015). While a baseline imbalance was observed post hoc (marital status) between treatment allocation, the EMA suggests that these variables should not be considered as a covariate in the primary analysis (European Medicines Agency, 2015). However, conducting exploratory analyses including such variables when large baseline imbalances are observed might be helpful to assess the robustness of the primary analysis. This was completed and results did not differ from the primary analyses.

Planned sub-group analyses evaluated the effects of age (<65 and ≥65 years of age) and the number of chronic conditions present (<4 and ≥4). A sensitivity analysis was also conducted excluding any couples from the analysis.

5.5.1 Primary outcome: EQ-VAS

Table 5.6 below presents the results of ITT and PP analyses of EQ-VAS outcomes at immediate follow-up using both adjusted and unadjusted models.

5.5.1.1 Intention to treat analysis: EQ-VAS

ITT analysis, adjusting for gender, baseline EQ-VAS score, area, number of conditions and age, showed a statistically significant difference (Mean Difference (MD) = 7.86; 95% CI = 0.92 to 14.80) between intervention and control participants for EQ-VAS at immediate follow-up. Excluding couples from the analysis the difference was still statistically significant (MD = 9.01; 95% CI = 1.40 to 16.61).

A sub-group analysis of EQ-VAS immediate follow-up scores for participants aged under 65 adjusting for the same variables mentioned above showed a statistically significant difference (MD = 13.46; 95% CI = 1.48 to 25.45) between intervention and control group participants. Furthermore, a sub-group analysis of study participants with four or more chronic conditions showed no evidence of a difference between intervention and control groups in EQ-VAS scores at immediate follow-up. However unadjusted models for those with four or more conditions, found a statistically significant difference between intervention and control groups (MD = 10.66; 95% CI = 1.99 to 19.34).

5.5.1.2 Per protocol analysis: EQ-VAS

Per protocol analysis was conducted on EQ-VAS scores at immediate follow-up in the same manner as the ITT analysis with both adjusted and unadjusted models presented. All models were adjusted for gender, baseline EQ-VAS score, area, number of conditions and age. In the per protocol analysis 14 intervention participants who provided immediate follow-up data for the EQ-VAS did not attend 3 or more intervention sessions and were removed from the analysis.

When both ITT and PP analyses reach the same conclusion, the researcher can be more confident in the accuracy of the results of these analyses. The results for the PP analyses were in line with the ITT analyses of EQ-VAS outcomes. In line with ITT analysis, adjusted PP analysis showed a statistically significant difference (MD = 8.73; 95% CI = 1.33 to 16.13) between intervention and control participants. Excluding couples from the analysis also showed a statistically significant difference between intervention and control groups on EQ-VAS immediate follow-up scores (MD = 10.35; 95% CI = 2.15 to 18.56).

In contrast to ITT analysis of EQ-VAS immediate follow-up outcomes for participants aged under 65, PP adjusted analysis showed no significant difference between intervention and control participants. However, PP analysis using unadjusted models for those aged under 65, found a statistically significant difference between intervention and control groups (MD = 14.53; 95% CI = 2.65 to 26.40).

In line with the ITT analysis, PP adjusted analysis of EQ-VAS immediate follow-up outcomes for study participants with four or more chronic conditions showed no statistically significant differences between intervention and control groups. The unadjusted model found a statistically difference between intervention and control groups (MD = 11.69; 95% CI = 2.22 to 21.16).

Table 5-6 Linear Regression Analyses of EQ-VAS (ITT and PP)

Outcome	ITT					PP				
	n	Intervention	Control	Mean difference [95% CI]	p- value ^b	n	Intervention	Control	Mean difference [95% CI]	p- value ^b
		Mean (SD) ^a	Mean (SD) ^a				Mean (SD) ^a	Mean (SD) ^a		
EQ-VAS										
Unadjusted	124	67.36 (19.81)	58.67 (20.97)	8.69 [1.44 to 15.94]	0.019	110	68.00 (18.42)	58.67 (20.97)	9.32 [1.83 to 16.83]	0.015
Adjusted ^c	124	66.97 (2.36)	59.12 (2.52)	7.86 [0.92 to 14.80]	0.027	110	67.68 (2.65)	58.96 (2.51)	8.73 [1.33 to 16.13]	0.021
Sensitivity analysis – Excluding couples										
Unadjusted	108	65.41 (20.20)	55.46 (20.12)	9.95 [2.24 to 17.67]	0.012	94	65.55 (18.77)	55.46 (20.12)	10.09 [2.08 to 18.09]	0.014
Adjusted ^c	108	64.98 (2.55)	55.97 (2.76)	9.01 [1.40 to 16.61]	0.021	94	65.69 (2.93)	55.34 (2.74)	10.35 [2.15 to 18.56]	0.014
Sub-group analyses – Age (<65 and ≥65) and number of conditions (<4 and ≥4)										
Age<65										
Unadjusted	53	65.97 (19.42)	48.79 (21.04)	17.17 [6.00 to 28.35]	0.003	46	63.32 (18.71)	48.79 (21.04)	14.53 [2.65 to 26.40]	0.018
Adjusted ^d	53	64.29 (3.71)	50.82 (4.13)	13.46 [1.48 to 25.45]	0.029	46	61.83 (4.54)	50.16 (4.32)	11.67 [-2.06 to 25.40]	0.093
Age ≥65										
Unadjusted	71	68.50 (20.30)	65.65 (18.17)	2.81 [-6.34 to 11.96]	0.542	64	71.43 (17.72)	65.65 (18.17)	5.79 [-3.21 to 14.78]	0.203
Adjusted ^d	71	67.50 (2.93)	66.69 (3.07)	0.80 [-8.08 to 9.69]	0.857	64	69.14 (3.05)	67.67 (2.85)	1.47 [-7.40 to 10.34]	0.740
No. of conditions <4										
Unadjusted	45	63.32 (22.63)	67.81 (21.78)	4.49 [-8.98 to 17.97]	0.505	41	67.86 (18.23)	63.32 (22.63)	4.55 [-2.70 to 13.27]	0.480
Adjusted ^e	45	67.16 (4.19)	64.20 (4.96)	2.96 [-10.72 to 16.65]	0.662	41	66.27 (3.88)	65.16 (4.20)	1.11 [-11.05 to 13.27]	0.853
No. of conditions ≥4										
Unadjusted	79	56.41 (20.03)	67.08 (18.70)	10.66 [1.99 to 19.34]	0.017	69	68.1 (18.86)	56.41 (20.03)	11.69 [2.22 to 21.16]	0.016
Adjusted ^e	79	65.96 (3.05)	57.55 (3.09)	8.41 [-0.42 to 17.24]	0.062	69	66.88 (3.61)	57.35 (3.14)	9.53 [-0.28 to 19.34]	0.057

^a For unadjusted models, the follow-up mean and standard deviation (SD) are presented, and for adjusted models, the mean predicted values from the models are presented.

^b P-values ≤0.05 are in boldface.

^c Adjusted for gender, baseline EQ-VAS, area, number of conditions at baseline and age

^d Adjusted for gender, baseline EQ-VAS, area and number of conditions at baseline

^e Adjusted for gender, baseline EQ-VAS, area and age

5.5.1.3 EQ-5D-3L index score analyses

The EQ-VAS was a primary outcome, with sample size calculation based on this, however the EQ-5D-3L, of which the EQ-VAS is one part, also contains an index score which can be calculated based on the descriptive system. Intervention participants had a mean EQ-5D-3L index score of 0.442 (SD = 0.354), while control participants had a mean score of 0.395 (SD = 0.364). Table 5.7 presents the results of ITT analysis of EQ-5D-3L index outcomes at immediate follow-up adjusted for gender, baseline scores, area, number of conditions and age. This adjusted analysis showed no statistically significant difference (MD = 0.04; 95% CI = -0.06 to 0.13) between intervention and control participants for EQ-5D index scores at immediate follow-up. A sensitivity analysis was conducted to examine the impact of excluding any couples from the analysis and similar results were seen.

Adjusted ITT analysis for participants aged under 65 showed no statistically significant differences (MD = 0.10; 95% CI = -0.07 to 0.27) between intervention and control participants in EQ-5D-3L index scores. Adjusted analysis examining index scores for those with four or more chronic conditions found no difference (MD = 0.08; 95% CI = -0.04 to 0.20) between intervention and control groups.

While overall the PP analyses revealed similar results to the ITT analyses, adjusted analysis examining EQ-5D index outcomes for participants with four or more chronic conditions showed a statistically significant difference (MD = 0.13; 95% CI = <0.01 to 0.26) between intervention and control groups.

Table 5-7 Analyses of EQ-5D-3L index score

Outcome	n	ITT		n	PP	
		Mean difference [95% CI]	p-value ^a		Mean difference [95% CI]	p-value ^a
EQ5D-index						
Unadjusted	132	0.08 [-0.04 to 0.20]	0.198	117	0.12 [-0.01 to 0.25]	0.076
Adjusted ^b	132	0.04 [-0.06 to 0.13]	0.992	117	0.08 [-0.02 to 0.18]	0.101
Sensitivity analysis - Excluding couples						
Unadjusted	116	0.10 [-0.03 to 0.23]	0.136	101	0.13 [-0.01 to 0.27]	0.063
Adjusted ^b	116	0.04 [-0.06 to 0.15]	0.412	101	0.10 [-0.01 to 0.21]	0.070
Sub-group analyses – Age (<65 and ≥65) and number of conditions (<4 and ≥4)						
Age<65						
Unadjusted	56	0.17 [-0.03 to 0.37]	0.095	49	0.13 [-0.08 to 0.35]	0.221
Adjusted ^c	56	0.10 [-0.07 to 0.27]	0.240	49	0.15 [-0.04 to 0.35]	0.114
Age ≥65						
Unadjusted	76	0.02 [-0.12 to 0.16]	0.787	68	0.11 [-0.03 to 0.24]	0.119
Adjusted ^c	76	-0.02 [-0.15 to 0.12]	0.788	68	-0.06 [-0.08 to 0.19]	0.379
No. of conditions <4						
Unadjusted	47	0.04 [-0.17 to 0.25]	0.719	42	0.04 [-0.19 to 0.27]	0.743
Adjusted	47	0.01 [-0.17 to 0.17]	0.994	42	0.03 [-0.14 to 0.20]	0.727
No. of conditions ≥4						
Unadjusted	85	0.10 [-0.06 to 0.25]	0.222	75	0.16 [-0.01 to 0.32]	0.058
Adjusted ^d	85	0.08 [-0.04 to 0.20]	0.188	75	0.13 [<0.01 to 0.26]	0.045

^a P-values ≤0.05 are in boldface.

^b Adjusted for gender, baseline EQ-5D index, area, number of conditions at baseline and age

^c Adjusted for gender, baseline EQ-5D index, area and number of conditions at baseline

^d Adjusted for gender, baseline EQ-5D index, area and age

5.5.1.4 Analysis of EQ-5D (descriptive system scores)

Table 5.8 presents a descriptive analysis of EQ-5D descriptive system for both intervention and control participants at baseline and immediate follow-up. These systems describe mobility, self-care activities, performance of usual activities, problems with pain and problems with anxiety/depression. Overall, there were no clear differences between groups across all these systems though trends towards improvement and mood related systems were observed.

At baseline, the majority of intervention (67%) and control participants (80%) identified moderate problems with mobility. At immediate follow-up moderate problems with mobility remained the majority category for both intervention (56%) and control (77%) participants.

In terms of self-care activities, at baseline, the majority of both intervention (69%) and control (58%) participants identified no problems with self-care activities. Of interest no participants identified severe problems with self-care activities at baseline. At follow-up the majority of intervention participants (68%) continued to identify no problems with self-care activities whilst the majority of control (50%) participants reported moderate problems with self-care activities.

Both intervention (59%) and control (70%) participants identified moderate problems performing usual activities at baseline. At follow-up moderate problems with usual activities remained the majority category for both intervention (57%) and control participants (60%).

Moderate problems with pain represented the largest proportion at baseline for intervention (50%) and control (51%) participants. At immediate follow-up 53% of intervention participants and 52% of control participants reported moderate problems with pain.

The majority of participants reported moderate problems with anxiety/depression at baseline, with 51% of intervention participants and 51% of control participants identifying problems in this category. Moderate problems with anxiety/depression remained the largest category at immediate follow up with for 46% of intervention participants and 55% of control participants.

Table 5-8 Descriptive analysis of EQ-5D index at baseline and immediate follow-up

	Intervention		Control	
	Frequency (%)	Frequency (%)	Frequency (%)	Frequency (%)
EQ-5d	Baseline	Follow-up	Baseline	Follow-up
	n=78	n=72	n=71	n=60
Mobility				
No problems	24 (31)	29 (40)	14 (20)	14 (23)
Moderate problems	52 (67)	40 (56)	57 (80)	46 (77)
Severe problems	2 (2)	3 (4)	0 (0)	0 (0)
Self-care				
No problems	54 (69)	49 (68)	41 (58)	29 (48)
Moderate problems	24 (31)	23 (32)	30 (42)	30 (50)
Severe problems	0 (0)	0 (0)	0 (0)	1 (2)
Usual activities				
No problems	27 (35)	27 (37)	15 (21)	15 (25)
Moderate problems	46 (59)	41 (57)	50 (70)	36 (60)
Severe problems	5 (6)	4 (6)	6 (9)	9 (15)
Pain/discomfort				
No problems	14 (18)	14 (19)	9 (13)	9 (15)
Moderate problems	39 (50)	38 (53)	36 (51)	31 (52)
Severe problems	25 (32)	20 (28)	26 (36)	20 (33)
Anxiety/depression				
No problems	28 (36)	33 (46)	22 (31)	21 (35)
Moderate problems	40 (51)	33 (46)	36 (51)	33 (55)
Severe problems	10 (13)	6 (8)	13 (18)	6 (10)

5.5.2 Primary outcome: FAI total score

Table 5.9 below presents the results of ITT and PP analyses of FAI total score outcomes at immediate follow-up using both adjusted and unadjusted models. Adjusted models included gender, baseline FAI total score, area, number of conditions and age.

5.5.2.1 Intention to treat analysis: FAI total score

ITT analysis, adjusted for gender, baseline FAI total, area, number of conditions and age showed no evidence of a statistically significant difference between intervention and control participants for FAI total scores (Table 5.9). A sensitivity analysis was conducted to examine the impact of excluding any couples from the analysis and similar results were seen.

Adjusted ITT analysis for participants aged under 65 showed a statistically significant difference in FAI total scores, with intervention participants having a mean difference of 5.00 points (95% CI = 1.29 to 8.72) higher than control participants at immediate follow-up.

Adjusted analysis examining FAI total score outcomes for study participants with four or more chronic conditions showed a statistically significant difference (MD= 2.86; 95% CI = 0.31 to 5.41) between intervention and control groups. The unadjusted model for those with four or more conditions also showed evidence of a statistically significant difference (MD = 3.85; 95% CI = 0.23 to 7.46) between intervention and control groups.

5.5.2.2 Per protocol analysis: FAI total score

A per protocol analysis was conducted on FAI total score outcomes in the same manner as the ITT analysis. Overall the per protocol analyses revealed similar results to the ITT analyses. As previously outlined, when both ITT and per protocol analyses reach the same conclusion, the researcher can be more confident in the accuracy of the results of these analyses.

In the adjusted models there was no evidence of a statistically significant difference between intervention and control participants for FAI total scores. However analysing FAI scores using unadjusted models found a statistically significant difference (MD = 3.12; 95% CI = 0.20 to 6.04) between intervention and control groups. This differed to ITT analysis, which showed no evidence of a difference between intervention and control participants on FAI total scores using adjusted or unadjusted models. This suggests that those participants attending three or more sessions are showing a difference in FAI total scores.

The adjusted per protocol analysis of outcomes for participants aged under 65 showed a statistically significant difference in FAI total scores, with intervention participants having a mean difference of 5.03 points (95% = CI 0.69 to 9.37) higher than control participants at immediate follow-up. This result was in line with the findings of ITT analysis for this sub-group.

Adjusted analysis examining FAI total score outcomes for participants with four or more chronic conditions showed a statistically significant difference (MD=3.64; 95% CI= 0.75 to 6.53) between intervention and control groups. Unadjusted models also found a statistically significant difference between intervention and control group participants (MD = 5.86; 95% CI = 2.13 to 9.59). These results are reflective of those found in the ITT analyses.

Table 5-9 Linear Regression Analysis of FAI total (ITT and PP)

Outcome	ITT					PP				
	n	Follow-up		Mean difference [95% CI]	p-value ^b	n	Follow-up		Mean difference [95% CI]	p-value ^b
		Intervention	Control				Intervention	Control		
		Mean (SD) ^a	Mean (SD) ^a			M (SD) ^a	M (SD) ^a			
FAI										
Unadjusted	121	26.74 (7.91)	25.19 (8.14)	1.55 [-1.36 to 4.45]	0.294	108	28.31 (7.16)	25.19 (8.14)	3.12 [0.20 to 6.04]	0.037
Adjusted ^c	121	26.59 (0.68)	25.37 (0.77)	1.22 [-0.84 to 3.29]	0.243	108	27.66 (0.78)	25.86 (0.79)	1.80 [-0.47 to 4.08]	0.119
Sensitivity analysis – Excluding couples										
Unadjusted	108	25.68 (7.73)	24.79 (7.84)	0.89 [-2.09 to 3.88]	0.555	95	27.23 (7.06)	24.79 (7.84)	2.44 [-0.60 to 5.48]	0.114
Adjusted ^c	108	25.90 (0.72)	24.51 (0.80)	1.39 [-0.79 to 3.57]	0.209	95	27.12 (0.83)	24.90 (0.82)	2.22 [-0.20 to 4.63]	0.071
Sub-group analyses – Age (<65 and ≥65) and number of conditions (<4 and ≥4)										
Age<65										
Unadjusted	50	26.21 (8.03)	20.82 (8.74)	5.40 [0.61 to 10.18]	0.028	44	26.95 (8.09)	20.82 (8.74)	6.14 [1.01 to 11.26]	0.020
Adjusted ^d	50	26.04 (1.15)	21.04 (1.32)	5.00 [1.29 to 8.72]	0.010	44	26.40 (1.40)	21.37 (1.40)	5.03 [0.69 to 9.37]	0.025
Age ≥65										
Unadjusted	71	27.1 (7.90)	28.29 (6.11)	-1.19 [-4.62 to 2.24]	0.491	64	29.21 (6.45)	28.29 (6.11)	0.92 [-2.22 to 4.06]	0.560
Adjusted ^d	71	28.21 (0.93)	27.16 (0.81)	-1.05 [-3.64 to 1.53]	0.417	64	28.51 (0.89)	29.03 (0.92)	-0.52 [-3.24 to 2.20]	0.701
No. of conditions <4										
Unadjusted	42	25.12 (7.86)	28.19 (7.25)	-3.07 [-7.97 to 1.83]	0.213	39	26.30 (6.89)	28.19 (7.25)	-1.88 [-6.53 to 2.76]	0.416
Adjusted ^e	42	25.21 (1.11)	28.04 (1.44)	-2.83 [-6.69 to 1.02]	0.144	39	26.23 (1.19)	28.30 (1.45)	-2.07 [-6.07 to 1.93]	0.298
No. of conditions ≥4										
Unadjusted	79	27.74 (7.87)	23.89 (8.25)	3.85 [0.23 to 7.46]	0.037	69	29.75 (7.11)	23.89 (8.25)	5.86 [2.13 to 9.59]	0.003
Adjusted ^e	79	27.28 (0.86)	24.42 (0.92)	2.86 [0.31 to 5.41]	0.028	69	28.56 (1.03)	24.92 (0.95)	3.64 [0.75 to 6.53]	0.014

^a For unadjusted models, the follow-up mean and standard deviation (SD) are presented, and for adjusted models, the mean predicted values from the models are presented.

^b P-values ≤0.05 are in boldface.

^c Adjusted for gender, baseline FAI total, area, number of conditions at baseline and age

^d Adjusted for gender, baseline FAI total, area and number of conditions at baseline

^e Adjusted for gender, baseline FAI total, area and age

Table 5.10 presents the frequency and percentage of participants whose scores improved, remained the same or disproved in intervention and control groups for both the EQ-VAS and FAI. In relation to the EQ-VAS, 62.8% (n=49) of intervention participants scores improved at immediate follow-up, while 52.1% (n=37) of control group participants improved. In relation to the FAI 64.1% (n=50) of intervention participants scores improved at immediate follow-up with 64.8% (n=46) of control participants scores improving.

Table 5-10 Frequency and percentage of participants in each group who improved, stayed the same or dis-improved for EQ-VAS and FAI Total

	EQ-VAS		FAI Total	
	n (%)		n (%)	
	Intervention n=78	Control n=71	Intervention n=78	Control n=71
Improved	49 (62.8%)	37 (52.1%)	50 (64.1%)	46 (64.8%)
Remained the same	11 (14.1%)	11 (15.5%)	2 (2.6%)	3 (4.2%)
Dis-improved	18 (23.1%)	23 (32.4%)	26 (33.3%)	22 (31.0%)

5.5.3 Description of FAI subscale scores

Table 5.11 presents descriptive analysis of FAI subscale scores for both intervention and control groups at baseline and immediate follow-up. All subscales had scores between 0-15 with higher scores indicating higher frequency of participation. Scores on all subscales were similar between arms. For intervention group participants there appeared to be a slight increase in mean outdoor scale at immediate follow-up. The work/leisure subscale had the lowest mean score of the three subscales.

Table 5-11 Descriptive analysis of FAI subscales at baseline and immediate follow-up

	Intervention		Control	
	Mean (SD)		Mean (SD)	
FAI	Baseline n=78	Follow-up n=68	Baseline n=71	Follow-up n=53
Domestic	10.9 (3.4)	10.6 (3.7)	10.2 (4.3)	10.2 (4.1)
Work/Leisure	6.2 (3.3)	6.8 (3.1)	5.8 (2.7)	5.7 (3.2)
Outdoors	8.6 (3.4)	9.3 (3.0)	9.1 (3.0)	9.3 (3.1)

5.6 Conclusion

This chapter presents the trial results for the two primary outcome measures, the EQ-VAS and FAI at immediate follow-up and presents baseline descriptive results for secondary outcome measures.

In total 149 participants were recruited at baseline across eight primary care team areas, with 18 participants providing no immediate follow-up data and a further 14 participants providing incomplete data i.e. 124 participants provided follow-up data for the EQ-VAS and 121 participants providing follow-up data for the FAI. Participants had a mean age of 65.7 (SD=9.9), 4.5 conditions (SD=1.9) and 8.8 medications (SD=5.2). The majority of participants were female, married, GMS card-holders and had primary level education.

For the primary outcome of the EQ-VAS, the main finding was that there was a statistically significant difference between intervention and control groups, with intervention participants having an EQ-VAS score 7.86 points (95% CI = 0.92 to 14.80) higher than control participants. Sub-group analysis of participants aged under 65 suggests a statistically significant difference between intervention and control groups with intervention participants having an EQ-VAS score 13.46 points higher (95% CI = 1.48 to 25.45) at immediate follow-up. In relation to the FAI the main findings was that there was no evidence of a statistically significant difference between intervention and control groups. Similarly to the EQ-VAS, sub-group analysis of participants aged under 65 suggested a statistically significant difference between intervention and control groups with intervention participants having an FAI score 5.00 points higher (95% CI = 1.29 to 8.72) at immediate follow-up. ITT analysis using unadjusted models for participants with four or more conditions found statistically significant differences between intervention and control participants for the EQ-VAS. ITT analyses using both adjusted and unadjusted models for participants with four or more conditions found statistically significant differences in FAI total scores at immediate follow-up.

The PP analyses for both primary outcomes generally supported the ITT analyses results. However, in relation to the EQ-VAS, only unadjusted PP analyses of participants aged under 65 and participants with four or more conditions found statistically significant differences between intervention and control groups. For the FAI, PP analyses using adjusted and unadjusted models for both those under 65 and those with four or more

conditions found statistically significant differences between intervention and control participants at immediate follow-up.

In relation to the study hypothesis, these findings allow rejection of the null hypothesis in favour of the alternative hypothesis that the intervention had an immediate post-intervention effect on health related quality of life in intervention participants compared to controls with a suggestion from sub-group analysis that this effect is greater in younger participants with higher numbers of conditions. The intervention does not appear to have had an immediate effect on frequency of activity participation, however sub-group analyses suggests an effect in younger participants with higher morbidity. The proceeding chapter presents the process evaluation findings.

Chapter 6 Process Evaluation

6.1 Introduction

This chapter presents the process evaluation results of the OPTIMAL RCT. The overall aim of the process evaluation was to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice. The objectives to achieve this aim were:

- To describe the recruitment process including sampling of sites and recruitment sources.
- To analyse the extent to which the OPTIMAL programme was delivered as intended and how and why it varied, i.e. to explore intervention fidelity.
- To quantify the dose received by the OPTIMAL programme participants i.e. programme attendance.
- To explore OPTIMAL facilitators' perceptions of the impact, delivery and acceptability of the OPTIMAL programme.
- To explore participants' perceptions of the impact, delivery and acceptability of the OPTIMAL programme.

As discussed in Chapter 4, the process evaluation was guided by examining the three functions of process evaluations outlined by the MRC guidance on process evaluations i.e. implementation, mechanisms of impact and context (Moore et al., 2015). The process evaluation results incorporate both qualitative and quantitative data and accordingly the results are presented in two parts. The first part reports quantitative data pertaining to implementation incorporating the first three objectives of the process evaluation i.e. the recruitment process, intervention fidelity and programme attendance (dose received).

The second part of the process evaluation results presents the qualitative results which addresses all five of the process evaluation objectives. The themes are presented according to the process evaluation functions in the MRC guidance on process evaluations i.e. implementation, mechanisms of impact and context. Qualitative data reporting perceived programme outcomes for participants are reported in Section 6.7. This chapter concludes with a summary of the process evaluation findings, both quantitative and qualitative, according to the process evaluation functions in the MRC guidance.

6.2 Part one: Quantitative process evaluation results

As stated in Chapter 4, quantitative process evaluation data were collected using study team recruitment logs, baseline participant questionnaires, therapist log/fidelity tool and the OPTIMAL programme attendance records. This section presents quantitative data related to recruitment, fidelity and attendance.

6.2.1 Recruitment

Difficulties with recruitment were encountered throughout the trial which resulted in a revised power calculation and a reduction in the sample size as outlined in Chapter 3, Section 3.10. This section describes the recruitment process including the profile of the eight primary care team areas who participated in the trial and delivered the OPTIMAL programme. The response and participation of GPs and primary care team members in each site who were invited to refer participants to the OPTIMAL study is reported. The recruitment issues experienced in the primary care team areas who agreed to participate in the trial but ultimately withdrew or deferred trial participation are accounted for. Finally information regarding recruitment rates and participant referral sources are described.

6.2.1.1 Profile of programme delivery sites

Table 6.1 provides general information about the context of programme delivery in terms of programme scheduling, area deprivation and venue. Eight primary care team areas in total, from three different HSE Community Healthcare Organisations (CHO), participated in the trial and delivered the OPTIMAL programme. All areas could be described as urban.

Information about area deprivation in each of the primary care team areas was gleaned from the 2016 Pobal HP Deprivation Index (Haase & Pratschke, 2017). This index uses census data to provide this description. The index provides a score to the area based on a national average of zero and ranging from approximately -40 (being the most disadvantaged) to +40 (being the most affluent). The index provided is based on the general site of programme delivery. This approach is somewhat limited as participants, while from the primary care team catchment area, may reside in areas of higher or lower deprivation. Area 1 had the lowest score of -22.33 whilst Area 4 had the highest score of

13.6. (Haase & Pratschke, 2017). Only two of the areas were classified as affluent with the remaining six areas categorised as between marginally above average and very disadvantaged.

Six of the eight programmes were delivered in the morning times, with two scheduled for afternoons. In terms of delivery sites, four of the intervention programmes were delivered in newly built primary care centres (PCC), with co-located GP services and local HSE primary care and social services. In two areas the programmes were delivered in local HSE health centres. In two of the primary care areas, the PCT was based in a HSE health centre, however there were no suitable facilities for group interventions available in the health centres. Therefore, in consultation with the occupational therapists involved in these areas, local family resource centres were hired by the researcher for the purposes of group intervention delivery.

Table 6-1 Programme delivery sites and timing

Area ID	Pobal HP Description 2016	Location	Programme delivery time	Programme time	Venue
1	Very disadvantaged (-22.33)	Urban	April-May 2016	AM	Local Family Resource Centre
2	Disadvantaged (-17.29)	Urban	May-June 2016	PM	PCC
3	Marginally below average (-2.46)	Urban	Sept-Oct 2016	AM	PCC
4	Affluent (13.6)	Urban	Nov-Dec 2016	AM	Health Centre
5	Disadvantaged (-18.52)	Urban	May-June 2017	AM	PCC
6	Very disadvantaged (-20.53)	Urban	May-June 2017	AM	PCC
7	Disadvantaged (-15.16)	Urban	Jan-Feb 2018	PM	Local Family Resource Centre
8	Affluent (10.07)	Urban	Feb-Mar 2018	AM	Health Centre

6.2.1.2 Primary care team participation and engagement in recruitment

As discussed in Chapter 3, Section 3.7, primary care occupational therapy managers were approached to permit their teams to take part in this trial with eight primary care team areas ultimately participating in this study over four recruitment blocks.

Table 6.2 presents information about the recruitment process in terms of promoting referrals to the OPTIMAL study from primary care teams and GPs in each area. In the majority of primary care team areas (6/8), the researcher presented information about the programme, study and referral process at the primary care team meeting. In two of the primary care team areas, the researcher did not present to the PCT. In one of these areas (Area 5) an OT involved in delivering the programme presented to the team about the study. In Area 8, no formal primary care team meetings were in operation at the time of the study.

In five of the eight areas, occupational therapy was the only PCT member to refer to the study. Area 3 had the highest rate of referrals from the primary care team, with nine referrals received. Further details about referral sources is provided in Section 6.2.1.4.

6.2.1.3 GP participation and engagement in recruitment

Table 6.2 also outlines data in terms of inviting GP practices to refer to the study and the resultant number of practices which referred in each area. Twenty-four general practices across the eight primary care team areas agreed to participate and refer. The researcher presented on the OPTIMAL programme and study at practice meetings in 15 of these 24 practices. The researcher also provided posters and information leaflets for the patient waiting rooms. In total referrals were received from 20 practices out of 24 practices who agreed to refer across the eight primary care teams but the number of referrals received varied by practice.

Table 6-2 Recruitment by PCTs and GP practices

Block	Area	Presented at PCT	No. of PCT referrals received ^a	No. of practices sent information packs	Practices agreeing to refer	Practice meetings attended	No. of practices who referred	No. of GP/PN ^b referrals received
1	1	Y	0	6	2	2	2	5
	2	Y	0	5	3	1	2	17
2	3	Y	9	5	2	2	1	8
	4	Y	1	19	5	2	5	5
3	5	N	3	7	3	2	3	6
	6	Y	0	8	3	2	2	15
4	7	Y	0	14	2	2	2	15
	8	N	0	13	4	2	3	10
Total		6/8	13	77	24	15	20	81

Note Referral numbers relate to referrals who consented and completed baseline assessment; Y=Yes N=No

^a Number of PCT referrals other than OT referrals

^b PN=practice nurse

6.2.1.4 Recruitment of participants: Referral sources

Table 6.3 presents referrals for each area by referral source in terms of frequencies and percentages. It also reports the overall total number of referrals by sources. It is clear from this table that numbers and sources of referrals varied by area and were generally lower than the target rates of 20-24 participants per area. Overall the largest source of referrals was from GPs (n=66; 44%) followed by OTs (n=39; 26%). Area 2 (n=17; 85%) and Area 6 (n=15; 88%) had the highest rate of GP referrals. Area 1 (n=13; 72%) followed by Area 5 (n=9; 45%) had the highest rate of OT referrals. Of note no referrals in any area were received from physiotherapists or social workers.

Table 6-3 Participant numbers by referral sources

Area ID	GP n (%)	PN n (%)	OT n (%)	PHN n (%)	DSN n (%)	DT n (%)	SLT n (%)	SR n (%)	Total number of referrals per area
1		5 (28)	13 (72)						18
2	17 (85)		3 (15)						20
3		8 (36)	5 (23)	8 (36)			1 (5)		22
4	3 (27)	2 (18)	5 (45)		1 (9)				11
5	6 (30)		9 (45)	2 (10)		3 (15)			20
6	15 (88)		2 (12)						17
7	15 (56)		1 (4)					11 (40)	27
8	10 (71)		1 (8)					3 (21)	14
Total	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
	66 (44)	15 (10)	39 (26)	10 (7)	1 (1)	3 (2)	1 (1)	14 (9)	149 (100)

Note GP=General Practitioner; PN=Practice Nurse; OT=Occupational Therapist; PHN=Public Health Nurse; DSN= Diabetes Specialist Nurse; DT= Dietician; SLT= Speech and Language Therapist; SR=Self-referral

6.2.1.5 Cancelled or deferred programmes

Difficulties were encountered throughout the trial with recruitment Table 6.4 summarises the issues gathered from recruitment logs in the sites that withdrew from the study or deferred participation (Further detail is provided in case studies in Appendix 21). Three

primary care areas were recruited in each of the original three blocks as planned, however in each block, one area either cancelled or deferred. A fourth block of recruitment with three primary care team areas was planned, however one area also cancelled. Therefore in total three areas withdrew from the trial (Area 9, Area 11, Area 12) and one area (Area 7) deferred and changed venue, participating successfully at a later date in the trial.

Information is provided about the relative affluence or disadvantage of each of the primary care team areas in which the intervention was cancelled or deferred according to the HP Deprivation Index (Haase & Pratschke, 2017). Three of the areas were classified as marginally above average with one described as disadvantaged.

Multiple reasons were recorded in recruitment logs explaining the need to either withdraw or defer study participation. In three areas there were low referral rates with one area (Area 9) receiving sufficient referrals but then having a high rate of participant attrition prior to consent and baseline data collection with this area ultimately being cancelled as a result. In three areas there were issues with staff capacity and loss which resulted in both managers and staff being reluctant to participate due to the resultant impact on caseload demands and waiting lists. Furthermore in two of the areas there were issues with venue suitability in terms of room availability suitable for group interventions, accessibility/safety concerns for those using mobility aids and the availability of parking and public transport links to the venue.

Information is provided about the referral sources of those referrals received in withdrawn or deferred areas. Referral sources varied by area.

Table 6-4 Withdrawn and deferred areas

Block	Area	Pobal HP Deprivation Index 2016 (Haase & Pratschke, 2017)	Total number of patients referred	Patient referral sources	PCT meeting attended	No of GP practices sent information	No of practices agreeing to refer	No. of practices who referred	Outcome	Reasons
Block 1	9 ^a	-12.53 (disadvantaged)	n=22	OT (n=11) PT (n=1) GP (n=8) SR (n=2)	Y	n=9	n=2	n=2	Withdrawn	<ul style="list-style-type: none"> • Change/loss of OT staff • High attrition prior to consent/baseline assessment • Issues with venue suitability
Block 2	7 ^b	-5.40 (marginally below average)	n=10	GP (n=10)	N	n=16	n=5	n=1	Deferred and changed delivery site (delivered in Block 4)	<ul style="list-style-type: none"> • Change/loss of OT staff • Low referral rate • Issues with suitable venue
Block 3	10	2.40 (marginally above average)	n=7	GP (n=6) PT (n=1)	Y	n=17	n=6	n= 2	Withdrawn	<ul style="list-style-type: none"> • Change/loss of OT staff • Low referral rate
Block 4	11 ^a	2.24 (marginally above average)	n=4	OT (n=2) SR (n=2)	Y	n=14	n=2	n=0	Withdrawn	<ul style="list-style-type: none"> • Low referral rate • Issues with venue suitability

Note GP=General Practitioner; PN=Practice Nurse; OT=Occupational Therapist; PHN=Public Health Nurse; DSN= Diabetes Specialist Nurse; DT= Dietician; SLT= Speech and Language Therapist; SR=Self-referral

^a Both Area 9 and Area 11 were separate primary care teams with the same overall primary care team area and manager

^b Area 7 was deferred from Block 2 to Block 4 and changed delivery site to another primary care team within the same primary care team area and manager

6.2.2 Fidelity

As described in Chapter 4, Section 4.4, OTs in each study site completed a self-report fidelity tool at the end of each session (See Appendix 14). Table 6.5 presents the results per area in terms of weekly session duration, self-reported fidelity to key programme components and adherence to the facilitator manual. For each session there were key intervention components and facilitators were asked to rate the delivery of each component (Yes/No). The fidelity tool for each weekly session had sections for facilitators to include comments about the session and reasons for deviation from the manual.

Facilitators rated their fidelity to the programme content as high in all programme sessions, with the only week in which any deviations were reported was the final programme session. Area 2 reported that in Week 6 they did not brainstorm local community resources. Area 8 reported that in the final session they did not review participants overall goals, brainstorm local community resources or provide programme certificates of achievement.

In terms of programme and session duration, all areas delivered six weekly sessions as planned. However there appeared to be wide variation in session duration despite facilitators in all areas reporting that all content was delivered as intended. All areas reported some deviations in session duration. In both Area 2 and Area 4, all programme durations were shorter than the intended 2 and a half hours duration. However it is interesting to note that Area 2 (see Table 6.6; Section 6.2.3) had the lowest mean weekly attendance of all areas and Area 4 had between five to six participants each week. On the final session, six out of eight areas reported a shorter session duration.

In terms of consistency of facilitators, only Area 1 and Area 2 noted a change in one facilitator on the final session owing to other professional commitments. In these cases another trained OT facilitated the session with the other regular OT facilitator.

Table 6-5 Results self-report fidelity tool

	Week 1		Week 2		Week 3		Week 4		Week 5		Week 6	
	Components delivered	Duration (Hours)	Components delivered	Duration (Hours)	Components delivered	Duration (Hours)	Components delivered	Duration (Hours)	Components delivered	Duration (Hours)	Components delivered	Duration (Hours)
Area											100%*	
1	100% (13/13)	2.5	100% (9/9)	2.75	100% (10/10)	1.83	100% (9/9)	2.5	100 % (9/9)	2.33	(10/10)	2.5
Area												
2	100% (13/13)	2	100% (9/9)	2	100% (10/10)	2.17	100% (9/9)	1.75	100% (9/9)	1.5	90% (9/10)*	2
Area	100% (13/13)											
3		2.58	100% (9/9)	2.5	100% (10/10)	2.5	100% (9/9)	2.5	100% (9/9)	2.5	100% (10/10)	2
Area	100% (13/13)											
4		2	100% (9/9)	2	100% (10/10)	2	100% (9/9)	2	100% (9/9)	1.5	100% (10/10)	2
Area												
5	100% (13/13)	2.58	100% (9/9)	2.58	100% (10/10)	2.5	100% (9/9)	2.33	100% (9/9)	2.42	100% (10/10)	3
Area	100% (13/13)											
6		2.5	100% (9/9)	2.5	100% (10/10)	2.5	100% (9/9)	2.5	100% (9/9)	2.5	100% (10/10)	2
Area	100% (13/13)											
7		2.5	100% (9/9)	2.5	100% (10/10)	2.5	100% (9/9)	2.5	100% (9/9)	2.5	100% (10/10)	2
Area	100% (13/13)											
8		2.5	100% (9/9)	2.5	100% (10/10)	2.5	100% (9/9)	2	100% (9/9)	2.5	60% (6/10)	2

Note Deviations from intervention protocol are highlighted in bold

*Denotes a different occupational therapist facilitator to regular facilitator

6.2.3 Attendance (dose received)

Rates of attendance varied by area (Table 6.6). For example, Area 2 appeared to have low rates of attendance overall with six out of 11 participants (54.54%) attending either none or one programme session. Five participants in Area 5 attended no programme sessions but overall participant numbers recruited for this area were high. In comparison all participants in Area 3 attended 4 or more sessions.

