

The role of eHealth to promote physical activity in people with cancer

Ciarán Haberlin

BSc (Physiotherapy), P.Grad. Cert (Clinical Exercise)

Supervised by Dr. Julie Broderick and Dr. Dearbhaile O'Donnell

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Summary

Early detection and increasingly effective treatments have led to improved survival rates for cancer. Therefore, the longer term health and well-being of cancer survivors has become an increasingly important area of focus. The benefits of PA (Physical activity) and exercise in patients with cancer has been well documented, with improvements in quality of life, function and a reduction in risk of recurrence among the benefits. The negative long term effects of many cancer treatments, such as those experienced following chemotherapy, have also been shown to have reduced following exercise. These benefits have resulted in the emergence of physical activity as a key component in the rehabilitation of cancer survivors. Despite these benefits however, physical activity levels in cancer survivors remain low. While traditional approaches to the promotion and uptake of PA behaviour have seen positive results in this cohort, the ability to maintain any positive changes in PA behaviour has proved difficult for those involved in the care of patients with cancer.

The emergence of eHealth may present an opportunity to address these issues. The use of eHealth interventions to promote physical activity is a burgeoning area of research, and thus far, results have been generally positive with regard to their efficacy. There is however, a paucity of evidence appraising eHealth PA interventions for cancer survivors. The focus of this thesis was to develop and refine a feasibility trial investigating such an intervention. This development included a systematic review of current literature in this area, exploratory research taking into consideration cancer survivors requirements, barriers and facilitators (Study 1 and Study 2), and finally a feasibility study of an eHealth intervention targeting physical activity behaviour in patients with cancer (Study 3).

Work for this thesis began with a systematic review of the literature, with the aim to explore existing research investigating the effects of eHealth in the promotion of PA in cancer survivors. Results from this review showed that the majority of studies reported that eHealth PA interventions improved PA in cancer survivors. It was also found that most studies included in the review used only subjective means of measuring physical activity and exercise, highlighting an area of development for any further research in this area. The low number of studies included also highlighted the novel and emergent nature of this research topic at the time.

In order to build on the knowledge gleaned from this review, an exploratory questionnaire-based study was conducted (Study 1). The aim of this questionnaire was to explore the role of technology and PA in the lives of cancer survivors in Ireland. In summary, this study showed that

smartphone penetration in this sample was 60.8% overall, indicating a majority of the sample had experience of using a smartphone. Of those participants that owned or had access to a smartphone, the majority expressed interest in a future study incorporating eHealth to promote physical activity. Notably, less than 1 in 5 participants had knowledge of the recommended physical activity guidelines.

Study 2 adopted a focus group design, and was developed to explore cancer survivor perceptions to using mobile technology for PA promotion. Mapping barriers to the possible use of mobile technology to increase PA was also an objective of this study, as was exploring potential features of an eHealth intervention that participants considered important in promoting physical activity. Results from this study showed that adequate training, education and support in both using technology, and adopting good PA behaviours, would be an important factor for participants in a future eHealth intervention. Desire for professional support in particular to prescribe specific physical activity goals was also mentioned, with this knowledge carried forward to the development of Study 3.

Study 3 was the culmination of the systematic review, Study 1 and Study 2, and its development was influenced heavily by the results of those particular studies. Study 3 was a feasibility study of an eHealth intervention using Fitbit technology, to promote physical activity in patients with cancer. Results from this study indicated that the intervention that was conducted was safe, acceptable and feasible. Results also showed some initial efficacy in improving self-report physical activity and quality of life. There was no significant difference in objectively measured PA achieved.

The research in this thesis offers preliminary results showing that an eHealth intervention, designed to impact physical activity through the use of Fitbit technology, was safe, acceptable and produced improvements in HRQOL, subjective PA and exercise capacity. Importantly, results from this thesis also provide researchers and clinicians with a further base of knowledge and insight into a burgeoning area of research which is rapidly evolving.

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List of Abbreviations

6MWT	<i>Six-minute walk test</i>
ACSM	<i>American College of Sports Medicine</i>
BCT	<i>Behavioural Change Technique</i>
BIA	<i>Bioelectrical impedance analysis</i>
BMI	<i>Body Mass Index</i>
CH	<i>Ciarán Haberlin</i>
CI	<i>Confidence Interval</i>
CPET	<i>Cardiopulmonary exercise test</i>
DM	<i>David Mockler</i>
DXA	<i>Dual energy X-ray absorptiometry</i>
ECG	<i>Electrocardiogram</i>
FACT-G	<i>Functional Assessment of Cancer Therapy: General</i>
FFM	<i>Fat free mass</i>
GSLTPAQ	<i>Godin-Shepard Leisure Time Physical Activity Questionnaire</i>
HRQOL	<i>Health related quality of life</i>
ICC	<i>Intra-class Correlation Coefficient</i>
IMPETUS	<i>Improving Physical Activity and Exercise with Technology Use in Survivors (of Cancer)</i>
JB	<i>Julie Broderick</i>
JM	<i>Jonathan Moran</i>
MET	<i>Metabolic equivalent of task</i>

MI	<i>Motivational Interviewing</i>
MRC	<i>Medical Research Council</i>
MVPA	<i>Moderate-Vigorous Physical activity</i>
NCRI	<i>National Cancer Registry Ireland</i>
PA	<i>Physical activity</i>
NCS	<i>National Cancer Strategy</i>
PACC	<i>Physical Activity and Cancer Control Framework</i>
PRISMA	<i>Preferred Reporting Items for Systematic Reviews and Meta-Analyses</i>
QOL	<i>Quality of Life</i>
RCT	<i>Randomised Controlled Trial</i>
RPE	<i>Rating of Perceived Exertion</i>
SCT	<i>Social Cognitive Theory</i>
SF-36	<i>Short Form 36</i>
SK	<i>Sinead Kiernan</i>
TTM	<i>Trans-Theoretical Model</i>
WC	<i>Waist Circumference</i>

Dissemination of research

Published papers

HABERLIN, C., BRODERICK, J., GUINAN, E. M., DARKER, C., HUSSEY, J. & O'DONNELL, D. M. 2019.

eHealth-based intervention to increase physical activity levels in people with cancer: protocol of a feasibility trial in an Irish acute hospital setting. *BMJ Open*, 9, e024999.

HABERLIN, C., O'DWYER, T., MOCKLER, D., MORAN, J., O'DONNELL, D. M. & BRODERICK, J. 2018.

The use of eHealth to promote physical activity in cancer survivors: a systematic review. *Support Care Cancer*.

Poster presentations

- Poster presentation at the 10th Trinity College Dublin International Cancer Conference 2016. ***'The use of eHealth to promote physical activity in cancer survivors: A systematic review.'***
- Poster presentation at the American Society of Clinical Oncology (ASCO) Cancer survivorship Symposium, Orlando, 2018. ***'Increasing physical activity in cancer survivors using eHealth: A focus group study.'***
- Poster presentation at 5th Annual SPHeRE Network Conference - 'Getting Research Into Policy and Practice'. ***'Exploration of the possible use of eHealth to promote physical activity in patients with cancer: A questionnaire-based study.'***

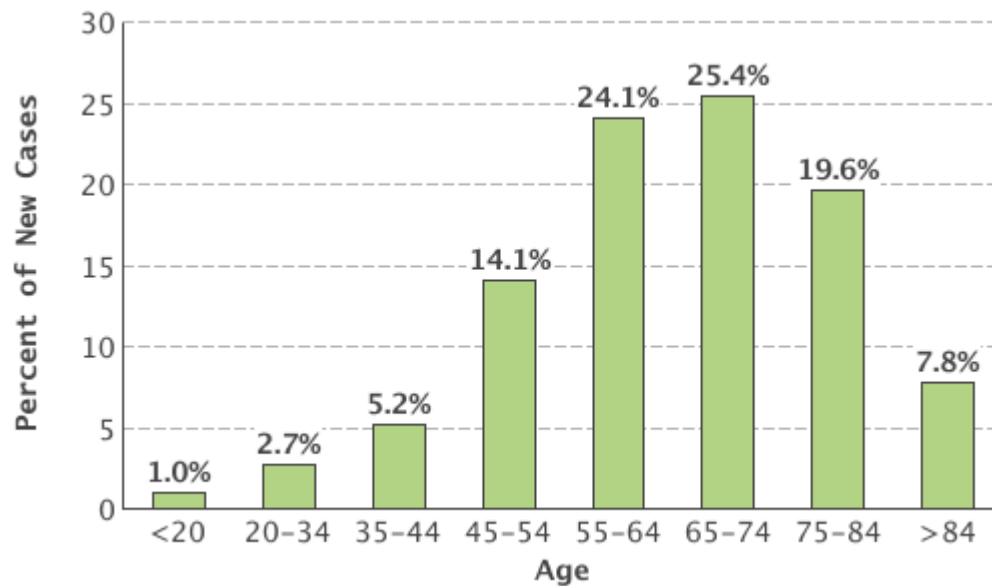
Chapter 1

1.1 Cancer-An overview

Cancer is defined as a collection of diseases in which ‘abnormal cells divide without control and can invade nearby tissues’(NCI, 2019a). The healthy process of cell division ensures that when new cells are formed, old or damaged cells are replaced by these new cells. In cancer, that process is disrupted, so that old and damaged cells are retained, while new cells are formed when they are not needed. The outcome of these new cells that divide without a function is often a tumour. A tumour is defined as ‘an abnormal mass of tissue that results when cells divide more than they should or do not die when they should.’(NCI, 2019a). In haematological cancers such as leukaemia, dysregulated cell division may occur without tumour formation; rather the malignant cells take over bone marrow or other organs in an infiltrating pattern.