Overall 32% (n=25) of participants attended all six sessions, however 11 participants (14%) attended no sessions. The per protocol analysis presented in the trial results specified that for inclusion participants were required to have attended 3 or more sessions (i.e. 50% of the programme), overall 59 participants (76%) attended 3 or more sessions.

Table 6.7 presents additional information on attendance in terms of weekly sessions by area. In terms of total weekly attendance, Session 1 had the highest attendance rate with 62 intervention participants (79%) attending. Session 5 was the least commonly attended session with 43 (55%) participants attending this session. Weekly attendance generally decreased over the course of the programme with a slight increase in attendance on the final session. The overall median number of sessions attended was 5, with Area 2 (Median=1) having the lowest median number of sessions attended and Area 4 having the highest (Median=6).

Table 6-6 Number of sessions attended by area

Site	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	Area 7	Area 8	
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (% of total participants)
Sessions attended									
0 sessions	1 (11)	2 (18)		1 (14)	1 (11)	1 (13)	5 (33)		11 (14)
1 session		4 (36)			1 (11)				5 (6)
2 sessions		1 (9)		1 (14)				1 (12)	3 (4)
3 sessions	2 (22)	1 (9)			1 (11)	1 (13)	1 (7)		6 (8)
4 sessions	2 (22)	1 (9)	3 (27)		1 (11)		3 (20)	2 (25)	12 (15)
5 sessions	3 (33)	1 (9)	3 (27)		2 (22)	3 (37)	2 (14)	2 (25)	16 (21)
6 sessions	1 (11)	1 (9)	5 (46)	5 (72)	3 (34)	3 (37)	4 (26)	3 (38)	25 (32)
≥ 3 sessions attended	8 (89)	4 (36)	11 (100)	5 (72)	7 (78)	7 (87)	10 (67)	7 (88)	59 (76)
Total number of intervention participants	9	11	11	7	9	8	15	8	78

Table 6-7 Weekly attendance by area

Site	Number of attendees (%)						Median (IQR)	Mean (SD)
	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6		
Area 1 (n=9)	8 (89%)	4 (44%)	6 (66%)	6 (66%)	5 (56%)	6 (66%)	4 (2)	3.9 (1.8)
Area 2 (n=11)	8 (73%)	5 (45%)	4 (36%)	2 (18%)	2 (18%)	3 (27%)	1 (3)	2.2 (2.0)
Area 3 (n=11)	10 (90%)	10 (90%)	6 (55%)	11 (100%)	11 (100%)	9 (82%)	5 (2)	5.2 (0.9)
Area 4 (n=7)	6 (86%)	5 (71%)	6 (86%)	5 (71%)	5 (71%)	5 (71%)	6 (4)	4.6 (2.5)
Area 5 (n=9)	7 (78%)	7 (78%)	6 (66%)	6 (66%)	4 (44%)	6 (66%)	5 (3)	4 (2.2)
Area 6 (n=8)	7 (88%)	7 (88%)	6 (75%)	5 (63%)	6 (75%)	5 (63%)	5 (2)	4.5 (2.1)
Area 7 (n=15)	8 (53%)	9 (60%)	10 (66%)	8 (53%)	6 (40%)	8 (53%)	4 (6)	3.3 (2.6)
Area 8 (n=8)	8 (100%)	7 (88%)	6 (75%)	5 (63%)	5 (63%)	7 (88%)	4.5 (2)	4.8 (1.4)
Total weekly attendance for intervention participants (n=78)	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Median (IQR)	Mean (SD)
n (%)	62 (79)	54 (69)	50 (64)	48 (62)	43 (55)	49 (63)	5 (3)	3.9 (2.2)

6.3 Part two: Qualitative process evaluation results

This section reports the findings from the qualitative component of the process evaluation. The themes and sub-themes are presented according to the process evaluation functions in the MRC guidance on process evaluations i.e. implementation, mechanisms of impact and context. Table 6.8 presents an overview of the themes according to the MRC process evaluation functions. Seven themes are related to implementation, three themes report data relevant to mechanisms of impact, two themes pertain to context and two themes to outcomes.

Table 6-8 Themes according to MRC process evaluation functions

	Implementation	Mechanisms of impact	Context	Outcomes
Focus	What is implemented and how?	How does the delivered intervention produce change?	How does context affect implementation and outcomes?	Qualitative findings to increase understanding of outcomes
Themes	Perceptions of OPTIMAL training and facilitator manual	Benefits of group-based intervention	Enablers to implementation	Programme benefits
	Reasons for low referrals	Benefits of goal-setting	Barriers to implementation	No programme benefits
	Appropriateness of recruited participants	Challenges with goal-setting		
	Recommended OPTIMAL recruitment strategies			
	Perceptions of programme organisation			
	Perceptions of programme content			
	Programme resources			
	Intervention recommendations			

6.3.1 Qualitative data sets

This section provides an overview of the qualitative data sets (i.e. OPTIMAL programme participant focus groups, occupational therapy facilitator interviews and other health professionals involved in programme referral and delivery). These data sets were analysed together as discussed in Chapter 4, Section 4.6.2, to produce themes and sub-themes.

6.3.1.1 Participant focus groups

Focus groups were conducted with intervention participants in each area on the final session i.e. eight participant focus groups were conducted. As described in Chapter 4, all focus groups were conducted by an occupational therapist with knowledge of the study and intervention, but not involved in intervention delivery, who had experience conducting focus groups. The number of participants in the focus group ranged from 3 to 9. The average focus group duration was 49.54 mins. Qualitative data reported from the focus groups in this chapter are presented alongside participant's ID and focus group ID (see Table 6.9).

Table 6-9 Profile of participant focus groups

Focus group ID	Area	Number of focus group participants	Length of focus group (mins)
FG1	1	6	49.54
FG2	2	3	46.59
FG3	3	9	45.41
FG4	4	5	38.52
FG5	5	6	46.23
FG6	6	5	47.20
FG7	7	8	46.30
FG8	8	7	44.42

6.3.1.2 Occupational therapy facilitator interviews

In total, 15 occupational therapist facilitator interviews were conducted. One occupational therapist facilitator was on maternity leave and unavailable for interview. All occupational therapist facilitators were female. Eight interviews were conducted in person, with seven being conducted over the phone. The mean duration of the interviews was 35.54 mins. Information regarding individual interviews is presented in Table 6.10.

Table 6-10 Profile of interview participants: Occupational therapist facilitators

OT ID	Area	Gender	Length of interview (mins)	Method
OT1	1	F	34.59	In person
OT2	1	F	36.47	In person
OT3	2	F	30.40	In person
OT4	2	F	48.01	In person
OT5	3	F	46.00	In person
OT6	3	F	39.00	In person
OT7	4	F	24.52	Telephone
OT8	5	F	43.13	Telephone
OT9	5	F	31.37	Telephone
OT10	6	F	31.01	In person
OT11	6	F	31.33	Telephone
OT12	7	F	31.37	Telephone
OT13	7	F	41.28	Telephone
OT14	8	F	37.00	In person
OT15	8	F	30.44	Telephone

Note OT=Occupational Therapist

6.3.1.3 Other health professionals involved in recruitment and programme delivery

Interviews were conducted with a sample of GPs involved in referring to the study and a sample of other health professionals involved in programme delivery i.e. physiotherapists and pharmacists. Interviews were conducted with four GPs, three physiotherapists and three pharmacists. All of these interviews were conducted by telephone except for one interview with a physiotherapist which was conducted in person. The average duration of these interviews were 21 mins 45 secs. Table 6.11 provides a profile of these interviews.

Table 6-11 Profile of interview participants: Other health professionals

Participant ID	Area	Length of interview (mins)	Method
GP1	6	29.00	Telephone
GP2	7	26.00	Telephone
GP3	8	18.12	Telephone
GP4	8	19.27	Telephone
PT1	5	39.00	In person
PT2	8	19.02	Telephone
PT3	3	25.02	Telephone
Pharm1	3	14.42	Telephone
Pharm2	7	15.00	Telephone
Pharm3	8	12.07	Telephone

Note GP=General Practitioner, PT=Physiotherapist, Pharm=Pharmacist

6.4 Themes related to implementation of the OPTIMAL programme

This section presents the results of the process evaluation relevant to the implementation of the intervention during the study i.e. what was delivered and how was this done or achieved. As described in Chapter 4, implementation involves examining how delivery is achieved in terms of training and resources and what is delivered in terms of fidelity, dose, adaptations and reach (i.e. the extent to which the intervention reached its intended audiences and how).

6.4.1 Perceptions of training and facilitator manual

As described in Chapter 4, OTs received a half-day of training and a facilitator manual to guide programme delivery. Physiotherapists and pharmacists did not receive any formal training but were provided with a session plan, notes and materials in advance of their respective sessions. This section provides information on the perceptions of occupational therapists, physiotherapists and pharmacists of the training and manual instructions they received as appropriate. Please see Table 6.12 below for an overview of this theme and sub-themes.

Table 6-12 Themes and sub-themes related to training and facilitator manual

Theme	Sub-themes
Perceptions of OPTIMAL training and facilitator manual	Training and manual sufficient for programme delivery Recommend changes to facilitator manual Self-study required

6.4.1.1 Training and manual sufficient for programme delivery

Occupational therapist facilitators were specifically asked about whether the training and facilitator manual provided were sufficient to enable successful delivery of the OPTIMAL programme. Generally the occupational therapists concluded that the training and manual were appropriate and allowed them to deliver the intervention. The occupational therapists indicated that the training session provided by the researcher was comprehensive, providing the information required to facilitate the programme.

"I thought the training was enough, the training covered everything that it needed." (OT12, Area 7)

The occupational therapists discussed the facilitator manual as particularly useful in helping them deliver the programme.

"The facilitator manual was excellent it was really helpful it meant as a clinician our time is... we are kind of torn each and everywhere. The manual was excellent because it meant then that each week we just needed to pull it out and read through ... we knew exactly what we needed to cover so I found the manual for us was really, really helpful." (OT15, Area 8)

As previously mentioned physiotherapists and pharmacists did not receive formal training but were provided with instructions from the facilitator manual in advance of their respective sessions. Both physiotherapists and pharmacists indicated that they felt this was sufficient to deliver their sessions and did not feel additional training was required to do so.

"Yeah, the information, I mean the book was really good. Obviously it's the kind of talk that I've probably given like a hundred times. or a few hundred times, so it was fairly easy to deliver, any physio should be able to deliver that kind of a talk and all the information in the book was very good and very well set out and had everything about what you needed to cover, it was really comprehensive." (PT2, Area 8)

"No, no, the material was fine, everything was fine from that point of view." (Pharm2, Area 7)

6.4.1.2 Recommend changes to facilitator manual

Despite occupational therapists commending the facilitator manual, recommendations for changes to the manual were made by some. Occupational therapists suggested that the manual be restructured in order to make its usage during sessions easier. In the facilitator manual the session plan, session slides and session notes were presented separately. It was suggested that these should be integrated together.

“Just about the layout of it, we needed to juggle it a little bit. Because you have, for each week, there’s three sections. So, you know you have the plan, the slides themselves and then the backup material for each slide. So you’re kind of flipping backwards and forwards between the first section of the book, for each week, if that makes sense...so maybe just a better flow to that for the facilitator.” (OT8, Area 5)

6.4.1.3 Self-study required

The majority of facilitators acknowledged that self-study was required in addition to the facilitator training in order to prepare for programme delivery. Many occupational therapists commented that they allocated time each week to review the relevant session content prior to the session. Physiotherapists and pharmacists indicated that they reviewed the materials prior to the session.

“I still think you have to prepare for each week ahead of going into the week so that you’re quite clear on what’s coming in the programme and so that you have your own thoughts together in terms of how you’re going to deliver it.” (OT6, Area 3)

“In general I thought it was, you know, handy enough like, I spent half an hour reading it before going in and I thought I was happy enough with it.” (Pharm1, Area 3)

Many occupational therapists felt that they would require less study or preparation time in future as they were more familiar with the intervention.

“If you were running the same programme, it would be a lot easier this time around. There would be less prep time.” (OT10, Area 6).

6.4.2 Recruitment

This section presents three themes and accompanying sub-themes relevant to recruitment as presented in Table 6.13 below.

Table 6-13 Themes and sub-themes related to participant recruitment

Themes	Sub-themes
Reasons for low referrals	Busy caseloads Unsuitable patients on caseload Resistance from team
Appropriateness of recruited participants	Characteristics of suitable participants Characteristics of unsuitable participants
Recommended recruitment strategies	Recommend multiple referral pathways Reviewing records and waiting lists Increasing awareness

6.4.3 Reasons for low referrals and uptake

Some insight into challenges and the reasons for low referrals was provided in qualitative data analysis. Some occupational therapists expressed surprise and disappointment at the lack of referrals from their primary care team colleagues despite awareness. This is illustrated by one of the physiotherapist interviewees commenting that despite having suitable patients on their caseload and being aware of the programme they did not refer, viewing it as an occupational therapy project. No referrals were received from physiotherapists in any of the eight areas.

“I'd heard through my manager but it was more, you know, that it was an occupational therapy focused thing but if we had any, if we had any clients, but I suppose we didn't know enough at that stage to get ourselves in gear to be referring into the OTs but certainly my clientele would be perfectly suited to that programme.” (PT2, Area 8)

A number of reasons for low referrals from within the occupational therapy and wider primary care team were suggested. Such reasons included time constraints due to busy caseloads, lack of suitable participants and/or resistance from the team.

“Was it just one more piece of information the team just couldn’t process, at that time?” (OT1, Area 1)

Some occupational therapists considered there to be resistance to the intervention from the primary care team and other occupational therapy colleagues.

“I found that when we tried to promote the group through the primary care team meetings, we didn’t get the most positive reaction, from the nurses. They would often say well how do you have time to run a group like that, you have such long waiting lists?” (OT4, Area 2)

Generating referrals from the occupational therapy team was difficult in some areas. In interviews occupational therapists expressed the view that generally, patients on the occupational therapy caseload were not suited to the OPTIMAL programme due to being too unwell or of a low functional level.

“So it didn’t really work from our team, we didn’t receive any occupational therapy referrals for OPTIMAL, but that’s just the nature of our occupational therapy service at the moment, there’s a little bit of firefighting going on. So the clients we are seeing are much more advanced in their conditions and their level of function would be quite low.” (OT13, Area 7)

GPs commented that they found the referral process easy but were surprised at the low uptake and interest among patients they approached.

“I thought it would be so easy because we have so many patients that fall in the category, you know, of having several co-morbid conditions... I was just surprised that people were less interested than I thought they'd be.” (GP3, Area 8)

The GPs provided a variety of potential reasons for low uptake including the programme not having a clear “*selling point*” (GP3) the chaotic nature of patients’ lives in deprived areas making it difficult to access or commit to services, patients’ focus on medical management and general disinterest in group interventions.

6.4.4 Appropriateness of recruited participants

Fourteen of the occupational therapist facilitators agreed that the majority of participants were appropriate for the OPTIMAL programme.

“No certainly from our perspective, from the participants that attended our group, everyone was appropriate, everyone engaged, everyone contributed vocally at each session...really there was nobody who sat quietly or didn’t participate. So I think we definitely had appropriate participants.” (OT15, Area 8)

Characteristics of appropriate and inappropriate participants were alluded to by occupational therapists, physiotherapists and OPTIMAL programme participants. Occupational therapists and physiotherapists suggested that participants should be of a certain functional level in terms of being independent in daily activities and having the ability to make changes to impact their health and well-being. The need for participants to have the ability to travel to the venue location was also emphasised. It is interesting to note that some occupational therapists described intervention participants of being of mixed ages and functional levels and did not perceive this to negatively impact group functioning.

“The main people I felt were appropriate for the group were people who were... even though they had their chronic condition, they were still trying to be as independent as they could be. They were able to make it to the group, either by walking, or getting the bus, or getting themselves there by their car. And I suppose, yea, like mainly that they were willing to engage in it.” (OT4, Area 2)

“Ideally the people who are at a stage where making lifestyle changes can actually impact on them. I know that’s really obvious to say but I suppose not catching people when they’re too unwell with multiples, co-morbidities” (PT3, Area 3)

The need for participants to have the motivation to make changes and be willing to engage in a group-based intervention was highlighted.

“I suppose maybe people, I feel, people who are proactive, want to play an active role in managing their health...So it was appropriate for everyone but I suppose

people who are mobile enough to get here themselves. Motivated to play this active role and advocate for themselves.” (OT14, Area 8)

“It’s almost where they’re at with the stages of readiness to change...” (PT2, Area 8)

A small number of occupational therapists viewed some participants as inappropriate for the intervention. Occupational therapists from two areas (Area 2 and Area 3) emphasized the need for participants to be referred based on need rather than programme eligibility criteria and felt that some GPs and practice nurses did not consider this.

“...the people who were referred by the practice nurses were not always suitable, the people that we referred (the OTs) into the group were a better person for the group. Whilst the other people referred by the practice nurses fulfilled the criteria they didn’t necessarily...they came and they had almost full attendance but even there at the end there today they said, well yeah it was very good and very interesting but I don’t really need it now, you know.” (OT5, Area 3)

Three occupational therapists from two areas (Area 5 and Area 8) and one participant suggested that participants with severe mental health issues struggled to engage in the intervention.

“I think she was involved in the mental health services and definitely there was a schizophrenia there, or something. She was sitting in the group asleep on certain days, so, she probably wasn’t at the optimum level of functioning for it.” (OT8, Area 5)

“...like not people suffering with severe depression. It mightn’t be suitable for them.” (ID86, Area 5)

6.4.5 Recommended OPTIMAL recruitment strategies

Strategies recommended to increase recruitment included using multiple referral pathways, reviewing records and waiting lists, and increasing awareness and rapport amongst primary care team members.

Multiple referral pathways including referrals from GPs, practice nurses and primary care team members were recommended.

“I think ideally it should be primary care referrals and GPs and nurses and people who understand these people and know them for a very long time.” (PT1, Area 5)

“I think recruiting through the GPs is probably the best way. They know what your situation is, that’s how I found out, my local GP, he said you’re at a stage now that this OPTIMAL thing could be some use to you. So he recommended me for it or something like that.” (ID136, Area 8)

Self-referrals were recommended by some health professionals and participants who advocated for the programme to be widely advertised in the community in local shops, community and health centres. Occupational therapists also recommended advertising the programme to local community groups such as active retirement and men’s sheds groups. Some occupational therapists and health professionals indicated that self-referral was congruent with self-management and identifying motivated participants whilst others expressed concern that it could result in inappropriate referrals.

“I think that self-referral would be really good because it kind of adds to the empowerment bit, that you’re giving people the tools to handle their own illness or their own problems, so that, by being allowed to access it themselves I think would be a good stepping point and that we’d recommend it.” (GP2, Area 7)

Identifying participants opportunistically during clinical encounters on an ongoing basis was recommended by both occupational therapists and GPs. GPs reported doing this in order to identify participants for the study, however some alluded that the business of day to day practice means that GPs would be liable to forget to refer during clinical encounters. Some occupational therapists and GPs proposed that ideally the

programme would need to be scheduled during the year with multiple times and locations so that participants could be advised of this when inviting them to attend.

“So it would be good if we were on our visits and we saw somebody who would be appropriate, we could just pop them on, if we had a rolling programme, just put them on the waiting list for it.” (OT14, Area 7)

However the need to review records and waiting lists was suggested by occupational therapists, GPs and physiotherapists as a recruitment strategy. GPs reported reviewing patient GMS lists and registers to identify and invite participants. Furthermore, physiotherapists suggested there could be cross referrals between physiotherapy groups and the OPTIMAL programme.

“I think we just printed a list of all the people with a medical card over forty and, you know, I know my own patients by name that are in these categories and so do my colleagues... You need to go in with the GPs and say here’s an idea, print out your GMS list of people over forty and have a quick look through it, identify them.” (GP1, Area 6)

“It certainly will be an avenue either for me to filter people from my class and groups into OPTIMAL or for them to be filtered from OPTIMAL into my classes.” (PT3, Area 8)

Some occupational therapists proposed inviting patients on the priority three occupational therapy waiting list to the OPTIMAL programme. Patients are placed on the priority three (P3) waiting list if they can be described as independent but requiring intervention to improve their quality of life.

“This group is actually really good for the likes of P3s. They’re on our waiting list for a year.” (OT8, Area 5)

Increasing awareness of the intervention to promote referrals from GPs and the primary care team was identified as important by occupational therapists. Occupational therapists recommended direct face to face contact with individual professions in addition to reminders about the programme via email and primary care team meetings. They suggested that ongoing reminders should be provided to the GPs and other primary care team professionals.

"I would've said it at the PCT but maybe you need to have just a one to one chat, even if it was informal, just about the programme, I don't know whether it would be something that we could talk to them at one of their staff meetings." (OT4, Area 2)

It was suggested that regular delivery and receiving positive feedback from programme participants would increase awareness and promotion of referrals in the future.

..over time that will change as well, if the OPTIMAL group was rolled out regularly, the referral rate would go up because people would know of the group and be more familiar with who would be appropriate or not." (OT12, Area 7)

GPs also alluded to wishing to build rapport and a closer working relationship with primary care professionals. They felt this would result in increased referrals from the GPs. Of the four GPs interviewed three described themselves as not being actively involved in a PCT.

"Personally, I'd certainly be open to primary care meetings. I think it would be nice to see a bit more interaction and that's where you get the actual face to face, you know how could we be utilizing the services a bit better and communicating better with each other because it's all a bit distant I suppose." (GP3, Area 8)

Some occupational therapists proposed that as occupational therapists traditionally provide individual home-based interventions there is a need to increase awareness of the availability of occupational therapy group-based interventions among the team.

"We need to get them to think, well actually, oh yea I can refer for a group. Maybe I should refer them in for a group. Just to get it on their (other PCT members) radar. They're so used to... I think we've set a status quo, with the OT service, they're used to the fact that we do one to one, we go out to the home. That's really traditionally what we've done." (OT1, Area 1)

6.4.6 OPTIMAL programme content and delivery

This section presents four themes and accompanying sub-themes relevant to the OPTIMAL programme content and delivery as presented in Table 6.14 below. The main themes identified are perceptions of programme organisation, perceptions of programme content, useful programme resources and intervention recommendations

Table 6-14 Themes and sub-themes relevant to OPTIMAL programme content and delivery

Theme	Sub-themes
Perceptions of programme organisation	Programme duration Session duration Session structure Facilitators
Perceptions of programme content	Reinforcing relevant common knowledge Varied experience of managing medication session Varied experience of maintaining physical activity session Tailoring content
Useful programme resources	Positive perception but varied use of programme booklet Additional programme resources Information on local resources
Intervention recommendations	Recommend OPTIMAL as routine practice Desire for individualised advice Inclusion of additional topics Involvement of other professionals Recommend increasing interactive programme components Recommend changes to booklet

6.4.7 Perceptions of programme organisation

6.4.7.1 Programme duration

Both occupational therapists and intervention participants reported that six weeks was an acceptable programme duration. Occupational therapists indicated that the programme duration did not detract too much from their normal caseload.

“Yeah, I felt six weeks was appropriate, as in I don’t think it ate too much into our caseload.” (OT14, Area 8)

Many participants indicated that the programme felt as if it went by quickly and attributed this to enjoyment.

“It went very quick. I came to the six weeks and I have to say like it just seemed to, when the girls are doing it, it just flies, the whole day seems to be gone.” (ID37, Area 2)

Additionally, a few therapists stated that the programme duration allowed the group to bond, content to be covered and changes to be observed.

“I thought six weeks was brilliant, it worked really well, the group really got to know each other...And by the end, the six weeks gave them enough time to actually see a change, an improvement and I thought that was quite good.” (OT12, Area 7)

Some participants recommended extending the programme length beyond the current duration of six weeks. Occupational therapists also reported that participants had expressed a desire for an extended programme to them but this was not something occupational therapists advocated for.

“It could go on, say probably a little bit longer there just say eight weeks, nine weeks.” (ID 90, Area 5)

However other participants argued that extending the programme duration could potentially alter the focus of the OPTIMAL programme, with one participant commenting that extending the programme for some people might relate to a desire for social interaction or companionship.

“I think what it is, is that they’re giving you the information over the six weeks. There’s no more information to give you. So you have to go to the book to kind of look back on things. You’re talking about companionship and meeting up with people. That’s a different thing.” (ID94, Area 6)

6.4.7.2 Session duration

Generally intervention participants and occupational therapists believed the session duration to be of a suitable duration. Both pharmacists and physiotherapists stated that they had sufficient time to deliver their respective sessions.

“Adequate I would have thought, I thought it was adequate, 2 ½ hours is long enough to spend and everything was very well covered from the book with the different sections, every six weeks, I could find nothing to criticise in it at all.” (ID142, Area 8)

“...you needed a good tea break in the middle for people to kind of relax and network and chat to each other...” (OT15, Area 8)

“No, I thought the length was good, yeah, length was fine. There was enough time for questions but it wasn’t like going on and on and so it felt like a good amount of time.” (PT2, Area 8)

In two areas (Area 2 and Area 4), occupational therapists commented that they felt the session duration could be shortened. Shorter session durations were observed in both these areas in the fidelity tool. In Area 2 this may be reflective of the small group numbers. In Area 4 one therapist stated they generally did not use the full session duration.

“The session length? We tended to go a bit quicker than the time given. I think we could’ve done it in a little bit shorter time.” (OT7, Area 4)

6.4.7.3 Session structure

The structure of programme sessions seemed to be perceived positively by occupational therapists in terms of information provision and discussion elements. The importance of the tea and refreshment break not only as a rest break but as means to promote social interaction was emphasised.

“I really liked the content of the slides, I liked the overall review at the start and generally content wise... I thought the tea breaks were well slotted in, it was nice to kind of have the speaking discussion piece about the content of that day. Then our little break and then we would come back and review the goals so that was nice.” (OT14, Area 8)

6.4.7.4 Facilitators

Generally occupational therapists were viewed as appropriate facilitators for the OPTIMAL programme by the occupational therapists, other health professionals and participants. Occupational therapists believed that the programme was congruent with the profession’s philosophy and skills in goal-setting and group facilitation. Participants were positive about the facilitation skills of the occupational therapists providing both practical and emotional support to participants. However the need and value of having other primary care team members involved in delivery was noted in order for participants to have access to specific expertise and credible advice.

“It is very occupational therapy focused so yeah, I think occupational therapists should run it but with the input from other professionals... It worked well I thought having the external speakers. I think that added a bit of excitement to the group. You know we were able to say we have someone else coming in.” (OT14, Area 8)

“I think for OPTIMAL, occupational therapists are definitely ideal to lead it out. I think if its more physical activity exercise orientated the physios are probably

better. But I do think any inter-disciplinary work is very worthwhile. I do think occupational therapists have specific training, physiotherapists have specific training as do the pharmacists. I think working together as a unit is very worthwhile but in terms of leading no I do think occupational therapists are suited to leading out on a programme like OPTIMAL for sure.” (PT2, Area 8)

The need for two occupational therapist facilitators was supported by occupational therapists who felt it was necessary for effective facilitation in terms of programme organisation, facilitating discussion and answering questions and managing and providing support to individual group members.

“It really was brilliant to have a second person. It is just nice to have the extra hands and make sure that everyone’s looked after. Even at breaks, in a social sense.” (OT2, Area 2)

6.4.8 Perceptions of programme content

6.4.8.1 Reinforcing relevant common knowledge

Both intervention participants and occupational therapists described the programme content as being comprehensive and relevant to the needs of those with multimorbidity. The programme content was described as practical and reinforcing common knowledge regarding self-management by both occupational therapists and participants. Occupational therapists alluded that the nature of this information meant it was easily understandable to participants.

“I found that it was very practical, which is something that I would choose myself, if I was looking at some difficulty that I had to deal with. It just seems to me to be good, down to earth information that I’ve got now that I didn’t have before and for that reason it’s, it’s been very helpful to me. And I’m in a better place now than I was when I came here first.” (ID37, Area 4)

“It’s simple information that’s reiterated. It wasn’t anything that required a huge amount of brain work in terms of the content. And I think that helps to engage

people from different social economic backgrounds. It's not intimidating.” (OT11, Area 6)

Both the pharmacists and physiotherapists indicated that they felt the programme content in their sessions was relevant and appropriate for participants needs.

“I thought the information was very good. I thought there was a lot of interesting stuff in it. And I thought the content was excellent and relevant.” (PT1, Area 5)

6.4.8.2 Varied experience of maintaining physical activity session

Participants' perceptions of the “Maintaining Physical Activity” session varied by site. The majority of participants appeared to have positive perceptions of this session with many reporting an increased awareness of the importance of exercise, knowledge of different ways to exercise and physical activity questions addressed. The occupational therapists and physiotherapists interviewed indicated that they felt the session was positively received and relevant to participants' needs and interests.

“I really felt like the exercise week, where they had the physiotherapist in that was something that as a group they seemed to all kind of engage in well and interact in well. I don't know is it because they were up and they were exercising as part of the session. And it was I suppose something that affected, or impacted all of them. Like, they all wanted to try and get some sort of exercise back into their lives.” (OT2, Area 2)

Participants appeared to particularly enjoy and engage well in the exercise demonstration and practice.

“It's a wakeup call. I'd be sitting around, lounging around, but even after the physio session and the demonstration of the simple exercises they were showing us, it would encourage you to get up and do something.” (ID136, Area 8)

However a small number of participants and some physiotherapists felt that the session did not cater to mixed abilities. The physiotherapist interviewed in Area 8 felt the exercises were too simple or basic given the high level of functioning of participants in

the group. In Area 3, two participants felt that the expectations in terms of exercise were too high given their diagnoses.

“She wanted us all to have our heart rate up, no matter what disability we had, we needed to have our heart rate up, now I haven’t had my heart rate up since my accident, I literally, I can’t, I can’t, so moving arms and legs sitting on a chair, I can’t.” (ID39, Area 3)

6.4.8.3 Varied experience of managing medication session

Most intervention participants appeared to enjoy the session on medication management with participants commenting that the pharmacist answered questions and eased their concerns about medications.

“Well I liked the pharmacist being in and I liked being able to talk to him one to one about my medication, that was very, very good.” (ID113, Area 7)

“Well there was a lot of questions that goes on in your mind about medicines and, you know, effects and everything and he did clarify some of them, so it would put your mind more at ease.” (ID43, Area 3)

In one area participants were disappointed as they felt the pharmacist would not answer any questions or queries but instead re-directed them to their doctor.

“But what they said was, when the pharmacist is here, we’re going to have question time. That’s great. Every question I asked the pharmacist, she said, ask your doctor.” (ID94, Area 6)

Similarly, there was some variation in occupational therapists’ perceptions of the “Managing Medication” session. Most occupational therapists considered the session to be of value and positively received by participants with participants learning about the pharmacist as a resource for managing multiple medications.

“The pharmacy session again, went really well, there was a great response...He was wonderful and like that it was perfectly delivered by the local pharmacist.” (OT2, Area 1)

While many occupational therapists felt the pharmacist interacted well with participants, in some areas (Area 2 and Area 5) where occupational therapists had some concerns about the session, it appeared to relate to the pharmacists' lack of experience in delivering group interventions.

"Well unfortunately you see the pharmacist wasn't exactly the most articulate fellow, lovely, but you know really intense and kind of a very intellectual guy, so he didn't come across amazingly, and unfortunately some of them couldn't hear him properly either because he spoke quite low and fast...but just in a group session he wasn't the best fellow for it...I just didn't think he, unfortunately, facilitated it as good as he could." (OT9, Area 5)

The pharmacists interviewed appeared to have different experiences of participants' level of medication knowledge based on their delivery site. While Pharm1 found participants to have an advanced level of knowledge, Pharm2 expressed surprise at the lack of knowledge participants had about simple medication information. Pharmacists commented that this made it more challenging to facilitate. Pharm3 stated that there was a wide variation of knowledge within the one group.

"Within the group there seemed to be some with excellent knowledge of the medicines and they knew what everything was for and why they're taking it whereas others were, like they were quite vague and that, they just take them out of a blister pack and they don't really know what they're for and what they're on or anything like that. So it's kind of hard then when you've such a different kind of a knowledge base in the group." (Pharm3, Area 8)

6.4.8.4 Tailoring content

Some occupational therapists, physiotherapists and pharmacists alluded to delivering additional content not prescribed in the facilitator manual in order to meet participants' needs. Often these additional topics arose and were addressed as a result of group interaction and discussion. Some occupational therapists indicated they were uncertain in terms of how flexible they could be with the programme content and resources. Examples of additional content delivered included falls prevention information and pharmacists providing information on medication costs.

“I suppose the only thing I wasn’t sure of was how much we could really veer off topic, you know. Or, you know if we were to come across, you know if this was rolling out and we were to come across maybe slightly different resources you know can we bring those in.” (OT1, Area 1)

“I deviated a little bit ‘cos we were talking about something. And they couldn’t get, oh yea; somebody said he wouldn’t get down to pick something up. ‘Cos he’d be afraid he wouldn’t be able to get back up again. So, actually we explored that further...So, you know, it wasn’t planned, it was just I had to, that was the direction they wanted me to take them.” (PT1, Area 5)

6.4.9 Useful programme resources

6.4.9.1 Positive perception but varied use of programme booklet

Intervention participants were provided with a number of resources as part of the programme including a participant booklet, a relaxation CD and additional materials to the topics as appropriate such as an exercise booklet (Chapter 3; Section 3.5.5). Both intervention participants and occupational therapists indicated that the participant booklet was considered to be useful but the actual use of the booklet varied between participants. From the occupational therapists’ perspective they felt having all the programme information and worksheets together for participants was helpful.

“You’re given a very good book actually, well bound, handouts, but this is very good and the material is very good.” (ID143, Area 8)

“The book that was the other thing they really loved. They had the resources, they all loved having their book. They also liked the sheets to write in because a lot of them wanted to mind the book.” (OT12, Area 7)

The majority of participants and occupational therapists considered the booklet to be a resource for the future, something to review for appropriate information as required. Occupational therapists also noted variation in participants’ booklet use.

“But I was glad that I’m getting the booklet and we can look back and see what we need when we need it.” (ID69, Area 4)

“I think there was some people who after they got it the first day forgot about it and kind of left it behind but there was other people who would have come back and said oh I read this in the booklet and they would have made a comment on something that they had read. So some people were definitely flicking through it after the sessions.” (OT15, Area 8)

A small number of participants stated that they did not find the booklet to be of benefit and could not envisage using it.

“...And you covered a certain amount, then it’s all in the book again, so I don’t know if you’re going to really go to the book and read it...” (ID52, Area 3)

6.4.9.2 Additional programme resources

The exercise booklet, which was a resource developed by the HSE, appeared to be highly appreciated by both intervention participants and occupational therapists alike.

“I also found that one of the booklets, in particular that exercise booklet was, again it’s a brilliant thing because you don’t, you know you say exercise, I think we all had the idea, well I certainly did that there has to be this pumping and intense situation where the exercises as you said earlier on, you can sit there and you can do that...so in relation to the giving out of that type of booklet is great.” (ID16, FG1)

“Yes they go away then and they really loved the handout that was given in terms of the exercises and they thought they were really useful and they really enjoyed that.” (OT13, Area 7)

Interestingly, there was very little feedback about the relaxation CD from participants. In one area (Area 3) participants advised that while they tried to use the CD they did not like the background music.

“In general, the only thing I found actually that didn’t fit was the recording that the music certainly didn’t fit in the CD, it didn’t fit in anyway.” (ID53, Area 3)

Occupational therapists had conflicting views on whether the provision of the CD was beneficial or not and whether the CD was or would be used in the future.

“I think there are definitely going to be a few people in the group who will probably never use it but there are some who will definitely use it. So you know it’s worth giving I suppose, I think it probably will be something that won’t be used by everybody but there’s a few at least who do. There was three ladies in particular who were really interested in the relaxation and had done some courses before, who said that they would keep it.” (OT12, Area 7)

6.4.9.3 Information on local resources

Participants valued the provision of information on local resources such as services, community groups and activities available in their area. This information was gained both through the peer learning process and information provided by the occupational therapists, physiotherapists and pharmacists. Occupational therapists and physiotherapists both indicated that this signposting of services and resources provided opportunities for participants to maintain engagement post programme.

“The other thing that OT5 did is she put together a leaflet on groups and services that’s local to the area, that’s a very positive thing because, I don’t know about everyone else, but I didn’t know about all of those local groups and contact numbers, which is very positive. Yeah, and if that was included or added on to each of the courses, you know, it, it enables people to be able to access what’s going on in their community.” (ID39, Area 3)

“I guess we gave them like initial information in terms of their primary care team who that was that sort of thing for each individual because there had been questions coming up around that.” (OT13, Area 7)

“I came along with lists of what was in my area, like what classes were available and what gyms and what rate you could get and things like that because that’s what they want to know at the end of it. They’re like okay, thanks for all that

information, we're really motivated now but what do we do, where do we go, like how much is it going to cost, all those kind of things.” (PT1, Area 5)

6.4.10 Intervention recommendations

6.4.10.1 OPTIMAL as routine practice

Many health professionals expressed the wish that OPTIMAL would be delivered as part of routine primary care practice. However the intervention would need to be planned and scheduled by the occupational therapists in relation to capacity and other group-based programmes being delivered. Programme scheduling would need to be communicated to all members of the primary care team.

“I definitely think it's something that should be rolled out, in the future, in community occupational therapy.” (OT11, Area 6)

“I think this would be a really welcome policy if an evidence base arises, I think it would be really, really useful and I certainly would use it, a hundred percent.” (GP4, Area 8)

There was a desire among some intervention participants for individualised advice in terms of individual chronic conditions and issues which was not provided for in this generic group-based intervention. Examples of this included a wish for tailored individual advice from the physiotherapist, pharmacist and dietary advice specific to their health conditions.

“I'd have liked a bit more information on what you can do to keep your strength up. I find I'm getting bent over sometimes, going up and down you know and things like that.” (ID95, Area 4)

Occupational therapists, physiotherapists and pharmacists also recognised the desire and need for individualised advice for some participants.

“The ones who are less familiar with the medicines maybe if you could go through them one by one with the patients but then you don't want to bore other members in the group either, you know.” (Pharm3, Area 8)

6.4.10.2 Inclusion of additional topics

Suggestions for additional topics were provided by some participants, occupational therapists, physiotherapists and pharmacists. There was a wide variety of topics suggested by participants including memory strategy information, ageing and retirement, managing money and generic medications. In line with participants, pharmacists suggested providing information on generic medications as well as costs.

“A lot of them are concerned about the cost of medication – and it probably is an important thing really to be discussing because it might be a barrier for them getting their medication.” (Pharm2, Area 7)

Occupational therapists suggested alcohol addiction, pain management and disclosure of health conditions. Occupational therapists in four areas recommended provision of falls prevention information.

“I wondered is there anywhere to put in a little bit of falls prevention?” (OT1, Area 1)

Many participants recommended having a follow-up session in order to provide support with maintaining changes. The occupational therapists also conveyed participants' desire for a follow-up session.

ID133: I think what we all said today as well was, I would love...

ID131: A follow up.

ID133: A follow up, maybe every 6 months or 3 months, whether it be by phone or post or, just to see are you keeping up your goals. I think it would give the support to one another. Like I'm still struggling with this or I'm doing great with that.

ID131: That would be one of the things that I would have found in things I would have done in the past that you go and you do something and then you're left out on your own with it. (FG7)

6.4.10.3 *Involvement of other professionals*

There were suggestions provided by a small number of participants in terms of involving other professionals in the delivery of OPTIMAL. In three areas a few participants recommended GP involvement. Whilst only a small number of participants suggested inclusion of a dietician, nine occupational therapists recommended inclusion of a dietician. While some occupational therapists felt comfortable delivering content around healthy eating, others felt uncertain of how to respond to participants' specific queries and felt that questions could be better addressed by dietician involvement. Additionally some occupational therapists reported there was no dietician in the area to refer onto regardless.

"A nutritionist definitely. Maybe more details on the food end of things, a little bit more." (ID145, Area 8)

"Well, I think I felt confident enough to do it (the healthy eating session component). I did feel that I needed obviously, to read up on it beforehand. But because it was basic stuff about the pyramid and things like that. It mightn't be a bad idea to get a dietician involved, in terms of making the smaller changes. Perhaps the dietician could have a bigger array of tips." (OT11, Area 6)

6.4.10.4 *Recommend increasing interactive programme components*

Participants, occupational therapists and other health care professionals supported the value of the interactive programme components more so than information provision and recommended increasing these.

"At times, I would've liked more of the group interaction, exploration of brainstorming. So, there was generally one brainstorming session, per group. And I probably would've liked a bit more of that I think." (OT8, Area 5)

This suggestion was made particularly in relation to the "Maintaining Physical Activity" session with many participants, occupational therapists and physiotherapists keen to emphasize the importance of allowing time for exercise demonstration and practice.

“I’d have liked a bit more of what you can do to keep your strength...A bit more exercise like, actually doing it, you know.” (ID71, Area 4)

Occupational therapists in two areas (Area 7; Area 8) felt that increased relaxation practice would have been beneficial for the participants in their particular groups.

“I suppose maybe in terms of well-being and mental health, we did look at relaxation and that was something that people had identified from the very beginning that they really would like to explore a bit, so possibly more on that would have been good but that’s only again based on the group that we had.” (OT12, Area 7)

6.4.10.5 Recommended changes to booklet

Both intervention participants and occupational therapists recommended some changes to be made to the programme booklet and format. Participants and occupational therapists from Area 3 and Area 5 suggested reducing the volume of content, the physical size and increasing the print size in the booklet.

“I can’t hold it...I think that was the medium that was used really, I mean it could be made a lot lighter.” (ID43, Area 3)

“One of the guys tried to follow the book every week. But in the slide the print was really, really small. That was something he struggled with. And I would agree with him on that.” (OT8, Area 5)

A need to simplify the programme worksheets, particularly the goal-setting sheets was proposed by some occupational therapists due to concerns about the literacy of some participants.

“Simplifying them, like if that was possible you know... if they could be simplified slightly, you know for those with the literacy problems.” (OT3, Area 2)

Some participants and physiotherapists recommended changes to the exercise questionnaire used in the ‘Maintaining Physical Activity’ session to prompt discussion as they felt it did not cater to mixed or low level abilities.

“....The physio one was very difficult because the physio questionnaire isn’t aimed for mixed abilities.” (ID46, Area 3)

6.5 Themes related to mechanisms of impact

This section presents the qualitative themes relevant to the mechanisms of impact i.e. the factors which contributed to the delivered intervention producing or not producing change as discussed in Chapter 4, Section 4.3 (Moore et al., 2014). Both intervention participants and healthcare professionals alluded to specific intervention components as being important in producing or eliciting change in terms of participants’ self-management behaviours and activity levels. Themes were identified in relation to benefits of the group intervention and benefits and challenges of goal-setting. Table 6.15 below presents the three themes and accompanying sub-themes developed pertaining to perceived mechanisms of impact.

Table 6-15 Themes and sub-themes related to mechanisms of impact

Theme	Sub-theme
Benefits of group-based intervention	Peer learning
	Peer support
	Sharing experiences
	Social interaction
	Making peer comparisons
Benefits of goal-setting	Provides focus and motivation
	Facilitates individual tailoring of content
	Goal attainment provides sense of achievement
	Participants learnt to set goals
Challenges with goal-setting	Non-commitment to process
	Difficulty completing goal-setting

6.5.1 Benefits of group-based interventions

6.5.1.1 Peer learning

Participants described “*bouncing ideas off each other*” (ID4, Area 1) and learning about strategies that fellow participants used and putting them into practice for themselves.

“It would be, you know from each participant here, there’d be certain things that perhaps I wouldn’t have thought of and that they would do, so therefore I’m going ‘oh yes I never thought of that one.’ But I can perhaps put that one into practice for myself. So when you have a group, a forum for want of a better word I suppose, that you pick up things from other people. And you learn from other people within the group”. (ID121, Area 7)

In line with participant perspectives, occupational therapists also supported the importance of peer learning amongst intervention participants. The occupational therapists provided some examples of peer learning including medication management, healthy eating, and relaxation techniques.

“I think there was, even from a peer perspective, a lot of very useful information shared about their experiences with certain things. Even you know when it came to pharmacy, things that they found really useful for managing their medications. Or, people had different relaxation techniques they used to mind their mental health. And that just got really good discussion going. And people, were saying ‘I’m going to try that this week.’ I just think that the peer discussion piece can be, dare I say it, even more valuable than the therapist actually imparting that recommendation on them, because they’ve been through it and it’s worked for them.” (OT1, Area 1)

6.5.1.2 Peer support

Both participants and occupational therapists viewed the peer support and encouragement as invaluable. Participants alluded to the support received from peers as reducing feelings of isolation and fostering camaraderie.

“It was sort of like a team. That’s the feeling I got here, I was part of a team. You feel, everyone understands where you’re coming from. You know, it’s all for common interest. And you know, a suggestion here, or a suggestion there helps you to get through, you know what I mean. You don’t feel so much alone anymore.” (ID 63, Area 6)

“Well, I think one of the main benefits that I saw, and maybe it’s because I don’t run groups that often, was the peer support.” (OT11, Area 6)

6.5.1.3 Sharing experiences

Participants spoke of the willingness of group members to share their experiences due a sense of mutual understanding. The importance of sharing experiences was also alluded to by the occupational therapists who viewed this as key in enabling peer learning and fostering cohesiveness.

“And I found the help with the group or the sharing with the group was very important. They were a lovely group of people and they were all willing to share their bit or have their say.” (ID127, Area 7)

“I’d say the group interactions would’ve been one of the major positive sides of the group as well. Like just with people sharing their experiences, or their challenges, or difficulties they face with their chronic conditions. Even if they weren’t specific to other members of the group. It kind of gave people a sense of, I’m not on my own, I’m not the only one in this scenario. It kind of developed this sense of comradery. Even if they weren’t going to meet up after the group. And it kind of was a bit of a sense of unity.” (OT4, Area 2)

Some participants described being reluctant to share difficulties and feelings around their health with their families and friends but stated they were comfortable doing so within the group.

ID4: There's things that we would talk about within this group that we wouldn't talk about elsewhere.

ID2: Yeah.

ID1: Even to your family.

Q: Even to your family.

ID7: Particularly to your family sometimes. (Area1)

6.5.1.4 Social interaction

Some participants alluded to feeling lonely and isolated and that the group provided them with an opportunity to meet and interact with others. Participants reported looking forward to the group each week and enjoying meeting people. The benefit of the intervention in providing social interaction and opportunities to participants was also identified by occupational therapy facilitators.

"It was so relaxed, the group I thought was fantastic. I mean I knew no one here before hand but I felt as if I did after the first session." (ID11, Area 1)

"I think for some of them it was even you know that they were quite socially isolated, and coming to the group was a way of meeting people, and a few of them were going to meet up afterwards and maybe go for a walk or coffee or something. So to break that cycle for them even was something that they would have got out of it." (OT10, Area 6)

6.5.1.5 Making peer comparisons

Participant focus groups suggested making peer comparisons was a benefit of the group. Participants appeared to make comparisons in two ways. Participants met those they viewed as similar to themselves and reported realising that they were "*not the only one*" living with and trying to manage multiple chronic conditions.

“For me personally it would be a situation where you’d realise that you’re not the only one and you realise that you’re not alone.” (ID1, Area 1)

In contrast, participants described meeting others they viewed as dissimilar as they appraised themselves to be ‘not as bad as them.’ There did not appear to be any qualitative findings of participants commenting on observing others doing well and providing them with motivation as a result.

ID111: I found I wasn’t as badly off as I thought I was.

ID112: And then hearing other people’s problems, realising you’re not so bad.

(Area 7)

6.5.2 Benefits of goal-setting

Many participants perceived goal-setting to be an important programme component and to have a positive impact.

“I think goal setting is a good idea” (ID95, Area 6)

Similarly the occupational therapists viewed the goal-setting component as the most “powerful” (OT8) or important component of the intervention. Some occupational therapists viewed it as a component which differentiated it from other group-based interventions with OT14 stating *“I think it’s the goals is what made it different to other groups.”* Occupational therapists in one area (Area 1) reporting that they were now incorporating goal-setting into their other occupational therapy led group-based interventions. Goal-setting benefits included focus and motivation to make changes, enabling individual tailoring and attainment providing a sense of achievement. Occupational therapists and participants also identified that participants gained a new skill of goal-setting.

6.5.2.1 Goal-setting provides focus and motivation

Participants identified goals as being a source of motivation and focus over the course of the intervention. Many participants described learning to set goals over the programme

duration and alluded to characteristics required for goals such as setting small, specific realistic goals and progressing gradually.

“Goal-setting was focusing wasn’t it, getting focused on something, I set very realistic goals that I knew I could do so I wasn’t too aspirational but because of that then I did them. So it definitely raised awareness. Also there was no judgment again, there was absolutely no judgement totally. And you didn’t even feel they were (the occupational therapists) just saying that, there really wasn’t a judgement, it was just to help us to focus on something. And it did, I definitely think it made me focus on something that week.” (ID146, Area 8)

Occupational therapists, similarly, perceived goal-setting to motivate participants to implement changes. Occupational therapists hypothesised that information provision alone does not always equate with participants making changes.

“I think it was a good motivator for them, and they knew they were going to be coming back and feeding back to the group, and they really did try with their goals...because you can give people all the information and they might just go home and not do anything about it, but if they know they have a goal it just supports them with getting to where they want to be.” (OT10, Area 6)

Sharing and reviewing goals with peers was also reported to be a motivating factor in the goal-setting process by both intervention participants and facilitators.

“And setting the goals as well, kind of gave you accountability, because you knew you were coming back the following week. And you know, you wanted to make more of an effort, because you didn’t want to say, ‘oh no I didn’t do anything, you know.’” (ID103, Area 6)

“My favourite part was that we got to recap on the goals because you know a lot of time you do a group and you make all these, or give advice and make recommendations but you never actually follow up to see how people are getting on implementing it. So I think that worked well, the goal review.” (OT14, Area 8)

In addition some participants believed writing down goals in their booklets was helpful in committing to goals *“I felt the same about writing it down, it focused the mind on your target” (ID 123, Area 7)*, whereas some occupational therapists acknowledged that not

all participants wrote down their goals, with some of this being attributed to literacy issues.

"...getting them to fill in the weekly goal sheets, it was very difficult." (OT2, Area 1)

6.5.2.2 Goal-setting enables individual tailoring

From the occupational therapists' perspective a benefit of goal-setting was that it enabled individual tailoring in terms of changes that participants would like to make within a group-based programme.

"I suppose I quite like the goal setting element of it, it was really useful in terms of making it more individualised." (OT12, Area 7)

"And they worked towards their own, completely individual goals." (OT2, Area 2)

6.5.2.3 Goal attainment provides sense of achievement

Many participants described the goal-setting process as being non-judgemental and acceptable not to achieve goals. Participants described a sense of achievement and satisfaction as they attained their goals.

"Well I used to not think about myself. My day would be getting up in the morning, cleaning the house, getting the dinner ready, making sure everything was ready for everybody else coming in and I never had time for myself. Whereas now at 11 o'clock that's it, I down tools and I get my jacket on and I go out and I do my walking right around. At first my friend came with me because I was a little bit on the nervous side and I didn't know what route she was going to take me. Now I do it on my own. I do feel, even though I'm knackered when I come back, I sit down and I say 'well now I'm after achieving something for myself'. Which I would not have originally done before and it makes me feel good." (ID17, Area 1)

The increased motivation and sense of achievement participants derived from goal attainment was noted by occupational therapists irrespective of the size of the goal or change.

“Even to realise that they can achieve, even if it is something really small, that they can do it, and it just gives them the confidence then to go on, I think.” (OT11, Area 5)

6.5.2.4 Participants learnt to set goals

Both participants and occupational therapists indicated that they felt they had learnt a valuable skill through goal-setting, expressing the hope they would continue to goal-set post programme in order to maintain and implement new changes.

“And I will definitely continue doing and keeping on my goals. I certainly wouldn’t be giving it up now because I felt it was doing me good.” (ID16, Area 1)

“Nearly all of them said that they will continue to write down their goals in the future and they found that really useful.” (OT13, Area 7)

6.5.3 Challenges in goal-setting

The theme ‘challenges in goal-setting’ reflects difficulties experienced by participants in the goal-setting process and challenges occupational therapists encountered in facilitating goal-setting.

6.5.3.1 Non commitment to goal-setting process

A small number of participants expressed a dislike of goal-setting, they viewed it as a coercive process to do things they didn’t want to do and reported ignoring this part of the programme session. Occupational therapists also reported that some participants had a lack of interest or commitment to the goal-setting process.

ID149: I suppose I have been so driven all my life academically mostly, but also in other ways. Suddenly I have decided I don't do things I don't feel like doing, I just, I kind of get up in the morning and say I am not going to go over and walk, I am not going to, it just happens but I still do a lot.

Q: Yeah but you found that the weekly goal setting didn't particularly help, is that what you're saying?

ID149: No I just ignored it.

(Area 8)

"I suppose people's personalities came out so some people didn't necessarily commit to the goals but they would say you know, 'I like to do what I like when I feel like it anyway' and you knew that's just them." (OT6, Area 3)

Some occupational therapists discussed a few individuals finding it difficult to understand the concept of goal-setting. Therapists noted that while the concept is very familiar to occupational therapists, it is new idea for participants.

"We talk about it and use it as a term in occupational therapy all the time, in our profession and use it. But for the man on the street, it's a very alien kind of wishy washy concept." (OT8, Area 5)

6.5.3.2 Difficulty completing goal-setting

The difficulties experienced by some participants in understanding goal-setting was also reflected in problems completing the goal-setting sheets by a small number of participants (n=8).

ID21: And I wouldn't be great for writing down things.

Q: Yeah.

ID30: Neither would I.

ID21: I have to say my writing, my English would be a disgrace where they come around and they help you fill in. (Area 2)

Occupational therapists in all eight areas reported providing individual support to participants to set goals and complete goal-setting worksheets. Difficulties completing

goal-setting sheets were attributed to problems in understanding, literacy and educational level and in a small number of cases physical health issues.

“Well, I think they struggled with the weekly goal setting definitely. I found that was, I don’t know whether that needs to be restructured, or put more simply, or maybe a different look on that. I don’t know. But they found it difficult to actually make goals.” (OT7, Area 4)

As a result of this difficulty in understanding in terms of the goal-setting concept and process, occupational therapists advised that time and support were required for individual participants to set goals. Occupational therapists indicated that generally the time provided for goal-setting was sufficient but that it was important to ensure that time was managed during the session to give goal-setting adequate time.

“We were going around during the goal-setting. We were definitely on the ball. We were trying to facilitate them. But maybe there was one or two individuals that needed a little more support.” (OT2, Area 2)

“We had a couple of people, we’d one lady with macular degeneration so we had to write it for her and read it for her and another lady who couldn’t write because of her tremor.” (OT5, Area 3)

6.6 Themes related to context

This section presents the qualitative themes relevant to the context i.e. factors external to the OPTIMAL programme that could act as an enabler or barrier to the OPTIMAL programme implementation and outcomes (Moore et al., 2015). These factors can vary by site or context. Table 6.16 presents the two themes and sub-themes which focused on enablers and barriers to implementation.

Table 6-16 Themes and sub-themes related to context

Themes	Sub-themes
Enablers to implementation	Administrative support Centrality of venue location to participants Managerial and collegial support
Barriers to implementation	Low participant numbers Resources Caseload demands and waiting lists

6.6.1 Enablers to implementation

6.6.1.1 Administrative support

The availability of administrative support and researcher support was considered to be an important factor by occupational therapists in assisting with programme organisation. In one area occupational therapists commented on the support they had from service-based administrators in sending participants reminders about the programme. Occupational therapists also commented on the support provided by the researcher in organising the materials and resources required to deliver the programme. GPs also alluded to administrative support assisting with identifying and inviting patients to participate.

“I suppose what took some of the stress off us for doing it is that you had a lot of the admin kind of bits and pieces done and having the box of manuals there to go, but you could easily do that with the right support in the team, do you know.”
(OT8, Area 5)

“Oh the occupational therapy secretary was great, every week, every Monday she would ring to remind and encourage and motivate participants to come to the next group session the next day which was invaluable, yea.” (OT1, Area 1)

6.6.1.2 Centrality of venue location to participants

The centrality of the venue location to participants' locality was viewed as a key facilitator in terms of implementation. Occupational therapists and GPs expressed concern that participants would not attend regularly if the venue was not easily accessible to participants with poor public transport links to the venue. Two GPs suggesting that provision of transport or delivering the programme within practices could increase participant engagement. Some occupational therapists commented that within their overall primary care area some teams had access to modern accessible facilities whereas other teams within the same area did not have such access.

“I think facilitating transport might make a huge difference to people. I think facilitating transport would be key to maintaining engagement.” (GP1, Area 6)

“But I definitely think this is where we need to be, the direction we need to be going in and I'll try and facilitate it as much as I can. But like, we have the facilities, it's just, it's a lot fairer for people, who are living in X, than say, people who are living in Y. I would not expect somebody to come from Y to here to attend a group. And that's where maybe we need to look at, yea there will be primary care centres built, around there, at some point. But at the moment there isn't really anywhere that you can go, to set up a group. And I don't expect somebody to come on two buses to get here. So, in ways, there are resources but they're only for certain areas.” (OT4, Area 2)

6.6.1.3 Managerial and collegial support

Another factor considered vital by occupational therapists, GPs and physiotherapists in implementing the programme was support from both management and colleagues.

“You would need people on board, you know what I mean. You would need people on board.” (OT11, Area 6)

“So you need staff that are, that get it and that’s why you need, health professionals who are interested. And who, you know, want to kind of lead on this.” (PT1, Area 5)

“I think a facilitator for patients is like a practice buy in, discussion at practice meetings, and obviously if it’s formalised as part of care there’s a bit more credibility.” (GP4, Area 8)

Support from management was viewed as important in a number of ways. Many of the occupational therapists involved reported that their managers encouraged them to be involved in the OPTIMAL study and were keen for them to deliver group-based interventions. In some areas, occupational therapy managers gave the occupational therapists protected time to research the programme and study the materials for each session.

“Our manager was happy for us to do the programme as well, which was, you know if you were trying to fight to do it, it would be a different story.” (OT10, Area 6)

“My manager would love if I did more and more and more health promotion, yeah.” (PT1, Area 5)

Occupational therapists and physiotherapists alluded to the conflicting interest for managers in tackling waiting lists whilst policy advocates for increased self-management support and chronic disease management in primary care. Managerial support was seen by both occupational therapists and physiotherapists as encouraging “buy in” (OT15) from colleagues.

“The thing is, you are always going to be overwhelmed! There is always going to be waiting lists! So yea, I do think you need a good supportive manager who is willing, because everyone is buying-in then, yea, and protects the time.” (OT9, Area 5)

“Without a doubt it is extra work, for staff on the ground and chasing and paper work and trying to keep on top of it all. Resources have to be available so managers have to see the value of it too and support that and allow staff time to develop it. So, it’s a huge piece of work really. But hopefully, there’s change within sort of the HSE and they see that you know.” (PT3, Area 3)

Whilst in some areas, occupational therapist facilitators viewed their occupational therapy colleagues as backing the OPTIMAL programme, others did not have the same experience. Some occupational therapists and physiotherapists stated that some of their colleagues lacked an interest in group and health promotion interventions.

“A colleague said to me “Oh I had a chuckle when you took that on”. That’s what they said, in other words that’s going to be a big piece of work, do you realise that, you know, on top of the work that you have. So, obviously we have to get from eleven to fifteen home visits a week. So, it was sort of a challenge to get that done as well as this. So, it would be something that I think the whole department would have to accept, as a team. And not just being left to a certain few people, for it to work.” (OT11, Area 6)

Both occupational therapists and physiotherapists who facilitated the programme felt that it was feasible to deliver the programme but indicated a shift in work practices would be required from some of their colleagues. This would ensure the work involved would be divided equally and not solely the responsibility of a few therapists.

“I suppose a bit of buy in from the team as well. So that it can be shared out in terms of the facilitation so that doesn’t always fall on the same people so buy in from the team.” (OT15, Area 8)

“...And you know the interest among the staff as well, you know ‘cos there are some people that just don’t want to run groups at all.” (OT3, Area 2)

6.6.2 Barriers to implementation

While many of the health professionals interviewed felt the OPTIMAL programme was feasible and of benefit to participants they did however highlight barriers to its

implementation as part of routine primary care practice. Three main barriers identified were: low participant numbers, resources and caseload demands and waiting lists.

6.6.2.1 Low participant numbers

The potential reasons for difficulties with referrals and recommendations regarding same was provided in Section 6.4.3. The low participant numbers recruited and poor attendance at the programme was an issue which some occupational therapists had experienced and which they anticipated could act as a barrier to future implementation.

“I think getting the numbers would be a challenge.” (OT8, Area 5)

“I suppose, again around the group numbers. Because you know, ‘cos we started off with a lot. But then, it did dwindle. Because I suppose there was kind of a big drop from the first week, to the second week.” (OT3, Area 2)

6.6.2.2 Resources

Resources in terms of sufficient funding was viewed as a potential barrier to implementing the programme in the future by all health professionals. The need for adequate funding for programme delivery including room hire, printing of participant booklets, payment to other professionals such as pharmacists and even refreshments for the tea break were identified. Pharmacists in particular noted the need to be compensated for time away from their own business to facilitate a session. Occupational therapists expressed concern that the programme components could be “watered down” without this funding.

“I guess that we would hope that there would be funding for the manuals and the resources for the group because the participants really value those. And I guess sometimes when they are translated to the HSE things can get watered down and people don’t necessarily feel they are being valued or it’s as valuable.” (OT13, Area 7)

“Hopefully, it will be resourced and whatever and that’s always a question about funding” (PT1, Area 5)

“Well you can’t do it for nothing. My kids still need to eat and go to school.”
(Pharm2, Area 7)

The availability of suitable rooms and facilities for group interventions was an issue in some areas. For example, the physiotherapist in Area 8 (PT2) reported that they had to hire rooms in order to deliver group interventions.

“I know, from going to other areas they just haven’t the resources to be able to actually hold a group, which is amazing, considering how they’re moving along, in primary care.” (OT2, Area 1)

Even in areas where group room facilities existed, there appeared to be a high demand for such spaces as they were often shared with other disciplines and services. In some areas there were difficulties in having sufficient equipment, such as chairs and a projector, and the increased time required to set up for the group as a result.

“Like I know it is a new primary care centre, but we had to be there an hour before the group to get chairs, and there was a fight over chairs, and we were robbing them from rooms, you know, and getting tables, bringing tables downstairs and stuff. It was the set-up that was the most challenging bit. That group room is likely to be booked months in advance, so you are probably not going to get that! Yea, and it is just shortage of chairs for some reason out there, for the amount of people that use the facility.” (OT10, Area 6)

Resourcing in terms of staff availability was another potential barrier to future implementation of the OPTIMAL programme. Occupational therapists and physiotherapists noted that staffing can fluctuate due to maternity, sick leave, annual leave and resignations at different time periods. There were also concerns expressed by the occupational therapists about the availability of both physiotherapists and pharmacists to facilitate their respective sessions.

“That is another barrier too it’s not always practical or possible to get other clinicians in the area to step in and help us for those sessions too you know for the physio sessions and all that. So we don’t always have those people available to do it.” (OT15, Area 8)

6.6.2.3 Caseload demands and waiting lists

Both occupational therapists and physiotherapists identified a core challenge to implementation of the OPTIMAL programme as their regular caseload demands and the need to manage and tackle waiting lists. They discussed that group-based programmes such as the OPTIMAL programme are not viewed as an essential or a core part of the primary care occupational therapy service making routine delivery problematic. The waiting lists must take priority “*Our priority has to be our waiting list*” (OT1, Area 1). At times of limited resources such as reduced staffing and resultant increased time constraints the perceived importance of delivering the OPTIMAL programme was considered to be lower. This finding is of particular interest given the reasons for primary care areas cancelling and deferring their participation in the trial as described in Section 6.2.1.

“I suppose, when you’re contending with massive waiting lists. And now, we’ve a lot more staff than we had last year. But this time last year there was about, you know, five people off at the same time. A couple of people on maternity leave. It just seemed like such a mountain to climb, to get this group going. But now this, fast forward a year. And like, we have a good cohort. And people are back from maternity leave. So, it is expected that we are rolling out these types of groups. And that we are getting involved in groups. Plus, managing the caseload like last year it would’ve been like just work on a caseload. Try and get through as much as you can. Get through the waiting list as much as you can.” (OT4, Area 2)

“I don’t think there’s enough being done at all, but it’s basically because there isn’t the resources there to do it, there isn’t the staffing to target people who are well, you know what I mean. All the target is at is either crisis management, people being discharged home, or people who have had an episode where they’ve either become frail or immobile or a fracture or whatever it is. So there definitely isn’t enough in terms of health promotion...” (PT2, Area 8)

There were differing views on whether the OPTIMAL programme was an effective use of staff time. Some occupational therapists felt delivering the OPTIMAL programme took time away from their caseload and this was an ineffective use of time if participant numbers and attendance were low. This was particularly reported as an issue by occupational therapists in Area 2. However, other occupational therapists,

physiotherapists and GPs argued that facilitating group interventions such as the OPTIMAL programme provided an opportunity to target waiting lists and individuals earlier in the trajectory of multimorbidity to maintain function and health. Indeed, a few occupational therapists reported that their service statistics or key performance indicators increased over the course of delivering the programme as delivering a group programme meant occupational therapists were providing interventions to increased numbers in a short period of time.

“You’re trying to intervene at that point in order for their conditions not to progress or impact on their functionality to such an extent. So again around health promotion and prevention, in terms of the primary care team if we could intervene with these kind of people at this time, it has a huge impact on the primary care team at a later stage when people are being referred to us at a real crisis point.”
(OT12, Area 7)

“We have been really impressed with how our primary care teams have adapted to, to the vast number waiting to see them especially, by doing classes, so the physios do back classes, the psychologists run stress classes, and these are very acceptable to our patients, so that’s why we were very excited about OPTIMAL.”
(GP1, Area 6)

“Our stats increased dramatically...It was a good use of our time, it added to our stats.” (OT14, Area 8)

6.7 Themes related to outcomes

Qualitative data also provided supplementary or complementary information about the effectiveness of the OPTIMAL programme i.e. trial outcomes. Thematic analysis resulted in the development of two themes related to perceived programme outcomes in terms of programme benefits and no programme benefits as presented in Table 6.17 below. The majority of data coded in relation to outcomes was from occupational therapy facilitator interviews and participant focus groups.

Table 6-17 Themes and sub-themes related to programme outcomes

Theme	Sub-theme
Programme benefits	Awareness of self-manager role Emotional benefits Increasing and modifying activity levels Making lifestyle changes Managing medical aspects of condition Onward referrals
No programme benefits	Already knew programme information Already living what we are learning

6.7.1 Programme benefits

6.7.1.1 Awareness of self-manager role

Occupational therapists spoke about OPTIMAL programme participants having an increased awareness of their role in self-management. Occupational therapists stated that OPTIMAL programme participants indicated that they were more in control of their health and well-being rather than having an external locus of control and being a passive recipient of care.

“What you would have found is that they were beginning to take more control or they were beginning to feel more responsible for their own health. So an awareness, I think we saw that they were beginning to just not accept everything, not this plodding along sort of attitude that we often have. They were beginning to be more objective and more analytical about ‘Okay where am I at now? What

does this mean for me? What can I do to improve my health? Where am I in this vicious circle?’ So I think you could see them becoming more in control and then the way they were talking was implying that too.” (OT6, Area 3)

Many participants described having an increased sense of control and ownership in terms of managing their health as a result of having knowledge of strategies which they could use to promote their health and well-being.

“You’re not just sitting down now and throwing in the towel, or whatever they call it. I can actually work on it, with the team.” (ID62, Area 4)

“You know it was, the idea was that we would be the captain of our own team, or you know medical professionals in our own team. That’s what I got on the first day. That this was going to give me the things I’ll need to manage my health. And it’s given me several of those. You know and I’m now the captain of my own team.” (ID77, Area 5)

6.7.1.2 Emotional benefits

Participants reported experiencing emotional benefits as a result of programme participation. Some participants discussed struggling to cope with their health conditions and experiencing low mood and anxiety prior to the programme.

“Well, I had four chronic diseases, okay. And so, they’re not visible ones and I don’t have any major physical pain. But I’ve diabetes, ischemic heart disease, anyway, enough of that. So I got into a very, very severe depression. And was not leaving my apartment, not going out.” (ID77, Area 5)

Participants described having improved mood as a result of programme participation. Occupational therapists echoed participants’ views by reporting observing improved mood among participants.

“So then when this came up I said right I’m going to go to that. It’s the best thing I’ve done because I’m definitely feeling much better in myself.” (ID122, Area 7)

“Every single person, just even their mood lifted as they were leaving the group. They were making strategies; they were striving to progress, to bring something back to each group. They were kind of invigorated by it.” (OT2, Area 1)

Both participants and occupational therapists alluded to participants having increased confidence to both cope with their health conditions and in their ability to participate and engage in activities.

“That’s what I got out of it; I got a bit more confidence, to get out even twice a week. For a bit of walking, or instead of sitting at home, on your own thinking about your illness.” (ID101, Area 5)

“They got kind of more confidence to move outside their own house.” (OT7, Area 4)

Participants discussed having increased motivation to be more active and to make lifestyle changes in an effort to manage their health.

“Well normally now before the course I’d just say ah here to hell with it, I’m going up, do you know to lie down and put on the telly and watch it but now I motivate myself differently and I just do it myself to try and get out of the house and just a bit of a change, which I thought was great.” (ID11, Area 1)

“It has motivated us I think to work harder at maintaining our health which I found great.” (ID53, Area 3)

Some participants discussed a shift in their thinking about their health. Participants discussed realising that despite their multimorbidity they did possess abilities and were capable of doing things whilst also accepting some of their limitations.

“It’s been working fabulous for us, over the last six weeks. Before the course, we were in a bit of, well I was anyway, I was in a bit of situation, where I didn’t want to do anything. Because I didn’t think I was able to do anything. But now I know I can. I mightn’t be able to do things as quick and maybe as much as I used to. But I can still do the same things.” (ID103, Area 6)

6.7.1.3 Increasing and modifying activities

Many participants discussed having increased activity levels and doing activities in different ways as a result of the programme. Increased levels of physical and leisure activities were reported by participants. Participants in all eight areas described increased levels of exercise as a result of the programme. One participant described building up her exercise over the course of the programme and completing a charity walk by programme completion which she had identified as a goal.

“The walk I never done, I tried and gave up. I’d get say from here to the coffee shop and then I’d go back. I’d say, ‘no what’s the point, what’s the point?’ And then, I was building it up and building it up. And then when I got to come on this course, the walk of hope came on. And when I started this I said that’s my achievement, on this course, I’m going to do it. I done it, I didn’t think I’d do it. I walk all the time now.” (ID90, Area 5)

Consistent with this, occupational therapists described an increase in participants’ reported participation in physical and leisure activities. Occupational therapists noted that participants were particularly focused on increasing their physical activity levels in weekly goals and seemed to be successful in doing so.

“Physical activity was a huge thing that we saw starting from week one. Even if people weren’t identifying that it was physical activity they wanted to do, a lot of people said they wanted to get out more. One gentleman got a Fitbit and he started counting his steps and he started off by aiming to do 5,000 steps a day and then it went up to 10,000 steps a day. He would have been very inactive prior to this. He would have had quite a high BMI as well. I suppose that was something that was identified as well, that people had gotten into bad habits. And they were going back to, trying to get back to their hobbies. Like one gentleman was going swimming every morning.” (OT13, Area 7)

Some participants explained that they were now recognising the importance of spending more time engaging in leisure activities such as the cinema or meeting friends. Similarly to participants, occupational therapists commented that they felt participants had an increased appreciation of the importance of leisure and social activities.

“What I found was I wouldn’t be as rigid with the housework, like normally before I’d go out I’d have to have everything done in the house and then I’d go and if I hadn’t I couldn’t go out, which was ridiculous. And it doesn’t matter if something is not done today, where Monday we went to the pictures, the 2 of us, ID131 and myself and like I mean I wouldn’t want you to see the spare room upstairs with the ironing but I don’t care!” (ID133, Area 7)

“And you know, a lot of them were getting out with friends, when they hadn’t in a long time.” (OT1, Area 1)

Some participants described modifying their daily routine and the ways in which they performed activities. Participants discussed using fatigue management strategies such as pacing, prioritising and positioning.

ID103: Yea, like don’t do too much in one day. Do it in little bits everyday.

ID106: Yea not exert yourself, don’t overdo it. Cos then that can add stress and that can add pain and so just do what you can like, yourself.

ID95: Yea pace yourself.

ID103: There’s no need to kill yourself it’ll be there tomorrow.

(Area 6)

6.7.1.4 Making lifestyle changes

The occupational therapists indicated that participants were making lifestyle changes such as improved diet and sleep routines. Participants’ comments supported these observations with participants reporting making dietary changes and changes to sleep routines.

“I have, because I’m diabetic and I’m you know, 30grams of this and 20grams of that. So, I got this idea, from the two facilitators. That to eat healthily, you have to shop healthily. So, I now have a generic shopping list that comes with me. I’ve done the research; I’ve looked at the packets, to make sure they’re below 1.5 in fat, all the things. So, now I know that if I buy X, Y and Z every week it will be right and signs of it, my blood sugars have dropped. My HB1AC is gone down.” (ID86, Area 5)

“Another person stopped having naps for so long as they felt that was actually stopping them from sleeping during the night.” (OT11, Area 6)

6.7.1.5 Managing medical aspects of conditions

Some participants and two GPs alluded to participants' improved medical management of their conditions in terms of knowledge and adherence to medication and confidence in communicating with their doctors.

“I hadn't realised how vague I had become about everything. And it just raised my awareness, like for example the medication one which I really didn't think I was going to have much to learn from that, I learned quite a bit. I also got a wakeup call as in I didn't really know for sure when was the best time to be taking stuff. And I was taking my medication at all the wrong times really. So one of my goals I gave myself was to go and look that up and I did and it was like oh my goodness, this is an empty stomach, oh my goodness this is with a meal. I was just taking it whenever, you know I was thinking I was great if I took it any time.” (ID145, Area 8)

“All the people who did it loved it and I saw big benefits in their health, especially the people with diabetes, a lot of their, I couldn't, I mean you'll have to come out actually –and that would be an interesting arm of your study, is to come out and see what their, what their visiting rate has been, what their you know, outcomes in terms of things like their HBA1C has been.” (GP1, Area 6)

6.7.1.6 Onward referrals

A positive benefit to the programme reported by occupational therapists was that some participants received onward referrals to other primary care professionals as individual needs were identified during the programme. Examples of referrals included to primary care counselling, dietician, physiotherapy groups and for individual occupational therapy.

“There was one participant – again who was kind of vulnerable to depression, I'd say had a history of depression, So we had, which is lovely here, we have this CIPC which is Counselling in Primary Care, it probably is everywhere, but

anyway, in fairness though we gave him the application and he did go to his GP, so he signed up for that and is going now which is great.” (OT9, Area 5)

6.7.2 No benefits

There were a small number of participants (n=4) who felt they didn't benefit from the programme. These participants felt they already knew the programme information and were currently managing well and employing such strategies in their daily lives.

“I said it to the girls earlier on, I haven't really got a huge amount out of it because I'm active anyway and I'm sort of taking care. But I did say that at the end of the day I'll hang on to the information and at some stage it may become relevant for me, more relevant.” (ID57, Area 3)

One participant in Area 5 commented that she did not understand the programme information.

“When I came in, like I didn't understand. I still didn't understand.” (ID87, Area 5)

From the occupational therapists' perspective, as outlined in previous qualitative findings about recruitment, some participants were considered as potentially inappropriate for the programme, particularly those who struggled to understand programme content and individuals with severe mental health conditions. However occupational therapists remarked that while some participants appeared to benefit more from the intervention they did not observe any negative impact as a result of participation.

“No, I don't think so. I think it was, there was nothing negative in the programme no. Nothing negative. I mean, for some of them the content was more difficult than for others. But I don't think there was anything negative no.” (OT4, Area 2)

6.8 Summary of process evaluation results

Figure 6.1 below summarises the key findings of the OPTIMAL process evaluation. In terms of implementation, difficulties were encountered with recruitment throughout the trial. Referral rates and sources varied by site however overall GPs and occupational

therapists were the main referral sources. Challenges with recruitment were attributed to busy caseloads, lack of suitable participants and/or resistance from the team. Suitable participants were deemed to have a particular level of function in terms of independence in daily activities and motivation to make changes. Strategies to promote future recruitment included using multiple referral pathways in terms of health professionals and community advertisement, identifying suitable patients on an ongoing basis, targeting waiting list patients and increasing awareness of the programme in the PCT.

Occupational therapists self-reported high levels of programme fidelity but variation in session duration were noted. Occupational therapists, physiotherapists and pharmacists alluded to delivering additional content not prescribed in the facilitator manual in order to tailor to participants' needs. Overall, 76% of participants attended 3 or more programme sessions although attendance rates varied by area.

Overall the intervention was positively received by all with clinicians expressing a desire for the intervention to be delivered in the future. Programme organisation, content and resources were generally viewed as acceptable by participants, occupational therapists, physiotherapists and pharmacists. Recommended changes included individualised advice, additional topics, involvement of other professionals, increasing interactive programme components and changes to the programme booklet and worksheets.

In terms of mechanisms of impact the group-based nature of the OPTIMAL programme and the goal-setting process were considered to be central to participants making behaviour changes by both participants and occupational therapists.

Regarding context of delivery barriers identified to the delivery of the intervention included low participant numbers, resources and waiting lists and caseload demands. Future implementation would require administrative support, suitable venues central to participants and managerial and collegial support.

In terms of outcomes benefits were reported for participants in terms of awareness of self-manager role, emotional benefits, increased activity levels, lifestyle changes, improved medical management and onward referrals to other professionals.