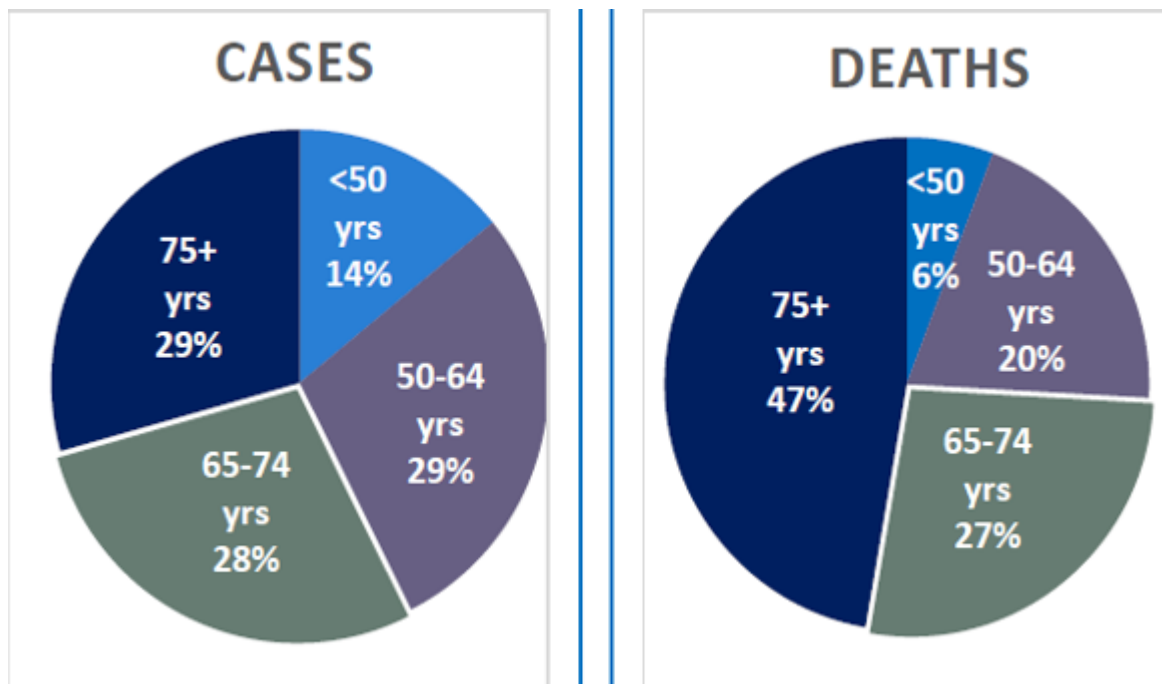
Cancer is caused by alterations in genes controlling our cellular processes. Such genetic changes can either be inherited in the germline (DNA in egg and sperm cells that join to form an embryo), occur because of DNA damage caused by aging or environmental exposures or both. Risk factors for developing cancer are categorised as either ‘modifiable’, which means that they are avoidable and can be targeted as part of a cancer prevention program, or ‘non-modifiable’. Age is a primary example of a non-modifiable risk factor for cancer. In fact, increasing age is regarded as the most important risk factor for cancer overall in the United States (NCI, 2019b). This can be seen below (Figure 1.1), where the percentage of new cancer diagnoses by age group in the United States is illustrated (NCI, 2019b).

Figure 1.1 Percent of New Cancers by Age Group: All Cancer Sites (Source: National Cancer Institute (NCI, 2019b))



Indeed, it has been reported within the same report, composed by the National Cancer Institute in the United States, that the median age of a cancer diagnosis is 66 years old (NCI, 2019b). In Ireland, this trend is similar, illustrated by the pie charts in Figure 1.2 below, where 86% of new diagnoses of cancer occur in people ≥ 50 years of age. Figure 1.2 also illustrates the relationship between age and mortality from cancer. The top risk factors for cancer in Ireland are as follows; cigarette smoking and tobacco use, infections, radiation, immunosuppressive medication, diet, alcohol, physical activity, obesity, diabetes and environmental risk factors (NCRI, 2018a).

Figure 1.2 Age profile at diagnosis and deaths-Ireland (Source: National Cancer Registry Ireland(NCRI, 2018a))



1.1.2 Staging

Staging of a cancer is the term given to describe the process of ascertaining how much cancer is in the body and where it is located (Department of Health, 2017). Staging aims to reflect the extent to which the cancer has spread through the body, including any infiltration of the cancer into the lymph nodes or bone marrow. Staging a cancer at diagnosis gives an indication of the potential treatment options and the chance of survival. Staging is made possible by the procedures involved in the diagnosis of cancer. While there are specific staging systems used for some cancers, such as blood borne cancers, in general the ‘TNM’ staging system is most commonly used for the majority of solid tumour types. This system was developed by the American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC) (Edge et al., 2010). It is based on the extent of the tumour (T), the extent of the spread to the lymph nodes (N) and the presence of metastasis (M). This is detailed below (Table 1.1.).

Table 1.1 TNM staging system

<i>'T' category-Primary Tumour</i>	
TX	Primary tumour cannot be evaluated
T0	No evidence of primary tumour
Tis	Carcinoma in situ (early cancer that has not spread to neighbouring tissue)
T1-T4	Size and/or extent of the primary tumour
<i>'N' category-Lymph nodes</i>	
NX	Regional lymph nodes cannot be evaluated
N0	No regional lymph node involvement (no cancer found in the lymph nodes)
N1-N3	Involvement of regional lymph nodes (number and/or extent of spread)
<i>'M' category-Metastases</i>	
M0	No distant metastasis (cancer has not spread to other parts of the body)
M1	Distant metastasis (cancer has spread to distant parts of the body)

The treating physician can use this staging system to determine the overall stage of a solid tumour type, which may then be assigned an overall stage between 0 and IV. Such staging is cancer-specific but in general stage I describes localised tumours, while stage IV indicates cancers which have metastasised substantially beyond the site of origin. Stage is an important determinant of survival (Department of Health, 2017), with details regarding survival after one and five years by stage at diagnosis detailed below (Table 1.2).

Table 1.2 Survival at one and five years for cancers diagnosed 2008-2012; by stage at diagnosis (Source: Department of Health, 2017)

Cancer Type	Survival at one year after diagnosis		Survival at 5 years after diagnosis	
	<i>Stage I</i>	<i>Stage IV</i>	<i>Stage I</i>	<i>Stage IV</i>
Colorectal cancer	98%	49%	95%	10%
Lung cancer	71%	16%	40%	3%
Breast cancer	99%	48%	94%	19%
Prostate Cancer	99%	78%	93%	36%
Pancreatic cancer	37%	14%	17%	4%
Ovarian Cancer	95%	51%	83%	15%

1.1.3 Incidence

Cancer is a leading cause of morbidity and mortality worldwide, with approximately 14 million new cases and 8.2 million cancer-related deaths in 2012, as reported by the World Cancer Report (Stewart BW, 2014). In Ireland, it was reported that cancer accounted for one third of all deaths in 2013, with 20,804 new cases presenting in the two year span between 2012 and 2014 (Department of Health, 2017). There has been a steady increase in cancer incidence in Ireland, with an approximate increase of 3% a year since 1994 reported. This is illustrated in Figure 1.3 below, adapted from National Cancer Registry Ireland (NCRI) (Department of Health, 2017). It is speculated that this increase may be partly due to a parallel increase in the number of the

population over the age of 65 years, correlating with age as a risk factor as described above. Other factors which could explain this rising incidence are the increases in risk factors such as obesity and alcohol consumption. Some of the increased incidence could be due to ascertainment i.e. as a result of more screening for cancer. In a study attempting to quantify the fraction of cancer attributable to lifestyle and environmental factors in the UK, 40% of the total cancer risk was attributed to five key lifestyle factors; use of tobacco, diet, overweight/obesity, alcohol and low physical activity (PA) (Parkin et al., 2011). With relevance for the program of research described in this thesis, over 6% of the total cancer risk was attributed to obesity and low PA. Both these factors are modifiable risk factors which will be discussed later in this chapter.

The most recent publication from NCRI (NCRI, 2018a) reported an estimated incidence of each particular cancer type (excluding non-melanoma skin cancer), and organised them by percentage and rank as shown in Figure 1.4 below. This shows that prostate and breast cancer were the most commonly diagnosed invasive cancers overall. Worldwide statistics on incidence are projected to continue this increasing trend, with statistics provided by the Global Cancer Observatory (Globocan, 2018) indicating a predicted increase of 61.7% in incidence of cancer up to 2040, distributed between male incidence estimated at 67.6% and female incidence at 55.3%.

Figure 1.3. Trends in cancer incidence (Ireland), 1994-2014 (Source: (Department of Health, 2017))

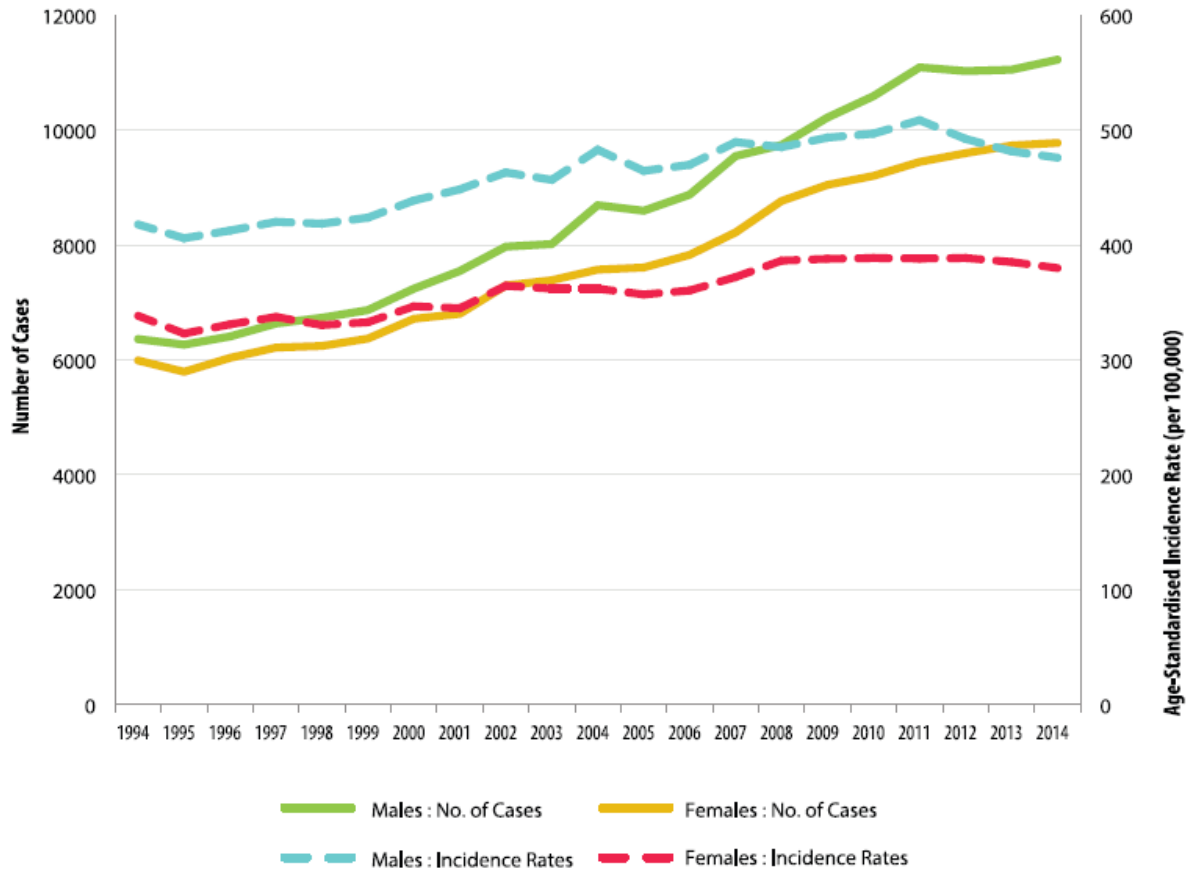
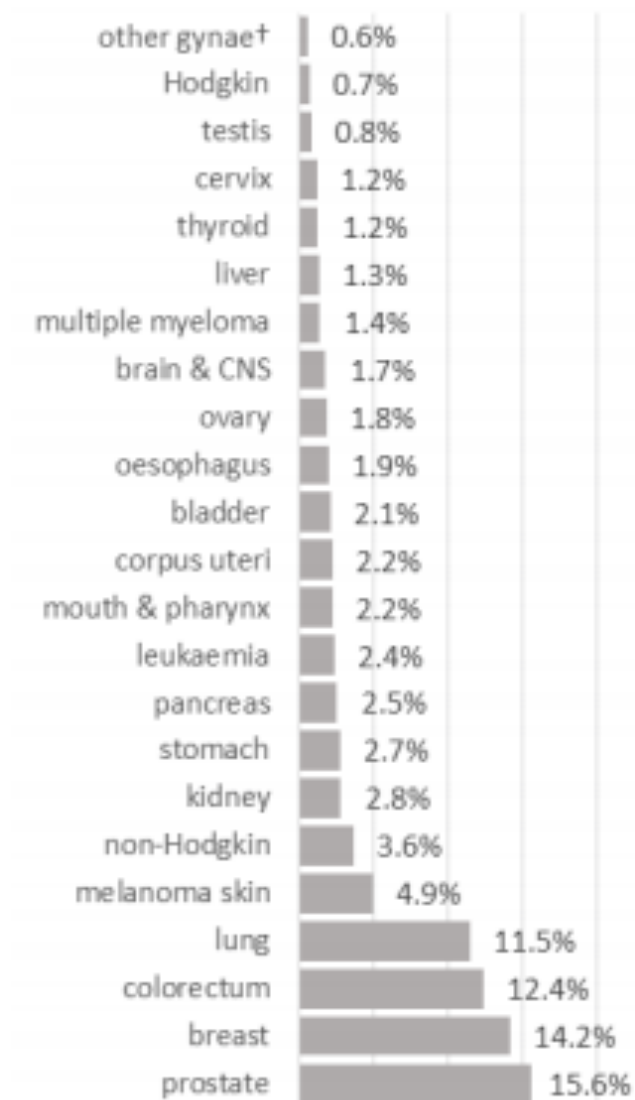