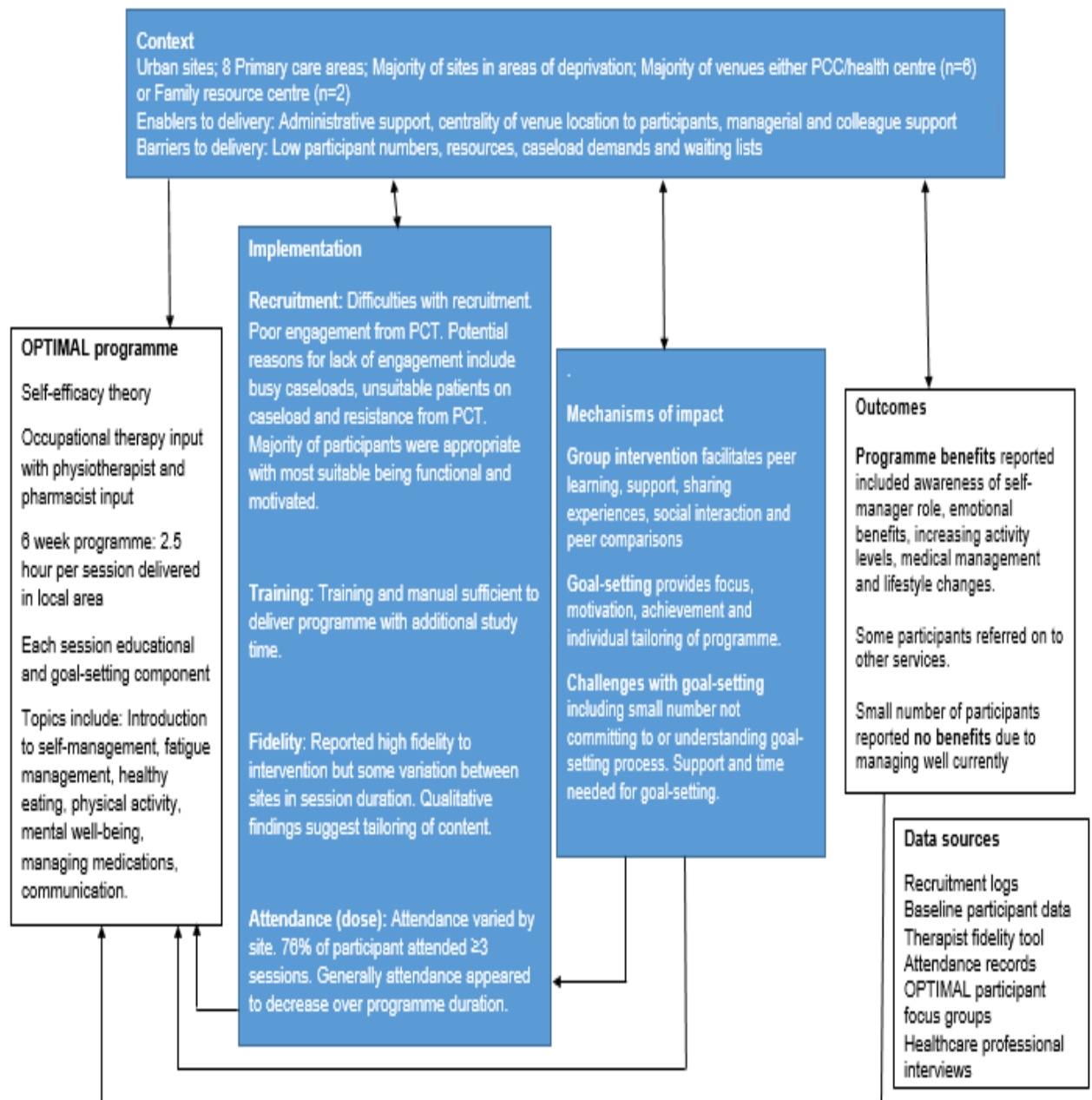


Figure 6-1 OPTIMAL process evaluation findings (adapted from Moore et al., 2014)

Chapter 7 Discussion

7.1 Introduction

This discussion chapter will review the aims of the research, summarise the main findings of the RCT and process evaluation in the context of previous research and outline the contribution the current study makes to the evidence base. This chapter will discuss the impact of the results in two main parts. In the first part the impact of the trial results and qualitative findings pertaining to participant outcomes will be discussed. The second part will explore the process evaluation results in relation to existing literature according to the three main functions of process evaluations: i) implementation, ii) mechanisms of impact and iii) context (enablers and barriers). The strengths and limitations of this study will then be considered and an assessment of the risk of bias in the OPTIMAL RCT will be provided. The impact of the findings will be outlined in relation to research, policy, service and society. The implications of the study's findings in relation to the next phase of the MRC framework, i.e. Phase IV or implementation, is considered with recommendations provided.

The overall aim of this study was to evaluate the effectiveness of the OPTIMAL programme, an occupational therapy led chronic disease self-management programme for individuals with multimorbidity in primary care, in improving health-related quality of life (HRQoL) and activity participation.

A secondary aim of this study was to conduct a process evaluation to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice and consider its potential implementation in clinical practice. The objectives to achieve this aim were:

- To describe the recruitment process including sampling of sites and recruitment sources.
- To analyse the extent to which the OPTIMAL programme was delivered as intended and how and why it varied, i.e. to explore intervention fidelity.
- To quantify the dose received by OPTIMAL programme participants i.e. programme attendance.
- To explore OPTIMAL facilitators' perceptions of the impact of the programme on participants and the delivery and acceptability of the OPTIMAL programme.
- To explore participants' perceptions of the impact, delivery and acceptability of the OPTIMAL programme.

7.2 Summary of main findings

The OPTIMAL RCT has shown that an occupational therapy led self-management support programme for individuals with multimorbidity in primary care, was effective in increasing HRQoL at immediate follow-up in intervention participants, particularly in those who are middle-aged. The intervention does not appear to have had an effect on frequency of activity participation other than in sub-groups of participants aged less than 65 years of age and those with four or more conditions.

In total 149 participants were recruited across eight HSE primary care team areas. At baseline participants were similar in terms of demographic characteristics and outcome measures. Participants had a mean age of 65.7 years with high levels of morbidity (average number of chronic conditions = 4.53) and polypharmacy (average number of medications = 8.8).

The study had a good retention rate with n=117 (79%) participants providing complete immediate follow-up data for the primary outcome measures. At immediate follow-up, adjusted ITT analysis found a significant difference in HRQoL (Adjusted EQ-VAS score; MD = 7.86; 95% CI = 0.92 to 14.80) in favour of intervention participants in comparison to controls. The results of adjusted ITT analysis of EQ-5D-3L index outcomes showed no statistically significant difference (Adjusted EQ5D index; MD = 0.04; 95% CI = -0.06 to 0.13) between intervention and control group participants at immediate follow-up. Pre-planned sub-group analysis for participants aged less than 65 years of age, using adjusted ITT models, found a statistically significant difference in HRQoL (Adjusted EQ-VAS score; MD = 13.46; 95% CI = 1.48 to 25.45) between intervention and control group participants at follow-up. No differences in HRQoL were found in adjusted sub-group analysis of participants with four or more chronic conditions between intervention and control groups at follow-up.

Adjusted ITT analysis found no significant differences in frequency of activity participation at follow-up between intervention and control group participants. However sub-group analysis of participants aged less than 65 years, using adjusted ITT analysis, found a significant difference in favour of the intervention group (Adjusted FAI; MD = 5.00 95% CI = 1.29 to 8.72) at follow-up. Sub-group analysis of participants with four or more chronic conditions, using adjusted ITT analysis, also found a significant difference

(Adjusted FAI; MD = 2.86; 95% CI = 0.31 to 5.41) between intervention and control participants at follow-up.

Per protocol analyses, for both HRQOL and frequency of activity participation, returned similar results to the ITT analyses, increasing confidence in accuracy of study results. However sub-group analyses of participants aged under 65 and for those with four or more conditions, using unadjusted models in PP analyses, found a significant difference between intervention and control participants in HRQOL (as measured by EQ-VAS) at follow-up. Sub-group analyses of participants aged under 65 and participants with four or more chronic conditions, using adjusted models in PP analyses, found a significant difference in frequency of activity participation at immediate follow-up.

The process evaluation results highlighted difficulties with recruitment and wide variation in referral sources by area. Issues were experienced with recruited sites withdrawing from the study (n=3 of the 12 sites originally agreeing to participate) and deferring study participation (n=1) to a later date. Reasons cited for sites withdrawing or deferring participation in the trial included low referrals, high attrition prior to consent and baseline assessment, loss of occupational therapy staff, low referral rate and issues with venue suitability. Difficulties encountered in recruitment resulted in the revision of power calculations and the reduction of trial power from 90% to 80%. Generally the largest source of referrals was from GPs (44%) followed by occupational therapists (26%) but as previously stated this varied widely by area. Qualitative process evaluation findings provided insight into the reasons for low referrals and uptake including primary care professionals' busy caseloads, unsuitable patients on caseloads and resistance from the PCT in delivering the programme. Recommended strategies to increase recruitment in the future identified by healthcare professionals and OPTIMAL participants included increasing awareness, use of multiple referral pathways and the review of waiting lists and caseloads.

Occupational therapists and other health professionals reported that the training and facilitator manual provided were sufficient to deliver the OPTIMAL programme. Occupational therapists reported high levels of programme fidelity but variation in session duration were noted. Occupational therapists, physiotherapists and pharmacists alluded to delivering additional content not prescribed in the facilitator manual in order to tailor the programme to participants' needs.

Overall the intervention was well received by participants and health professionals who perceived that the intervention improved participants' activity levels, emotional well-being and self-management skills. The group-based nature and goal-setting components of the programme were perceived as being important mechanisms of change. Barriers and facilitators to future implementation and effectiveness were identified and included managerial and collegial support, sufficient participant numbers, resources and caseload demands.

7.3 OPTIMAL RCT results in the context of the current evidence

This trial investigated the effectiveness of the OPTIMAL programme in increasing HRQoL and frequency of activity participation for individuals with multimorbidity in primary care settings as per Stage III of the MRC framework (Medical Research Council, 2008). This RCT builds on the previous developmental and feasibility research which developed and piloted the OPTIMAL programme (Garvey et al., 2015; O' Toole et al., 2013). The updated Cochrane review of trials of interventions for multimorbidity showed heterogeneity in interventions, inclusion criteria, outcomes, and effects, concluding that there was little evidence that existing interventions for multimorbidity improved clinical outcomes or quality of life. The review suggested that interventions were more likely to be effective if they focused on risk factors common across co-morbid conditions or on generic outcomes such as daily functioning and should target individuals with multimorbidity across the age-spectrum (S. M. Smith et al., 2016). The immediate follow-up results of the OPTIMAL trial suggests that the OPTIMAL programme, a patient-oriented intervention delivered by occupational therapists, improves HRQoL and is effective for younger individuals with multimorbidity.

Occupational therapy as a profession, has been proposed to be particularly suited to providing interventions to those with multimorbidity to improve function and quality of life. However, there has been limited high quality evidence of occupational therapy interventions for those with multimorbidity (Hand, Law, et al., 2011; Hand, Letts, et al., 2011; Leland et al., 2017; Mercer et al., 2009). One other RCT of an occupational therapy intervention for those with multimorbidity was identified in the literature, this study focused on the effectiveness of home-based interventions including assistive devices and/or environmental modifications (Gitlin et al., 2009; Gitlin et al., 2006). The OPTIMAL trial as far as the researcher is aware, is the first RCT of a group-based occupational therapy led self-management programme designed specifically for those with

multimorbidity in primary care. This intervention as a professionally led self-management programme for those with multimorbidity differs to lay-led generic self-management programmes for single and common chronic conditions. The OPTIMAL programme focuses specifically on improving activity participation and functional abilities of participants while also addressing generic self-management knowledge and skills across different conditions and the prioritisation of health problems through goal-setting. Previous studies examining chronic disease self-management programmes for people with single conditions have only presented sub-group analyses on outcomes in participants with multimorbidity attending the same programme (Kenning, Coventry, & Bower, 2014; Lorig et al., 2001; Lorig et al., 1999; Panagioti et al., 2014; S. M. Smith et al., 2016).

7.3.1 Health related quality of life

The findings of increased HRQoL, as measured by EQ-VAS, was also supported by qualitative findings with participants reporting feeling better and more confident in managing their health and engaging in their role as self-managers. These findings are consistent with results from the previous pragmatic pilot RCT of the OPTIMAL programme (Garvey et al., 2015). A difference of 7.86 points were found in EQ-VAS scores. While there is no specific data pertaining to clinically significant differences in EQ-VAS for those with multimorbidity, improvements of 8.7 points have been reported as a moderate effect size and changes of 14 points representing a large effect size in clinically ill patients (as opposed to population norms) (Roset et al., 1999). An estimation of 8 points in the EQ-VAS has been reported as a minimal clinically important difference (MCID) in patients with COPD post pulmonary rehabilitation and 8 to 12 point scores in cancer patients (Pickard, Neary, & Cella, 2007; Zanini et al., 2015). Previous studies of lay-led self-management programmes have found differing results in relation to HRQoL, as measured by the EQ-VAS (Griffiths et al., 2005; Turner, Anderson, Wallace, & Bourne, 2015). Turner et al. (2015) found a significant difference at 6-month follow-up in EQ-VAS scores in a trial of disease specific self-management programmes for those with single chronic conditions (COPD, depression, diabetes and pain). However the difference, an increase of less than 2 points, was small. In contrast Griffiths et al. (2005) found no difference in EQ-VAS scores with 82% of study participants having more than one condition. The results from this RCT are indicative of a moderate improvement in EQ-VAS scores.

Previous research has consistently highlighted the negative impact that multimorbidity has on HRQoL. Addressing HRQoL has been identified as an important aim of multimorbidity interventions as it has been associated with health and social outcomes (Fortin et al., 2004; Kanesarajah et al., 2018; S. M. Smith et al., 2016). Systematic reviews of self-management interventions for chronic disease and multimorbidity have been unable to draw conclusions about their effectiveness in improving self-rated health and quality of life (Health Information and Quality Authority, 2015; National Guideline Centre, 2016). As previously stated, results of the OPTIMAL trial indicate a moderate improvement in health-related quality of life. This result is important to consider in relation to the findings of the updated Cochrane meta-analysis of HRQoL which was completed by the authors of 3D trial. The updated review, to examine the impact of interventions for those with multimorbidity on patients' quality of life (Salisbury et al., 2018), included trials from the Cochrane review, an additional seven trials and the results of the 3D trial. The findings showed that, although different studies used a range of strategies to improve care, there is evidence that interventions for those with multimorbidity provide little or no benefit in terms of quality of life. The pooled effect estimate was very small and the confidence interval overlapped zero. However, the updated analysis showed high levels of heterogeneity, therefore the pooled effect should be treated with caution. Additionally, a funnel plot suggested the possibility of publication bias, with all of the largest trials showing no evidence of benefit whereas several small studies, some of which are pilot studies, provided positive findings. While the results of improved HRQoL in the OPTIMAL trial are noteworthy, these findings should be interpreted with caution. The OPTIMAL trial was smaller in sample size compared to the six of the eight studies included in the updated review. The results of improved HRQoL pertain to immediate post-intervention, therefore the results of 6-month follow-up analyses of HRQoL in the OPTIMAL trial will be particularly important to consider as the majority of studies included in the updated Cochrane meta-analysis had much longer follow-up periods.

An additional analysis of HRQoL was undertaken in this study, using EQ-5D index scores. No significant differences were found between intervention and control groups in adjusted ITT analysis of EQ-5D-3L index scores at immediate follow-up. However, adjusted PP analysis of participants with four or more conditions found a significant difference (MD=0.13; 95% CI <0.01 to 0.26) between intervention and control participants at immediate follow-up. The follow-up period in this study was short and longer periods of time have been required to detect changes in HRQoL, as measured by EQ-5D index scores. Furthermore, the EQ-5D index score was not a primary outcome measure, with the study powered on the basis of EQ-VAS scores. While the index scores

of the EQ-5D-3L are appropriate for conducting cost-effectiveness analyses, the use of index scores as a means of measuring change in HRQoL is more controversial due to the use of weighted profile data to calculate the scores which were developed specifically for cost effectiveness analyses (Parkin, Rice, & Devlin, 2010). The EuroQoL group recommends presenting descriptive analysis of the EQ-5D descriptive system and hypothesis testing using the EQ-VAS scores (Szende et al., 2014). Comparison of the OPTIMAL trial results with results from recently published intervention studies for those with multimorbidity in primary care, in relation to EQ-5D index scores, is discussed further in Section 7.3.1.1.

The findings of sub-group analysis suggested a significant difference in HRQoL, as measured by EQ-VAS, for participants aged less than 65 years of age. Unadjusted per protocol analysis also suggested a significant difference in HRQoL, as measured by EQ-VAS, for those with four or more chronic conditions. Only two of the areas were classified as affluent with the remaining six of the recruitment sites categorised as between marginally above average and very disadvantaged according to the 2016 Pobal HP Deprivation Index (Haase & Pratschke, 2017). Previous research has found that HRQoL decreases with multimorbidity, and is exacerbated by higher deprivation and younger age which may be linked to increased stress experienced by those in such circumstances (Lawson et al., 2013). There is a need to prioritise interventions to improve HRQoL for younger adults with multimorbidity in deprived areas (Lawson et al., 2013; S. M. Smith et al., 2016). While sub-group analyses can provide useful information to individualise patient care, criteria should be applied to determine between credible and less credible analyses. Such criteria include: i) whether chance can explain the sub-group effect; ii) if the effect is consistent across studies; iii) a small number of pre-specified sub-group analyses with accompanying rationale; and iv) pre-existing biological support (Sun, Ioannidis, Agoritsas, Alba, & Guyatt, 2014). As outlined in Chapter 3, Section 3.13, two sub-group analyses were pre-specified in the OPTIMAL trial i.e. the effects of age (<65 and ≥65 years of age) and the number of chronic conditions present (<4 and ≥4). These were included based on the literature which recommends targeting of multimorbidity interventions across the age range and evidence suggesting that those with higher levels of morbidity are at risk of poorer outcomes (S. M. Smith et al., 2016). While the results of these sub-group analyses should be interpreted with caution and further research is needed, given the study was not powered to detect these differences, they suggest that the OPTIMAL programme may be particularly effective in increasing HRQoL for younger individuals with higher levels of morbidity. It has been suggested that older individuals with multimorbidity may self-develop coping strategies over the years living with

multimorbidity (N'Goran et al., 2017). The OPTIMAL programme may provide a means of intervening with younger adults with multimorbidity to develop effective self-management strategies at an earlier stage in their illness trajectory, thus enhancing HRQoL.

Research has previously indicated that HRQoL as an outcome takes time to demonstrate improvement with some literature recommending periods between 6-12 months to evaluate quality of life in self-management programmes (Panisch et al., 2018; S. F. Wu et al., 2011). While the follow-up period reported for this PhD is short, improvements were demonstrated in HRQoL. The results of six-month follow-up analyses are not yet complete and are beyond the scope of this thesis, however it will be important to ascertain if changes in this outcome are sustained. A number of factors are associated with lower HRQoL and act as barriers to self-management in those with multimorbidity. Such factors include lower levels of physical functioning, less knowledge about medical conditions, less social activity and persistent depressive symptoms (Bayliss, Ellis, & Steiner, 2007). Some of these factors were targeted in the OPTIMAL programme and results from secondary outcomes analyses, which are being collected as part of six-month follow-up, may provide more information on whether these outcomes are associated with or influenced the effects on HRQoL.

There are a number of potential mechanisms of change for this improvement in HRQoL. Qualitative findings demonstrated that both participants and health care professionals perceived the group-based and goal-setting components of the intervention as being important in making behavioural changes. Participants particularly commented on making comparisons with others which resulted in realising their own abilities and acknowledging that while some participants were of similar health and function, others were more unwell. These processes in turn may have resulted in participants viewing their own health and quality of life in a more favourable way. The professional led nature of the intervention may have been important in fostering a supportive environment, by harnessing the benefits of peer support and interaction while ensuring each participant derived individual benefits and a sense of achievement. Discrepancy in goal attainment has been associated with lower levels of quality of life in those with chronic conditions (Kuijjer & De Ridder, 2003). Changes in patients' behaviour in relation to engagement in physical activity, social activity and social supports have been found in previous studies of chronic disease self-management behaviour to be predictive of quality of life (Cramm & Nieboer, 2015). A core component of the OPTIMAL programme was the setting of individual weekly goals in such activities and behaviours. Qualitative findings indicated

that participants did set goals in these areas and derived a sense of achievement from goal attainment and this may in turn have enhanced their perceptions of quality of life.

7.3.1.1 OPTIMAL EQ5D index findings in the context of recent multimorbidity intervention research

Two other studies published since the updated Cochrane review, the CarePlus study (Mercer et al., 2016) and the 3D study (Salisbury et al., 2018), have examined the effectiveness of interventions on HRQoL as measured by the EQ-5D index. Table 7.1 compares the EQ-5D index results of the OPTIMAL, CarePlus and 3D studies. While the OPTIMAL programme can be categorised as primarily a patient-oriented intervention, according to the EPOC, both the CarePlus and 3D studies were multifaceted comprising elements of professional, patient, organisational and financial interventions (Effective Practice and Organisation of Care, 2015). These interventions have been previously described in Chapter 2, Section 2.4. The CarePlus study was a pilot RCT, whereas the 3D study was the largest RCT ever conducted of an intervention for patients with multimorbidity in primary care. Baseline index scores were lower in the OPTIMAL study than that in the CarePlus or 3D studies. Both the OPTIMAL and 3D study found no difference between intervention and control groups in EQ-5D index scores at follow-up. While the CarePlus study found a significant difference at 6 month follow-up in favour of the CarePlus intervention, this was not sustained at 12 month follow-up (Mercer et al., 2016). As previously reported, an updated 2016 Cochrane meta-analysis on HRQoL found that interventions for multimorbidity are associated with little or no meaningful benefit in quality of life. A possibility of publication bias was noted whereby all the largest trials showed no evidence of benefit whereas several small studies, some of which are pilot studies, provide positive findings (Salisbury et al., 2018). This is particularly important to consider in the context of the CarePlus study results and indeed the OPTIMAL trial results of improved HRQoL as measured by EQ-VAS.

It is important to note that both the CarePlus and 3D study used the newly developed EQ-5D-5L while OPTIMAL used the 3L. The EQ-5D-5L includes the same questions as the EQ-5D-3L but includes five levels of responses rather than three and has been argued to be more sensitive to change. Data about the variability of the five-level (5L) version of the EQ-5D is more limited than for the three-level (3L) version, however power calculations for both the CarePlus and 3D studies used estimates from the EQ-5D-3L (van Reenen & Oppe, 2015b). The baseline index scores in the CarePlus and 3D study

were similar whereas those in the OPTIMAL study were lower. However the differences in baseline scores between studies may also be reflective of differences in the 3L and 5L measures of the EQ-5D, with the 5L reported to have higher discriminatory power. High baseline scores may mean there is less room for participants to improve, however despite participants in both the 3D and CarePlus studies having similar baseline index scores and the OPTIMAL programme participants having a lower baseline index score, only the CarePlus study demonstrated a change in index scores. The interventions all varied in duration (6 weeks to a year). Interventions may not have been of sufficient intensity or duration to effect changes. Achieving changes in HRQoL for individuals with multimorbidity may require sustained interventions over a long period of time. Both the 3L and 5L versions of the EQ-5D include measures of self-reported abilities in areas such as mobility, self-care and usual activities. The interventions examined in the OPTIMAL and 3D studies may not have sufficiently targeted these functional concerns. Alternatively, lack of changes in the index scores in both the OPTIMAL trial and 3D study may be related to the index score not being an appropriate measure of HRQoL. As previously discussed, EQ-VAS scores are preferred for hypothesis testing. Consensus should be reached on the most appropriate measure for HRQoL in studies evaluating the effectiveness of multimorbidity interventions.

Table 7-1 Comparison of EQ-5D index scores with recent intervention trials

EQ-5D index	Baseline Mean (SD)		Adjusted mean difference (95 % CI)	p-value
	Control	Intervention		
OPTIMAL				
Immediate follow-up	0.395 (0.364)	0.442 (0.354)	0.04 (-0.06 to 0.13) ^a	0.992
CarePlus study				
6 months	0.419 (0.325)	0.419 (0.318)	0.13 (0.01, 0.25) ^b	0.039
12 months	0.419 (0.325)	0.419 (0.318)	0.06 (-0.02, 0.14) ^b	0.150
3D study				
9 months	0.542 (0.292)	0.574 (0.282)	0.01 (-0.01, 0.03) ^c	0.530
15 months	0.542 (0.292)	0.574 (0.282)	0.00 (-0.02, 0.02) ^c	0.930

^a Adjusted for baseline scores, gender, age, number of conditions and area, ITT

^b Adjusted for baseline score, age, gender and Hospital Anxiety and Depression Scale caseness, ITT

^c Adjustment for baseline measures of the outcome, and stratification (area) and minimisation (practice deprivation and list size) variables, ITT

7.3.2 Frequency of activity participation

This RCT found no significant differences between intervention and control group participants in frequency of activity participation. Interestingly, adjusted sub-group analysis of participants aged less than 65 years of age found a significant difference in frequency of activity participation in favour of the intervention group at follow-up. Adjusted sub-group analysis also suggested significant differences for those with four or more chronic conditions in favour of intervention participants at immediate follow-up. These findings are similar to the sub-group analyses of HRQoL. However, as with findings pertaining to HRQoL, it must be noted that the study was not adequately powered to detect differences in sub-groups and further research is required to explore these findings in these sub-groups and corroborate these findings (Sun et al., 2014).

The OPTIMAL programme has a specific focus on improving activity participation and function of participants and is delivered by occupational therapists for whom the promotion of health and well-being through occupation (activity) is at the core of the profession. Outcomes pertaining to activity participation have not traditionally been examined in detail in previous research of self-management interventions (Augustine et al., 2011). The reasons for the overall non-significant finding in frequency of activity participation is important to explore. This result differs to those found in the pilot RCT which found a significant improvement in frequency of activity participation for the intervention compared to the control group. However the previous study's findings were limited by its small sample size (Garvey et al., 2015). It is important to note that participants in the current study had baseline FAI total scores which were approximately five points higher than baseline scores in the pilot RCT. This is despite participants in both studies having similar demographic characteristics in terms of age and number of chronic conditions (Garvey et al., 2015). This suggests that participants in this study may have had a higher level of functioning and consequently less room to improve as a result of the intervention.

The findings in this RCT are consistent with a review conducted by the National Guideline Centre which found very low quality evidence of improvements in functioning and participation in previous studies of self-management interventions with those with multimorbidity (National Guideline Centre, 2016). It is important that outcomes pertaining to function and participation are explored in future high quality studies of interventions for multimorbidity. Improvement in such outcomes are a purported aim of self-management interventions in terms of role management and a key priority for those with

multimorbidity (Lorig & Holman, 2003; Noel et al., 2005). Outcomes pertaining to activity participation and function are included as part of the recommended core set of outcomes for multimorbidity research (S. M. Smith et al., 2018).

The results relating to activity participation contrast to the findings of qualitative analysis which found that participants perceived benefits as a result of the OPTIMAL programme in increasing and modifying activities. The follow-up period may have been too short to detect a difference in frequency of activity participation. However the results of sub-group analyses suggest that those under 65 years of age and those with higher levels of morbidity may have increased their activity levels. Perhaps those with younger multimorbidity and those with higher numbers of conditions were initially less active in social and community activities and thus had more room to improve. Such individuals may have had more motivation to increase activity participation as a result of comparisons with their peers who were active.

One of the underlying values of occupational therapy is the importance of engaging in valued activities to promote health and well-being (American Association of Occupational Therapy, 2014). This was emphasised through the programme's content and goal-setting component. Participants may have been engaging more in valued activities as opposed to increasing overall activity levels. Participants also reported modifying activities and routines for example using fatigue management strategies such as planning, prioritising and pacing which may be indicative of modified activities and routines as opposed to overall increases in activity levels.

Again, the results of 6-month follow-up will be important in determining if participants increased their activity levels and if changes made as a result of the programme are sustainable. Other secondary outcomes, such as the NEADL and COPM focus on other dimensions of activity participation and function such as independence and occupational performance and satisfaction. These outcomes are being collected as part of six-month follow-up.

7.4 Process evaluation results in the context of the current literature

The process evaluation was guided by the MRC guidance on process evaluations and aimed to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice (Moore et al., 2015). The evaluation helps us to understand implementation, the mechanisms through which the OPTIMAL programme did and did not produce change, and the role of context in shaping implementation and effectiveness.

7.4.1 Implementation

The process evaluation provided rich quantitative and qualitative data that highlighted how the OPTIMAL programme delivery was achieved in terms of training and resources, what was delivered in terms of fidelity, dose and adaptations made to the OPTIMAL programme. Data pertaining to recruitment and reach was also explored.

7.4.1.1 Training

Training given was outlined in Chapter 4, Section 4.4.2, and participating healthcare professionals perceived this training and materials provided to support delivery of the OPTIMAL programme to be useful and adequate with some additional study time. Insufficient training has been previously identified as a barrier to successful delivery of self-management interventions (Jordan & Osborne, 2007). The training appears to have adequately prepared professionals to deliver the OPTIMAL programme as intended as high levels of fidelity were reported across sites.

Other popular chronic disease self-management interventions such as the Stanford chronic disease self-management programme and the Flinders programme require facilitators to engage in more intensive training (Lawn & Schoo, 2010). Interventions which require health professionals to attend extensive training reduces clinical time and increases costs. It appears that the OPTIMAL programme is generally in keeping with professionals' existing knowledge and skills and requires minimal resources in order to train healthcare professionals. A strength of this study is the use of practicing primary care occupational therapists rather than the use of research occupational therapists.

7.4.1.2 Fidelity

Occupational therapists self-reported high levels of programme fidelity. The training and facilitator manual were provided to ensure consistent standards regardless of the various sites and programme facilitators involved. There was no setting of a priori cut-off criterion for measurement of good fidelity. However variation in session duration between sites was noted. Additionally qualitative data suggested that some programme facilitators delivered additional content not prescribed in the facilitator manual in order to tailor the programme to meet participants' needs.

The MRC guidance on process evaluations recognises the challenges between maintaining fidelity and the degree of flexibility or tailoring permitted in the evaluation of complex interventions in multi-site trials (Moore et al., 2015). The guidance suggests that pragmatic evaluators must accept that interventions will be adapted in different contexts and that such adaptations should be monitored in order to understand why the adaptations took place and if they influenced the functioning of the intervention (Moore et al., 2015). Toomey, Matthews, and Hurley (2017) suggested three factors should be considered as influencing fidelity in complex behavioural change interventions including provider, participant and programme factors. In this study fidelity may have been influenced by professionals reporting that the OPTIMAL programme was generally within their existing knowledge and skill-set.

It appeared that group size, dynamics and individual participant needs may have been influential in deviations from the intervention protocol. For example in areas where group size or attendance were low, this may have resulted in sessions being of a shorter duration as there may have been less opportunity for in-depth peer discussion and learning. Conversely, groups with positive dynamics and interaction could result in enhanced and longer discussions.

A criticism of the Stanford chronic disease self-management intervention is that the highly structured protocol used to deliver the intervention makes it difficult to address individual learning needs, learning styles and learning speeds (Lawn & Schoo, 2010). Such prescriptive approaches while ensuring fidelity to the programme aims and content may negate tailoring the intervention to meet the specific needs of the group. For example participants and therapists in some areas described literacy problems resulting in participants not completing programme worksheets and goal-setting sheets. This was

highlighted as a potential issue in training and facilitators were encouraged to be flexible and adapt accordingly to these needs.

Existing qualitative research highlights that those with multimorbidity and healthcare professionals involved in the care of individuals with multimorbidity have expressed a strong desire for interventions which are multi-dimensional, patient-centred and tailored to individual needs and priorities (Noel et al., 2005; Noël et al., 2007; Sevick et al., 2007). An advantage of the OPTIMAL programme is that the programme is delivered by qualified professionals. Their professional knowledge and skills should equip them to use their clinical reasoning skills to address the unique needs of the group and issues as they arise over the course of the programme. Such queries or issues may not be directly addressed in the facilitator manual or programme content but could be relevant to self-management and activity participation. It was evident from the qualitative findings that issues not explicitly covered in the programme arose organically during peer discussion and interaction, for example falls prevention. A toolkit of resources on additional topics relevant to self-management and activity participation in multimorbidity could be developed to address additional issues not covered in the core programme content as appropriate. A recently published Taxonomy of Everyday Self-management Strategies (TEDSS) could provide a useful framework to develop resources for this toolkit. This TEDSS framework details strategies for role, emotional and medical management divided into five goal-oriented domains (internal strategies, social interaction strategies, activities strategies, health behaviour strategies and disease controlling strategies), and two additional support-oriented domains (process strategies and resource strategies) (Audulv, Ghahari, Kephart, Warner, & Packer, 2018). Taking such an approach or adaptation to the OPTIMAL programme would need to be evaluated. Furthermore, clinicians need to consider onward referrals to other professionals and programmes if the additional issues are outside the scope of a self-management intervention.

Finally, programme factors (availability of resources and materials) did not appear to negatively impact fidelity (Toomey et al., 2017). Resources and materials were prepared, organised and funded by the researcher as part of the research grant. In this study facilitators commented positively on the programme resources and reported such resources to be beneficial, enhancing programme delivery.

7.4.1.3 Recruitment

7.4.1.3.1 Profile of recruited participants

Recruited OPTIMAL participants in this RCT appeared to be generally younger older adults than many of the existing multimorbidity trials (S. M. Smith et al., 2016), with a mean age of 65 years. The majority of participants were female, lower educational status and high levels of morbidity (with a mean of four chronic conditions). As previously discussed only two of eight primary care team areas in the study were classified as affluent with the remaining six areas classified between marginally above average to very disadvantaged according to the Pobal HP deprivation index (Haase & Pratschke, 2017). The profile of participants in the current study differs from that reported in previous self-management research with the majority of participants being of a higher socio-economic status, older adults and female (Greenhalgh, 2009; Horrell & Kneipp, 2017). The Cochrane review of multimorbidity interventions highlighted that the majority of existing interventions target older adults and emphasised the need to target younger adults with multimorbidity and those in deprived communities (S. M. Smith et al., 2016). The findings of increased HRQoL, as measured by EQ-VAS, as result of the OPTIMAL programme given the profile of participants is promising. Sub-group analyses indicating that younger participants and those with higher levels of morbidity may benefit in terms of both primary outcomes warrants further investigation.

7.4.1.3.2 Appropriateness of recruited participants

Qualitative findings indicated that the majority of participants were viewed as appropriate for the programme by both healthcare professionals and participants. The most suitable participants were described as having a certain level of functional independence and the motivation to make changes. It may be that participants with higher levels of function and motivation attended and engaged more with the intervention as they did not face the same physical and emotional barriers to participation. This in turn may have influenced healthcare professionals' perceptions of the most suitable or appropriate participants. Previous research provides support for this with individuals with multimorbidity with higher physical function twice as likely to attend a chronic disease self-management intervention compared to those with lower physical function (Dattalo et al., 2012).

It is important to consider whether those who required intervention and could benefit most were being targeted for the OPTIMAL programme, particularly in light of the high baseline scores in the FAI. A balance is required in terms of recruiting those who could benefit from the OPTIMAL programme and not targeting those who have deteriorated to a level where they will not benefit. This requirement differs to other interventions for those with multimorbidity, such as those evaluated in the 3D study, as OPTIMAL requires active patient engagement in terms of goal-setting, review, group discussion and activities in order to make lifestyle and behaviour changes (Salisbury et al., 2018). The heterogeneous nature of the multimorbidity population means that participant selection for intervention, in terms of ensuring external validity while at the same time demonstrating effectiveness, is a key issue (S. M. Smith et al., 2013). Research on moderators in terms of those who benefit the most from self-management interventions has been inconclusive with some suggesting that individuals with multimorbidity with depression, lower self-efficacy and lower function benefit the most while others have found no consistent moderating effects (M. Harrison et al., 2012; Reeves et al., 2008; Ritter, Lee, & Lorig, 2011). Self-management interventions aim to prevent deterioration of health through provision of strategies to mitigate ill health and manage chronic conditions, hence early provision of such interventions is useful (Health Service Executive, 2017). Previous studies of chronic disease self-management interventions have recruited more motivated individuals in better health which has been mainly attributed to the voluntary nature of recruitment used in these studies (Brady et al., 2013; Nolte, Elsworth, Newman, & Osborne, 2013). The majority of study participants were recruited via health professionals in this RCT. It may be possible that healthcare professionals were gatekeeping by not approaching or inviting participants they deemed as too ill or disabled to participate. Additionally transport issues may have meant that some eligible participants who were less well and less mobile chose not to take part in the study. Treatment burden may have also resulted in eligible individuals declining to participate in this study i.e. that the OPTIMAL programme itself represented an excessive burden for individuals with multimorbidity, alongside their burden of illness.

However, healthcare professionals in some sites commented on a mixed profile of participants in terms of age, functional status and conditions. Previous research suggests that self-management groups which are heterogeneous in terms of age, conditions and functional status may face difficulties in engaging and retaining participants and managing peer comparisons (Hudon et al., 2016). However this did not appear to be the case in this intervention with many participants reporting positively on the dynamics within the group in terms of learning, support and social interaction.

Information about the numbers of individuals who declined to participate and their reasons for not participating were not collected in this study. Further research is required to determine which participants benefit most and should be targeted for the OPTIMAL programme. This may inform recruitment methods in the future for example whether cut-off scores on baseline functional outcome measures should be used. If further large scale research corroborates findings of improved outcomes as a result of the OPTIMAL programme for younger individuals and those with four or more conditions, this may provide a way to target programme recruitment for those most likely to benefit. It may also provide a selling point to both healthcare professionals involved in referring participants and eligible participants by marketing the programme towards younger individuals and those with higher levels of morbidity.

7.4.1.3.3 Recruitment difficulties

The process evaluation results highlighted difficulties with recruitment, this resulted in the RCT's power being reduced to 80%. In other studies of self-management interventions the number of participants per group ranged from 8 to 15 (G. Foster, Taylor, Eldridge, Ramsay, & Griffiths, 2007; Griffiths et al., 2005). In this study the number of participants per group in each site ranged from 7-15 participants. This was a pragmatic parallel RCT with referral to the study designed to reflect current referral pathways for primary care services in Ireland. The use of standardised referral pathways has been recommended to foster integration of programmes within health systems and continuity of care (Jordan & Osborne, 2007). The previous pilot RCT also experienced difficulties with recruitment (Garvey et al., 2015). Difficulties with recruitment have also been reported in previous trials of chronic disease self-management programmes in primary care settings with both GPs and other health professionals being found to be low sources of referrals (Horrell & Kneipp, 2017; A. Kennedy, Gask, & Rogers, 2005; A. Kennedy, Rogers, et al., 2005; Packer et al., 2012). It is important to note that while the study was pragmatic, it was a trial and had time constraints for programme delivery and study completion. Implementation and bedding down of a new intervention takes time for clinicians to become familiar with it. Clinicians receiving positive feedback from patients who have participated in the intervention could increase professionals' familiarity with the programme and increase referrals over time.

7.4.1.3.4 Referral sources

Overall, GPs and occupational therapists were the highest source of referrals to this study, referrals from other professionals in HSE PCTs were generally poor. However it is important to note that referral sources did vary by site. GPs were the overall highest referrer in this RCT with this finding differing to previous studies of self-management interventions whereby GPs were found to be poor referrers (Packer et al., 2012). It is important to acknowledge that in pragmatic trials additional professional time and enthusiasm are often provided (Pinnock et al., 2014). The researcher in this study was affiliated with an academic GP department and this may have also supported GP engagement in the study. Furthermore, patients with multimorbidity form a large portion of Irish general practice (Glynn et al., 2011). This may have increased the relevance of the intervention and study to the GPs, however a large number of GP practices who were invited to participate did not respond or chose not to participate and data is not available exploring their perspective given this lack of participation. It is well documented that Irish general practices are currently facing difficulties due to high workloads (Darker et al., 2015; Teljeur, O'Dowd, Thomas, & Kelly, 2010). The renegotiation and revision of GP contracts may support chronic disease management and involvement in PCTs which could increase referrals to programmes such as OPTIMAL in the future (Darker et al., 2015). A study of recruitment for a trial of chronic disease self-management for older adults with multimorbidity through general practices found that minimizing the impact of the research on the practices' day-to-day operations and engaging general practitioners in the research helped the trial reach recruitment targets (Reed, Barton, Isherwood, Baxter, & Roeger, 2013). This was achieved through research staff assisting GPs to identify eligible patients through electronic practice registers and provision of financial incentives for identification of patients. It was not possible to employ such strategies in this study due to resource and financial constraints.

GPs in this study reported that they found the referral process to be straightforward but some expressed disappointment at the low level of uptake among the patients approached. Endorsement of self-management interventions for those with multimorbidity in primary care by general practitioners alongside expectation of personal benefit and altruism are important factors in patients' decision to participate (Reed et al., 2013). Reasons for participation did not emerge as a main theme in participant focus groups so it is not possible to determine if such factors influenced participation in this trial.

Occupational therapists were the second highest source of referrals in this study, however there was variation between sites in the number of referrals from occupational therapists. Some occupational therapists reported that many of the patients on their caseload were unsuitable for the OPTIMAL programme due to significant functional decline and an inability to attend interventions outside of their home. This is in line with previous research of occupational therapy in primary care, including Irish primary care settings, which suggest that much of the occupational therapy caseload is focused on high-risk patients' home safety and functional independence (Tinnelly & Byrne, 2016; Turcotte et al., 2015).

7.4.1.3.5 Reasons for recruitment difficulties

Qualitative results suggested that difficulties with recruitment were due to busy caseloads, unsuitable patients on caseload and resistance from the team. Previous research has cited similar factors limiting recruitment including lack of engagement of GPs and healthcare professionals due to time constraints, work practices and fragmented health service delivery including poor communication and multidisciplinary working within PCTs and other services (Jordan & Osborne, 2007; Newman et al., 2004).

The qualitative results suggest that health care professionals viewed low referrals as being associated with work demands and the nature of their caseload. The literature supports such assertions with Irish primary care professionals reporting challenges with large caseloads and waiting lists (Kelly et al., 2016; N. Kennedy et al., 2015; Tierney, O'Sullivan, et al., 2016; Tinnelly & Byrne, 2016). Professionals appear to find it difficult to balance the desire to provide interventions such as the OPTIMAL programme while addressing waiting lists for those requiring more urgent interventions (Tinnelly & Byrne, 2016).

Resistance from the team was another issue that was raised by some as associated with low referrals. This may be reflective of the aforementioned workload demands, waiting lists and difficulties with multidisciplinary team working reported in Irish primary care literature (N. Kennedy et al., 2015; Tierney, O'Sullivan, et al., 2016). The low level of referrals from HSE PCT members in some areas, other than occupational therapists, likely reflects local context in terms of staffing and team dynamics. Of particular interest in this study is that no referrals were received from primary care physiotherapists in any

of the eight primary care team areas involved. This finding is somewhat surprising and warrants further exploration. Recent research on the role of physiotherapists in primary care in Ireland suggests that the profession whilst valuing group-based interventions viewed their involvement as limited due to resource allocation and role conflicts (French & Galvin, 2017). Difficulties with PCT working were also identified and waiting lists varied between areas (French & Galvin, 2017). These findings are similar to the difficulties faced by primary care occupational therapists in Ireland. Physiotherapists had a role in the OPTIMAL programme with some of the physiotherapists interviewed in this study reporting that they would have suitable patients on their caseload. It is difficult to ascertain the reasons for non-referrals but it may be indicative of busy caseloads and perceived conflicts regarding ownership and roles in self-management intervention.

As aforementioned, evidence suggests that there are difficulties with effective team working in primary care teams in Ireland (A. Kennedy, Vassilev, James, & Rogers, 2016; O'Reilly et al., 2017). Recruitment in this study involved a certain level of interdisciplinary team working. The variation in referral sources between areas may be indicative of difficulties with team functioning. Such challenges need to be addressed if interventions such as OPTIMAL are rolled out in the future as they will require healthcare professionals to work together to identify and refer on as appropriate to provide interventions to those who need it in order to address needs in a holistic manner. An important factor to address in PCTs may be team leadership, currently this role is not formally established in Irish PCTs (N. Kennedy et al., 2015). This means that there is no one setting direction for the team. This may partially explain the lack of referrals from other primary care professionals for the OPTIMAL programme. Other primary care team professionals may have viewed the programme as solely the responsibility of the occupational therapists rather than the whole team and something which patients on their caseload could benefit from.

Problems with recruitment reported in other self-management research included a low profile and lack of awareness of self-management programmes within the health system and broader community and uncertainty among healthcare professionals of the evidence of programme benefits (Jordan & Osborne, 2007). Qualitative findings indicated that professionals were aware of the programme and efforts were made to increase awareness of the study among GPs and the PCT through personal communications and presentations to practices and PCT meetings. This is in line with recommended strategies to promote engagement by professionals including provision of training, education and dissemination to health care professionals about self-management

interventions (Jordan & Osborne, 2007). As previously stated, embedding the OPTIMAL programme into routine primary care practice may take time and referrals from the PCT could increase with familiarisation through dissemination of evidence and feedback from participants previously involved. The recent publication of the HSE Self-Management framework and the appointment of self-management coordinators in each HSE CHO may assist with this embedding. The role of these self-management coordinators includes mapping and identifying gaps in existing self-management support services; developing local directories of services and promoting engagement with self-management services by healthcare professionals and individuals with chronic conditions (Health Service Executive, 2017).

7.4.1.4 Attendance (dose received)

Intervention participants in this study attended a mean of 3.9 (SD=2.2) of the six sessions. However, as outlined in the results, average attendance varied by site. While 59 participants (76%) attended 3 or more programme sessions, 11 participants (14%) did not attend any sessions. Low attendance coupled with low number of participants recruited in some sites posed difficulties and was reported by some occupational therapists in interviews as a barrier to future implementation of the OPTIMAL programme. Attendance was also an issue in the pilot RCT of the OPTIMAL programme, however attendance in this trial appears to be somewhat better than that previously observed (Garvey et al., 2015). The findings of per protocol analyses (including intervention participants who attended three or more sessions) produced similar improvements to ITT analyses but increases in HRQoL were of a slightly greater magnitude, which suggests a dose-response relationship. Reported attendance in previous studies of chronic disease self-management interventions have varied. A Cochrane review of lay-led self-management programmes reported similar attendance to this trial. The review found that between 51% and 87% participants attended at least half the self-management programme sessions, and between 8% and 29% never attended any sessions (G. Foster et al., 2007). A number of factors may have affected attendance. Barriers to attendance at self-management interventions reported in other studies of self-management interventions included poor health, fatigue, medical appointments and scheduling conflicts as reasons for non-attendance (Hudon et al., 2016). A limitation of this study is that it is not possible to determine reasons for non-attendance as data were not collected on this and therefore it is difficult to provide recommendations to maintain attendance. One possible suggestion is the use of an

orientation session prior to programme commencement to ascertain and encourage commitment, those who are not fully committed may opt out at this stage (Jiang et al., 2015). However, while this may be more efficient it may also increase the time and resources required to deliver such programmes.

7.4.1.5 Perceptions of programme delivery and content

7.4.1.5.1 Programme duration

The majority of participants described the six week programme duration and the session duration (2½ hours) as being acceptable. This duration is similar to other chronic disease self-management interventions such as the Stanford CDSMP (Lawn & Schoo, 2010). Some participants expressed a desire for an extended programme duration. Primary care occupational therapists face challenges with work and caseload demands with the literature reporting limited involvement as a result in group-based interventions (Tinnelly & Byrne, 2016; Wood et al., 2013). Therefore, it is perhaps unsurprising that the majority of occupational therapists were not in favour of extending the programme further. In the first pilot study of the OPTIMAL programme, qualitative findings were similar with participants viewing the duration as acceptable but desiring an extended programme (O' Toole et al., 2013). A small number of participants recommended a follow-up or booster session. Participants in other qualitative studies of chronic disease self-management studies have made similar recommendations due to concerns about their ability to maintain behaviour changes without the group support (Barlow, Bancroft, & Turner, 2005). There is limited research on the effectiveness of such booster sessions on outcomes (Quinones et al., 2014). Extending the programme duration or inclusion of booster sessions increases the clinical resources and time commitment required from both healthcare professionals and participants. Increased resources would need to demonstrate enhanced clinical benefits and maintenance of acceptable participant attendance.

7.4.1.5.2 Occupational therapists as facilitators

Participants reported that the occupational therapists created a positive group environment and provided practical and emotional support. Such support was important

in enabling participants to engage in the group activities but also to foster a positive group dynamic which enabled peer discussion, learning and support. There are potential risks that participants may feel isolated, perceiving themselves to be dissimilar or worse off than their peers in group-based interventions (Embuldeniya et al., 2013; Rogers, Gately, Kennedy, & Sanders, 2009). Skills are required in managing such group dynamics, including individual group member roles, in order to prevent negative social comparisons (Rogers et al., 2009). Both occupational therapists and other healthcare professionals viewed the intervention as being within their expertise and skill-set. Occupational therapists have training in group interventions. While peer leaders offer many potential benefits in acting as models, health-care professionals with their knowledge and skills can act as powerful models, foster opportunities for peer learning and modelling and address factual issues related to an illness. Occupational therapist facilitator training should continue to emphasise the importance of a facilitation style which is participant centred, promotes autonomy, encourages peer support and provides positive feedback (Hughes et al., 2017; Sharma, Wallace, Kosmala-Anderson, & Turner, 2013). The suitability of occupational therapists to lead the OPTIMAL programme within PCTs is discussed in further detail in Section 7.4.3.1.

It is noteworthy that some occupational therapists recommended the inclusion of a dietician to facilitate content related to healthy eating. This is consistent with other research which examined the role of primary care occupational therapists in health promotion interventions whereby occupational therapists expressed reluctance and a lack of knowledge in providing interventions pertaining to the adoption of a healthy diet (Turcotte et al., 2015). It is interesting to note that in qualitative data some participants did report making lifestyle changes in relation to their diet with only a small number of participants recommending inclusion of a dietician in future interventions. It is also important to recognise the scope of occupational therapy practice and that individual participants may require specialist advice in relation to healthy eating. This should be recognised and onward referrals to dieticians made as appropriate. The inclusion of a dietician should be considered in future studies of the OPTIMAL programme however this may prove difficult as not all primary care teams in Ireland currently have access to a dietician (Mc Hugh, O'Mullane, Perry, & Bradley, 2013).

7.4.1.5.3 Professional versus lay facilitators

There is limited research examining the effect of group facilitators in chronic disease self-management interventions on participant outcomes (Mills et al., 2014). The popular Stanford CDSMP is mainly delivered by lay leaders, although some programmes use a combination of professional and peer leaders (Lorig, Hurwicz, Sobel, Hobbs, & Ritter, 2005; Lorig et al., 1999). The use of lay leaders has been argued to be easier to implement as lay leaders are more readily available, are cheaper and proposed to be more effective models of self-management than healthcare professionals (Lorig & Holman, 2003). These assertions are not supported by research evidence with limited evidence comparing the effectiveness of lay led and professional interventions (Griffiths et al., 2007). However both professional and lay leaders in the Stanford model have required up to 20 hours of training and ongoing support to deliver the programme. As previously discussed occupational therapists in this study received a half-day of training to deliver the OPTIMAL programme and felt adequately prepared to deliver the programme. Furthermore difficulties have been encountered with implementing lay-led interventions in primary care (Jordan & Osborne, 2007). These lay led interventions have been criticised as having modest effects with the results being disappointing in comparison to other professionally led programmes that have elements of chronic disease management, such as cardiac and pulmonary rehabilitation which have been shown to be effective (Health Information and Quality Authority, 2015). This is the first study to examine participant and professional perceptions regarding delivery of an occupational therapy led self-management programme for multimorbidity in primary care.

7.4.1.5.4 Programme content

Both healthcare professionals and participants stated that the programme content was relevant. The programme content aligns well with the challenges of self-management identified by those with multimorbidity who report difficulties managing physical and emotional symptoms such as depression, pain, and fatigue and accessing healthcare and communicating with health care providers (Liddy et al., 2014). The importance placed on addressing function rather than managing the medical aspects of conditions is a consistent priority of those living with multimorbidity across many studies (Cheraghi-Sohi et al., 2013; Liddy et al., 2014; Noel et al., 2005). Of interest some participants

indicated that the programme content did not necessarily instil new knowledge or learning but rather focused on reinforcement and implementation of this knowledge into daily routines. This is consistent with findings in other studies which found that self-management interventions while reinforcing existing knowledge enabled participants to translate this knowledge into practice (Barlow, Bancroft, et al., 2005).

Participants and health professionals were mostly positive about content and delivery of the respective sessions delivered by the physiotherapist and pharmacist, however some variation was noted between sites. In relation to the “Maintaining Physical Activity” session participants reported enjoying the session and the practical exercise demonstration component. Both participants and healthcare professionals recommended that time for exercise demonstration and practice should be increased in the session. Sessions pertaining to physical activity have been reported to be particularly valued and enjoyed by participants in chronic disease self-management programmes (Dongbo, Ding, McGowan, & Fu, 2006). Both physiotherapists and participants commented on the mixed abilities and capacity in the group for exercise and the need to account for this within the session. This issue has been noted in the literature with recommendations that self-management programmes need to consider the diversity of abilities including prior exercise experience, level of physical functioning and beliefs about exercise (Barlow, Bancroft, et al., 2005). In order to meet the needs of such a heterogeneous group of participants it is important to adapt a broad view of exercise to include everyday activities and address cognitive components to exercise including barriers, benefits and motivations (Barlow, Bancroft, et al., 2005). It is noteworthy that many participants reported setting goals around physical activity and increased physical activity as a result of the programme. However no specific self-report measures of physical activity or objective measures of physical function components were conducted.

Participants’ experiences of the “Managing Medication” session were mostly positive, with participants reporting that the pharmacist eased their concerns about medication and increased their awareness of the availability of local community pharmacists to provide medication support. All participants in this study were taking multiple medications with a mean number of 8 medications and previous research indicates this is a concern for individuals with multimorbidity (Noel et al., 2005; Noël et al., 2007). Content on managing medication has been reported as useful in other self-management intervention studies (Dongbo et al., 2006). A unique feature of the OPTIMAL programme is that the programme is professionally-led which enables participants’ queries to be addressed. However a small number of participants and occupational therapists reported that some

pharmacists were reluctant to answer specific questions and may have been inexperienced in facilitating a group-based intervention. It may be that some pharmacists were reluctant to answer questions if the participant was not under their direct care. An important aim of this session was to increase participants' awareness of their pharmacist as a resource to address individual concerns. This should be reinforced in future programmes. While pharmacists were advised of common conditions present in the group prior to the session, it should be considered if participants' questions could be submitted to the pharmacist in advance of the session. This would allow the pharmacist to tailor the session and address queries accordingly. Pharmacists were provided with the facilitator manual but did not attend formal training. Pharmacists reported that the content was easy to deliver and within their professional expertise, however training around delivering group interventions could be considered in future. Occupational therapists should also be advised to provide support to pharmacists in managing group dynamics. The process evaluation highlighted the need for sufficient remuneration and mechanisms to support pharmacy involvement in delivering the OPTIMAL programme.

Qualitative data indicated that participants and healthcare professionals valued the provision of information about local resources. Provision of such information has been included in other chronic disease self-management interventions and is worthwhile as self-management is directly affected by factors related to one's local community and resources (Franek, 2013; Grady & Gough, 2014; Lawn & Schoo, 2010). Facilitating the use of local resources may assist participants in maintaining changes and there was evidence from the qualitative data that some participants had joined or were planning to join local groups and other professionally led lifestyle programmes post-intervention. Community participation in primary care is enshrined in Irish primary care policy, however it appears that such participation is limited by current challenges in functioning of PCTs and a lack of clarity on community participation (Tierney, McEvoy, Hannigan, & MacFarlane, 2018). Making links with local community partners such as family resource centres would enable healthcare professionals to advise patients of groups and projects being delivered in these centres and reciprocally for resource centre users to receive support from the PCT or engage in interventions such as OPTIMAL.

7.4.1.5.5 Programme resources

Both participants and professionals valued the resources (programme booklet, relaxation CD, exercise booklet and other HSE health promotion materials) provided in the

programme but reported varied use of these resources. Resources such as the programme booklets and relaxation CDs are commonly provided in other self-management interventions, however there appears to be limited research on participants' perceptions and use of these (Dongbo et al., 2006; Lawn & Schoo, 2010). Some participants and healthcare professionals recommended simplifying the booklet, reducing the overall content and increasing the print and font size of programme materials. It is noteworthy that the majority of participants (38%; n=56) had primary school education. In light of this participant profile and recommendations in qualitative data, it would be important that all written programme materials should be reviewed to ensure they are literacy friendly. It is important that the interactive nature remains at the core of the programme rather than information provision. This is supported by qualitative data in which both participants and healthcare professionals considered interaction and discussion as central to peer learning, modelling and ultimately behaviour change. Furthermore a recent systematic review of the effectiveness of self-management interventions for those of low income and low health literacy found that effective interventions tended to focus on problem-solving, goal-setting and resource utilisation (Schaffler et al., 2018).

7.4.1.5.6 Disease specific versus generic programmes

Whilst generally programme content was perceived as sufficient, a range of recommendations for additional content were provided by participants. This variation in topics may reflect the individual needs of participants in the groups and a desire for individual and disease-specific advice. While facilitators should be flexible in tailoring programme content to meet the unique needs of participants in the group, once relevant to self-management and activity participation, some of the topics may reflect a desire for disease-specific information for some participants. In the pilot study of the OPTIMAL programme and in other chronic disease self-management programmes there is evidence of participants requesting disease-specific information (Barlow, Bancroft, et al., 2005; Francis, Feyer, & Smith, 2007; O' Toole et al., 2013). The inclusion criteria in this RCT was very broad and consequently participants had multiple and a wide range of conditions. This contrasts to inclusion criteria in other studies of generic chronic disease self-management which typically include participants with common chronic conditions (Lorig et al., 1999). The advantages and disadvantages of disease specific versus generic self-management programmes has been outlined in the literature (Health Information and Quality Authority, 2015). It has been acknowledged that certain chronic

conditions involve quite specific self-management tasks which may not be catered for in generic programmes (Newman et al., 2004). Given the variety of conditions participants have in the OPTIMAL programme, a disease-specific approach would not be appropriate. A benefit of the programme being professionally-led within primary care settings is the opportunity to identify the need to and refer onto other professionals in order to meet individual participant needs. There was evidence from the qualitative evaluation that referrals to other primary care professionals for individual participants did occur. Information was provided for specific disease support organisations and disease-specific self-management programmes in the programme booklet. Participants should be encouraged to follow-up with their GP about uncertainties or queries they may have about elements of the medical management of specific chronic conditions.

7.4.2 Mechanisms of impact

The qualitative process evaluation found that the group-based nature and goal-setting components of the programme were perceived as important mechanisms of change by participants and facilitators alike. There is limited research evidence about the mechanisms of change by which chronic disease self-management interventions achieve their effects (M. Harrison et al., 2011; Nossum, Rise, & Steinsbekk, 2013). One of the functions of process evaluations is to explore the mechanisms through which interventions bring about change. Such understanding is vital to replicate the effects of the intervention if they occurred (Moore et al., 2015). The theory of self-efficacy, which underpins the OPTIMAL programme, proposes that goal-setting and the group process provides opportunities for performance mastery, modelling, reinterpretation of symptoms and social persuasion and are key to intervention effects (Lorig & Holman, 2003). The qualitative process evaluation findings suggest that these components were part of the mechanisms of change in the OPTIMAL programme. However such results should be interpreted with caution as analyses of self-efficacy measures are being collected as part of six-month follow-up and may further elucidate findings about the influence of self-efficacy and mechanisms of change.

7.4.2.1 Group-based nature of programme

Results suggest that the OPTIMAL programme provided participants with a safe space and environment to express their concerns and generate solutions in managing

multimorbidity. Consistent with this study's findings, a recent systematic review of qualitative literature of both facilitators and participants in chronic disease self-management group programmes found that participants valued being part of a group and interacting with others who had similar health experiences (Hughes et al., 2017). Group-based programmes provide social benefits and the benefits of sharing knowledge and skills with other members. In accordance with the descriptions of social interaction, support and sharing in this study, the qualitative literature identified social benefits including a sense of solidarity, acceptance and understanding as a result of participation in chronic disease self-management interventions (Davisson & Swanson, 2018; Hughes et al., 2017; Odgers-Jewell, Hughes, Isenring, Desbrow, & Leveritt, 2015). Similarly to the findings in this study, participants in other chronic disease self-management programmes have differentiated between the support provided in the group to that received from family and friends. Participants may minimise the impact of their conditions to their family and friends due to guilt and feeling like a burden whereas within the group they feel understood (Hughes et al., 2017). A concern expressed by some occupational therapists in this study is that peer interaction and support formally ceases when the programme is complete. It is possible that peer support could continue if participants decided to remain in contact post programme however given the short follow-up period, it cannot be determined if this occurred. This highlights the importance of developing strong links with other community resources and partners in order to provide this support for those participants who require it. Evolving social prescribing interventions in primary care could support this in the future (O' Donnell & Smith, 2018). Social prescribing interventions link patients with non-medical sources of support within a community such as social activities, financial advice and employment (O' Donnell & Smith, 2018).

Participants and facilitators discussed a benefit of the programme as peer learning. This peer learning occurred through participants' engagement in group discussions, problem-solving and goal-setting. The facilitators enabled this through involving group members whilst also providing information and suggestions for self-management strategies. Advocates of lay-led chronic disease self-management interventions have suggested that such programmes provide superior opportunities for peer learning and modelling to programmes which are healthcare professional led (Coleman et al., 2012; Newman et al., 2004). This study highlights that the same mechanism can be facilitated by occupational therapists with their existing skills in group interventions.

The interactive nature of the group also allowed participants to make peer comparisons. Participants appeared to make comparisons in two ways viewing participants as either

similar or dissimilar to themselves. Such comparisons can be classified as upward or downward comparisons (Barlow, Bancroft, et al., 2005; Hughes et al., 2017; Rogers et al., 2009). Downward comparisons were reported with participants discussing meeting others whom they perceived as being in worse health than themselves as a positive experience, as it put their own health problems into perspective. This may result in participants feeling more positive about their own health and motivated to manage their symptoms to prevent deterioration (Forsyth, 2018; Hughes et al., 2017). Upward comparisons involve observing others doing well and this acting as a source of motivation for others and are less common than downward comparisons (Forsyth, 2018; Hughes et al., 2017). This is consistent with results in this study as there were no qualitative findings indicating that such comparisons were made. Whilst there were no negative experiences reported as a result of such comparisons, it is worth considering whether those who may have benefited most from the intervention, i.e. those who are less active or struggling to manage their conditions, did not participate or dropped out from the programme as a result. As previously discussed groups which are heterogeneous in terms of age, conditions and functional status may face difficulties in engaging and retaining participants and managing comparisons (Hudon et al., 2016; Rogers et al., 2009). However based on findings in this study this did not appear to be an issue, perhaps healthcare professionals were able to manage the heterogeneity and dynamics in the group to maintain positive engagement.

The OPTIMAL facilitator training and manual emphasised the importance of the delivery of the interactive components which are a key part of the group process, rather than simple didactic methods. Despite this some participants and facilitators recommended increasing interactive components including group discussion. Group processes during self-management programmes may be more important than programme content in improving outcomes. A previous study found that high participant activity or participation levels as rated by facilitators was associated with improved participant coping skills (Nossum et al., 2013). Previous studies of self-management interventions delivered by healthcare professionals found that interactive, practical and hands-on activities greatly improved the programmes (Odgers-Jewell et al., 2015). A criticism of programmes which are healthcare professional led is that the emphasis is on patient compliance with medical management and this emphasis constrains opportunities to provide support, reassurance and enhance self-efficacy (Hughes et al., 2017). This can be the result of insufficient knowledge and training of the theory of self-management and self-efficacy (Odgers-Jewell et al., 2015). Occupational therapists in the OPTIMAL programme received training about self-efficacy theory and self-management interventions. The

facilitator training and manual should continue to emphasise that group processes and interactive components are more important than the educational content. It may be useful as part of facilitator training to allow prospective facilitators to evaluate their leadership style to ensure that facilitators are maintaining a patient-centred and collaborative approach in self-management interventions.

7.4.2.2 Goal-setting

Participants described goal-setting as providing focus and motivation. Goal-setting is one of the skills theorised to be necessary to successfully self-manage multimorbidity (Bratzke et al., 2015; Lenzen, Daniëls, van Bokhoven, van der Weijden, & Beurskens, 2017). The purpose of goal-setting is to address individual needs, facilitate behavioural change, problem-solving and skills mastery and consequently enhance self-efficacy (Lorig & Holman, 2003). Individual weekly goal-setting and review has been identified as a key component of the programme in previous research of the OPTIMAL programme (Garvey et al., 2015; O' Toole et al., 2013). The weekly goal review provides an opportunity for peer learning and modelling. Engagement in goal-setting appeared to have prompted participants to take action in participating in activity and practicing self-management strategies. Reviewing goals with other participants may have resulted in peer comparisons. Both these processes may have contributed to increased HRQoL and activity participation for participants less than 65 years of age and those with higher numbers of chronic conditions. Despite the literature promoting the use of goal-setting in self-management interventions there is limited research into how goal-setting is defined and used in self-management interventions particularly for those with multimorbidity (Lenzen et al., 2017). There is also limited evidence comparing the effectiveness of chronic disease self-management programmes which include goal-setting and those which do not. However a recent systematic review which evaluated the content and effectiveness of goal-setting in diabetes self-management intervention concluded that goal-setting interventions appear to be associated with reduced HbA1C levels (Fredrix, McSharry, Flannery, Dinneen, & Byrne, 2018).

While the majority of participants and facilitators were positive about goal-setting and its' benefits there were some challenges identified with the process. Occupational therapists perceived some participants as struggling to understand the concept. This is perhaps unsurprising given that participants may lack experience with goal-setting and may not expect healthcare professionals to engage with them in discussions about goals not

directed at medical management (Lenzen et al., 2016). The majority of participants in this study had primary level education and this may have contributed to difficulties in understanding this concept. This finding highlights the importance of facilitators using understandable language when explaining and assisting participants to formulate goals and providing relatable examples of goals encompassing the full scope of self-management i.e. role, emotional and medical management. Some occupational therapists recommended that the goal-setting process and worksheets be simplified.

A small number of participants disliked or did not engage in the goal-setting process viewing it as a coercive process. However the participants in the current study who stated they did not like goal-setting did report enjoyment from other aspects of the programme. It is possible that even if participants did not set goals themselves they may still have benefited from observing others setting and reviewing goals in terms of peer learning and modelling which can also enhance self-efficacy. However prospective participants should be clearly advised of this programme component when being informed of the OPTIMAL programme in future practice and research. It is acknowledged that some participants are not able or willing to participate in self-management goal-setting and this may reflect their stage in terms of readiness to change (Lenzen et al., 2016). Literature from rehabilitation suggests that not all patients appreciate a need for goal-setting (Plant, Tyson, Kirk, & Parsons, 2016).

7.4.3 Enablers and barriers to implementation

The enablers and barriers in this study are similar to the factors affecting implementation of primary care teams in Ireland (O'Reilly et al., 2017; Tierney, O'Sullivan, et al., 2016). The results of the process evaluation indicated that the intervention was viewed as generally acceptable to the front-line healthcare professionals involved in referring participants and delivering the programme. Key enablers identified by many healthcare professionals included administrative, managerial and collegial support.

Barriers to implementation conveyed were funding, staff availability, waiting lists and caseload demands. Occupational therapists and physiotherapists in this study reported challenges with balancing the need to address waiting lists and heavy caseload demands whilst endeavouring to provide interventions such as the OPTIMAL programme. Caseload demands are further exacerbated by staff changes and loss. GPs also alluded to heavy caseload demands, with the busy nature of general practices making it

challenging to remember to refer suitable patients to the OPTIMAL programme. These qualitative findings are consistent with the literature that primary care in Ireland is currently under developed and under resourced (Kelly et al., 2016; Tierney, McEvoy, et al., 2016; Tierney, O'Sullivan, et al., 2016). Whilst Irish health policy advocates for the provision of chronic disease management and self-management supports at a primary care level, it remains that inadequate resources make it difficult to implement such interventions on a regular basis (Darker et al., 2015; Flannery & Barry, 2003; French & Galvin, 2017; Tinnelly & Byrne, 2016). Based on the qualitative findings current service priorities in HSE primary care teams appear to be focused on individual home-based interventions for high-risk and functionally disabled patients rather than group-based interventions such as OPTIMAL delivered within the community to support those at an earlier stage in their illness trajectory.

It is perhaps unsurprising that administrative, managerial and collegial support were cited as factors required to support delivery of the OPTIMAL programme. Without this support, particularly in times of constrained resources and increased service demands, it would not be feasible to deliver the programme. The recent frameworks published by the HSE on chronic disease self-management support may encourage commitment from HSE managers to release staff to deliver the OPTIMAL programme (Health Service Executive, 2016, 2017). Administrative support was reported to be required to organise and contact participants about the programme. The need for administrative support has been highlighted in previous studies of primary care team working in Ireland (O'Reilly et al., 2017; Tierney, O'Sullivan, et al., 2016; Tinnelly & Byrne, 2016).

7.4.3.1 Professional roles in primary care

Other factors which are vital to consider in terms of healthcare professionals facilitating the OPTIMAL programme is their understanding of their professional role, the underlying philosophy of care and competency. Examining such factors in relation to occupational therapists raises questions about how occupational therapists view their role within primary care. International and national evidence suggests that primary care occupational therapists work mostly with an elderly population with a focus on equipment provision, functional assessment and environmental adaptations (Tinnelly & Byrne, 2016; Turcotte et al., 2015). This is despite the underlying philosophy and scope of occupational therapy practice being much broader, encompassing participation in valued activities and strategies to improve quality of life (American Association of Occupational

Therapy, 2014). Occupational therapists and physiotherapists in this study indicated that the OPTIMAL programme was in line with the role of occupational therapists and the profession's underlying philosophy. Irish primary care occupational therapists are currently contending with large waiting lists and report struggling with unrealistic caseloads and inadequate resources (Brennan, 2017; Tinnelly & Byrne, 2016). No Irish position statement on primary care occupational therapy practice has been developed. Occupational therapists should be provided with protected time to deliver self-management interventions and other group-based interventions. Alternatively, in the current context it may be more realistic for a separate protected primary care occupational therapy role to be established, focusing on provision of interventions, such as the OPTIMAL programme, to those who have not progressed to significant functional disability to improve participation in instrumental activities of daily living and quality of life.

The delivery of the OPTIMAL programme by occupational therapists limits its' implementation in primary care systems outside of Ireland where occupational therapists may not be a core member of the primary care team, as is the case for example in the United States (Halle et al., 2018). It must be considered then whether occupational therapists are the most suitable professional to deliver the OPTIMAL programme particularly given the current service priorities in primary care occupational therapy as previously discussed. It is important to note that the OPTIMAL programme recognises the need for an interdisciplinary approach to self-management in those with multimorbidity with programme delivery involving other primary care professionals. Occupational therapists have particular expertise in enabling individuals to self-manage their role and activity (occupation) participation. Such a focus is in line with the preferences of those with multimorbidity (Bratzke et al., 2015; Noel et al., 2005). Certain elements of the OPTIMAL programme particularly the introductory session, fatigue management and maintaining mental well-being particularly draw on this expertise. An occupation-centred lens likely influences programme delivery overall e.g. in the goal-setting component. A high quality RCT comparing the clinical and cost effectiveness of the OPTIMAL programme delivered by different primary care professionals may be useful in determining the best approach in delivering the programme. It would be particularly important to examine outcomes related to function and activity participation in such a trial.

Issues around facilitators' perceived competency to deliver the OPTIMAL programme are important to address to support implementation. While the training and facilitator

manual were deemed to be sufficient in this study, some occupational therapists and physiotherapists suggested that not all their colleagues would feel confident and competent in delivering the OPTIMAL programme. Many facilitators in this RCT would have volunteered or put themselves forward to deliver the programme which may reflect an increased interest and experience in group-based interventions. Given current service constraints and priorities some healthcare professionals may feel ill equipped and inexperienced to deliver OPTIMAL or similar interventions. It is vital that training is provided to up-skill primary care professionals in such interventions. A key action identified in recent Irish health policy is the training of health professionals to incorporate prevention and support for behaviour change and self-management as part of routine healthcare delivery (Health Service Executive, 2015b, 2016). Such training may increase professionals' perceptions of competency levels to deliver programmes such as OPTIMAL. This should be further supported with training in specific self-management interventions such as OPTIMAL. Providing all primary care professionals with this training may create a culture shift whereby staff adjust their perceptions of their role. A shift in culture and work practices are required in order for HSE staff to engage in self-management interventions and such change take time.

Increased awareness of the recent policies in self-management support and health behaviour change among staff and observation of their colleagues successfully facilitating the intervention within current primary care practice may also support future implementation. Research suggests that intervention characteristics such as evidence of benefit, ease of use and adaptability to local circumstances influence implementation of complex interventions in practice (Lau et al., 2015).

7.4.3.2 Venue

Some occupational therapists identified difficulties securing suitable rooms for group-based interventions. While the majority of programmes were delivered in primary care centres some programmes were delivered in community resource centres due to a lack of suitable facilities. The availability of suitable facilities and space for group interventions has been identified as a barrier to the delivery of group-based interventions by occupational therapists in previous research, not all existing PCTs are located in PCCs or have access to suitable facilities (S. M. Higgins, Schwartzberg, Bedell, & Duncombe, 2014; Tinnelly & Byrne, 2016). The availability of suitable facilities will be an important consideration for future implementation of the OPTIMAL programme. Research suggests

that venues for chronic disease self-management programmes should be easily accessible by public transportation at a low cost as this may influence recruitment and attendance (Horrell et al., 2017). All primary care team areas in this study were in the Dublin Mid-Leinster region with programmes delivered in urban sites. This limits the generalisability of the study's findings to primary care team areas in this region. If the OPTIMAL programme was to be delivered in rural areas it would be particularly important to consider transport and access.

7.4.3.3 Funding

Regardless of sufficient personnel support for the OPTIMAL programme adequate funding and resources are required to deliver the intervention as highlighted in qualitative data. Delivery of the programme incurs costs in terms of the programme resources (participant booklet, refreshments, room hire, sessional rates for pharmacists) and staff time. Failure to secure commitment for the required resources could result in sporadic implementation of a diluted or adapted version of the OPTIMAL programme which may not be as effective. Whilst outside the scope of this thesis, a cost-effectiveness paper is planned in order to inform and justify funding resources for the OPTIMAL programme. The delivery of interventions such as OPTIMAL within primary care require both top-down and bottom-up support.

7.5 Strengths and limitations

This study evaluated the effectiveness of the OPTIMAL programme in improving health-related quality of life and frequency of activity participation in a theory informed and pragmatic parallel RCT in Irish primary care settings, as per Stage III of the MRC framework. As discussed in Chapter 3, the design of the OPTIMAL programme and current study using the MRC framework is a strength of this study. To the researcher's knowledge this is the first RCT of an occupational therapy led self-management intervention for those with multimorbidity in primary care. The pragmatic nature of the RCT, conducted within Irish primary care settings, is also a strength as it demonstrates that the positive results of the OPTIMAL programme occurred in real primary care settings. The conduct of a concurrent process evaluation strengthens this study as it informed interpretation of RCT results and identification of barriers and enablers to the OPTIMAL programme. The use of both qualitative and quantitative data in the process

evaluation, as recommended by the MRC guidance, helps to understand complex pathways. A number of other strengths and limitations which relate to the OPTIMAL study are discussed below.

There were both strengths and limitations relating to recruitment. The setting ensured a range of participants were recruited who are representative of those with multimorbidity in primary care settings. However, difficulties were encountered with recruitment during the trial with recruitment taking longer than anticipated. One limitation is that views of non-responding and non-participating general practices were not ascertained. Furthermore it may have been beneficial to interview primary care professionals in primary care team areas involved in the study who did not refer to provide further information about barriers to recruitment.

A further limitation is that data regarding the number of patients approached by GPs and PCT clinicians was not collected given the pragmatic nature of the study setting so it is not possible to determine an overall response rate or draw definitive conclusions about the generalisability of the programmes to all those with multimorbidity in primary care settings. A major strength of this study was that retention was high (79%) at immediate follow-up which may be primarily related to the short follow-up period but will also be examined at six month follow-up which is beyond the scope of this thesis.

A limitation of data collection in the current study is that a single assessor was not used to conduct baseline assessments. However the researcher is conducting all six-month follow-up assessments on a face to face basis. The risk of the variety of assessors involved is that assessors may understand and administer outcome measures in different ways. However training was provided in administration of outcome measures in order to minimize the risk of rater bias (Hoyt, 2000). This is particularly important when patient reported outcome measures are used however all outcome measures used in this study have proven validity (Hoyt, 2000).

Another limitation, resulting from difficulties with recruitment (previously described), was that the original power calculation had to be revised and the overall power of the study dropped from 90% to 80%. This limitation increases the possibility of making a Type II error due to an inadequate sample size i.e. failing to reject a false null hypothesis (also known as a "false negative" finding).

In terms of limitations of the qualitative process evaluation data, while conducting interviews with all healthcare professionals involved in referring participants or delivering the programme may have been beneficial to provide richer contextual data, due to resource and time constraints it was not possible to do so. Additionally it may have been beneficial to interview participants who declined participation in the study or who did not attend the intervention. Reasons for non-attendance would have been beneficial to systematically record. A record of participant engagement and non-engagement in weekly-goal setting would have strengthened findings about goal-setting as a mechanism of change in the programme.

Treatment burden was not assessed in this study, this is a study limitation given that it is recommended that process evaluations should assess treatment burden as a result of participation in interventions for multimorbidity (S. M. Smith et al., 2013).

A further limitation of the process evaluation is that other methods such as observation or recording were not used in order to monitor fidelity. The decision to use self-report fidelity tools was made due to resource constraints and the desire to maintain blinding of the researcher to participant allocation. Some discrepancy was noted between the self-report fidelity tool and qualitative findings around content delivery and session duration. For example in qualitative interviews occupational therapists and physiotherapists reported delivering additional content including falls prevention information and pharmacists described providing information on medication costs. Delivery of this additional content was not recorded in the fidelity tool.

7.6 External validity

External validity refers to how applicable the study results are to other settings and participants (Fortin & Smith, 2013). This study was conducted in Irish primary care settings with the programme led by occupational therapists. Thus the OPTIMAL programme is only generalisable to primary care settings where occupational therapists are working.