Figure 1.4. Estimated rank of the most commonly diagnosed invasive cancers: annual average 2015-2017 (Source: National Cancer Registry Ireland(NCRI, 2018a))



1.1.4 Survival

Irish statistics for overall net survival from all invasive cancers (excluding non-melanoma skin cancer) estimate a survival rate of 76% at one year from diagnosis, 61% at five years, and 57% at ten years (Department of Health, 2017). Table 1.3 below shows that statistics for 5-year net survival have demonstrated a steady improvement since 1994 (Department of Health, 2017).

These data show an increase in cancer survivors in Ireland, where there are currently more than 170,000 cancer survivors living with and beyond cancer (NCRI, 2018). A cancer survivor is defined as anyone who has been diagnosed with cancer, from the time of diagnosis through the rest of their life (Denlinger et al., 2014). This trend mirrors international trends, with early detection and increasingly effective treatments leading to a projection of approximately 18 million cancer survivors living in the United States by 2022 (de Moor et al., 2013).

Table 1.3. Five-year net survival in Ireland (Source: National Cancer Registry Ireland(NCRI, 2018a))

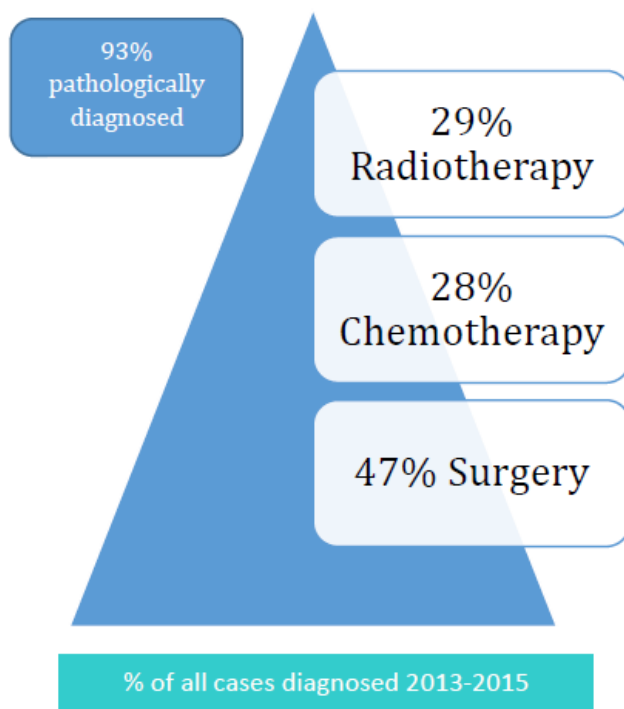
<i>Diagnosed</i>	<i>Net Survival (age standardised)</i>	<i>95% Confidence Interval</i>
1994-1998	Male: 40% Female: 37.8%	Male: 39.4-40.7% Female:37.3-38.3%
1999-2003	Male:48.8% Female:51.7%	Male:48.2-49.5% Female:51.1-52.3%
2004-2008	Male: 57.5% Female:55.5%	Male:56.9-58.1% Female:54.9-56.0%
2009-2013	Male: 61.3% Female: 59.8%	Male:60.6-61.9% Female:59.1-60.5%

1.1.5 Treatments

Three main modalities of treatment are used to treat cancer. These consist of surgery, radiation therapy and systemic therapy, the latter including cytotoxic chemotherapy, targeted therapy, hormone therapy and immune therapy. Patients often have a combination of the treatments above, depending on the location, type, size and molecular signature of the cancer. Below is an illustration of data from the National Cancer Strategy (Department of Health, 2017) which shows

the percentage of cases diagnosed in Ireland between 2013 and 2015 that received each of the three main treatment options (Figure 1.5).

Figure 1.5 Treatment within 1 year amongst all diagnosed cancer cases 2013-2015 (Source: National Cancer Strategy 2017-2026 (Department of Health, 2017))



1.1.5.1 Surgery

Surgery is used to remove all, or part of a tumour. In most cancer surgery, the aim is to remove all visible tumour. In certain cancers, removing part of a tumour (sometimes referred to as “debulking”) may also be useful.

1.1.5.2 Radiation therapy

Radiation therapy uses high doses of radiation to a specific area of the body to kill cancer cells and ultimately shrink tumours. Radiotherapy achieves this by damaging the DNA of cancer cells, so that their growth is affected and they stop dividing. The majority of radiotherapy techniques

utilise external beam radiotherapy, which uses a linear accelerator to produce high energy X-rays. The other main technique used is called brachytherapy, and involves the use of a radioactive source emitting radiation over a small distance. The importance of radiotherapy, in the context of treatment options for patients with cancer, was highlighted in a study by Delaney et al. (2005). This study reported that the percentage of patients with cancer in whom radiotherapy was indicated as part of an optimal treatment plan was shown to be 52%. These results indicate the integral part that radiotherapy holds in an optimal and effective treatment plan for patients with cancer.

1.1.5.3 Systemic therapy

Chemotherapy

Chemotherapy describes the use of drugs to slow or stop the growth of cancer cells. The term “chemotherapy” when used in the context of cancer treatment is usually reserved for cytotoxic agents. Cytotoxic drugs lead to the death of multiplying cells by various mechanisms, including direct damage to DNA or by blocking the synthesis of DNA. The proliferation of cancer cells follows a cell cycle involving a series of specific cellular processes. This first involves an ‘S’ phase, where DNA is synthesised and the amount of chromosomal material is doubled. The second cellular process that occurs is called mitosis ‘M’, where the chromosomal material that was synthesised and paired is separated, resulting in cell division. Cytotoxic chemotherapy drugs can disrupt this cycle, and thus halt cancer cell division, causing death of the cell. There are certain drugs used in chemotherapy that are only effective at certain phases in this cell cycle. This specificity is detailed in Table 1.4 below (Tobias et al., 2015) where the cell cycle and phase specificity of each cancer drugs are represented.

Table 1.4 Phase specificity of anticancer drugs (Source: Tobias et al., 2015)

<i>Phase of cell cycle</i>	<i>Effective chemotherapy agents</i>
'S' phase-DNA synthesis	Cytosine arabinoside, methotrexate, 6-mercaptopurine, hydroxycarbamide
'M' phase-Mitosis	Vinca alkaloids, taxoids
Phase non-specific	Alkylating agents, nitrosoureas, antibiotics, procarbazine, cisplatin

Other systemic therapies

Hormone therapy, targeted therapy and immune therapy have established themselves as effective additions to traditional multimodality treatment plans, such as those detailed above. Chemotherapy is widely utilised in the majority of treatment plans for patients with cancer. However it has limitations, including systemic toxicity and absence of selectivity for tumour cells against healthy cells, often resulting in diminished drug concentrations in tumour cells (Xu and McLeod, 2001). Targeted therapy aims to reduce these systemic effects and toxicity to off-target cells through use of drugs which target one or more specific steps in the growth of a particular cancer types, within tumour cells or the tissue environment that promotes cancer growth (Padma, 2015). Targeted therapies may work by blocking the process of cancer cell proliferation, promoting cell cycle regulation, inducing apoptosis or autophagy through the specific delivery of drugs to cancerous cells (Padma, 2015).

1.1.6 Side effects of cancer treatment

Cancer survivors must not only contend with the effects of the cancer itself, but also with side-effects associated with their treatment regimen. These side effects can vary from acute to chronic or persistent, and can significantly affect a cancer survivor's quality of life.

1.1.6.1 Fatigue

One of the most common side effects of treatment, which can arise from surgery, chemotherapy and radiotherapy, is fatigue. Cancer-related fatigue is defined as 'a distressing, persistent, subjective sense of physical, emotional, and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning' (Berger et al., 2015). The prevalence of cancer-related fatigue was reported to be 80% in one cross-sectional study conducted among 1569 patients who were receiving chemotherapy and/or radiotherapy (Henry et al., 2008), indicating the strength of impact that this side effect exacts on patients with cancer undergoing treatment. Unfortunately this side effect can also be experienced in the medium to long-term time period after initial treatment, with patients in one study reporting lasting fatigue months to years later (Curt et al., 2000).