As previously discussed the primary care team areas involved in this study were based in the Dublin/Mid Leinster region with the majority of sites being classed as urban. In terms of deprivation only two of the primary care team areas were classified as affluent according to the Pobal HP Deprivation Index, with the remainder categorised between

marginally below average to very disadvantaged. As a result these primary care areas are not representative of all HSE primary care team areas. However it remains that multimorbidity is more common in areas of higher deprivation and among those of a lower-socioeconomic status (Pathirana & Jackson, 2018).

The inclusion criteria in this RCT specified that participants should be aged over 40 years of age, have two or more chronic conditions and be in receipt of four or more repeat medications. The definition of multimorbidity used in this study is commonly used and simple. Multimorbidity is prevalent in Ireland in primary care settings (Glynn et al., 2011). There is increased recognition that multimorbidity is not confined to older adults and interventions are required to address the needs of those with multimorbidity across the age spectrum (S. M. Smith et al., 2016). Thus this criteria would be considered broad and replicable in many Irish primary care settings.

7.7 Assessment of RCT risk of bias

Bias refers to any factor or process that deviates the results or conclusions of a trial systematically away from the truth. This can occur due to poor design, conduct, or analysis of a trial (J. P. T. Higgins et al., 2011). Bias is particularly an issue for pragmatic trials of complex interventions where 'real world' estimates are paramount (N. Foster & Little, 2012). Potential bias in this study is examined based on the sources of bias specified in Cochrane Risk of Bias Tool for Randomized Controlled Trials (J. P. T. Higgins et al., 2011).

7.7.1 Selection bias

Selection bias refers to systematic differences in baseline characteristics of the groups that are compared. Randomization if successfully accomplished prevents selection bias (J. P. T. Higgins et al., 2011). As described in Chapter 3, Section 3.8, participants were randomised into intervention or waiting list control groups after baseline data collection in order to avoid any recruitment bias relating to participant preference or researcher influence (Medical Research Council, 2008; Schulz et al., 2010). Sequence generation and allocation was carried out remotely by an independent statistician using a computer-generated sequence which minimised the risk of selection bias. As discussed baseline characteristics of intervention and waiting list control groups were similar. In instances

where couples were recruited, they were randomised as a unit and minimisation was used to ensure an even distribution of couples between intervention and control. A sensitivity analysis was used in final data analysis to test the effect of their involvement in the trial and it indicated that inclusion of couples did not affect results.

7.7.2 Performance bias

Performance bias refers to systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest (J. P. T. Higgins et al., 2011). Blinding of participants, personnel and researchers are strategies which can be employed to reduce the risk of performance bias, however challenges with blinding are common in trials of non-pharmacological interventions in primary care (Boutron et al., 2007; N. Foster & Little, 2012). It was not possible in this study to blind participants or intervention facilitators to allocation.

For participants any observed effect may be due to attention inherent in the research process rather than the intervention itself, particularly given the subjective self-report nature of outcomes used. Knowledge of allocation may affect participants' behaviour in the trial and their responses to subjective outcome measures (Karanicolas et al., 2010). This bias is termed the "Hawthorne Effect" (McCambridge, Witton, & Elbourne, 2014). All outcome measures used in this study were patient reported outcome measures which are in line with the recently published core outcome set for multimorbidity research (S. M. Smith et al., 2018). The use of an attention control group could have been used rather than usual care to minimise the risk of this attention bias, this however would have raised the cost of the trial.

Blinded clinicians are much less likely to transfer their attitudes to participants or to provide differential treatment to the intervention and control groups than are unblinded clinicians (Karanicolas et al., 2010). Referring clinicians and programme facilitators were aware of participants' allocation and this could have influenced their behaviour. Strategies to minimise performance bias in relation to clinicians include standardising study procedures. All occupational therapists received training in the conduct of the OPTIMAL study and delivery of the OPTIMAL programme. All healthcare professionals involved in delivering the intervention were provided with a facilitator manual. Reported fidelity to the intervention protocol was high.

7.7.3 Detection bias

Detection bias is defined as systematic differences between groups in how outcomes are determined (J. P. T. Higgins et al., 2011). Strategies to minimise this risk include blinding of the outcome assessor. In this study the researcher was blinded to participant allocation to intervention or waiting list control and recorded instances of where blinding was broken as outlined in Chapter 3, Section 3.12. This was particularly relevant at six-month follow-up assessment whereby the researcher is conducting these assessments face to face. The frequency of broken blinding will be reported as part of six-month follow-up assessments. The risk of detection bias at immediate follow-up was low due to the collection of data via postal questionnaire.

7.7.4 Attrition bias

Attrition bias refers to systematic differences between groups in withdrawals from a study (J. P. T. Higgins et al., 2011). In order to minimise the effect of any attrition bias, the completeness of outcome data for primary outcomes should be described and intention-to-treat (ITT) analyses performed as recommended by CONSORT guidelines. The completeness of the outcome data collected was reported in Chapter 5, Section 5.2, and was 79%. Missing outcome data was relatively balanced in numbers across the intervention and control groups.

The results of ITT were reported in Chapter 5. ITT analytic strategy reduces bias in treatment effects arising from missing data in trials as it involves the analysis of all trial participants who were randomised, regardless of adherence to the treatment protocol. As discussed in Section 3.13, a complete case analysis was used here to avoid misleading results as only outcome data was missing.

7.7.5 Reporting bias

Reporting bias refers to systematic differences between reported and unreported findings (J. P. T. Higgins et al., 2011). The trial was registered with the ISRCTN register, a simple numeric system used for the unique identification of RCTs worldwide. The trial number is ISRCTN67235963. This thesis presents the results of immediate follow-up data whereas the trial registry indicates that the formal study end point will be six months

and the collection of this follow-up data is ongoing and beyond the scope of this thesis. Primary outcome measures were identified as the EQ-VAS and FAI. Other secondary outcome measures including the NEADL, SEMCD, HADS, COPM and GAS were collected as part of six-month follow-up as discussed in Chapter 3, Section 3.9.3. The results of analyses of primary and secondary outcome measures will be reported at a later date.

7.7.6 Other biases: Risk of contamination

A potential risk in the current study is that of contamination whereby participants in the intervention or control group get mixed or in the case of this RCT those allocated to the waiting list control group receive the OPTIMAL programme. The risk of contamination in this study however is low given its nature and as no participants from the control group attended the group-based programme. The OPTIMAL programme is not routinely offered in primary care and not all of the participants recruited to the study are receiving primary care occupational therapy services currently. It was therefore unlikely that those randomly allocated to the control group would receive any of the elements of the OPTIMAL programme.

It is also possible that a co-intervention bias may have occurred as participants may have been receiving other interventions at the time of the group such as other therapies or medication changes. It would be difficult to account for changes in medication given the complex care routines involving multiple chronic conditions and multiple health care providers. The random allocation of participants to control and intervention groups would decrease the impact of this bias as it should be balanced across groups. Additionally information pertaining to healthcare utilisation including other services received from healthcare professionals was collected at baseline and six-month follow-up. As previously discussed reporting of this data is beyond the scope of this thesis but will be presented elsewhere.

While cluster randomisation is frequently used to overcome the risk of contamination between treatment groups the risk of contamination using individual randomisation in this study is considered to be low (Murphy et al., 2006). Balance between arms is more likely to be achieved using individual randomisation given the differences in socioeconomic status in different primary care team areas (Torgerson, 2001). This can be challenging to achieve with cluster randomisation as simple randomisation of clusters, even with

relatively large numbers, can still result in an imbalance (Torgerson, 2001). Cluster trials are generally more expensive to conduct due to the increased number of participants required to be recruited and the complexity in their design, conduct and analyses (Murphy et al., 2006). Limited funding was available to conduct this study.

7.7.7 Summary of risk of bias

The design and conduct of the OPTIMAL RCT has ensured that where possible the risk of bias has been minimised. Table 7.2 below summarises assessment of risk of bias in the OPTIMAL RCT. It is possible that some performance bias may have been introduced as it was not possible to blind participants to allocation and the nature of the patient reported outcome measures may have resulted in participants providing socially desirable responses. Overall the trial was designed and conducted in such a way to provide meaningful data pertaining to the effect of the OPTIMAL programme by having strong internal validity (Fortin & Smith, 2013).

Table 7-2 Assessment of risk of bias in the OPTIMAL RCT

Type of bias	Method of bias/reduction	Assessment of risk of bias
Selection bias	Participant recruitment with baseline data collection prior to allocation.	Low
Performance bias	Standardised study procedures. Blinding of participants and intervention facilitators not possible. Patient reported outcome measures used with risk of provision of socially desirable responses.	High
Detection bias	Blinding of PhD candidate collecting six-month follow-up data and record of broken blinding maintained.	Low
Attrition bias	Missing data similar across intervention and control groups. ITT analyses used as recommended in CONSORT guidelines.	Low
Reporting bias	Reported as per pre-determined primary outcome measures and pre-define sub-group analyses.	Low
Risk of contamination	Contamination between groups unlikely due to nature of intervention and not part of routine primary care. Record maintained of health care utilisation at 6 month follow-up.	Low

7.8 Impact of findings

It is vital that researchers identify and describe research impacts in order to facilitate comparisons across projects and time. The Research Impact Framework was developed to assist researchers to systematically identify a range of specific and verifiable impacts related to their work (Kuruville, Mays, Pleasant, & Walt, 2006). The framework covers four broad areas of impact: i) research-related impacts, ii) policy impacts, iii) service impacts (health and inter-sectoral) and iv) societal impacts. Within each of these areas, prompts and descriptive categories are provided in order to identify these impacts and facilitate comparisons with other projects (Kuruville et al., 2006). Table 7.3 outlines the framework and descriptive categories in each area.

Table 7-3 Research Impact Framework

Research impacts	Policy impacts	Service impacts	Societal impacts
Type of problem/knowledge	Level of policy-making	Type of services: health/inter-sectoral	Knowledge, attitudes and behaviour
Research methods	Type of policy	Evidence-based practice	Health literacy
Publications/papers	Nature of policy impact	Quality of care	Health status
Products, patents and translatability potential	Policy networks	Information systems	Equity and human rights
Research networks	Political capital	Services management	Macroeconomic/related to the economy
Leaderships and awards		Cost-containment and cost-effectiveness	Social capital and empowerment
Research management			Culture and art
Communication			Sustainable development outcomes

7.8.1 Research related impacts

The findings of this study have significant research related impacts. This study has contributed to the field of multimorbidity intervention research through the evaluation of the effectiveness of an occupational therapy led self-management intervention in primary care. It has addressed a number of research gaps including the need for multimorbidity interventions to target individuals with multimorbidity across the age spectrum and for

such interventions to address generic outcomes such as function in line with recommendations from NICE and the Cochrane review (National Institute for Clinical Excellence, 2016; S. M. Smith et al., 2016). The effectiveness of the intervention in improving health related quality of life strengthens the evidence base of multimorbidity interventions. There is limited high quality research on occupational therapy interventions for those with multimorbidity in primary care settings despite suggestions that occupational therapists are suited to providing interventions for this population. This study contributes to the evidence base of occupational therapy interventions in primary care. The OPTIMAL programme differs to occupational therapy interventions such as equipment provision and home adaptations which are most commonly provided in Irish primary care (Tinnelly & Byrne, 2016; Turcotte et al., 2015).

The study has contributed to the field of intervention research through the use of the MRC framework to guide the evaluation of the OPTIMAL programme. This framework has guided the research through all stages of development and evaluation of the intervention in prior studies which assisted in the conduct of this trial (O' Toole et al., 2013). The process evaluation was guided by the MRC recommendations on process evaluation (Moore et al., 2015). This process evaluation highlighted challenges in recruitment and barriers and enablers to delivery of the OPTIMAL programme in the current context of primary care in Ireland. It demonstrates the value of concurrent process evaluations alongside RCTs to inform findings. There are plans to disseminate the findings of the RCT and process evaluation in high impact journals. This dissemination is important to increase the impact of the research.

7.8.2 Policy related impacts

Targeting chronic disease and incorporating chronic disease management and self-management support has been repeatedly identified in recently published Irish health care policies, HSE implementation plans and chronic disease management frameworks (Health Service Executive, 2015b, 2016, 2017). Furthermore, the development of Integrated Care Programmes (ICPs) and National Clinical Programmes (NCPs) is a major element of the health reform agenda (Department of Health, 2012; Health Service Executive, 2015a; Smyth et al., 2017). An NCP and ICP is being developed for the prevention and management of chronic diseases. These programmes aim to design an integrated model of care with re-orientation of service delivery and associated resources in order for those with chronic diseases to receive timely and appropriate care. However

both the ICPs and NCPs are focused on single common chronic diseases rather than multimorbidity (Health Service Executive, 2015a).

There are no specific policies, care pathways or support programmes addressing the needs of those with multimorbidity in Irish primary care settings. Therefore the findings of this study have the potential to influence policy and practice to address the needs of those with multimorbidity. Furthermore many of these aforementioned policies and frameworks specifically emphasise the increased burden of chronic disease in those from deprived areas and the need to address social inequities in health. Many of the primary care areas involved in this study were areas of disadvantage and the OPTIMAL programme has potential to address their needs as recommended in current policies.

The HSE has been advised and informed of this study since its inception. The researcher received approval from the HSE Primary Care Research Committee in order for this study to be carried out within HSE primary care teams. A final report of findings will be submitted to them as part of this approval. The researcher has also presented to HSE primary care general managers and HSE primary care occupational therapy managers in the largest Community Health Organisation (CHO) in Ireland. A HSE primary care general manager, who has a background as an occupational therapist, is a member of the Trial Steering Committee. Further efforts will be made to disseminate the results of this study, including the process evaluation and six-month follow-up results, to inform policy-makers and advisors. The results of the process evaluation will be particularly important given the enablers and barriers identified to the delivery of the OPTIMAL programme. Difficulties were experienced delivering the intervention despite current policy advocating for a strong primary care system and chronic disease self-management supports. Consideration of these factors would be key if the OPTIMAL programme was to be delivered in primary care. Key stakeholders to consider for dissemination include the HSE Health and Well-Being Division which is responsible for clinical programmes related to self-management, HSE primary care management, the Association of Occupational Therapists of Ireland (AOTI), and the HRB Clinical Trials Network.

7.8.3 Service related impacts

7.8.3.1 Occupational therapy services

A number of service related impacts can be observed from the OPTIMAL RCT and process evaluation. The study demonstrated that an occupational therapy led self-management intervention increased HRQoL among individuals with multimorbidity in primary care settings. Occupational therapists and participants viewed the intervention as useful and beneficial. Occupational therapists felt that the intervention was consistent with their professional role and skill set and suitable for delivery in primary care.

However, the findings from the process evaluation suggest to deliver the OPTIMAL programme routinely would require managerial and collegial support alongside provision of appropriate resources. Primary care occupational therapy in Ireland currently faces challenges in tackling waiting lists amidst constrained resources (Brennan, 2017). Occupational therapy service priorities are centred on addressing the needs of those who are experiencing significant functional difficulty or those considered to be a safety risk (Tinnelly & Byrne, 2016). Interventions for those who are independent but require intervention to improve their quality of life are deemed the lowest priority. Integrating the OPTIMAL programme into routine primary care would require a shift in operational priorities and culture in Irish primary care occupational therapy practice from a reactive to a proactive service. Evidence of sustainability and cost effectiveness will be required in order to justify this shift.

7.8.3.2 Primary care services

The OPTIMAL programme was found to be effective and delivered successfully within Irish primary care which suggests that the intervention has the potential to be adopted into routine practice. The primary care team and GPs who were involved in referring to and delivering the programme alluded to the potential value of the intervention. Given the high prevalence of multimorbidity in primary care settings, OPTIMAL offers an effective intervention to improve HRQoL which GPs and other healthcare professionals can refer to. Such interventions are in line with current Irish health policies and priorities.

Despite the high prevalence of multimorbidity in Irish primary care settings difficulties with recruitment were highlighted in the process evaluation. Referral sources varied widely by area. Many GP practices were approached to be involved in referring patients but only a small number agreed and subsequently referred. There were limited referrals from some primary care professional disciplines e.g. physiotherapy. Similarly to primary care occupational therapists many other professionals faced challenges with busy caseloads. Such difficulties demonstrate challenges in interdisciplinary working in primary care teams. The potential for other referral pathways should be considered. The renegotiation of the current GP contract to support involvement in primary care teams and chronic disease management may be important. Furthermore reimbursement and funding for pharmacists to be involved in the OPTIMAL programme would need to be addressed. There is no evidence presently to suggest whether the OPTIMAL programme effects healthcare utilisation and consequently costs.

7.8.4 Societal related impacts

The potential of a societal impact was not specifically measured with this study design. However the findings of this study of increased HRQoL, if sustained over time, may be indicative of those with multimorbidity managing their health and maintaining function. Thus these individuals may require less healthcare interventions and supports in the future.

7.9 Phase IV: Implementation

This study has presented the findings of the immediate post intervention results as per stage III of the MRC framework and the process evaluation results. The OPTIMAL RCT has shown that an occupational therapy led self-management support programme for individuals with multimorbidity in primary care, was effective in increasing self-reported HRQoL at immediate follow-up in intervention participants. The long term impact and cost-effectiveness of the intervention is important to establish and will add important information to the research findings presented in this study.

Phase IV of the MRC framework is the final phase involving the long-term dissemination, surveillance, monitoring and application of the intervention in real life contexts (Medical Research Council, 2008). It aims to evaluate the implementation by healthcare services

of research findings and the translation of interventions of proven efficacy in research settings into routine care (Pinnock et al., 2014). While Phase IV of the MRC framework is beyond the scope of this study, the results of 6-month follow-up and cost-effectiveness analyses will inform if a Phase IV implementation study of the OPTIMAL programme should be carried out. This study, if warranted based on these analyses, would involve a national evaluation of the OPTIMAL programme, focused on implementation and the extent to which HSE primary care services could deliver and mainstream this intervention alongside the clinical and cost-effectiveness of the intervention. Such a study should be based on the current study's evidence. A number of issues were identified in this study, particularly in the process evaluation, which would need to be addressed in order to optimise the intervention for future implementation. Section 7.10 examines the implementation of the OPTIMAL programme within Irish primary care settings based on this study's findings using Normalisation Process Theory (NPT). Recommendations for Phase IV based on the current study's findings are described in Section 7.11.

7.10 Implementation of the OPTIMAL programme in primary care: Normalisation process theory

The RCT and process evaluation findings indicate that the OPTIMAL programme has the potential to be adapted into routine practice however both enablers and barriers were identified to such implementation as discussed in Section 7.4.3. Although this study was a pragmatic trial, Pinnock et al. (2014) highlights that even pragmatic trials with broad entry criteria recruit selected populations with additional professional time and enthusiasm provided to deliver interventions in trials. Consideration of whether an intervention such as the OPTIMAL programme can be normalised into practice is important as effects are likely to be attenuated when an intervention competes with the demands of busy clinical practice, or may vary depending on the healthcare context (Pinnock et al., 2014). Normalisation process theory (NPT) provides a theoretical approach and framework to describe, assess and enhance implementation through identification of factors that promote or inhibit the routine integration of complex intervention into everyday practice (May & Finch, 2009). The potential barriers and enablers to the implementation and sustainability of the OPTIMAL programme within Irish primary care settings based on the findings in this study are summarised using NPT in Tables 7.4 to Table 7.7 from both an organisational (HSE primary care), health professional and participant perspective. The constructs and sub-constructs of NPT were previously summarised in Chapter 3, Section 3.16.

In relation to coherence (Table 7.5), i.e. whether stakeholders can make sense of the OPTIMAL programme, OPTIMAL was viewed as fitting in with current policies and frameworks from the HSE regarding self-management and chronic disease management in primary care, however it is different to interventions currently provided for the multimorbidity population in primary care. Healthcare professionals and participants viewed the programme as valuable, describing similar benefits in terms of activity participation and self-management. Cognitive participation (Table 7.6) relates to whether stakeholders can get others involved in implementing the OPTIMAL programme. Commitment and engagement in the programme and study varied by site, with some sites withdrawing or deferring participation in the trial. Referrals also varied by site with poor engagement in terms of referrals from some PCT members. While healthcare professionals viewed the OPTIMAL programme as within the scope of primary care practice, provision of the intervention was viewed as a secondary to managing existing waiting lists and caseloads. Efforts to sustain the programme long-term were not assessed due to the short follow-up in this study, however the need for buy in from management and colleagues alongside resources (clinical personnel, venue, time and funding) for future programme delivery in practice was highlighted. Collective action (Table 7.7) focuses on what needs to be done to make the OPTIMAL programme work in practice. There were concerns identified in terms of the need for buy in from management and front-line PCT members and allocation of funding and resources for future programme delivery. While the programme was delivered as intended, team working in terms of referrals for the programme was an issue. Ongoing and individualised communication with team members about the programme may have been helpful. The programme was fitting with professionals existing skill sets, with OPTIMAL training being sufficient to deliver the programme. The programme was relevant and appropriate for participants but there is a need to ensure the programme and materials are literacy friendly. Finally reflexive monitoring (Table 7.8) relates to whether the programme can be monitored and evaluated. Individually both healthcare professionals and participants viewed the programme as effective. There was evidence of professionals tailoring and adapting the programme to meet participants' needs, with both professionals and participants recommending adaptations for future programmes based on their experience.

Table 7-4 Findings according to NPT framework: Coherence

NPT construct	NPT sub-construct	HSE primary care	Healthcare professionals	Participants
Coherence: Can stakeholders make sense of the OPTIMAL programme?	1. Differentiation	OPTIMAL fits with current policy direction in the HSE for self-management support and chronic disease management in primary care.	Viewed OPTIMAL as different to current primary care practices for those with multimorbidity.	Valued OPTIMAL and different to usual primary care services.
	2. Communal specification	Self-management and chronic disease management key areas of development, however existing policies not directed at multimorbidity specifically. Managers supportive in small number of PCTs involved- not clear if purpose and benefit will be understood across primary care services.	Understood value of self-management support and reported benefits for participants.	Understand purpose of programme and reported benefits in terms of activities and self-management.
	3. Individual specification	Not examined. Healthcare professionals highlight need for resources (clinical personnel, space, time and funding) for programme delivery in practice.	Indicated that the OPTIMAL programme was in line with their roles in primary care. Pharmacists identified the need for remuneration for involvement.	Emphasised the need for interaction and goal-setting in OPTIMAL. Small number of participants disliked or did not participate in goal-setting.
	4. Internalization	Recognition of self-management as intervention to reduce burden of chronic disease.	Saw the potential value of OPTIMAL and benefits reported as means of intervention for participants with multimorbidity.	Enjoyed and valued programme with benefits reported. Valued programme resources.

Table 7-5 Findings according to NPT framework: Cognitive participation

NPT construct	NPT sub-construct	HSE primary care	Healthcare professionals	Participants
Cognitive participation: Can stakeholders get others involved in implementing the OPTIMAL programme?	5. Initiation	OPTIMAL aligned with policy guidelines on self-management and chronic disease management in primary care	Varied in different sites with some sites withdrawing/deferring trial participation. Low referral rate from GPs and HSE PCTs in some sites.	Limited Qual data from GPs suggesting that some patients approached declined. Future research needed. Valued participating in OPTIMAL programme.
	6. Enrolment	HSE managers supported professionals to attend training and deliver OPTIMAL in eight sites. However study cancelled in three sites due to concerns about resources.	Agreed OPTIMAL in line with role and primary care. Concerns expressed about need to address waiting list as priority and for GPs caseload demands. Provision of OPTIMAL programme secondary to this.	Attendance generally good across sites for six-week programme. Limited information on refusals to participate or attrition. Findings indicate participants viewed role as self-managers.
	7. Legitimation	Only small number of PCTs bought in as part of study. Not possible to ascertain sustainability of support in terms of resources. Grant funded resources for OPTIMAL programme	Not all healthcare professionals bought in. Primary care practice dominated by waiting lists. No response from many GP practices invited to refer. Poor referral rate from HSE PCT members. Not all HSE professionals desire involvement in OPTIMAL.	Recruitment and attendance varied in sites. Need to examine refusal to participate and attrition to determine if those with multimorbidity generally buy into programme.
	8. Activation	Some sites withdrew from study. Support provided for purpose of study for OPTIMAL but long-term support post study not clear.	Delivered in sites as intended with good fidelity. Sustainability not evaluated due to short follow-up period and nature of study.	Overall good attendance with 76% attending 3 or more sessions but varied by site. No evidence of sustainability of changes due to short follow-up.

Table 7-6 NPT constructs and sub-constructs: Collective action

NPT construct	NPT sub-construct	HSE primary care	Healthcare professionals	Participants
Collective action: What needs to be done to make the OPTIMAL programme work in practice?	9. Interactional workability	Grant funded resources for OPTIMAL programme. Not possible to determine if top-down support and resources will be provided in future.	Professionals delivered OPTIMAL as intended with high fidelity reported. Variable by site in terms of recruitment. Some sites withdrew participation due to low recruitment, staff shortages and caseload demands.	Overall good attendance and engagement reported. Variable attendance in sites and small number of participants not engaging in goal-setting.
	10. Relational integration	Management withdrew support for PCTs involvement in some sites due to resource and caseload demands.	Query regarding PCT relationships given low referrals. Those involved in delivering programme stated it was in line with respective professional roles. However need for buy in from all PCT colleagues identified. Additional personalised communication to PCTs may have been helpful.	Generally positive views of professionals involved in programme delivery.
	11. Skill set workability	Self-management and chronic disease management viewed as remit of all primary care professionals in recent policies.	Healthcare professionals viewed OPTIMAL as in line with existing skill set and training sufficient for delivery. OTs existing service priorities on home-based intervention for functionally disabled individuals.	Participants viewed as suitable appropriate for programme. Programme viewed as relevant to participants. Need for literacy friendly materials.
	12. Contextual integration	Primary care at forefront of self-management and chronic disease management policies. OPTIMAL fits well with policies. Resources in terms of clinicians and funding for OPTIMAL delivery required beyond grant funding.	Administrative support recommended. Caseload demands for GPs and PCTs make referral and delivery difficult. Priority is tackling OT and physiotherapy waiting lists which compete with ability to deliver OPTIMAL. Pharmacists need to be paid for OPTIMAL delivery. Not all PCTs have access to venues suitable for OPTIMAL.	Not possible to determine if appropriate for rural sites. Need to keep cost to participants down by using venues easily accessible by public transport.

Table 7-7 NPT constructs and sub-constructs: Reflexive monitoring

NPT construct	NPT sub-construct	HSE primary care	Healthcare professionals	Participants
Reflexive monitoring: Can the OPTIMAL programme be monitored and evaluated?	13. Systematisation	Not determined as of yet. Results of six-month follow-up and cost effectiveness needed need to be completed and disseminated to HSE.	Positive feedback from professionals about impact of OPTIMAL on participants. Barriers (low participant numbers, resources, caseloads) need to be addressed to mainstream OPTIMAL.	Positive feedback from OPTIMAL participants in terms of programme benefits and intervention content and delivery.
	14. Communal appraisal	No indication or reporting of this. Future research needed	No reporting of collective formal or informal assessment between GPs and PCTs about the OPTIMAL programme. Future research needed.	No reporting of this. Future research needed.
	15. Individual appraisal	No formal feedback on this and not possible to determine without six-month follow-up and cost-effectiveness analysis	GPs viewed intervention for patients as worthwhile but highlighted business of day to day practice makes referrals difficult and suggested need for practice register review and admin support to recruit. OTs and physiotherapists while viewing the intervention as worthwhile for themselves and participants viewed it as competing with the service priority of tackling waiting lists.	Participants viewed the intervention as providing benefits and the personal costs in terms of time and commitment as acceptable. Examination of treatment burden as an outcome would have been beneficial.
	16. Reconfiguration	N/A	Recommended use of multiple referral pathways and increased communication with PCT colleagues. Tailored the intervention to meet individual needs as issues arose organically during programme. Provided onward referrals as appropriate for individual participants.	Recommended use of multiple referral pathways and increasing awareness of programme availability. Recommended changes to programme based on experience including increasing interactive programme components, additional topics and simplification of programme booklet.

7.11 Recommendations for implementation

7.11.1 Recruitment and retention

In terms of recruitment of participants to the OPTIMAL programme the following recommendations are made:

- The eligibility criteria for the OPTIMAL programme should remain the same as the OPTIMAL trial i.e. those with two or more conditions and on four or more repeat medications but that study findings emphasise that an effort should be made to ensure middle aged patients and those with higher numbers of chronic conditions are invited and included.
- The primary care areas involved in the OPTIMAL trial were urban, it would be important for rural areas to be involved in order to establish if the intervention is acceptable within this context.
- Information about the OPTIMAL programme should be communicated and disseminated to GPs via the Irish College of General Practitioners.
- Occupational therapists should employ strategies to increase awareness and referrals of the OPTIMAL programme among primary care professionals. Such strategies include dissemination of the OPTIMAL study findings, meetings with managers and staff of individual healthcare professional disciplines and regular reminders of OPTIMAL programme dates.
- Referral pathways in this study mirrored that currently in place in PCTs and was found to be acceptable. The same referral process should be utilised.
- HSE primary care healthcare professionals and GPs should review records of active and closed cases in order to identify suitable participants. Electronic records would assist with this process.
- The recruitment process in relation to how primary care healthcare professionals and GPs identify patients should be examined in more detail i.e. whether patients are identified prospectively or through review of caseloads or waiting lists.
- The numbers of patients identified using these methods and the rate of uptake among patients approached should be examined.
- The reasons for individuals choosing not to participate should be recorded.

- The experiences of those who drop-out from the intervention should be monitored.
- Records of attendance should be maintained and reasons for not attending the programme should be logged.

7.11.2 Training

Findings from the process evaluation informed the following recommendations for OPTIMAL programme training:

- The OPTIMAL programme and facilitator manual are sufficient to train professionals in programme delivery. This training should be provided to HSE primary care occupational therapists.
- Pharmacists may require additional training and/or support in delivery of the managing medication session. Occupational therapists should be cognisant of the need to support pharmacists in managing group dynamics as they may not be experienced in delivering group interventions, this should be emphasised in OPTIMAL programme training.
- It is recommended that proposed training in health behaviour change and self-management interventions in recent health policy and frameworks is provided to HSE primary care staff (Health Service Executive, 2016, 2017). Information about the OPTIMAL programme should be included as part of this training. This may increase awareness and acceptability of group-based interventions such as OPTIMAL.
- Fidelity in Phase IV should be monitored using multiple methods including intermediate observation or routine session recording to report actual fidelity, with timely remedial feedback.

7.11.3 OPTIMAL programme elements

While the study results suggest that the OPTIMAL programme content and delivery were generally acceptable the following suggestions are made for Phase IV:

- The programme and session duration should remain as delivered in the current study in order for the intervention to be acceptable to participants and facilitators.
- Facilitators should ensure that interactive components, rather than didactic components, form the core of each OPTIMAL session. Session plans should be reviewed in order to ensure that interactive components form the majority of the session.
- Programme content in relation to healthy eating should be reviewed and revised by a dietician. Referrals for individual participants requiring specific dietary advice and intervention to dieticians should be made by occupational therapists as appropriate.
- It is recommended that the content of the “Maintaining Physical Activity” session is reviewed and revised by a physiotherapist to increase exercise demonstration and practice. Content should include a broad view of exercise to include everyday activities and address cognitive components to exercise including barriers, benefits and motivations in order to meet the needs of a variety of functional abilities and exercise levels.
- Each primary care team area should develop and provide information on local resources including local services and activities. Provision of such information was valued by participants in this study.
- A toolkit of resources of additional topics relevant to activity participation and self-management should be developed. Occupational therapists can draw on this toolkit in order to deliver a tailored programme suitable for individual group needs. The recently published Taxonomy of Everyday Self-management Strategies (TEDSS) could provide a useful framework to develop resources for this toolkit (Audulv et al., 2018).
- Opportunities for individual participant referral to other healthcare professionals and groups should be provided following programme completion as appropriate to meet individual and disease-specific needs.

- Primary care teams should develop links with local community partners such as resource centres. This would enable healthcare professionals to advise patients of groups and projects being delivered in these centres and reciprocally for resource centre users to receive support from the PCT or engage in interventions such as OPTIMAL.
- The majority of study participants had primary school education in the OPTIMAL trial. The OPTIMAL programme materials and participant booklet should be reviewed and revised as appropriate to ensure it is literacy friendly.
- The goal-setting format and worksheets in particular should be revised in order to ensure they are simple and literacy friendly.
- Examples of a variety of goals should be explained and included in participant booklets ranging from health behaviour change to social and physical activity participation.
- Participants' engagement in weekly goal-setting should be monitored. Engagement in this programme element and its impact on outcomes should be explored.
- A commitment to funding of the resources needed for programme delivery including participant booklets, refreshments and sessional rates for pharmacists will be required.

7.11.4 Recommendations for future research

- Outcomes: The primary outcome measures of the FAI and EQ-VAS should be utilised. Other measures of activity participation are being collected as part of six-month follow-up data and will provide additional information on the need for inclusion of other outcomes of activity participation and function. The use of the EQ-5D-5L questionnaire instead of the EQ-5D-3L questionnaire should be considered as the 5L version is considered to have higher discriminatory power and sensitivity (van Reenen & Oppe, 2015a, 2015b).
- Inclusion of the Multimorbidity Treatment Burden Questionnaire (MTBQ) should be considered (Duncan et al., 2018).
- Inclusion of measures pertaining to medication beliefs and/or adherence and physical activity levels could also be considered as content pertaining to these

outcomes were delivered but no specific measure of these outcomes were included.

- Sub-group analyses of age (<65 and ≥65 years of age) and the number of conditions present (<4 and ≥4) should be conducted given the findings in the OPTIMAL trial.
- Future evaluations of the OPTIMAL programme could compare the clinical and cost effectiveness of the OPTIMAL programme delivered by primary care professionals other than occupational therapists.
- Normalisation Process Theory (NPT) should be used to consider issues around implementation in future evaluations.

7.11.5 Public and patient involvement (PPI)

- Phase I and Phase II of the MRC framework involved the collection of qualitative data from participants with multimorbidity. This helped inform the development and refinement of the programme prior to Phase III.
- It was planned to include a patient representative in the trial governance structures of this Phase III study, however delays were encountered in establishing committees for independent chairs and patient representatives in HRB Primary Care Clinical Trials Network Ireland.
- It is recommended that public and patient involvement should be included in future evaluations of the OPTIMAL programme. Such involvement would be beneficial in reviewing participant and programme materials, planning and managing the study and disseminating and implementing the results into practice.

7.12 Conclusion

Multimorbidity negatively impacts functioning, quality of life, psychological well-being and health care utilisation. The need for the development and rigorous evaluation of interventions for those with multimorbidity in primary care settings has been identified (S. M. Smith et al., 2016). Interventions specifically targeting function and quality of life may be suitable for those with multimorbidity. Occupational therapy has been proposed as

suitable profession to provide interventions to this population given its generalist approach and focus on such outcomes (Leland et al., 2017; Mercer et al., 2009). However high quality evidence regarding occupational therapy interventions for those with multimorbidity in primary care settings is limited. This study aimed to evaluate the effectiveness of the OPTIMAL programme, an occupational therapy led self-management support programme for individuals with multimorbidity in primary care, as per Stage III of the MRC framework. A process evaluation was also conducted to understand the functioning and effects of the OPTIMAL programme by examining how the intervention was delivered and received in practice. This study has found that the OPTIMAL programme improves health-related quality of life at immediate follow-up in individuals with multimorbidity. While both participants and healthcare professionals valued the intervention, the process evaluation highlighted difficulties with recruitment and identified barriers and enablers to delivery of the OPTIMAL programme within Irish primary care settings. A larger national evaluation of the implementation of the OPTIMAL programme, incorporating recommended adaptations would add further understanding to effective interventions for those with multimorbidity in Irish primary care settings.

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Appendix 1 Consort Guidelines for Parallel RCTs

Section/Topic	Item No	Checklist item	Reported in section
Title and abstract			
	1a	Identification as a randomised trial in the title	Introduction
	1b	Structured summary of trial design, methods, results, and conclusions	Summary
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Introduction;1.4
	2b	Specific objectives or hypotheses	Introduction (1.4.2); Chapter 3 (3.4); Chapter 4 (4.2)
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Chapter 3 (3.4)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Chapter 3- sample size (3.10)
Participants	4a	Eligibility criteria for participants	Chapter 3 (3.7.4); Chapter 4 (4.3.2)
	4b	Settings and locations where the data were collected	Chapter 3 (3.11); Chapter 4 (4.5.2)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Chapter 3 (3.5)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Chapter 3 (3.9)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	Chapter 3 (3.10)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Chapter 3 (3.8)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Chapter 3 (3.8)

Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Chapter 3 (3.8)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Chapter 3 (3.8)
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Chapter 3 (3.12)
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Chapter 3 (3.13)
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Chapter 3 (3.13)
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Chapter 5 (5.2)
	13b	For each group, losses and exclusions after randomisation, together with reasons	Chapter 5 (5.2)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Chapter 5 (5.2); Chapter 6 (6.2.1)
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Chapter 5 (5.3)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Chapter 5 (5.2; 5.4)
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Chapter 5 (5.6)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A

Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Chapter 5 (5.6)
Harms	19	All important harms or unintended effects in each group	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Chapter 7 (7.5)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Chapter 7 (7.5)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Chapter 7
Other information			
Registration	23	Registration number and name of trial registry	Registered ISRCTN67235963.
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Health Research Board

Appendix 2 Literature Review Search Strategies

Search terms (AND, OR, NOT) and truncation (wildcard characters like *)	<p>Self-management, self-management support, self-care, patient education, psychoeducation, patient training, patient skills, patient skills, health education, health behaviour change, behaviour modification, self-help, disease management, expert patient</p> <p>Multimorbidity, multimorbid, co-morbidity, co-morbid, , multi-disease, chronic disease</p> <p>Occupational therapy, occupational therapist, activities of daily living, activities, participation, function, independence, rehabilitation, counselling,</p> <p>Primary care, primary health care, community, home-based, domiciliary, outpatient care, general practice, family practice</p>
Databases searched	<p>PubMed, CINAHL, the Cochrane Database of Systematic Reviews, ProQuest and PsychINFO, Google Scholar, Lenus and RIAN.</p>
Years of search	<p>No limit applied</p>
Language	<p>English</p>
Types of studies to be included	<p>Quantitative or qualitative</p>

Appendix 3 OPTIMAL session plans

SESSION 1 Group Plan: Introduction to Self-Management

Aims of the Session:

- ✓ To introduce group members
- ✓ Provide overview of purpose and content of programme
- ✓ Explore relationship between activity, health and management of chronic conditions
- ✓ Establish group expectations
- ✓ Explain goal-setting process
- ✓ Set overall programme goals

1. Plan for the day: Lecturette (2-3 mins)

- Welcome all members to the group. Explain where bathrooms, exits, parking etc.
- Overview of today

2. Introduction to facilitators and participants: Ice breaker activity (10 mins)

- **Introduction** to group facilitators
- **Ice breaker game** – Everybody talks to the person beside them for 5 minutes and finds out three things about them and introduces them to the rest of the group.

3. Introduction to i) group, ii) self-management and iii) programme overview: Lecturette (20 mins)

- i) Introduction to the group (5 mins)
 - Why are we here? General overview of the purpose of the programme
- ii) Introduction to self-management (10 mins)
 - Introduction to Self-Management
 - Self-management skills
 - Aims of the self-management programme
- iii) Overview of the six week programme (5 mins)
 - Overview of what topics will be covered each week within the six week programme
 - Discuss learning strategies

- Briefly outline the type of activities that can be expected in this group and importance of interactive strategies for learning

4. Being a group-what works and doesn't: Discussion (5 mins)

- Explore people's previous experience of participating in group programmes/projects
- Discuss as a group- what worked, what didn't work in previous groups people were involved in?