1.1.6.2 Pain

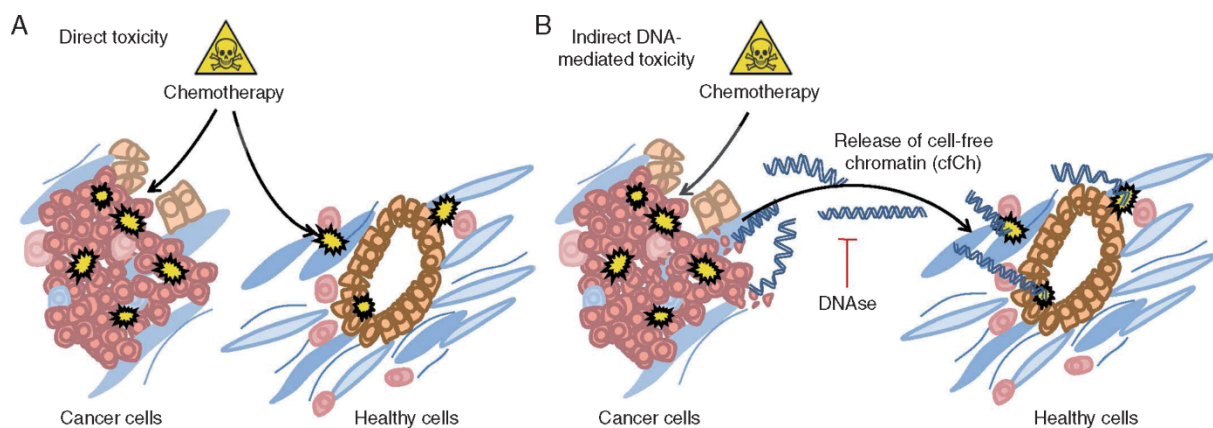
This is also a significant and prevalent side effect of treatment for cancer, and can be considered as distinct from cancer-related pain. According to the cross-sectional study referenced above, among patients with cancer, 48% reported pain as a side-effect (Henry et al., 2008). Pain can arise from a number of sources, with post-surgical pain and pain after radiation recognised causes of pain.

1.1.6.3 Toxicity

The adverse effects of chemotherapy can cause cardiac, neurological, renal and hepatic toxicities (Livshits et al., 2014a). Chemotherapy can primarily cause toxicity by damaging both

cancer and healthy cells, with chemotherapy drugs causing DNA damage in both (Helleday, 2017). A study by Mitra et al. (2017) suggested a secondary mechanism of toxicity caused by chemotherapy treatment, whereby cell-free chromatin (cfCh), released by the chemotherapy-affected cancer cell, may itself cause inflammation and DNA damage to healthy cells. These mechanisms are illustrated below in Figure 1.6, showing the primary mechanism of toxicity caused by chemotherapy, as well as the suggested secondary effect.

Figure 1.6 Primary and secondary mechanisms of chemotherapy-induced toxicity (Source: (Helleday, 2017))



Cardiac toxicity

This is typically caused by the anthracycline group of chemotherapy agents, and can manifest as cardiomyopathy, typically causing decreased left ventricular ejection fraction (Carver et al., 2013). It achieves this through oxidative stress, mitochondrial dysfunction, myofilament degradation and endothelial cell dysfunction caused by chemotherapy (Carver et al., 2013). Cardiotoxicity can also result in dysrhythmia, ischaemic ECG (Electrocardiogram) changes and congestive heart failure (Plenderleith, 1990). Herceptin, a targeted therapy consisting of a monoclonal antibody against the Her2 protein is also associated with cardiac toxicity. Herceptin is used as standard adjuvant therapy in breast cancer patients whose tumours over-express the

Her2 protein, some of whom will also receive anthracycline as part of their adjuvant chemotherapy, putting them at increased risk of cardiotoxicity (Volkova and Russell, 2011).

Neurological toxicity

Chemotherapy agents such as the vinca-alkaloids, cisplatin and the taxanes are amongst the most common drugs causing neurotoxicity in patients with cancer (Verstappen et al., 2003). These agents can cause peripheral neuropathy, a common manifestation of neurotoxicity in patients following chemotherapy (Livshits et al., 2014b).

The cumulative effect of these side effects can cause a 'symptom burden' on a person treated for cancer, resulting in a cascade of a variety of negative, physical, and emotional responses (Gapstur, 2007). The challenge for healthcare professionals, after a patient has concluded cancer treatment, can often centre on ameliorating these side-effects. Consideration and appreciation of these side effects is an important step in understanding the impact of cancer, and cancer treatment, on each patient.

The increasing numbers of survivors in Ireland, and indeed worldwide, was detailed earlier in this chapter. The result of this increase in survivorship is that many people are coping with the side-effects of cancer treatment for longer. The role of health care providers has therefore expanded to include the promotion of good health behaviours that are effective in alleviating the burden that cancer brings. One such behaviour, which has established itself as effective method to combat these disease, treatment and lifestyle-related side effects of cancer, is PA.

1.2 Physical Activity (PA)

Physical activity is defined as 'any bodily movement produced by skeletal muscles that results in energy expenditure' (Caspersen et al., 1985). Exercise has been defined as 'physical activity

that is planned, structured, repetitive, and purposive in the sense that improvement or maintenance of one or more components of physical fitness is an objective' (Caspersen et al., 1985). The benefits of PA and exercise in patients with cancer has been well documented, with improvements in quality of life, function and a reduction in risk of recurrence among the benefits (Schmitz et al., 2010). Indeed, there are a number of mechanisms by which PA could favourably influence the risk of both occurrence and recurrence of cancer. Below are some mechanisms of benefit of PA in cancer.

1.2.1 Obesity and overweight

PA is an integral component of maintaining a healthy body weight, particularly when balancing calories expended with calories consumed. Low PA levels can contribute to an individual's risk of obesity, which has been shown to increase the risk of a variety of different cancer types (Lauby-Secretan et al., 2016). Obesity is the abnormal or excessive accumulation of body fat that presents a risk to health (Lauby-Secretan et al., 2016). Overweight and obesity is typically measured by calculating an individual's body mass index (BMI). This is calculated by dividing someone's weight in kilograms by the square of their height in meters. The definition of being overweight in terms of BMI is a measure of 25.0 to 29.9, while the definition of obese is a measure of 30 and above, with a BMI of 40 and above indicating severe obesity (WHO, 2000). It has been reported that women who are overweight or obese are two to four times as likely as women who are normal weight to develop endometrial cancer (Setiawan et al., 2013). Further evidence of the relationship of obesity and increased risk of cancer was reported in a systematic review examining the association between obesity and developing colorectal cancer, with results indicating people who are obese have a 30% higher chance of developing colorectal cancer than someone who is at a normal weight (Ma et al., 2013). In Ireland, it has been reported that over 400 new cases of colorectal and breast cancer combined each are a result of excess body weight (Department of Health, 2017). The risk of recurrence of cancer in cancer survivors

is also increased with obesity, with growing evidence in breast cancer survivors showing that obesity is associated with a greater risk of recurrence (Bergom et al., 2016).

The positive effect of PA and exercise on obesity, chronic inflammation and increased adiposity, is commonly referenced as one of the main exercise-related mechanisms of cancer prevention. There is an established link between increased BMI, obesity and cancer risk (Renehan et al., 2008). There is also an established link between chronic inflammation and cancer risk (Coussens and Werb, 2002). Exercise (both resistance and aerobic) has been shown to be beneficial in reducing body weight, BMI and fat mass in patients with cancer (Schmitz and Speck, 2010). A study conducted by Beavers et al (Beavers et al., 2010) also reported that chronic inflammation was reduced in individuals with high PA, and that aerobic exercise would also be effective in individuals with chronic diseases that were already in a state of elevated inflammation.

1.2.2 Risk of occurrence

High levels of PA are associated with a reduced risk of several cancer types, in particular colon cancer, breast cancer and endometrial cancer. There is an abundance of research and evidence investigating the relationship between colon cancer risk and PA. A 24% reduction in risk of colon cancer was associated with individuals with higher levels of PA, when compared to individuals with lower levels of PA in a meta-analysis conducted in 2009 which investigated the association between PA and risk of colon cancer (Wolin et al., 2009). The results and conclusions from that meta-analysis were further corroborated in 2016 when a pooled data analysis across various studies from the United States and Europe was conducted to determine the association of leisure-time PA and the incidence of a variety of common cancers (Moore et al., 2016). Results from that second study showed that high versus low levels of leisure-time PA were associated with reduced risk of cancer in 13 out of the 26 cancer types that were investigated. High levels of PA were associated with a 16% reduction in colon cancer risk. As previously mentioned, breast and endometrial cancer have also been investigated for a reduction in risk associated

with high levels of PA. There was an average of 12% risk reduction associated with high PA levels in a meta-analysis conducted investigating the relationship between PA and risk of breast cancer in 2013 (Wu et al., 2013). Similarly, another meta-analysis conducted in 2013 reported an average risk reduction in endometrial cancer associated with high versus low PA was 20% (Schmid et al., 2015).

1.2.3 Risk of recurrence in survivorship

PA and exercise may also be beneficial in reducing risk of recurrence in cancer survivors, following a similar trend to the evidence regarding risk of occurrence above detailed above. Recurrence means the presentation of cancer again in an individual, after the first primary cancer has become undetectable. Recurrence frequently manifests itself as metastatic cancer which is often no longer treatable with curative intent. Engaging in regular PA has been shown to reduce the risk of recurrence in cancer survivors in some groups. In a study conducted with breast cancer patients in 2005, those that performed moderate levels of exercise following their breast cancer diagnosis showed between 26% and 40% less risk of death, death by cancer and breast cancer recurrence than those participants who performed the lowest level of PA (Holmes et al., 2005). Further evidence indicating the positive effect of PA on recurrence was reported in a meta-analysis conducted in 2011, showing a reduction in breast cancer recurrence of 24% with post-diagnosis PA (Ibrahim and Al-Homaidh, 2011).

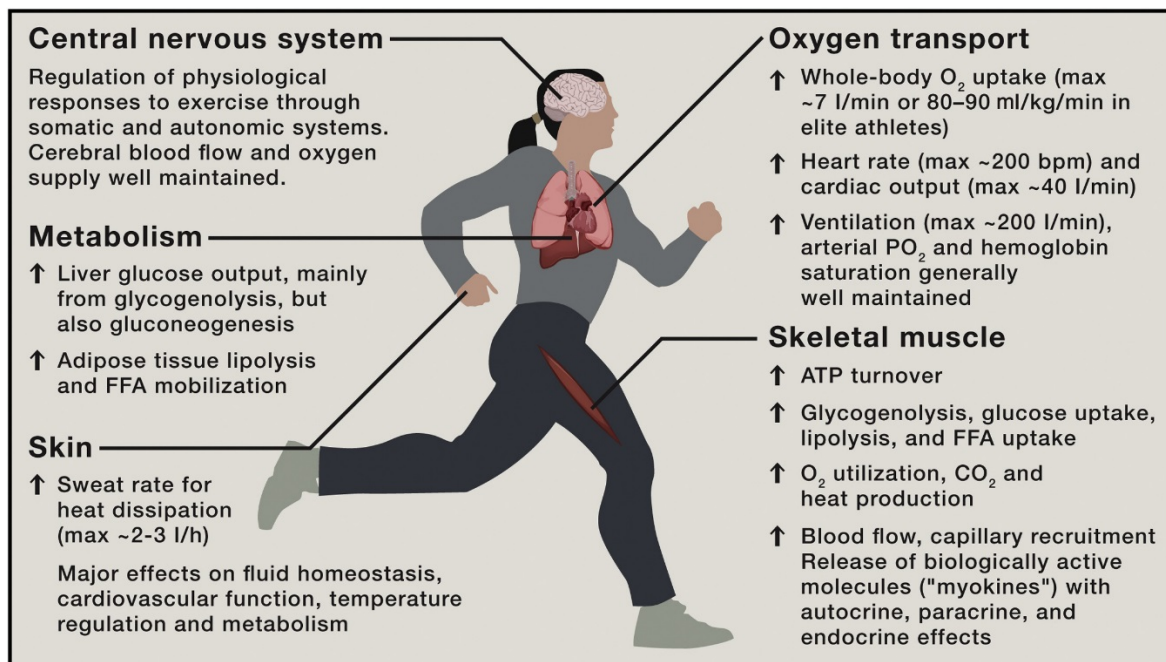
1.2.4 Cancer-protective effects of exercise and PA

The results and studies discussed above highlight the epidemiological evidence that exists linking PA, exercise and reduced risk of cancer. Exercise and PA have been shown to produce a range of positive effects on a variety of outcomes in patients with cancer, including cardio-pulmonary fitness, physical functioning, body composition, depression and fatigue (Hojman et

al., 2018). The manner in which exercise achieves these benefits and the reduced risk of cancer is less well understood, however several studies have attempted to provide insights into the protective effect of exercise and PA. One of the first pieces of evidence to highlight the mechanisms of exercise affecting cancer risk was a study published in 2008 (McTiernan, 2008). This detailed a number of potential mechanisms of exercise positively affecting cancer risk, including the reduction of sex hormones, improved insulin resistance and the reduction of systemic inflammation. These mechanisms and the ability of exercise to modulate the processes associated with carcinogenesis will be discussed below, with particular focus on the biological mechanisms that are involved in this modulation.

Exercise produces physical and endocrine effects in the body, many of which have the potential to regulate cancer biology and progression (Hojman et al., 2018). These effects are present in various systems in the body, including the metabolic, respiratory, cardiovascular and hormonal systems. These physiological effects of exercise on the body are illustrated in Figure 1.7 below (Hawley et al., 2014).

Figure 1.7 The Physiological Responses to voluntary, dynamic exercise (Source: Hawley et al., (2014))



These effects represent the triggers for the mechanisms detailed below, ultimately impacting on tumour growth, tumour metabolism and metastatic profile.

Intra-tumoral effects of exercise

Tumour growth has been extensively studied in a number of preclinical murine studies. One demonstrated a reduction of 67% in tumour growth rate with exercise training performed in rodents (Pedersen et al., 2015). It has been hypothesised that the mechanisms behind this reduction in growth rate are related to a disruptive effect that exercise may have on molecular signalling events in tumour cells that instigate tumour growth and formation (Hojman et al., 2018). Several studies have examined one particular molecular pathway, the Hippo signalling pathway, and the effect that exercise has on it. The Hippo pathway is a complex signalling cascade controlling a variety of critical biological processes and human diseases, including organ growth control, stem cell function, tissue regeneration and tumour suppression (He et al., 2016). A recent review highlighted how the Hippo pathway was affected by exercise in human subjects

(Gabriel et al., 2016), and introduced a possible link between exercise and the control of tumour growth. More specific to the pathology of cancer is a study by Dethlefsen et al. (2017), which sought to investigate the effect of exercise-induced circulating factors on breast cancer viability and tumorigenesis. They did this through the inoculation of breast cancer cells into mice. Results from their study showed that exercise-conditioned serum from both women with breast cancer and healthy women decreased breast cancer cell viability in-vitro by 11% to 19%. This study also reported a reduction of 50% in tumorigenesis. These results appeared to be mediated through the induction of catecholamines, such as epinephrine and norepinephrine, by an acute bout of exercise. It was suggested that these catecholamines directly regulated the Hippo signalling pathway mentioned above, resulting in a suppression of breast cancer cell viability and reduced tumour formation (Dethlefsen et al., 2017).

It should be noted that this experiment involved a single bout of acute high intensity exercise and further research is required into potential mechanisms of tumour control associated with regular PA and exercise. However, the results described above are important in identifying at least one molecular pathway which has plausible mechanisms of reducing cancer cell growth and progression through exercise, through identification of the factors that serve to regulate it.

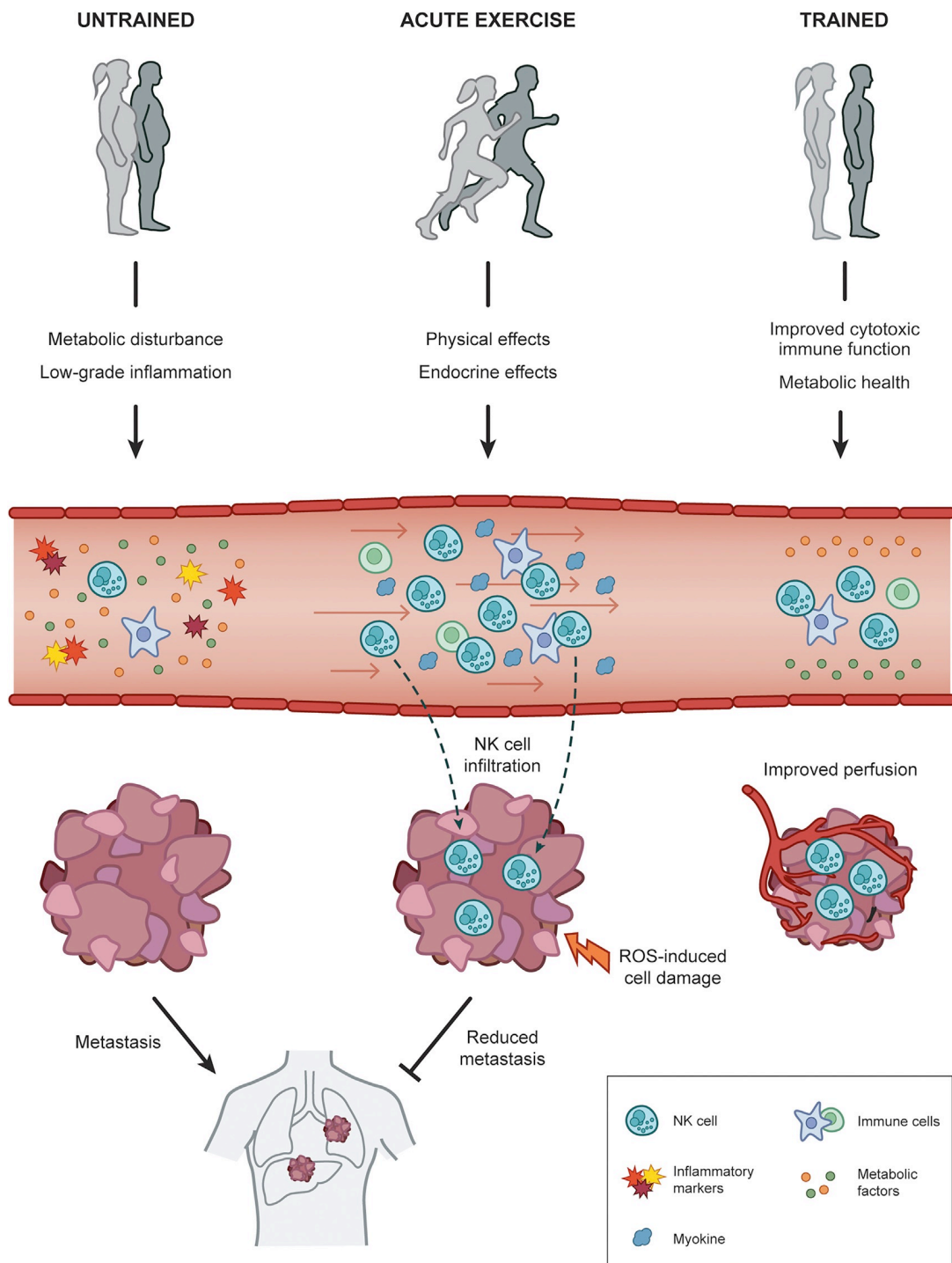
Immunological effect

The cellular immune system also has a role in tumour growth suppression. In a study by Idorn et al. (Idorn and thor Straten, 2017) it was shown that there was a much denser infiltration of immune cells, such as natural killer cells (NK cells), in tumours in animals who had exercised versus those who had not. This increased infiltration of immune cells may be as a result of typical exercise responses, such as blood flow induced shear force (Idorn and Hojman, 2016). NK cells are important in the examination of the immune response to exercise, as NK cells have been shown to have the ability to kill cancer cells (Karre et al., 1986). The temperature increases associated with exercise also play a role in increasing the numbers of NK cells infiltrating the

tumour, with elevated core body temperature shown to increase the immune response (Evans et al., 2015).

A further effect of exercise is the release of myokines from contracting muscles. Myokines are peptides that are released from muscles and have a paracrine, autocrine or endocrine effect (Pedersen and Febbraio, 2008), with regulation of energy exchange and metabolism in other organs among their primary effects. Inhibition of breast cancer cell viability (Gannon et al., 2015), as well as a reduction in tumorigenesis (Aoi et al., 2013), have been reported as a result of this release of specific myokines, triggered by exercise. The various mechanisms by which exercise can affect tumour growth and progression are illustrated in Figure 1.8 below. It illustrates the beneficial mechanisms induced by both an acute bout of exercise, and by long term training. These mechanisms, as detailed above, include the release of systemic factors such as catecholamines and myokines, as well as increased temperature and improved blood flow.

Figure 1.8 Molecular Mechanisms Linking Exercise to Cancer Protection (Source: (Hojman et al., 2018))



1.2.5 Muscle function

Muscular function has been shown to be strongly associated with cancer-specific mortality risk and tolerance of treatment (Christensen et al., 2014). In patients with cancer, decreased muscle mass is a prevalent condition affecting all disease stages (Prado et al., 2008). A study by Freedman et al. (2004) highlighted this decreased muscle mass, with results from that study indicating losses of lean body mass during chemotherapy, a trend continued beyond the end of treatment. Muscle strength has also been shown to be reduced in patients with cancer, with one study reporting up to 30% difference in upper body muscle strength between patients with breast cancer and healthy participants (Harrington et al., 2011). Sarcopenia, a combination of low muscle strength, decreased muscle mass and a reduction in physical performance is also prevalent among older patients with cancer, with various studies showing that sarcopenia affects between 12.5% and 57.7% of the geriatric cancer population (Dunne et al., 2019). The causes of this muscle dysfunction are various, with some being specific to the cancer itself, with others being related to lifestyle factors and to cytotoxic chemotherapy. Age, malnutrition and physical inactivity have been suggested as causes of muscle dysfunction in patients with cancer (Christensen et al., 2014).

Recently, growing evidence indicates that muscle dysfunction in cancer may be attributed to tumour-derived factors causing systemic inflammation, leading in turn to the degradation of healthy muscle tissue (Tisdale, 2010). Currently, only preclinical studies in murine models have investigated this theory, however they have highlighted the potential pathophysiology behind this cause of muscle dysfunction. The secretion of tumour-derived factors such as parathyroid-hormone-related protein (PTHrP) and myostatin have been shown to have a negative impact on muscle function and to accelerate muscle wasting in murine models of colon and lung cancer (Gallot et al., 2014, Kir et al., 2014). An important clue about the potential therapeutic benefit of exercise in combatting this muscular dysfunction was shown in a 2016 study. Pederson et al

demonstrated that when running wheels were utilised by mice, the loss of muscle mass induced by the tumour derived factors was negated (Pedersen et al., 2016).