5. Being a group- group expectations: Brainstorm (10 mins)

- Brainstorm group behaviours and boundaries – Confidentiality, listening, setting goals etc (*Compile on flip chart*)
- Develop group expectations poster – All group members sign

6. The vicious symptom cycle: Lecturette (5 mins)

- Explain that the symptoms that we experience living with chronic conditions can be caused by a number of different causes and not just solely the disease. This programme will look at how these conditions can affect health and how to manage it.

7. Impact of multimorbidity on activity: Lecturette (10 mins)

- Impact of multimorbidity on activity and health
- Explain that multimorbidity for some people can affect their activity levels, their emotions and can cause challenges to people in terms of managing the medical aspects of their condition- juggling multiple appointments, health professionals and medications.
- Explain that people can still live a healthy life and be healthy while living with chronic conditions. Health is not about whether you do or don't have health conditions but rather having well-being from a physical, social and mental perspective.
- Explain that research has shown that increased activity levels are associated with better quality of life, higher levels of happiness, better levels of physical health, improved cognition and mood.

8. Impact of multimorbidity on activity: Brainstorm on flipchart (10 mins)

- Divide flipchart into two halves (activities and barriers to engagement)
- Ask the group for examples of activities people need and like to do (self-care, productive, leisure/social)

- Any barriers that have been stopping people from participating in these activities?
- Explain that hopefully we can address these barriers in the coming weeks to increase people's participation in important activities

9. Tea Break (15 mins)

10. Distribution and purpose of handbook: Lecturette (10 mins)

- Explain sections- Coinciding with topics that will be covered in group, personal goals discussed with OT and goal setting sheets. Important to bring every week to set goals and keep track. Booklet also serves as a personal resource where you can read back over what has been covered during the week.

11. Explanation of goal setting: Lecturette (20 mins)

- Explain role of goal-setting in self-management. An important part of this programme is setting weekly goals. This will help in making lifestyle changes to manage symptoms better and increase activity levels. It is also a challenging part of the programme. Some participants may find the concept of goal-setting difficult to grasp (explain it's like making weekly New Year resolutions).
- Explain that weekly goal-setting can be for setting goals for something you want to do, can be an activity, can be something like eating healthier.
- It's important to break these goals into smaller manageable goals and the weekly goal setting will help in doing this..
- Goal-setting: When we set goals we should try and make them **SMART goals**. This means they should be Specific, measurable, attainable, realistic, timed
- Explain each week we will review goals as a group to help each other problem solve and find solutions for issues that stop us from reaching our goals.
- **Explain goal setting sheets.** Go through examples. Compare 2 examples of walk/social activity, you might do something once this week or a few times. Remind participants again to think about things that they discussed having difficulty with facilitators in their first meeting. Next week will be setting first weekly goals.

12. Setting goals: Overall Programme Goal-Setting (30 mins)

- Overall programme goal-setting is likely to take some time as it will be something that participants are not familiar with. Explain to participants that having now had an overview of the programme, they will be setting some goals to help guide weekly goal-setting.

- Distribute OPTIMAL overall programme goal (GAS) sheets. Explain to participants that they need only to complete sections in RED. OTs will go around helping participants.
- Participants can work together in pairs if they wish. Be mindful of participants with low literacy levels, they may require some individual assistance in making SMART goals.
- Ask participants to share with the group some of their overall programme goals.
- Collect goal sheets and redistribute them each week for when participants are setting their weekly goals.

13. Closing: Lecturette (2-3 mins)

- Thank participants for coming.
- Remind participants to try out their goals this week and that they can read over the information from this week in their booklets.
- Advise participants that next week we will be covering managing tiredness/fatigue and health eating.
- Remind participants to bring their booklets.
- *Remember to assist any participants that require additional help with their goals.

SESSION 2 Group Plan: Fatigue Management and Healthy Eating

Aims of the Session:

- ✓ To identify times of fatigue and particular ADLs which exacerbate fatigue
- ✓ To identify, learn and incorporate strategies to help reduce and minimise fatigue during ADLs and daily routine
- ✓ To increase awareness of the importance of healthy eating for self-management
- ✓ To identify ways to change diet for healthy eating

1. Introduction to the group: Lecturette (2-3 mins)

- Welcome everybody back. Remind members where the toilet is and that they are free to get up and move about if they wish
- Introduce any new group members
- Remind participants of group expectations – poster made in first week
- Explain purpose of this week's session – managing time and energy better, healthy eating
- Why fatigue management is important in self-management: Symptoms Cycle

2. Fatigue management principles: Lecturette (15 mins)

- What causes fatigue? Relationship between fatigue and chronic diseases
- Fatigue : Under and over-activity; Fatigue and mood
- Explain The Four P's- Planning, Prioritising, Pacing and Positioning

3. Managing fatigue in daily activities: Activity (Worksheet (10 mins) and Group Discussion (10 mins)

- Leave Slide 13 on the screen to remind participants of the different fatigue management principles. Ask participants to look at the worksheet in the booklet- they can choose whether to complete it or not but it is to guide their thinking as they will be feeding back to the group (Be mindful of those with low literacy levels).
- Ask them to think of 3 daily activities that they regularly do and to rate their fatigue and then based on the strategies discussed (4 P's), participants are to think if there are any other ways to do these activities differently to manage their energy levels. Facilitators will need to go around the group to ensure

participants understand what they are doing. Allow participants to work with a partner if they wish to help come up with examples.

- After 10 minutes of doing the worksheet, go around to each participant and ask them would they share an activity that they find fatiguing or that they gave a higher rating to and consider ways that they could manage their fatigue during that activity or do things differently. This should foster discussion, sharing and learning- allow members to offer suggestions, explore if others have had similar difficulties.

4. Managing fatigue sample strategies: Lecturette (10 mins)

- Briefly explain some examples of ways to manage fatigue in common ADLs- some of this may already have been touch on in group discussion/worksheet.
- Can demonstrate some simple assistive devices if appropriate and available that assist with managing fatigue.
- Explain more detail provided on same in booklet.

5. Tea Break (15 mins)

6. Healthy Eating: Lecturette (15 mins)

- Explain reasons for healthy eating. Why healthy eating is important in self-management (5 mins)
- Food Pyramid – Explain (10 mins)

7. Healthy Eating: Brainstorm Challenges and small changes (15 mins)

- Brainstorm as a group using flipchart
- What do people find are the challenges to eating healthy?
- Is there a small change that you could make to your eating?

8. Setting goals: Activity Goal-Setting (30 mins)

- Distribute overall programme goal-setting sheets completed in first week of the programme. If an individual did not attend the first programme session- OT should spend some time individually helping them complete overall programme goal-setting sheet before setting a goal for the week while the other participants are deciding on their weekly goals.
- Provide time to complete the weekly goal-setting sheet. Encourage people to review their overall programme goal-setting sheets and to think of lifestyle changes they wish to make (this could be triggered by content covered in this week's session) or a social or physical activity they would like to engage in.

- Participants can work together in pairs if they wish and remind participants they can write their goals in their handbook if they want. Be mindful of participants with low literacy levels, they may require some individual assistance in making SMART goals and do not force anyone to complete the worksheet but ensure they are thinking of all the different areas to make a SMART goal.
- When all participants have decided on a goal for the week, go to each person; ask them do they have any goal for the week. One facilitator can write on the flipchart in a brief sentence the person's goal for the week (Keep the flipchart sheet). Ask for a volunteer to get started.
 - What is their goal?
 - Confidence level (0=not at all confident to 10=very confident). If participants rate themselves as lower than 7, ask them what the barriers are and encourage the group to come up with possible solutions/suggestions to make the goal more realistic and increase the participant's confidence.
 - Importance of achieving it?
 - Any barriers and how to overcome them?
- If someone is having difficulty making a goal, ask others for suggestions. If the participant is continuing to struggle the OT can assist them individually after the session.

9. Closing: Lecturette (2-3 mins)

- Thank participants for coming.
- Remind participants to try out their goals this week and they can read over the information from this week in their booklets if they wish.
- Advise participants that next week we will be covering maintaining physical activity which will be co-facilitated by a physiotherapist- remind them to wear comfortable shoes/clothes- short practice session.
- Remind participants to bring their booklets.

*Remember to assist any participants that require additional help with their goals.

SESSION 3 Group Plan: Maintaining Physical Activity

Aims of the Session:

- ✓ To develop an understanding of the benefits of physical exercise to maintain healthy lifestyles and manage chronic diseases.
- ✓ To gain an understanding of the different types of exercise and appropriate exercises for members to keep physically active
- ✓ To identify exercises that members could engage in at home

1. Introduction to the group: Lecturette (2-3 mins)

- Welcome everybody back
- Provide outline of session
- Introduce physiotherapist. OTs should remain in the session. It provides opportunities to listen to the advice being provided, reinforce and tie it in with remaining sessions, help manage group dynamics and provide assistance if required.
- Relate back importance of physical activity in managing symptoms (Vicious Symptoms Cycle)

2. Physical activity- Benefits of Exercise: Lecturette by Physiotherapist (10 mins)

- Overall focus is for physiotherapist to discuss benefits of exercise and types of exercise and recommended physical activity levels for those with chronic conditions as per 2009 HSE National Guidelines on Physical Activity.
- Explain how exercise is medicine
- Benefits of exercise for those with chronic conditions- prevention and maintenance of health.

3. Godin Physical Activity Levels- Are you meeting recommended levels: Activity (Worksheet and Group Discussion) (10 mins)

- Explain how active Irish people are and get participants to complete exercise questionnaire to increase their awareness of their activity levels. OTs may need to provide assistance- be mindful of participants with lower literacy levels.

4. Continue Lecturette by Physiotherapist (15 mins)

- Are people meeting the recommended levels? Explain recommended activity levels- participants to consider are they meeting them
- FITT principles- when exercising
- Types of exercise (aerobic, strengthening, flexibility, balance), examples and recommended levels
- Sticking to exercise programmes- some tips
- Physiotherapist can *discuss* how to exercise safely and within limits – warm up, which activities, when to stop (safety precautions)

5. Keeping fit at home (15 mins)

- Group can *brainstorm* exercises they do at home or exercises they would like to – advice from physiotherapist (5 mins)
- Demonstrate and practice with participants simple exercises that participants can complete in their own home (10 mins)

6. Question and Answer: Activity (10 mins)

- Opportunity for members to ask physiotherapist any questions relating to exercise or physical activity. Be mindful of directing participants back to their GP for specific advice relating to their health conditions and exercise

7. Tea Break (15 mins)

8. Halfway Review: Activity (10 mins)

- Redistribute overall programme goal sheets. Now at the halfway stage, looking at the overall programme goals that you set, how do you think you're getting on?

9. Goal Review: Activity (30 mins)

- Ask for a volunteer to start to share how they got on with their goal this week. Ask them what their goal was? How they got on? (Did they fully achieve the goal? - Was it easy, manageable or ok, quite difficult or very difficult?).
 - If someone achieved the goal, how did that make them feel?
 - If people didn't achieve their goals what were the barriers?
 - For those that didn't achieve their goal, reassure them that it is ok and that we all face challenges from time to time. Ask the person and group for possible suggestions to overcome the barrier, facilitators then can offer some ideas too.

10. Setting goals: Activity Goal-Setting (30 mins)

- Provide time to complete the weekly goal-setting sheet. Encourage people to review their overall programme goal-setting sheet and to think of lifestyle changes they wish to make (this could be triggered by content covered in this week's session) or a social or physical activity they would like to engage in.
- Participants can work together in pairs if they wish and remind participants they can write their goals in their handbook if they want. Be mindful of participants with low literacy levels, they may require some individual assistance in making SMART goals and do not force anyone to complete the worksheet but ensure they are thinking of all the different areas to make a SMART goal.
- When all participants have decided on a goal for the week, go to each person; ask them do they have any goal for the week. One facilitator can write on the flipchart in a brief sentence the person's goal for the week (Keep the flipchart sheet). Ask for a volunteer to get started.
 - What is their goal?
 - Confidence level (0=not at all confident to 10=very confident). If participants rate themselves as lower than 7, ask them what the barriers are and encourage the group to come up with possible solutions/suggestions to make the goal more realistic and increase the participant's confidence.
 - Importance of achieving it?
 - Any barriers and how to overcome them?
- If someone is having difficulty making a goal, ask others for suggestions. If the participant is continuing to struggle the OT can assist them individually after the session.

11. Closing: Lecturette (2-3 mins)

- Thank participants for coming.
- Remind participants to try out their goals this week and that they can read over the information from this week in their booklets.
- Advise participants that next week we will be covering maintaining mental health and well-being.
- Remind participants to bring their booklets.

SESSION 4 Group Plan: Maintaining Mental Well-Being

Aims of the session:

- ✓ To identify triggers and signs which indicate stress or low mood
- ✓ To understand how stress affects daily activities
- ✓ To understand how daily activities can help to manage stress/low mood
- ✓ To explore a range of coping mechanisms and identify potential sources of support
- ✓ To analyse difficulties sleeping and identify strategies which may help

1. Introduction to the group: Lecturette (2-3 mins)

- Welcome everybody back. Remind members where the toilet is and that they are free to get up and move about if they wish
- Remind participants of group expectations – poster made in first week
- Explain purpose of this week's session – management of mental health and well-being and strategies for getting a good night's sleep
- Briefly explain how maintaining mental-well being is important in managing symptoms and health (vicious symptoms cycle)

2. Causes and Signs of Low mood/Stress: Brainstorm (15 mins)

- How can feeling worried or stressed affect our ability to take part in activities? What happens when we are anxious? What do people do when they are anxious in the group? e.g. do they avoid situations
- How do you deal with things that are worrying you?
- What do you do to relax?

3. Worry worksheet: Activity (15 mins)

- Support participants to complete worksheet on anxiety levels and share information with group.

4. Maintaining Mental Well-Being: Lecturette (30 mins)

- Highlight that low mood, stress and worry can affect our health including our mind, physical health, feelings, relationships and daily activities. Many of these things will hopefully have been touched upon by participants in the worksheet activity and discussion. The purpose of the lecturette is to summarise their points.

- State the key points in terms of some physical signs that we are down or worried, the impact on patterns of thinking, the change in our daily routines with an increase in unhealthy activities and a decrease in activities that keep us well.
- Provide top 10 tips on managing stress, many of these participants will have generated in the brainstorm/worksheet. Ask them to check out 50 ways to take a break in their participant booklets.
- State that the 3 main ways to help mind our mental health: i) to tackle anxiety challenge negative thoughts, ii) make sure we are engaging in healthy activities and iii) learn relaxation strategies.
- Three types of relaxation: i) Distraction, ii) Visualisation and iii) Breathing exercises when you need to relax quickly or in a panic.
- Sleep: Routine and Naps

5. Tea Break (15 mins)

6. Guided visualisation: Activity (10 mins)

- Practice guided visualisation as an example of a relaxation strategy

7. Goal Review: Activity (30 mins)

- Ask for a volunteer to start to share how they got on with their goal this week. Ask them what their goal was? How they got on? (Did they fully achieve the goal? - Was it easy, manageable or ok, quite difficult or very difficult?).
 - If someone achieved the goal, how did that make them feel?
 - If people didn't achieve their goals what were the barriers?
 - For those that didn't achieve their goal, reassure them that it is ok and that we all face challenges from time to time. Ask the person and group for possible suggestions to overcome the barriers, facilitators then can offer some ideas too.

8. Setting goals: Activity (30 mins)

- Provide time to complete the weekly goal-setting sheet. Encourage people to review their overall programme goal-setting sheet and to think of lifestyle changes they wish to make (this could be triggered by content covered in this week's session) or a social or physical activity they would like to engage in.
- Participants can work together in pairs if they wish and remind participants they can write their goals in their handbook if they want. Be mindful of participants with low literacy levels, they may require some individual assistance in making SMART goals and do not force anyone to complete the worksheet but ensure they are thinking of all the different areas to make a SMART goal.

- When all participants have decided on a goal for the week, go to each person; ask them for their goal for the week. One facilitator can write on the flipchart in a brief sentence the person's goal for the week (Keep the flipchart sheet). Ask for a volunteer to get started.
 - What is their goal?
 - Confidence level (0=not at all confident to 10=very confident). If participants rate themselves as lower than 7, ask them what the barriers are and encourage the group to come up with possible solutions/suggestions to make the goal more realistic and increase the participant's confidence.
 - Importance of achieving it?
 - Any barriers and how to overcome them?
- If someone is having difficulty making a goal, ask others for suggestions. If the participant is continuing to struggle the OT can assist them individually after the session.

9. Closing: Lecturette (2-3 mins)

- Thank participants for coming.
- Remind participants to try out their goals this week and that they can read over the information from this week in their booklets.
- Advise participants that next week we will be covering managing medications and a local community pharmacist will be co-facilitating the session.
- Remind participants to bring their booklets.

SESSION 5 Group Plan: Managing Medications

Aims of the Session:

- ✓ To improve awareness and understanding of the medications members are taking
- ✓ To discuss and develop strategies for members to effectively and safely manage their medication regimen
- ✓ To provide opportunities for members to ask questions relating to their medicines

1. Introduction to the group: Lecturette (2-3 mins)

- Welcome everybody back. Remind members where the toilet is and that they are free to get up and move about if they wish
- Remind participants of group expectations – poster made in first week
- Explain purpose of this week's session – medication management. Medication one aspect of managing health
- Introduce pharmacist to the group

2. Managing Medications: Lecturette by Pharmacist (25 mins)

- Overall focus of lecturette is to increase participant's understanding of why they take medications and how to effectively manage their medication regime with an emphasis on managing multiple medications.
- Why do we take medications and what do we need to know about taking any medication?
- What are potential side effects and what to do if concerned about potential side effects?
- Ways to manage taking multiple medications? How do we make sure we are taking the right medication at the right time?
- Keeping up with your medicines – where and how to store medications, ways to remember to take medications.
- What to ask your doctor and pharmacist about medications?

3. Thoughts of medication and barriers to managing medication: Group Discussion (15 mins)

- Group can **brainstorm** their thoughts/common concerns about their medication and barriers to medication management (Use flipchart to write down participants' suggestions- divide page in half).

4. Demonstration of products (10 mins)

- e.g. pill box, blister packs

5. Question and Answer: Activity (15 mins)

- Opportunity for members to ask pharmacist questions relating to medications. The purpose of the Q&A is for members to be able to ask some generic questions about what their medications are for, what to eat with their medications, differences between brand and generic medicines etc.
- Useful time for pharmacist to advise of services available in pharmacy (medication disposal, individual consultations etc).
- Be mindful of directing participants back to their GP or local pharmacist for specific advice relating to their medications. Participants may not be aware that many pharmacies have private consultation suites.

6. Tea Break (15 mins)

7. Goal Review: Activity (30 mins)

- Ask for a volunteer to start to share how they got on with their goal this week. Ask them what their goal was? How they got on? (Did they fully achieve the goal? - Was it easy, manageable or ok, quite difficult or very difficult?).
 - If someone achieved the goal, how did that make them feel?
 - If people didn't achieve their goals what were the barriers?
 - For those that didn't achieve their goal, reassure them that it is ok and that we all face challenges from time to time. Ask the participant and group for possible solutions to barriers, facilitators then can offer some ideas too.

8. Setting goals: Activity (30 mins)

- Provide time to complete goal-setting sheet. Encourage people to think of new things that haven't tried in a while, might be related to this session, or might be a social or physical activity or their overall programme goals. Might want to try a goal from last week.
- Participants can work together in pairs if they wish and remind participants they can write their goals in their handbook if they want. Be mindful of participants with low literacy levels, they may require some individual assistance particularly in the first week in making SMART goals.
- Go to each person; ask them do they have any goal for the week. Ask for a volunteer to get started.
 - What is their goal?

- Confidence level (0=not at all confident to 10=very confident). If participants rate themselves as lower than 7, ask them what the barriers are and encourage the group to come up with possible solutions/suggestions to make the goal more realistic and increase the participant's confidence.
- Importance of achieving it?

9. Closing: Lecturette (2-3 mins)

- Thank participants for coming.
- Remind participants to try out their goals this week and that they can read over the information from this week in their booklets.
- Advise participants that next week is the final session and we will be covering communicating with health professionals and providing an overall review of the programme.
- Remind them there will be a lunch after the programme and during that time a recorded group discussion will take place and some forms completed.
- Remind participants to bring their booklets.

SESSION 6 Group Plan: Communicating with Health Care Professionals & Programme Review

Aims of the session:

- ✓ To identify barriers/problems in communicating with health professionals
- ✓ To identify effective strategies to improve skills in information seeking, verifying and provision with health care professionals
- ✓ To identify methods of communicating with family and friends around health conditions
- ✓ To provide an overview of the programme content covered
- ✓ To review weekly goals & overall programme goals

1. Introduction to the group: Lecturette (2-3 mins)

- ✓ Welcome everybody back. Remind members where the toilet is and that they are free to get up and move about if they wish
- ✓ Remind participants of group expectations – poster made in first week
- ✓ Explain purpose of this week's session – communication with health care professionals. Being able to communicate effectively with health professionals is an important part of being active in managing one's own health by getting the information needed and ensuring that the health professionals get information required to provide help
- ✓ Discuss how this is the last session of the programme and an important part of today's session is reviewing what has been covered and how participants feel their own goal achievement has been

2. Communicating with Health Professionals: Lecturette (15 mins)

- Communication strategies for interacting with health professionals.
- Ways to help get the most from your visit with your doctor or other health care professional- emphasise idea of partnership.

3. Reflecting on past communication difficulties and new solutions: Group Discussion (15 mins)

- Ask members to think of a time or an example when they had difficulty communicating with a health care professional (ask them not to give names of the professional). Ask for a volunteer to give an example. Use one or two examples and use as the basis of discussion.

- Based on strategies discussed ask the participants for barriers that resulted in the miscommunication and possible solutions (Take Part) for effective communication with health professionals.

4. Communicating with families: Group Discussion/Lecturette (10 mins)

- Flag change of focus towards how we can communicate with our family and friends about our health. Sometimes it can be hard for family and friends to understand the difficulties our health problems can cause us- symptoms invisible.
- Family/friends may try to help too much or do more than we wish them to do or conversely not understand its impact and not provide help that we need.
- Ask participants to brainstorm ways/strategies to improve communication with family/friends about our health. Remember to keep the discussion tight i.e. remind members that you are look for solutions rather than specific issues they have with family/friends.
- Provide brief lecturette regarding strategies to improve communication with family/friends regarding health

5. Programme Review: Lecturette (15 mins)

- Recap on principles of self-management- vicious symptoms cycle, self-management skills, content covered each week and key messages/take home points from these sessions.

6. Tea Break (15 mins)

7. Goal Review: Activity (30 mins)

- Ask for a volunteer to start to share how they got on with their goal this week. Ask them what their goal was? How they got on? (Did they fully achieve the goal? - Was it easy, manageable or ok, quite difficult or very difficult?).
 - If someone achieved the goal, how did that make them feel?
 - If people didn't achieve their goals what were the barriers?
 - For those that didn't achieve their goal, reassure them that it is ok and that we all face challenges from time to time. Ask the participant and group for possible solutions for the barrier, facilitators then can offer some ideas too.

8. Overall Goal Review: Activity Discussion (20 mins)

- Distribute overall programme goal sheets. Over the last few weeks does anybody feel they have achieved their goals?
- Or did they achieve something else?

9. Community Resources: Brainstorm and Presentation of Certificate (15 mins)

- Ask participants what they are going to do on the mornings they usually have their group now that the programme is finishing? People in the group have a lot of knowledge about things they could do and places for activities. Where can people go for more information on their health conditions or support? Where could people go for activities or other groups? (Brainstorm on flipchart)
- Following discussion hand out resource sheet with local organisations and activities that happen in the area.
- Certificates are awarded to each group member- to remind each of you of all you have learnt and that you are a self-manager and a reminder of your achievements.

Appendix 4 Goal Attainment Scaling Form

OPTIMAL Programme Goals Record Sheet

Name:.....

Think of some **health changes** and/or **activities** you would like to achieve by the end of the 6-week OPTIMAL programme.

You can make **1-6 goals** that you would like to do by the end of the programme. Try and make your goals **SMART**.

Rate how **important** and **difficult** the goal is. Rate at the OPTIMAL programme start whether you can do this goal somewhat or if you can't do it at all. Only fill out the **RED** sections.

	Goals	Importance	Difficulty	OPTIMAL Start	Goal Achievement	
1.		0 (not at all) 1 (a little) 2 (moderately) 3 (very)	0 (not at all) 1 (a little) 2 (moderately) 3 (very)	<input type="checkbox"/> Some function (able to do some of it) <input type="checkbox"/> None (as bad as can be)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> As expected <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse
2.		0 (not at all) 1 (a little) 2 (moderately) 3 (very)	0 (not at all) 1 (a little) 2 (moderately) 3 (very)	<input type="checkbox"/> Some function (able to do some of it) <input type="checkbox"/> None (as bad as can be)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> As expected <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse
3.		0 (not at all) 1 (a little) 2 (moderately) 3 (very)	0 (not at all) 1 (a little) 2 (moderately) 3 (very)	<input type="checkbox"/> Some function (able to do some of it) <input type="checkbox"/> None (as bad as can be)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> As expected <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse

OPTIMAL Goal Record Sheet continued

	Goals	Importance	Difficulty	OPTIMAL Start	Goal Achievement	
4.		0 (not at all) 1 (a little) 2 (moderately) 3 (very)	0 (not at all) 1 (a little) 2 (moderately) 3 (very)	<input type="checkbox"/> Some function (able to do some of it) <input type="checkbox"/> None (as bad as can be)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> As expected <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse
5.		0 (not at all) 1 (a little) 2 (moderately) 3 (very)	0 (not at all) 1 (a little) 2 (moderately) 3 (very)	<input type="checkbox"/> Some function (able to do some of it) <input type="checkbox"/> None (as bad as can be)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> As expected <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse
6.		0 (not at all) 1 (a little) 2 (moderately) 3 (very)	0 (not at all) 1 (a little) 2 (moderately) 3 (very)	<input type="checkbox"/> Some function (able to do some of it) <input type="checkbox"/> None (as bad as can be)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> As expected <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse

OT Notes on why goal achievement below/above expected level?:

Summary

Baseline GAS T-score:	Achieved GAS T-score	Change in GAS T Score
------------------------------	-----------------------------	------------------------------

Appendix 5 OPTIMAL Weekly goal-setting and review sheets

In writing your action plan, be sure it includes

1. **what** you are going to do.
2. **how much** you are going to do.
3. **when** you are going to do it, and
4. **how many** days a week you are going to do it.

This week I will _____ (what)
 _____ (how much)
 _____ (when)
 _____ (how many)

Steps required to achieve goal:

- 1.
- 2.
- 3.
- 4.
- 5.

What supports/enablers are available to help me achieve this goal?

What barriers may there be to me achieving this goal?

How confident are you
 (0= not at all confident; 10= totally confident) _____

	Check Off	Comments
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

Goal Review

Time taken to complete the task:

This task was: Easy OK Quite Difficult Very Difficult

Specific difficulties identified:

Strategies to improve performance:

Appendix 6 Original sample size calculation

Sample size calculation was based on the primary outcomes i.e. the Frenchay Activities Index and the EQ-VAS. Sample size was calculated using data from the pilot RCT carried out in the same primary care setting with similar participants (Garvey et al., 2015). In relation to participant loss to follow up, a loss to follow up of 30% was anticipated. This was higher than the attrition in the pilot trial but took into account the longer follow-up period. Separate sample size calculations were performed for the two primary outcome measures.

1. Frenchay Activity Index

The pilot RCT reported FAI baseline scores of 20.9 (SD 7.5). The intervention group improved by 4 points and the control group dis-improved by 0.2 point. To improve a baseline FAI score of 20.9 by 4 points, with 90% power, required a sample size of 150 in total (n=75 per group).

Improvements of 4 points have been reported as clinically significant in older patients with stroke (Forster et al., 2009). To allow for a 30% loss to follow up of participants, 45 participants were added. Therefore, a sample of 195 participants was required to show a clinically significant improvement in FAI scores.

2. The pilot RCT reported EQ-VAS scores of 53.9 (SD 24.3). Improvements of 8.7 points have been reported as a moderate effect size and changes of 14 points have been reported as representing a large effect size in clinically ill patients (as opposed to population norms) (Roset, Badia, & Mayo, 1999). In the pilot RCT, the intervention group scores improved by 11 points and the control group dis-improved by 0.5 points. To improve a baseline EQ-VAS score of 53.9 by 14 points, with 90% power, required a total sample size of 130 (n=65 per group). To allow for a 30% loss to follow up, 40 participants were added. Therefore a total sample of 170 participants was required to show a clinically significant improvement in EQ-VAS scores.

Therefore to have 90% power to detect a clinically relevant change in both primary outcomes measures at a 0.05 significance level and to allow for 30% loss to follow-up, a sample of 200 participants was needed.

Appendix 7 Information Packs for GPs and Primary Care Professionals



Dear _____,

We are starting an exciting new study in XXX in the XXX. We are investigating the effectiveness of OPTIMAL, which is an occupational therapy led, group-based self-management programme for people with multimorbidity. The overall aim of OPTIMAL is to increase peoples' activity participation levels and to improve their multimorbidity self-management strategies. The programme involves weekly group meetings over a period of six weeks and is led by your local Occupational Therapists. It focuses on areas such as fatigue and energy management, healthy eating, keeping physically active, medication management, stress and anxiety management and communicating effectively with health professionals.

The OPTIMAL programme will run in your area in XXX in XXX. We are now recruiting participants for this study and we are asking health professionals, primary care team members, local GPs and practice nurses to consider and refer suitable patients (Patients aged 40 and over with at least two conditions and on at least four regular medications). The study design is a randomised controlled trial with the control group being randomly allocated to a waiting list to receive the programme once the main study is finished after 6-months. All patients who agree to participate will be assessed using standardised assessments, three times as follows: i) Baseline (before OPTIMAL starts), ii) Immediate follow-up (after OPTIMAL finishes) and iii) at 6-month follow up. We hope to recruit 15 people per intervention group and 15 people per control (waiting list) group. Therefore 30 people will be recruited for the study in your primary care team area. OPTIMAL is also being run in other PCT areas in Dublin and Kildare.

Please find enclosed further information on the programme, the referral procedure and referral form. The research team will follow-up this letter with a phone call to confirm if the practice is willing to be involved and to refer eligible patients and to answer any queries in relation to the programme and study.

We would like to extend our gratitude in advance for your consideration and should you have any further queries about the research project please contact a member of the research team.

Yours sincerely,

Ms. Lynn O' Toole
HRB Fellow,
Discipline of
Occupational Therapy,
Trinity College
T: XXX; E: XXX

Prof Susan Smith,
Professor of Primary
Care Medicine,
RCSI Department of
General Practice,
Beaux Lane House,
Lower Mercer Street, 2,
Ireland
T: XXX; E: XXX

Dr. Deirdre Connolly,
Associate Professor,
Discipline of
Occupational Therapy,
Trinity Centre for Health
Sciences,
St. James Hospital,
James St.,
Dublin 8
T: XXX; E: XXX

Dr. Fiona Boland,
RCSI,
Population Health
Sciences
123 St Stephens
Green 2 Ireland
T: XXX; E: XXX

OPTIMAL Programme

What is the OPTIMAL programme?

The OPTIMAL Programme aims to increase peoples’ activity participation levels and to improve their self-management strategies for their multimorbidity. It is a group-based programme run over a six-week period, meetings last approx. 2.5 hours and occur once a week.

Where will the programme be held?

This programme will be delivered in XXX. A patient’s home address is not important once they are happy to travel to the location.

How will the study be conducted?

A study is being conducted to determine the impact of this programme on activity participation and quality of life. This is a randomised controlled trial with a waiting list control group. This means in order to determine if the programme is effective, some participants will receive the programme while others are randomly allocated to a waiting list to receive the programme after 6-month follow-up. All patients who agree to participate will be assessed three times as follows: i) Baseline (before the programme starts and prior to allocation), ii) Immediate follow-up (after the programme ends) and iii) at 6-month follow up.

How many patients need to be recruited?

Each group will consist of between 10 and 12 participants. Allowing for attrition, it is planned to recruit 15 people per intervention group and 15 controls (waiting list). Therefore 30 people will be recruited for the group in the XXX area.

Who is eligible for the programme?

Inclusion criteria	Exclusion criteria
<p>Participants must:</p> <ul style="list-style-type: none"> ✓ Be over 40 years of age ✓ Have a minimum of two chronic conditions ✓ Have a minimum of four repeat, different medications ✓ Be able to travel to the primary care/health centre in which the programme will take place 	<p>Participants must not be:</p> <ul style="list-style-type: none"> ✗ Someone with a significant physical or mental illness, which is likely to impair capacity to participate in the programme.



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin



HRB Health
Research
Board

Referral Procedure: OPTIMAL Programme

The following steps are taken:

1. Decide how you will identify suitable patients (The research team is happy to visit you or discuss with you how this can be done)
2. Identify suitable patient and discuss proposed intervention with them (Participant information leaflets will be provided)
2. If patient is interested in participating, please give them a copy of a participant pack (provided by the research team if your practice wishes to participate)
3. Complete the Primary Care Team Referral Form
4. Send referral form via email, fax or post to:

XXXXXX
XXXXXX

The **OT Dept. will contact patients to verify if they are willing to participate.**

5. If patient wishes to participate, they will then be contacted by the OT Department to arrange a time for getting patient consent and for initial assessment

Please contact Ms. Lynn O' Toole (Principal Investigator) with any queries regarding the study. P: XXX E: XXX



Self-Management Programme
for chronic health conditions

Learn what you can do to live well, stay
active and manage your health

Appendix 8 OPTIMAL Referral form for GPs and Primary Care Professionals



PRIMARY CARE TEAM REFERRAL FORM



The OPTIMAL Programme and Study: Occupation based, self management programme for people with **multimorbidity**

Please ensure all sections complete & consent received from Client

Client Name			
Address		DOB	
		Day Month Year	
		Gender <input type="checkbox"/> Male <input type="checkbox"/> Female	
Tel/Mobile #		Consent to receive Text messages? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Parent/Guardian/ NOK		GP Name (if any)	
Relationship to client		Address	
Tel / Mobile #		Tel #	
GMS/CHI no:			

Referral To <small>Tick box for discipline(s) you are referring to</small>	
Health & Social Care Professionals (PCT / HSCN)	All referrals can be emailed, faxed or posted to:
To: Primary Care Occupational Therapy Dept. Fax: <input type="checkbox"/> OPTIMAL Programme: OT Occupation based, six-week, self management programme for people with multimorbidity	

Reason for Referral <small>Please be specific</small>	OPTIMAL Programme: Occupation based, self management programme for people with multimorbidity
---	---

Relevant History/ Issues of Concern	(Have a minimum of two chronic conditions- please specify conditions)
--	---

Medications	(To be eligible, patients must have a minimum of four repeat medications) Please state number of repeat medications: _____
--------------------	---

Social Circumstances	Live alone? <input type="checkbox"/> Yes <input type="checkbox"/> No With whom? _____
-----------------------------	---


Mobility	<input type="checkbox"/> Independent <input type="checkbox"/> With Aid <input type="checkbox"/> Wheelchair
Other professionals involved in client's care?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <small>If "Yes" provide name & contact details</small>

HAS CLIENT (OR PARENT/CAREGIVER) CONSENTED TO THIS REFERRAL?	<input type="checkbox"/> Yes <input type="checkbox"/> No
---	--

HAS CLIENT (OR PARENT/CAREGIVER) CONSENTED TO SHARING OF HIS/HER INFORMATION?	<input type="checkbox"/> Yes <input type="checkbox"/> No
--	--

Referred By	Name / Title	Date
	Signature	Tel #
Preferred method of contact:	<input type="checkbox"/> Telephone <input type="checkbox"/> Fax <input type="checkbox"/> Email	
PCT / HSCN / OOH Co-op / Hospital Dept		

Appendix 9 OPTIMAL Poster



*Self-Management Programme
for chronic health conditions*

A free 6-week group programme on practical strategies
to manage your health and live an active life

Do you:

- Have two or more long term health conditions?
- Take four or more prescribed medications?
- Want support managing your health conditions?

To find out more about taking part in a study of the
programme please contact XXXXXXXX
(Programme Coordinator)
Phone: XXXXXXXX

Appendix 10 Participant Information Leaflet and Consent Form



PARTICIPANT INFORMATION LEAFLET

The OPTIMAL study: A randomized controlled trial and process evaluation of an OccuPaTional therapy led self MAnagement support programme for patients with muLtimorbidity in primary care.

Researchers: Ms. Lynn O' Toole, Dr. Deirdre Connolly, Prof. Susan Smith & Dr. Fiona Boland

I am inviting you to take part in a research project. However before you decide to take part you should understand why it is being done and what it will involve. You should read this leaflet carefully and discuss it with others before you decide if you want to take part.

Why is this project being done?

This study aims to investigate the impact of an occupational therapy led self-management programme, named OPTIMAL, on your activities, quality of life and confidence. This is a group programme which is facilitated over a 6-week period and aims to assist and educate individuals on how to incorporate chronic disease management strategies into their daily routines to maintain function and improve their overall health. In total 6 group sessions will be run over six weeks, each session lasting approximately 2 hours and 30 minutes.

What have I been chosen?

You are being asked to participate in this research project as you have been identified by your health professional or you have identified yourself as a suitable participant for this project. To be eligible for this project, participants must be:

- Over 40 years of age
- Have two or more chronic or long-term conditions
- Take four or more prescribed regular medications.

Please check with your GP or other health professionals that you are eligible to participate. The design of the study is that participants will be randomly allocated to either start the OPTIMAL self-management programme immediately or allocated to a waiting list for the self-management programme to start at a later date. Being allocated to the OPTIMAL programme waiting list is in relation to the OPTIMAL programme only and not in relation to normal treatment or your usual primary care services. The purpose of the waiting list is to act as a comparison which helps to show whether the programme is effective or not. If you are randomly allocated to the waiting list you will be offered the self-management programme when the research is completed if the programme is found to be effective.

What would I have to do?

If you are allocated to start the self-management programme immediately you will attend a group session every week for six weeks in your local health or community centre. Each session will last 2 hours and 30 minutes and will have a tea/coffee break in the middle. An occupational therapist will run the group with input from a physiotherapist and pharmacist. Sessions will cover topics such as dealing with stress, tiredness, communicating with health professionals, managing medications and exercise. The occupational therapist will help you work towards personal goals in activities and health management.

All participants whether attending the programme or allocated to the OPTIMAL programme waiting list will be assessed three times to identify if the programme helps improve activities,

mood, confidence, and overall well-being. This will happen before the programme starts, after the programme ends and six months later. These assessments will take approximately 45 minutes to complete and will take place in your local Health Centre. For those participating in the self-management programme, the purpose of assessment is to note if there is any change following the self-management programme. For those on the waiting list, the assessment is to note if there is any difference between those who receive the programme and those who don't, to see if the programme is effective or not.

To find out your opinion of the programme and how to improve it, one group interview will be held on the day of the final programme session. This interview will be audio recorded and you can be provided with a written copy of this recording if you wish. This interview will take approx 30-40 minutes and lunch will be provided on this day.