The effect of exercise on general muscle function in humans with cancer has also been widely investigated, with positive results reported. Courneya et al. (2007) reported significant increases in muscle strength following a resistance exercise program in patients with breast cancer undergoing chemotherapy. That same study also reported significant increases in lean body mass, highlighting the potential of exercise to combat the aforementioned effects of cancer on lean body mass. More recently, it was shown that a 3-month exercise program combining aerobic and resistance training preserved appendicular lean mass ($P = 0.019$), as well as preventing whole body fat increases in patients with prostate cancer undergoing androgen deprivation therapy (Cormie et al., 2015).

1.3 Survivorship

Survivorship is increasingly recognised as a distinct stage in the care of patients with cancer. The increasing numbers of survivors means that healthcare directed at this stage is important. Figure 1.9 below illustrates the place of survivorship in the cancer care continuum (Department of Health, 2017).

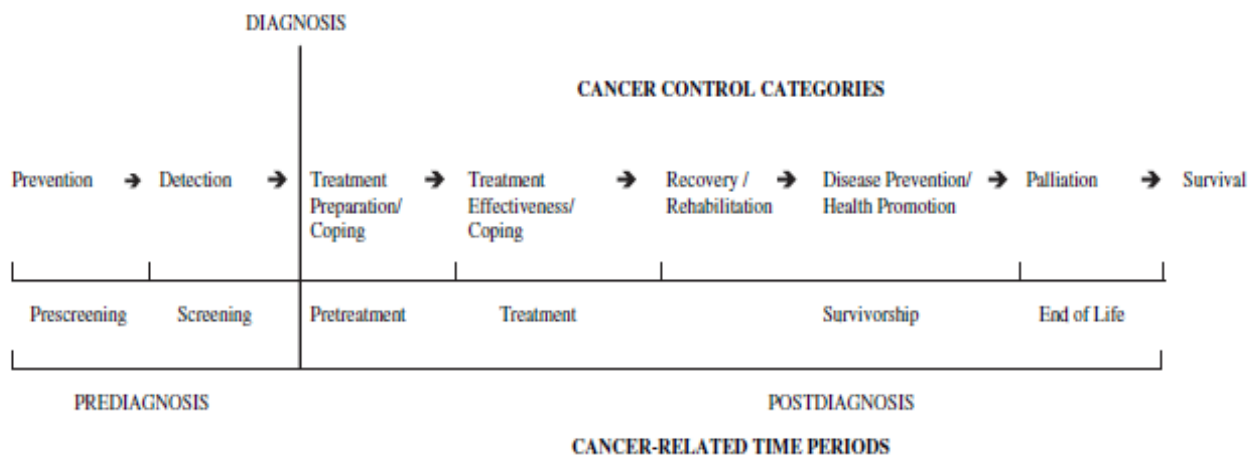
Figure 1.9: The Continuum of cancer care (Source: National Cancer Strategy 2017-2026 (Department of Health, 2017))



The concept of survivorship is integrated in a PA framework which was designed in 2007 (Courneya and Friedenreich, 2007), and defines specific stages of the cancer continuum where PA can be integrated. This framework is called the Physical Activity and Cancer Control (PACC) framework, and is illustrated in Figure 1.10 below. The focus of this thesis will be on the

prescription of exercise and PA in the survivorship phase of cancer care, specifically in patients who have concluded their treatment.

Figure 1.10 Physical Activity and Cancer Control Framework (Courneya and Friedenreich, 2007)



This framework illustrates stages in the timeline of a cancer survivor where exercise and PA have been shown to provide benefit and highlights the place of PA promotion in cancer survivorship. Its accompanying text organises and identifies objectives for future PA interventions to achieve and attempt to address at each specific time point. Consultation of this framework was an important aspect of the research described in this thesis.

1.3.1 Evidence for exercise and PA interventions in patients with cancer

An abundance of literature has followed the guidelines and example provided by the PACC framework (Courneya and Friedenreich, 2007), with increasingly high numbers of publications advocating for the benefit of exercise and increased PA in patients with cancer. A recent systematic review (Cormie et al., 2017) investigated the impact of exercise in cancer survivors on; 1) cancer mortality and recurrence and 2) the adverse effects of cancer and its treatment. That systematic review included 100 studies in total in its final analysis, including meta-analyses,

epidemiological studies and randomised controlled trials. Participants were mainly comprised of breast cancer (66%), colorectal cancer (15%), and prostate cancer (14%) patients. Final results reported clear associations between higher levels of PA and reduced risk of cancer specific mortality, cancer recurrence and all-cause mortality. Results also indicated that in comparison with patients who practiced no/less exercise, patients who engaged in regular activity experienced fewer adverse effects. One potential limitation was the risk of self-report bias that was inherent in all of the included studies, who used only self-report or interview-administered questionnaires to evaluate PA and exercise behaviours. Despite this, results from this study are still indicative of a substantial benefit of exercise in patients with cancer.

Further evidence supporting the prescription of exercise and PA in cancer survivors was provided by a recent systematic review and meta-analysis conducted by Scott et al (Scott et al., 2018), which investigated the effects of exercise therapy on cardiorespiratory fitness in patients with cancer. Results from 48 randomised control trials, representing 3632 patients with cancer, demonstrated a significant association between exercise therapy and an increase in exercise tolerance ($p < .001$). In spite of the significant body of evidence supporting PA and exercise interventions in the care of the cancer survivor, more research on the optimal dosage of exercise and PA are required, as well as further investigation into efforts to improve the long term adherence of survivors to behaviours such as exercise and PA.

1.3.2 PA guidelines

Despite the volume and variety of studies supporting the benefits of PA in patients with cancer, of which some salient ones have been detailed above, insufficient levels of PA are unfortunately prevalent among cancer survivors (Broderick et al., 2014b, Courneya et al., 2008, Smith and Chagpar, 2010). The American Cancer Society (ACS) have published guidelines on optimal PA for cancer survivors, recommending at least 150 minutes of moderate intensity exercise per week (Rock et al., 2012). Despite these recommendations, it has been shown that a high percentage

of cancer survivors are not meeting these guidelines. One such study, which examined PA levels of 1,160 cancer survivors at the conclusion of their treatment regimen, reported 42.2% of these patients were deemed 'inactive' (defined as 0 MET h/wk) or 'insufficiently active' (defined as 0.01–8.74 MET h/wk) (Troeschel et al., 2018). In this case, MET h/wk represented the metabolic equivalent of task (MET) value of each activity performed, multiplied by the number of times that activity was performed that week. MET values are used to describe intensity of an exercise or activity, and are the ratio of your working metabolic rate relative to your resting metabolic rate. Similarly, another large study of 2062 cancer survivors in Canada reported that only 42.2% of participants were meeting PA guidelines (Forbes et al., 2014). The time since diagnosis for the participants in this study was <5 years for 64% of the sample, while the remainder were diagnosed ≥5 years.

The challenge remains for healthcare providers, and all those involved in the care of cancer survivors, to address the disconnect between ideal and actual PA levels and to deliver PA prescription and advice in a manner that is effective and capable of promoting adherence.

1.4 Behavioural Change

Changing a patient's behaviour can be a complex and multi-faceted task for health care professionals. Behaviours are often long-standing and habitual, with resistance to change often hindering a health care professional's best efforts to change the damaging behaviour. Interventions designed to change behaviours such as PA, typically have many interacting components, making it particularly difficult to ascertain effectiveness of each component (Craig et al., 2008). Behavioural change science has evolved as a framework for efforts to change behaviour in healthcare, with a number of healthcare interventions now grounded in a variety of behavioural change theories and techniques. Any intervention designed to change or improve PA can be influenced by behavioural change techniques. A behavioural change technique (BCT) can be defined as 'the smallest identifiable components that in themselves have the potential

to change behaviour' (Michie, 2016). It has become increasingly important to both identify and understand the effectiveness of each individual BCT, in order to ensure any intervention can be replicated and examined in depth for its effectiveness. The process of understanding this has been greatly aided by the development of a taxonomy of BCT in 2011 (Michie et al., 2011). The rationale behind creating a taxonomy of BCTs was to 'improve the effectiveness of interventions to change behaviours.' In this particular taxonomy, all behavioural change interventions examined were designed to improve PA and eating behaviours.

Historically, the difficulty up to then had been the unreliable reporting of detailed behavioural change intervention components in research which hindered the ability to isolate which aspects of the intervention were having a positive effect on the targeted behaviour. This issue was summarised as follows: 'replication, accumulation and application of evidence depend on the ability to reliably specify the details of intervention content' (Michie et al., 2011). The taxonomy was the result of a multi-centre collaboration who applied the proposed taxonomy to two systematic reviews designed to review interventions improving PA. One was a review whose stated aim was to gather and analyse intervention studies which aimed to increase self-efficacy for PA (Ashford et al., 2010). That review also hoped to explore the intervention techniques used and any consequent change in self-efficacy. Self-efficacy is a concept of particular interest to the field of PA behaviour change and to this program of research.

1.4.1 Self-efficacy

Self-efficacy can be defined as 'the belief in one's capabilities to organise and execute the courses of action required to produce given attainments' (Bandura, 1997). The importance of self-efficacy and the reason for its recurrent presence and consideration in effective behavioural change interventions is indirectly supported by its role as an important predictor of various health behaviours. Self-efficacy is predictive of smoking cessation (Baldwin et al., 2006), PA behaviour (Sharma et al., 2005, Rovniak et al., 2002), and adoption and maintenance of PA

(Strachan et al., 2005). Taking into account that clear predictive relationship between self-efficacy and improved PA behaviours, the key for behavioural change interventions is the incorporation of BCTs which increase an individual's self-efficacy. The systematic review by Ashford et al. (Ashford et al., 2010), mentioned above, included 27 studies in its goal to explore intervention techniques used and consequent changes in self-efficacy. Results from the systematic review showed that in interventions that utilised techniques such as vicarious experience and feedback on past or others performance there were significantly higher levels of PA self-efficacy than in interventions that did not use these techniques. The opposite effect was also studied, with results showing that interventions that utilised persuasion, graded mastery and barrier identification techniques produced lower levels of self-efficacy than interventions without these techniques.

When a health care professional attempts to design and conduct an intervention to produce behaviour change, understanding which BCT is most suitable and potentially most effective for their purpose is imperative. Reviews such as those above contribute greatly to the evidence aiding this difficult task. Interestingly, that research by Ashford et al. (2010) not only investigated the use of intervention techniques to promote self-efficacy, but also detailed what theoretical models were used by each study included. Among the most commonly used behavioural change theories that were used in that review were the 'Social Cognitive Theory'(SCT) (Bandura, 1977) and the 'Trans-Theoretical model'(TTM) (Prochaska and DiClemente, 1982). The SCT is a commonly used behavioural change theory in interventions designed to promote PA. The SCT consists of four different constructs, self-efficacy, outcome expectations, goal setting, and barriers and facilitators. Similarly, the TTM has a number of different components, including stages of change, processes of change, self-efficacy, and decisional balance. It is worth noting that self-efficacy is contained within both theories, indicating one of the reasons why these particular theories are used when targeting behaviour change in PA.

As evidenced above, behavioural change psychology is now firmly entrenched in healthcare interventions targeting specific behaviours like PA. Behavioural change theory has been proven to increase the efficacy of PA interventions in cancer survivors (Short et al., 2013). This improvement in efficacy as a result of the adoption of a theoretical framework was supported by a further study, which showed an improvement in the likelihood of cancer survivors making and sustaining a positive change in exercise behaviours when the intervention targeted theoretical determinants (Loprinzi et al., 2012). Therefore, the consideration, presence and adoption of behavioural change theory throughout this research was essential in order to design an optimal PA intervention for cancer survivors. The final component in explaining the background to the research in this thesis is the introduction of eHealth.

1.5 eHealth

The low levels of PA in cancer survivors, as well as the need to optimise and improve current PA interventions, have prompted clinicians to explore novel approaches to increase PA levels among cancer survivors. eHealth is an emerging concept in healthcare which may present as a potential solution in this regard. The World Health Organisation (WHO) defines eHealth as the transfer of health resources and health care by electronic means (WHO, 2005). This includes, but is not limited to, the delivery of health information through internet and mobile technologies. There is immense potential in the use of eHealth for delivering remote, personalised PA prescription. Indeed, some of the suggested benefits of using internet technology in health-care include convenience for users, easy storage of large amounts of information, ease of updating information and ability to provide personalized feedback (Griffiths et al., 2006b). A number of these suggested benefits are of particular interest to health care providers wishing to conduct an intervention designed to change an individual's behaviour, which in this case is PA. eHealth would enable practitioners to prescribe PA in a manner which is specific and personalised to an individual, as well as fluid enough to be able to adjust as

appropriate. eHealth also offers the opportunity for an individual to become autonomous with their PA prescription, with remote technology potentially reducing the need for regular face-to-face contact with a health care professional. The eHealth strategy for Ireland (Department of Health, 2013) reiterates this thought by suggesting that the proper introduction and utilisation of eHealth will ensure that 'the patient is placed at the centre of the healthcare delivery system and becomes an empowered participant in the provision and pursuit of their health and wellbeing'. In the context of behavioural change interventions, promoting autonomy, empowerment and self-efficacy are also integral components to an effective and successful intervention.

There is a paucity of evidence appraising eHealth PA interventions for cancer survivors. There are a number of systematic reviews which have been published focusing primarily on eHealth-based PA interventions in community dwelling adults or general populations (Norman et al., 2007, Krebs et al., 2010, Davies et al., 2012, Foster et al., 2013, Aalbers et al., 2011). Results from these studies consistently supported the effectiveness of eHealth interventions for promoting PA. The benefits of ehealth to improve PA in patients with cancer therefore offers great potential and is an area in which there is a considerable knowledge gap regarding the effectiveness and feasibility of such a technological intervention.

1.6 Medical Research Council Guidelines

The work presented here was designed to address this knowledge gap, and, ultimately, to design an eHealth intervention where the primary aim was to promote improved PA behaviours in cancer survivors. The process of commencing this began with a consideration of the Medical Research Council (MRC) recommendations on designing and conducting a complex intervention (Craig et al., 2008). The aim of these recommendations is to 'to help researchers and research funders to recognise and adopt appropriate methods' for designing a complex intervention. They define a complex intervention as any intervention which contains several interacting

components, but also contain a number of difficult and variable behaviours, groups or outcomes. The process of developing a complex intervention is detailed and discussed in these recommendations, providing researchers in healthcare with a valuable framework to consult when designing a complex intervention. The main message from these recommendations is that before a substantial evaluation is undertaken, such as a randomised controlled trial (RCT), the intervention must be developed to the point 'where it can reasonably be expected to have a worthwhile effect' (Craig et al., 2008).

This can be achieved by modelling the development of the intervention on the following steps;

- An identification of existing evidence-This step calls for a thorough examination of existing literature in the area of the proposed intervention. This can involve an investigation of methods and outcomes previously used in other studies. Conducting a systematic review is recommended, provided no recent systematic review in the area has already been completed.
- An identification and development of theory-This step calls for the researcher to develop a theoretical understanding of the likely process of change. This can be achieved through the assimilation of current research and existing theory.
- A model of the process and outcomes- Prior to a full scale investigation, a model of the processes and outcomes that are going to be potentially included in a full evaluation should be undertaken. This can take the form of a number of smaller studies, with the result being a greater understanding of the processes and outcomes to be included in a full scale intervention.

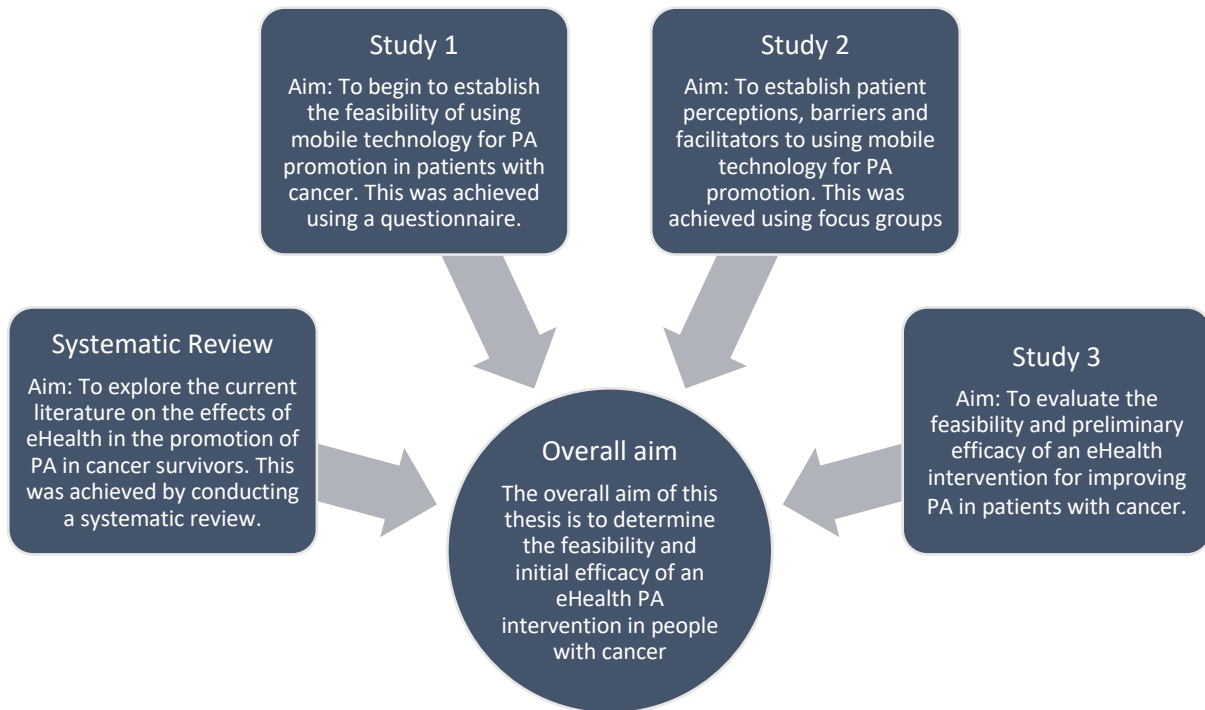
The framework recommended by the MRC detailed above can be seen throughout the entirety of this thesis, as it has informed the structure of this research. Each chapter of this thesis describing a study that was conducted in alignment with these guidelines includes a graphic illustrating the particular aspect of the guidelines that the specific study fulfils. The first example

of this influence is that the first research conducted in this thesis was a systematic review of the existing literature, which will be described below in Chapter 2.

1.7 Thesis Aims and Objectives

With consideration for the paucity of research in the area of eHealth interventions targeting improved PA behaviours in cancer survivors, which will be highlighted in the systematic review in Chapter 2, and the MRC guidelines detailed above, the focus of this thesis was to develop and refine a feasibility trial investigating such an intervention. This development included a systematic review of current literature in this area, qualitative research taking into consideration cancer survivors requirements, barriers and facilitators (Study 1 and Study 2), and culmination in a feasibility study of an eHealth intervention targeting PA behaviour in patients with cancer (Study 3). The overall aim, as well as individual study aims, are illustrated in Figure 1.11 below. Study-specific objectives will be detailed throughout the thesis in the appropriate chapters.

Figure 1.11 Thesis overall and individual study aims



Chapter 2

2.1 Systematic review of literature

To our knowledge, no systematic review has synthesized the literature on eHealth interventions to increase PA in people with cancer. The objective of this systematic review was to address this gap, by investigating the efficacy of eHealth interventions in increasing PA among cancer survivors. This review also represents the first step in the development of our final feasibility study, in alignment with the framework recommended by the MRC.

This study has been published in the Supportive Care in Cancer Journal (Appendix 1)

HABERLIN, C., O'DWYER, T., MOCKLER, D., MORAN, J., O'DONNELL, D. M. & BRODERICK, J. 2018. The use of eHealth to promote physical activity in cancer survivors: a systematic review. Supportive Care Cancer.

2.1.1 Methods

Study design

This systematic review was conducted to identify eHealth interventions with a primary or secondary aim to increase PA in people with cancer. The systematic review follows guidelines of the “Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)” statement (Moher et al., 2009) and meets the criteria outlined in “A Measurement Tool to Assess Systematic Reviews (AMSTAR)” checklist (Shea et al., 2007). A protocol outlining the planned search strategy and method of analysis for this review was registered online with a PROSPERO, a registry of systematic reviews (CRD42016037593).

Eligibility criteria

Experimental studies (randomized control trials, pre-post design, quasi-experimental) and observational studies, with or without controls, were eligible for inclusion if they evaluated an eHealth-based intervention (internet and mobile technologies) delivered to cancer survivors and included PA as a primary or secondary outcome measure. Single or multi-modal interventions were included. Studies were excluded if only telephone calls, SMS or conference calls were used. Review articles were excluded.

PA is a complex multi-dimensional construct which is challenging to measure accurately (Broderick et al., 2014b). PA can be measured objectively (e.g. indirect calorimetry, accelerometers, pedometers) or by using self-report methods (e.g. questionnaire, logbook). Domains of PA can be considered on a continuum from light activity (e.g. slow walking, playing most musical instruments) through to moderate level activity (e.g. brisk walking, recreational badminton) and vigorous activity (e.g. jogging, fast bicycling). Sedentary behaviour is generally referred to as low levels of activity, similar to resting levels (e.g. watching television or lying down) (Ainsworth et al., 2011). There are many different ways of quantifying PA. This review included PA measured by self-report, objective, or direct methods, and expressed PA in a number of ways, including but not limited to, MET-minutes.week⁻¹, minutes in light, moderate and/or vigorous PA per week, and meeting/not meeting PA guidelines (150 minutes per week of moderate/vigorous activity)(Schmitz et al., 2010).