Is this research likely to benefit anyone?

If the OPTIMAL programme is found to be effective it may help you to identify and address difficulties with your daily activities and give you an increased awareness of strategies for managing your health. It may also give you an opportunity to meet other similar minded individuals and to gain insight into others' self-management techniques. Furthermore, if OPTIMAL is effective it may be used by occupational therapists to help people manage their health and everyday activities. However, if the programme is found not to be effective there may be no direct benefits to you.

Would there be any risks?

There are no anticipated risks associated with taking part in this study and if you experience any difficulties you can discuss these with the therapist running the group or with your own GP or Primary Care Team member.

Will there be any costs?

Participants will have to organise transport to and from the group in the health centre. Otherwise the programme is free of charge, including the refreshments mentioned above.

What about confidentiality?

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the study or programme group. If you wish, you can request and share your assessment scores with your health professionals in case there is anything you want to talk about. All data collected will be stored securely and confidentially for five years and then destroyed.

Is this project covered by insurance?

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Do you have to take part?

If you decide to volunteer to participate in this study, you may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study. It will not affect your current or future care from primary care and you do not have to give a reason for not taking part. However if you decide to participate you understand that the investigators may withdraw your participation in the study at any time without your consent.

Does this project have permission to be carried out?

This project has Research Ethics Committee approval from Trinity College Dublin.

Who should you talk to if you have any questions or concerns?

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Ms. Lynn O' Toole, who can be telephoned at XXX or XXX. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.



Informed Consent Form

PROJECT TITLE: The OPTIMAL study: A randomized controlled trial and process evaluation of an OccuPaTlional therapy led self MAnagement support programme for patients with muLtimorbidity in primary care.

PRINCIPAL INVESTIGATORS: Ms. Lynn O’ Toole, Dr. Deirdre Connolly, Prof. Susan Smith & Dr. Fiona Boland

BACKGROUND:

This study aims to investigate the impact of an occupational therapy led self-management group, named OPTIMAL, on your activities, quality of life and confidence. The OPTIMAL programme involves attending group sessions, once a week for six weeks in your primary care centre. Sessions will cover techniques to deal with issues such as stress, tiredness, communicating effectively, managing medication and exercise. The programme will also help you work towards personal goals in activities and health management.

The design of the study is that participants will be randomly allocated to either start the self-management group immediately or to a waiting list. The purpose of the waiting list is to act as a comparison which helps to show whether the programme is effective or not. If you are randomly allocated to the waiting list you will be offered the self-management group when the research is completed if the programme is found to be effective. Regardless of whether you start the programme immediately or are on the waiting list, you will be assessed three times in order to establish if the programme helps improve activities and overall well-being, This will happen before the group starts, after it ends and six months later. These assessments will take place in your local primary care centre. To find out your opinion of the group and how to improve it, a group discussion will be held with all programme members on the final programme session. This will be audio recorded and you can read a copy of this recording if you wish.

If you decide to volunteer to participate in this study, you may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study. It will not affect your current or future care from primary care and you do not have to give a reason for not taking part.

Your identity will remain confidential. Your name will not be published or disclosed to anyone outside the study or programme group. If you wish, you can request and share your assessment scores with your health professionals in case there is anything you want to talk about. All data collected will be stored securely and confidentially for five years and then destroyed. In the case that my information may be needed for future studies, my consent will be sought again to do this. I agree to have my information included in any presentations or publications related to this study however I understand that this information will not be identifiable.

DECLARATION:

I have read, or had read to me, the information leaflet for this project and I understand the contents. I have had the opportunity to ask questions and they have been answered to my satisfaction. I freely agree to be part of this study, though without prejudice to my legal and ethical rights. I understand that I may withdraw from the study at any time and I have received a copy of this agreement. I understand that the investigators may withdraw my participation in the study at any time without my consent.

PARTICIPANT'S NAME:

CONTACT DETAILS:

PARTICIPANT'S SIGNATURE

Date:.....

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S SIGNATURE:..... **Date:**.....

Appendix 11 Baseline Participant Questionnaires



Participant Name: _____ Date: _____ Location: PCC/Home (please circle)

Assessor: _____ Time take for assessment completion: _____

**Please check that information regarding numbers and types of conditions, numbers of repeat medications and GMS eligibility and referral source is completed on referral from. LOT will require this information*

1. Age	
2. Gender (please ✓ applicable box)	Male <input type="checkbox"/> Female <input type="checkbox"/>
3. Marital Status (please ✓ applicable box)	Single <input type="checkbox"/> Married <input type="checkbox"/> In a Relationship <input type="checkbox"/> Separated/divorced <input type="checkbox"/> Widowed <input type="checkbox"/>
4. Living Situation (please ✓ applicable box)	Living alone <input type="checkbox"/> Living with family <input type="checkbox"/> Living with others than family <input type="checkbox"/>
8. Highest level of education (please ✓ applicable box)	Primary <input type="checkbox"/> Secondary to inter cert/junior cert level <input type="checkbox"/> Secondary to leaving cert level <input type="checkbox"/> College/University <input type="checkbox"/>
9. Current employment status (please ✓ applicable box)	Full-time <input type="checkbox"/> Part-time <input type="checkbox"/> Unemployed <input type="checkbox"/> Retired <input type="checkbox"/> Full-time housewife <input type="checkbox"/> Not working currently due to diagnosis/treatment <input type="checkbox"/> Education/Training <input type="checkbox"/> Other <input type="checkbox"/> Please specify _____
10. Health Care Use	
a) In the last 6 months, about how often did you visit your GP?	
b) In the last 6 months, how many times did you visit a hospital Emergency Department (sometimes called A&E or Accident and Emergency) as a patient?	
c) In the last 6 months, how many times were you admitted to a hospital? For how many nights?	_____ times Stay one _____ nights Stay two _____ nights Stay three _____ nights
c) In the last 6 months, about how many visits did you make to a hospital as an out-patient? (Include all types of consultations, tests, operations, procedures or treatments)	
d) In the last 6 months, have you received services from other health professionals	Yes <input type="checkbox"/> No <input type="checkbox"/> If yes... (tick all those that apply- only include OT/Physio external to the OPTIMAL programme): Public Health or Community Nurse <input type="checkbox"/> Occupational therapy <input type="checkbox"/> Physiotherapy services <input type="checkbox"/> Speech & Language Therapist <input type="checkbox"/> Social work services <input type="checkbox"/> Psychological/counselling services <input type="checkbox"/> Home help <input type="checkbox"/> Other <input type="checkbox"/> Please specify _____

EQ-5D

By placing a tick in one box in each group below, please indicate the statements that best describe your own health state today.

Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

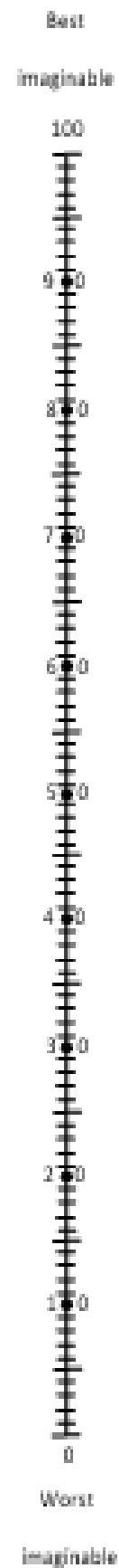
Anxiety/Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own
health state**



The Frenchay Activities Index

Below are statements about how frequently you engage in different activities. Please circle the answer which most closely applies to you.

In the last **three months** how often have you:

1. Prepared meals	Most days	1 – 2 times a week	Less than once a week	Never
2. Done the washing up	Most days	1 – 2 times a week	Less than once a week	Never

In the last **three months** how often have you:

3. Washed clothes	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
4. Light housework (dusting, polishing, ironing)	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
5. Heavy housework (hovering, changing beds, cleaning windows, etc)	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
6. Local shopping	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
7. Social outings (clubs, cinema, meeting friends etc)	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
8. Walked outside for more than 15 minutes (approx 1 mile)	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
9. Actively pursued a hobby	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
10. Driven a car/gone in a bus	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never

In the last **six months** how often have you undertaken:

11. Travel, outings/car rides	At least weekly	Between 3-12 times (once every two weeks to once a month.)	1-2 times in past six months	Never
12. Gardening	All necessary	Moderate	Light	Never
13. Household DIY/car maintenance	All necessary	Moderate	Light	Never
14. Read books (not paper/magazines)	More than one a fortnight	One a fortnight	One in six months	Never

15. Gainful work (paid work only)	Over 30 hours/week	10-30 hours/week	Up to 10 hours/week	None
-----------------------------------	--------------------	------------------	---------------------	------

Nottingham Extended ADL Scale

The following questions are about everyday activities. Please answer by ticking ONE box for each question. Please record what you have ACTUALLY done in the last few weeks.

DID YOU.....	Not at all	with help	on your own with difficulty	on your own
1. Walk around outside?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Climb stairs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Get in and out of a car?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Walk over uneven ground?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Cross roads?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Travel on public transport?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Manage to feed yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Manage to make yourself a hot drink?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Take hot drinks from one room to another?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Do the washing up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Make yourself a hot snack?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	No	With help	On your own with difficulty	On your own
12. Manage your own money when out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Wash small items of clothing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Do your own housework?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Do your own shopping?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Do a full clothes wash?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Read newspapers or books?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Use the telephone?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Write letters?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Go out socially?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Manage your own garden?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Drive a car?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Self-Efficacy for Managing Chronic Disease 6-Item Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

not at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | totally confident

2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

not at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | totally confident

3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

not at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | totally confident

4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

not at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | totally confident

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?

not at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | totally confident

6. How confident are you that you can do things other than just taking medication to reduce how much your illness affects your everyday life?

not at all | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | totally confident

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the six items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate is best

D	A		D	A	
		1. I feel tense or 'wound up':			8. I feel as if I am slowed down:
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		2. I still enjoy the things I used to enjoy:			9. I get a sort of frightened feeling like 'butterflies' in the stomach:
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite often
3		Hardly at all		3	Very often
		3. I get a sort of frightened feeling as if something awful is about to happen:			10. I have lost interest in my appearance:
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take quite as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		4. I can laugh and see the funny side of things			11. I feel restless as I have to be on the move:
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		5. Worrying thoughts go through my mind			12. I look forward with enjoyment to things:
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		6. I feel cheerful			13. I get sudden feelings of panic:
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		7. I can sit at ease and feel relaxed:			14. I can enjoy a good book or radio or TV program:
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not often	2		Not often
	3	Not at all	3		Very seldom

*Please check you have answered all questions

Total Score: Depression (D) _____ Anxiety (A) _____ (0-7=normal; 8-10=borderline; 11-21=abnormal)

CANADIAN OCCUPATIONAL PERFORMANCE MEASURE

Authors:

Mary Law, Sue Baptiste, Anne Carswell,
Mary Ann McColl, Helene Polatajko, Nancy Pollock

The Canadian Occupational Performance Measure (COPM) is an individualized measure designed for use by occupational therapists to detect self-perceived change in occupational performance problems over time.

Client Name:		
Age:	Gender:	ID#:
Respondent (if not client):		
Date of Assessment:	Planned Date of Reassessment:	Date of Reassessment:

Therapist:
Facility/Agency:
Program:

**STEP 1:
IDENTIFICATION OF OCCUPATIONAL PERFORMANCE ISSUES**

To identify occupational performance problems, concerns and issues, interview the client, asking about daily activities in self-care, productivity and leisure. Ask clients to identify daily activities which they want to do, need to do or are expected to do by encouraging them to think about a typical day. Then ask the client to identify which of these activities are difficult for them to do now to their satisfaction. Record these activity problems in Steps 1A, 1B, or 1C.

**STEP 2:
RATING
IMPORTANCE**

Using the scoring card provided, ask the client to rate, on a scale of 1 to 10, the importance of each activity. Place the ratings in the corresponding boxes in Steps 1A, 1B, or 1C.

STEP 1A: Self-care

Personal Care
(e.g., dressing, bathing,
feeding, hygiene)

Functional Mobility
(e.g., transfers,
indoor, outdoor)

Community Management
(e.g., transportation,
shopping, finances)

IMPORTANCE

STEP 1B: Productivity

Paid/Unpaid Work
(e.g., finding/keeping
a job, volunteering)

Household Management
(e.g., cleaning,
laundry, cooking)

Play/School
(e.g., play skills,
homework)

STEP 1C: Leisure

Quiet Recreation
(e.g., hobbies,
crafts, reading)

Active Recreation
(e.g., sports,
outings, travel)

Socialization
(e.g., visiting,
phone calls, parties,
correspondence)

IMPORTANCE

STEPS 3 & 4: SCORING - INITIAL ASSESSMENT and REASSESSMENT

Confirm with the client the 5 most important problems and record them below. Using the scoring cards, ask the client to rate each problem on performance and satisfaction, then calculate the total scores. Total scores are calculated by adding together the performance or satisfaction scores for all problems and dividing by the number of problems. At reassessment, the client scores each problem again for performance and satisfaction. Calculate the new scores and the change score.

Initial Assessment:

OCCUPATIONAL PERFORMANCE PROBLEMS:

1. _____
2. _____
3. _____
4. _____
5. _____

PERFORMANCE 1

SATISFACTION 1

Reassessment:

PERFORMANCE 2

SATISFACTION 2

SCORING:

Total score = $\frac{\text{Total performance or satisfaction scores}}{\text{\# of problems}}$

PERFORMANCE SCORE 1

SATISFACTION SCORE 1

PERFORMANCE SCORE 2

SATISFACTION SCORE 2

/

=

/

=

/

=

/

=

CHANGE IN PERFORMANCE = Performance Score 2 - Performance Score 1 =

CHANGE IN SATISFACTION = Satisfaction Score 2 - Satisfaction Score 1 =

Appendix 12 Immediate Follow-Up Questionnaires



Name: _____

Date: _____

EQ-5D

By placing a tick in one box in each group below, please indicate the statements best describe your own health state today.

Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

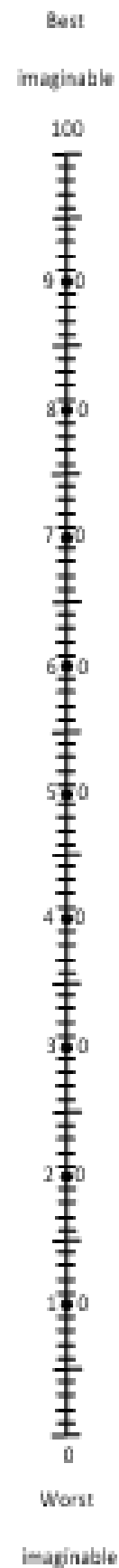
Anxiety/Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own
health state**



The Frenchay Activities Index

Below are statements about how frequently you engage in different activities. Please circle the answer which most closely applies to you.

In the last **three months** how often have you:

1. Prepared meals	Most days	1 – 2 times a week	Less than once a week	Never
2. Done the washing up	Most days	1 – 2 times a week	Less than once a week	Never

In the last **three months** how often have you:

3. Washed clothes	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
4. Light housework (dusting, polishing, ironing)	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
5. Heavy housework (hovering, changing beds, cleaning windows, etc)	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
6. Local shopping	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
7. Social outings (clubs, cinema, meeting friends etc)	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
8. Walked outside for more than 15 minutes (approx 1 mile)	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
9. Actively pursued a hobby	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never
10. Driven a car/gone in a bus	At least weekly	3-12 times (between once/week to once a month)	1-2 times in past 3 months (less than once a month)	Never

In the last **six months** how often have you undertaken:

11. Travel, outings/car rides	At least weekly	Between 3-12 times (once every two weeks to once a month.)	1-2 times in past six months	Never
12. Gardening	All necessary	Moderate	Light	Never
13. Household DIY/car maintenance	All necessary	Moderate	Light	Never
14. Read books (not paper/magazines)	More than one a fortnight	One a fortnight	One in six months	Never

15. Gainful work (paid work only)	Over 30 hours/week	10-30 hours/week	Up to 10 hours/week	None
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Appendix 13 Ethical Approval Letter



Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Lynn O'Toole
Discipline of Occupational Therapy
Trinity Centre for Health Sciences
St. James Hospital
James St.
Dublin 8

Ref: 150900

Title Of Study: "The OPTIMAL study: A randomized controlled trial and process evaluation of an OccuPaTional therapy led self MAagement support programme for patients with muLtimorbidity in primary care."

Dear Lynn,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in November 2015, we are pleased to inform you that the above project has been approved without further audit.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Dr. Ruth Pilkington".

Dr. Ruth Pilkington
Chairperson
Faculty Research Ethics Committee

Dáire na nEalaíochtaí Sláinte
Foinseamh na Ceimice, Coláiste na Tríonóide,
Ollscoil Átha Cliath,
Baile Átha Cliath 2, Éire.

Faculty of Health Sciences
Chemistry Building,
Trinity College Dublin,
The University of Dublin,
Dublin 2, Ireland.

www.healthsciences.tcd.ie

Appendix 14 Fidelity Tool

Session One: Introduction to self-management

Date: _____ Time start: _____ Time end: _____ Location: _____

Duration of session: _____

How many facilitators delivered the programme: _____ (Please make a note of change of facilitators if they are not the same)

How many people attended the session: _____ (Please remember to record individual participant attendance)

Please indicate if the following content and activities were covered in today's session

Content/Activity	Completed	Time taken	Comments (Any additional comments success/challenges in completing content/activity)
1. Plan for the day: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
2. Introduction to facilitators and participants: Ice breaker activity	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3. Introduction to group, self-management and programme overview: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4. Being a group- what works and doesn't : Brainstorm	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5. Being a group- group rules: Brainstorm	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6. The vicious symptom cycle: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7. Impact of multimorbidity on activity: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		

8. Impact of multimorbidity on activity: Brainstorm	Yes <input type="checkbox"/> No <input type="checkbox"/>		
9. Tea Break	Yes <input type="checkbox"/> No <input type="checkbox"/>		
10. Distribution and purpose of handbook: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
11. Explanation of goal setting: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
12. Setting overall programme goals: Activity Did all participants overall programme goals Please indicate how many set goals X/X	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> ____ / ____		
13. Closing: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		

Did you follow and complete the programme content as outlined in the facilitator manual Yes No

If no, please indicate why: _____

What went well today?

What problems, if any, arose in the group today?

Session Two: Fatigue Management and Healthy Eating

Date: _____ Time start: _____ Time end: _____ Location: _____

Duration of session: _____

How many facilitators delivered the programme: _____ (Please make a note of change of facilitators if they are not the same)

How many people attended the session: _____ (Please remember to record individual participant attendance)

Please indicate if the following content and activities were covered in today's session

Content/Activity	Completed	Time taken	Comments (Any additional comments success/challenges in completing content/activity)
1. Introduction to the group: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
2. Fatigue management principles: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3. Managing fatigue in daily activities: Activity (Worksheet and Group Discussion)	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4. Managing fatigue- Sample strategies: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5. Tea Break	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6. Healthy Eating: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7. Healthy Eating: Brainstorm (Challenges and small changes)	Yes <input type="checkbox"/> No <input type="checkbox"/>		

8. Setting goals: Activity Did all participants set a goal for the week? Please indicate how many set goals X/X	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> _____ / _____		
9. Closing: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		

Did you follow and complete the programme content as outlined in the facilitator manual Yes No

If no, please indicate why: _____

What went well today?

What problems, if any, arose in the group today?

Session Three: Maintaining Physical Activity

Date: _____ Time start: _____ Time end: _____ Location: _____

Duration of session: _____

How many facilitators delivered the programme: _____ (Please make a note of change of facilitators if they are not the same)s

How many people attended the session: _____ (Please remember to record individual participant attendance)

Please indicate if the following content and activities were covered in today's session

Content/Activity	Completed	Time taken	Comments (Any additional comments success/challenges in completing content/activity)
1. Introduction to the group: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
2. Physical activity- Benefits of exercise: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3. Godin Physical Activity Levels- Are you meeting recommended levels: Activity (Worksheet and Group Discussion	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4. Continue Lecturette by Physiotherapist (15 mins) Recommended Levels, Types and Designing a Programme: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5. Question and Answer: Activity	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6. Tea Break	Yes <input type="checkbox"/> No <input type="checkbox"/>		

7. Halfway Review: Activity	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8. Goal Review: Activity How many participants achieved their goal this week? X/X	Yes <input type="checkbox"/> No <input type="checkbox"/> ____ / ____		
9. Setting goals: Activity Did all participants set a goal for the week? Please indicate how many set goals X/X	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> ____ / ____		
10. Closing: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		

Did you follow and complete the programme content as outlined in the facilitator manual Yes No

If no, please indicate why: _____

What went well today?

What problems, if any, arose in the group today?

Session Four: Maintaining Mental Well-Being

Date: _____ Time start: _____ Time end: _____ Location: _____

Duration of session: _____

How many facilitators delivered the programme: _____ (Please make a note of change of facilitators if they are not the same)

How many people attended the session: _____ (Please remember to record individual participant attendance)

Please indicate if the following content and activities were covered in today's session

Content/Activity	Completed	Time taken	Comments (Any additional comments success/challenges in completing content/activity)
1. Introduction to the group: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
2. Causes and Signs of Low mood/Stress: Brainstorm	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3. Worry worksheet: Activity	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4. Maintaining Mental Well-Being/Sleep: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5. Tea Break	Yes <input type="checkbox"/> No <input type="checkbox"/>		

6. Guided visualisation: Activity	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7. Goal Review: Activity How many participants achieved their goal this week? X/X	Yes <input type="checkbox"/> No <input type="checkbox"/> ____ / ____		
8. Setting goals: Activity Did all participants set a goal for the week? Please indicate how many set goals X/X	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> ____ / ____		
9. Closing: Lecturette			

Did you follow and complete the programme content as outlined in the facilitator manual Yes No

If no, please indicate why: _____

What went well today?

What problems, if any, arose in the group today?

Session Five: Managing Medications

Date: _____ Time start: _____ Time end: _____ Location: _____

Duration of session: _____

How many facilitators delivered the programme: _____ (Please make a note of change of facilitators if they are not the same)s

How many people attended the session: _____ (Please remember to record individual participant attendance)

Please indicate if the following content and activities were covered in today's session

Content/Activity	Completed	Time taken	Comments (Any additional comments success/challenges in completing content/activity)
1. Introduction to the group: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
2. Managing Medications: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3. Thoughts of medication and barriers to managing medication: Group Discussion	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4. Demonstration of products: Demonstration	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5. Question and Answer: Activity	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6. Tea Break	Yes <input type="checkbox"/> No <input type="checkbox"/>		

7. Goal Review: Activity How many participants achieved their goal this week? X/X	Yes <input type="checkbox"/> No <input type="checkbox"/> ____ / ____		
8. Setting goals: Activity Did all participants set a goal for the week? Please indicate how many set goals X/X	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> ____ / ____		
9. Closing: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		

Did you follow and complete the programme content as outlined in the facilitator manual Yes No

If no, please indicate why: _____

What went well today?

What problems, if any, arose in the group today?

Session Six: Communicating with Health Professionals and Review

Date: _____ Time start: _____ Time end: _____ Location: _____

Duration of session: _____

How many facilitators delivered the programme: _____ (Please make a note of change of facilitators if they are not the same)s

How many people attended the session: _____ (Please remember to record individual participant attendance)

Please indicate if the following content and activities were covered in today's session

Content/Activity	Completed	Time taken	Comments (Any additional comments success/challenges in completing content/activity)
1. Introduction to the group: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
2. Communicating with Health Professionals: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
3. Reflecting on past communication difficulties and new solutions: Group Discussion	Yes <input type="checkbox"/> No <input type="checkbox"/>		
4. Communicating with families: Group Discussion/Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5. Programme Review: Lecturette	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6. Tea Break	Yes <input type="checkbox"/> No <input type="checkbox"/>		

Goal Review: Activity	Yes <input type="checkbox"/> No <input type="checkbox"/>		
How many participants achieved their goal this week? X/X	____ / ____		
Overall Goal Review: Activity (Discussion)	Yes <input type="checkbox"/> No <input type="checkbox"/>		
Community Resources: Brainstorm	Yes <input type="checkbox"/> No <input type="checkbox"/>		
Presentation of Certificate	Yes <input type="checkbox"/> No <input type="checkbox"/>		

Did you follow and complete the programme content as outlined in the facilitator manual Yes No

If no, please indicate why: _____

What went well today?

What problems, if any, arose in the group today

Appendix 15 Participant Focus Group Topic Guide

Group Design and content

Did the length of the group suit you? – 6 weeks for 2.5 hours per week?- Too much or too little?

What is your **opinion of the topics** covered during the group?

Which ones **were most helpful?**

Which ones **were least helpful?**

Were there topics not covered that you would have liked?

What should be included?

How would you get people to come to a group like this?

What is your opinion of changing the programme to an **online programme?**

Lets discuss how the group affected you, if it all over the last few weeks.

Impact of group

Did the group make any difference in how you **manage your health?**

Yes – how?

No – why not?

Did the group make any difference in your daily **activities or routine?**

Yes – how?

No – why not?

What did you learn about managing your condition in the group?

Do you think these impact/effects last now that the group is ending?

If the groups made an impact on you – why was that?

If you feel the groups didn't really change things for you – why was that?

Lets' turn to the goal setting that we did every week in the group

Goal Setting

What are you opinions of the weekly goal setting?

What helped? What didn't help?

Did you find filling out the **goal setting sheets** helpful?

Did you look at the goal setting sheet during the week?

Do you think the group was enough to help achieve your goals/ difficulties you identified that you set when you first met the occupational therapists? Why/Why not? What else other supports if any would you have liked?

On the group booklet that was provided to you

Group Booklet

To what extent was the booklet helpful? [*Probe: what makes you think this?*]

How often, if at all, did you look at the booklet and information provided [*Probe: Which sections did you use? What made you decide to look at these sections?*]

Is there anything else that would be useful to help you manage your health and participate in activities that should have been included?

Thank you very much for your time and participation!

Appendix 16 Interview Guide Occupational Therapists

Patient Recruitment/Referrals

- How did you decide who to refer to the programme?
- Who do you think are the most appropriate/suitable patients to participate in this programme?
- Were there other referral pathways? How did these work? What do you think would be best referral pathway?
- Were the patients referred always appropriate – if not – expand to give examples.

OPTIMAL Programme Impact

- Do you feel the programme met the needs of the patients referred?
- What impact do you feel, if any, did the programme have on participants? Do you feel the participants benefited from the programme?
- Were there any potential disadvantages? Any concerns?

OPTIMAL Programme Content/Format

- General content? Any suggestions?
 - What is your opinion of the group that you ran? What went well?
 - What didn't work well?
- What is your opinion of the topics covered during the group sessions?
 - Which ones were most helpful?
 - Which ones were least helpful?
 - Were there topics not covered that you feel need to be included to address the needs of those in the programme?
- Were there topics covered that you feel could be excluded?
- What is your opinion on the frequency of sessions/length of sessions?
- What is your opinion of the weekly goal setting? Do you think it was helpful?
- How useful do you think the patient booklet/ relaxation cd was to the patients?
- To you, which were the most valuable components of the intervention?
- Would you suggest any changes?

OPTIMAL Training

How did you find running the self-management group?

- How did you find the programme information/training sessions?
- Did the therapist training help/prepare you in providing the intervention to the participants?
- Would you suggest any changes?

Implementation in primary care

- In your opinion, how relevant is the self-management programme for patients with multimorbidity in primary care?
- Do you think a programme like this could be successfully integrated/rolled out into primary care?

- What are the facilitators/challenges to these types of programmes?
Would you want to continue providing the intervention to other patients as part of your practice after the OPTIMAL study?

Appendix 17 Interview Guide Physiotherapists

Patient Recruitment/Referrals

- Would you consider referring patients on your caseload to this programme? Why or why not?
- What do you think would be best referral pathway for this type of programme?
- Who do you think are the most appropriate/suitable patients to participate in this programme?
- What is your experience of health promotion interventions in the area? Is there enough on offer already?
- Are you part of a Primary Care Team and if so how does it function?

OPTIMAL “Maintaining Physical Activity” Content/Format

- How did you find running the “Maintaining Physical activity” session as part of the OPTIMAL programme group?
- What are your opinions of the “Maintaining Physical Activity” session?
 - What went well?
 - What didn't work well?
 - Were the topics not covered that you feel need to be included in the session to address the needs of those in the programme?
- What is your opinion on the length of “Maintaining Physical Activity” session?
- To you, which were the most valuable components of the session?

OPTIMAL “Maintaining Physical Activity” Materials

- Where the materials provided to you prior to the session sufficient in order to facilitate the session successfully? Why/Why not?

Implementation in primary care

- In your opinion, how relevant is the self-management programme for patients with multimorbidity in primary care in your service area? Is the programme content relevance to concerns/issues of clients in area? Why/Why not?
- How successfully could a programme like this be integrated/rolled out into primary care? What are the facilitators/challenges to these types of programmes and your involvement as a physiotherapist in these type of health promotion programmes?
- Would you consider being involved in delivering the “Maintaining Physical Activity” session of the OPTIMAL programme as part of your practice after the OPTIMAL study if it was rolled out in the future?
- Are primary care occupational therapists the most suitable profession to lead on or provide this type of intervention? Why/Why not?

Appendix 18 Interview Guide Pharmacists

OPTIMAL “Managing Medications” Content/Format

- How did you find running the “Managing Medications” session as part of the OPTIMAL programme group?
- What are your opinions of the “Managing Medications” session?
 - What went well?
 - What didn’t work well?
- Were there topics not covered that you feel need to be included in the session to address the needs of those in the programme?
- What is your opinion on the length of “Managing Medications” session?
- To you, which were the most valuable components of the session?
- OPTIMAL “Managing Medications” Materials
- Were the materials provided to you prior to the session sufficient in order to facilitate the session successfully? Why/Why not?

Implementation in primary care

- How do you find managing complex multimorbidity and polypharmacy?
- What is your opinion on the need for pharmacists
- Providing support for medicines management in primary care?
- To be involved in health promotion programme for patients in primary care?
- What are the facilitators/challenges to your involvement as a pharmacist in these type of health promotion programmes?
- Would you consider being involved in delivering the “Managing Medications” session of the OPTIMAL programme as part of your practice after the OPTIMAL study if it was rolled out in the future?

Appendix 19 Interview Guide GPs

Patient Recruitment/Referrals

- How did you decide who to refer to the programme?
- Who do you think are the most appropriate/suitable patients to participate in this programme?
- What do you think would be best referral pathway?

OPTIMAL Programme Content Impact

- Do you feel the programme met the needs of the patients referred?
- In terms of content- did you think the topics covered were relevant?
 - Do you have any recommendations on content that should be included in programmes for those with multimorbidity?
- What impact do you feel, if any, did the programme have on participants? Do you feel the participants benefited from the programme?
- Were there any potential disadvantages? Any concerns?

Implementation in primary care

- In your opinion, how relevant is the self-management programme for patients with multimorbidity in primary care?
- Do you think a programme like this could be successfully integrated/rolled out into primary care?
- What are the facilitators/challenges to these types of programmes?
 - In terms of GP referrals?
 - In terms of resources required?
- Would you recommend/refer other patients with multimorbidity to the programme in the future?
- Do you have recommendations for future programmes?

Appendix 20 Healthcare Professionals Invitation Letter, Information Leaflet and Consent Form for Interview



PARTICIPANT INFORMATION LEAFLET FOR PRIMARY CARE TEAM MEMBERS

The OPTIMAL study: A randomized controlled trial and process evaluation of an OccuPaTional therapy led self MAnagement support programme for patients with muLtimorbidity in primary care.

Researchers: Ms. Lynn O' Toole, Dr. Deirdre Connolly, Prof Susan Smith & Dr. Fiona Boland

As you are aware a research project is ongoing investigating the effectiveness of OPTIMAL. OPTIMAL is an occupational therapy led self-management programme for people with multimorbidity. The overall aim of this group-based intervention is to increase peoples' activity participation levels and to improve their self-management strategies of their multimorbidity.

As part of the evaluation of the programme, we are seeking health professionals who have been involved in referring patients to the OPTIMAL programme or who have delivered the intervention to take part in an individual semi-structured interview. The purpose of this interview is to examine your experience and views of the feasibility of implementing this intervention in a primary care setting and the appropriateness and acceptability of the programme.

What would I have to do?

If you decide to take part this will involve participating in an individual interview which will last approximately 30-40 minutes. This interview will be audio recorded and you can read a copy of this recording if you wish. The interview can be arranged at a time that is suitable for you and can take place at the Primary Care Centre or be conducted via telephone.

Is this research likely to benefit anyone?

Unfortunately, there are no direct benefits to you for taking part in this study beyond professional satisfaction that you are participating in research and service development. However, the findings of the study may be valuable in identifying the feasibility, appropriateness and acceptability of the OPTIMAL intervention which could be a more efficient way of delivering OT services and thus reduce waiting times for services which would reduce practitioner stress.

What about confidentiality?

Your identity will remain confidential. Each participant will be given an identity code to ensure their details remain anonymous. Your name will not be published and will not be disclosed to anyone outside the study group. The interview will be audio recorded and transcribed into text format. All audiotapes will be destroyed once transcripts have been

completed. You will receive a copy of this transcript if you wish. You will be entitled to make any changes to your statements if you so wish. All data collected will be stored securely and confidentially for five years and then destroyed. Access to this information will be limited to those carrying out the research study.

Would there be any risks?

There are no anticipated risks associated with taking part in this study.

Will there be any costs?

There are no costs associated with participating in these interviews.

Is this project covered by insurance?

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Do you have to take part?

If you decide to volunteer to participate in this study, you may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study. However if you decide to participate you understand that the investigators may withdraw your participation in the study at any time without your consent.

Does this project have permission to be carried out?

This project has Research Ethics Committee approval from the Faculty of Health Sciences Ethics Committee, Trinity College Dublin.

How do you take part?

If you wish to participate in the interviews or would like to get some further information about the study before making your decision, please contact Ms. Lynn O' Toole directly (Ph: 8963220/ otoolelm@tcd.ie). Thank you very much for taking the time to read this information leaflet and for considering participating in this study. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Informed consent form for primary care team members



PROJECT TITLE: The OPTIMAL study: A randomized controlled trial and process evaluation of an OccuPaTlonal therapy led self MAnagement support programme for patients with muLtimorbidity in primary care.

Researchers: Ms. Lynn O' Toole, Dr. Deirdre Connolly, Prof Susan Smith & Dr. Fiona Boland

I am invited to participate in an individual interview as part of the evaluation of OPTIMAL, the occupational therapy led self management support programme for patients with multimorbidity in primary care. I am being invited to participate in this interview as a health professional who has been involved in referring patients to the OPTIMAL programme or delivering the intervention.

If I agree to participate, this will involve me participating in an audio-recorded individual interview about my experience and views of the feasibility of implementing this intervention in a primary care setting and the appropriateness and acceptability of the programme. This interview will last approximately 30-40 minutes. I understand that this interview will be audio recorded and I can have access to the transcript of the interview if I wish.

I understand that I may not benefit directly from participating in this research, however it will provide me with an opportunity to discuss my views of the feasibility, appropriateness and acceptability of the OPTIMAL intervention in primary care. I understand that my participation is voluntary and that I can withdraw at any time without any consequences.

All information which is obtained from me during this research will be treated confidentially. My name will not be published or disclosed to anyone. This will be done by coding the interview transcript and storing it in a locked filing cabinet and on a password protected computer. Only those carrying out this research project will have access to this information. In the case that my information may be needed for future studies, my consent will be sought again to do this. I agree to have my information included in any presentations or publications related to this study however I understand that this information will not be identifiable.

If I have any questions about this research I can contact and ask Lynn O' Toole at Ph: XXX or at E: XXX

I understand what is involved in this research and I agree to participate in the study.

Signature of participant

Date

I believe the participant is giving informed consent to participate in this study

Signature of researcher

Date

Appendix 21 Case studies of cancelled and deferred primary care study areas

This appendix provides a narrative summary of the issues gathered from recruitment logs in the sites that agreed to participate in the study but withdrew from the study or deferred participation.

Area 9

Area 9 experience difficulties with recruitment rates. It was originally planned that Area 9 would be delivered as part of Block 1. It was planned to deliver the programme in a modern primary care centre which had suitable facilities for group intervention delivery. However this venue did not have parking facilities for patients and there were limited public transport options to the centre. Some GP practices who had agreed to refer but were not located within this centre reported that patients were reluctant to attend a primary care centre which was not their local centre (albeit within the same locality and within walking distance). In terms of recruitment while sufficient numbers of patients were initially referred to the programme as part of Block 1 of recruitment, 9 out of 22 patients referred declined to participate when contacted by the gatekeeper. Reasons given for no longer wishing to take part included programme timing not suitable, distance, transport difficulties. OTs also reported concerns about time and resource commitments for them as professionals in delivering the intervention and participating in the study. These difficulties resulted in Area 9 withdrawing from the study.

Area 10

Area 10 experienced difficulties with venue suitability, low recruitment rates and loss of staff, during the recruitment period of Block 2. It was planned to deliver the programme in a local HSE health centre, however there were concerns regarding the venue suitability including rooms suitable for a group-based intervention and problems regarding venue accessibility for those with mobility issues. In terms of recruitment issues, while five practices agreed to refer participants, only one practice referred, with 10 referrals being received from this practice. No referrals were received from any member of the PCT including the occupational therapists. Reasons given for difficulties in recruitment included staff shortages in the wider primary care team including occupational therapy, focus on addressing occupational therapy waiting list, lack of

patient interest and wide geographical area covered by team and lack of transport and ability for patients to travel.

Due to staff loss on the occupational therapy team, the need to address waiting lists and low number of referrals received, the occupational therapy manager requested to defer the programme in order for there to be sufficient staff to run the programme and additional time to generate referrals. Area 10 was deferred and ultimately changed delivery site to another primary care team within the same primary care team area and manager (i.e. successfully delivered in Area 7 as part of Block 4).

Area 11

It was planned that Area 11 would be delivered as part of Block 2. Area 11 was part of the same overall primary care team area and manager as Area 1 which had successfully participated in the study as part of Block 1 of recruitment. The occupational therapists in Area 11 wished to participate in the study due to the team's perceived success of the study in Area 1. However Area 11 experienced difficulties with low recruitment rates and loss of staff, during the recruitment period of Block 2 resulting in the programme being deferred to Block 3. The occupational therapy manager advised the researcher that they had lost a number of staff over a short time period and the priority was addressing waiting lists. Across both blocks of attempted recruitment only six referrals in total were received. While a number of general practices were approached regarding referring patients to the study, only two agreed to refer, with a total of six patients being referred by GPs. One referral was received from the primary care physiotherapist. Given the ongoing difficulties in recruiting sufficient participant numbers for the study to proceed across two Blocks of recruitment, Area 11 withdrew from the study.

Area 12

Area 12 was part of the same primary care area and manager as Area 9. The occupational therapy team agreed to participate in the study as part of Block 4. Area 12 also experienced difficulties with venue suitability and recruitment.

The health centre in Area 12 had limited transport links and no parking, availability of space suitable for group interventions was also limited. It was decided to hire a local community centre which had been used previously for other occupational therapy group interventions. However Area 12 experienced difficulties with recruitment with only four

referrals being received, two as a result of self-referral and 2 from occupational therapists. The occupational therapists reported that they had invited a number of open and closed cases to participate in the study but there was limited interest. While a number of general practices were invited to participate in the study, only two practices agreed to refer eligible patients, with no referrals ultimately being received from GPs. Owing to these difficulties the area withdrew from the study.