Data sources & search strategy

A comprehensive search strategy (Appendix 2) was designed in collaboration with a senior medical librarian with specialist knowledge in systematic review searching (DM). The search strategy consisted of a search of six electronic databases: PubMed, CINAHL, EMBASE, PsychInfo, Web of Science and SCOPUS. Search terms included key-words and medical subject headings

adapted for each database. These related to three categories: 1) the condition (e.g. 'cancer', 'neoplasm', 'tumour', 'cancer survivor'), 2) technology (e.g. 'teleHealth', 'telerehabilitation', 'mobile health', 'Mhealth', 'eHealth', 'e-health', 'mobile technology', 'smartphone'), and 3) PA (e.g. 'exercise', 'physical activity', 'exercise therapy', 'physiotherapy'). No limit on the year published was applied as it was anticipated that the search strategy would produce only articles published in approximately the last ten years, due to the burgeoning nature of this technology. Databases were searched until March 2017. A grey literature search using Google Scholar and WorldCat search engines was performed; government reports were searched using the Google search engine and a combination of key word text. The bibliographies of all investigations selected for the review, as well as those of previous reviews were examined to identify further studies.

Selection of eligible studies

Articles were retrieved and all duplicates were removed. Two researchers (CH and JM), independently screened titles and abstracts to identify studies potentially meeting the eligibility criteria. Any disagreements between researchers were resolved by consensus and/or discussion with a third researcher (JB). Full-texts were retrieved and examined in detail to assess for inclusion in this review. Two researchers (CH and JM), independently screened these full texts to identify studies to be included in the final analysis. As with the screening of the titles and abstracts, any disagreements between researchers were resolved by a third researcher (JB).

Risk of bias

Two researchers (CH and JM) independently appraised the risk of bias of included studies; in cases where between-researcher disagreements could not be resolved by discussion to achieve consensus, a third reviewer (JB) arbitrated. The Downs and Black checklist (Appendix 13) was used to assess the risk of bias of observational studies (Downs and Black, 1998). This checklist

contains 27 items, with a maximum possible score of 31 points. The Cochrane Collaboration's tool (Higgins et al., 2011) (Appendix 15) was used to assess risk of bias for the remaining studies, which includes the following domains; sequence generation (randomization); allocation concealment; blinding of participants, personnel and investigator; incomplete data (e.g. losses to follow-up, intention-to treat analysis); selective outcome reporting; and other possible sources of bias.

Data extraction & Analysis

Data was extracted by two researchers (CH, JM) onto standardized data abstraction forms (Appendix 17). Disagreements between researchers were resolved by discussion to achieve consensus. Failing agreement a third member of the research team (JB) arbitrated.

Aggregation of results through quantitative synthesis was planned, however these were not completed due to the heterogeneity of studies in terms of study design, participants, interventions, and outcomes. Consequently, a narrative synthesis of study interventions and results was completed. A number of sub-group analyses were also planned, including: self-report and objectively measured PA; intervention focus (smart phone applications vs. web-based interventions); study design (control vs. no control group, randomized vs. non-randomized controlled trial). Ultimately, these could not be conducted due to insufficient data in the included studies.

2.1.2 Results

Study selection

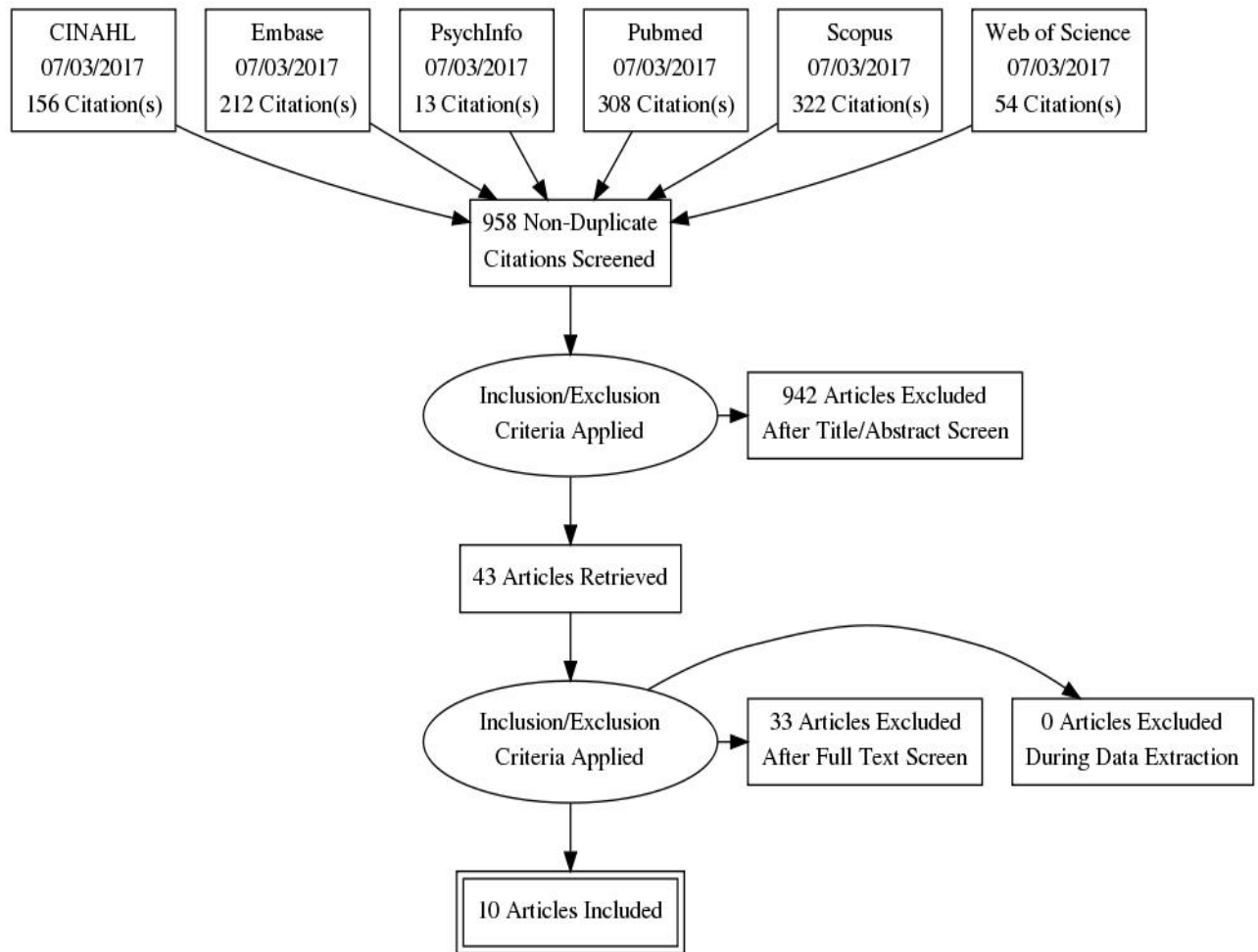
A total of 1065 articles were identified using the searches described. Following the first screening of titles and abstracts, 43 articles remained. After review of the full-text versions of these articles, 10 studies, published between 2012 and 2017 were included in the review. The PRISMA flow chart (Moher et al., 2009) below (Figure 2.1) summarizes the search strategy.

Randomized controlled trials predominated (n=7) (Lee et al., 2014, Hatchett et al., 2013, O'Carroll Bantum et al., 2014, Uhm et al., 2017, Kanera et al., 2017, Sturgeon et al., 2017, Short et al., 2017), while the remaining studies were non-controlled trials (Hong et al., 2015, McCarroll et al., 2015, Hooke et al., 2016a). Table 2.1 describes methodological features of these studies.

Participant characteristics

Participant characteristics are summarized in Table 2.2. In total, 1,994 participants were initially recruited into the included studies, 671 of these were control group participants, with an overall drop-out rate of 34.7% across studies. Just over 87% of participants were female (n=1744); reflecting the fact that the majority of studies included patients with breast or endometrial cancer.

Figure 2.1 PRISMA Flow Diagram



Risk of Bias of included studies

The Cochrane Collaboration’s tool (Higgins et al., 2011) for assessing risk of bias was used to evaluate the seven included RCTs (Appendix 15). Using the Cochrane tool, the overall risk of bias in the studies by Lee et al. (2014), Short et al. (2017), Sturgeon et al. (2017) and Kanera et al. (2017) was assessed as low, while the studies by O’Carroll Bantum et al (O’Carroll Bantum et al., 2014), Hatchett et al (Hatchett et al., 2013) and Eun Uhm et al (Uhm et al., 2017) were rated as

'unclear risk of bias'. Two non-randomised studies (McCarroll et al., 2015, Hong et al., 2015) were scored for risk of bias using the Downs and Black tool (Downs and Black, 1998), scoring 12, 13 respectively out of a possible score of 31. As some sections of the Downs and Black tool were not applicable to the study by Hooke et al. (2016), it scored 14 out of a total of 22. All 3 of these studies rated poor in quality, according to scoring categories defined by a review conducted by Hooper et al (Hooper et al., 2008). This review stated that scores of 26-28 rated as excellent quality, 20-25 rated as good quality, 15-19 rated as fair quality and a score of ≤ 14 was considered poor quality.

Table 2.1 Included study methodology

<i>Author, year</i>	<i>Country</i>	<i>Design</i>	<i>Duration</i>	<i>Inclusion criteria</i>	<i>Exclusion criteria</i>
Hatchett et al, 2013	USA	RCT	12 weeks	<p>Aged ≥ 18 years</p> <p>Female breast cancer survivors</p> <p>Completion of cancer treatment</p> <p>Ability to access and navigate the Internet</p> <p>Ability to communicate through email</p> <p>Ability to complete online questionnaires</p> <p>Not engaged in moderate or vigorous physical activity at the outset of the intervention</p> <p>Ability to engage safely in physical activity</p>	None specified
Kyung Lee et al, 2014	South Korea	Pilot RCT	12 weeks	<p>Aged ≥ 20 years</p> <p>Diagnosed with stage 0-III breast cancer within the previous 2 years</p> <p>Undergone curative surgery and completed primary cancer treatment within 12 months prior to study starting</p> <p>Serum haemoglobin ≥ 10g/dl</p> <p>Has not performed ≥ 150min moderate exercise per week and/or not consumed five servings of fruit and vegetables per day</p> <p>Ability to use a computer</p>	<p>Currently receiving cancer treatment</p> <p>Serious psychological disorder</p> <p>Infectious condition</p> <p>Visual or motor dysfunction</p>

				Home internet access Mobile phone user	
O'Carroll Bantum et al, 2014	USA	RCT	6 weeks	Aged ≥ 18 years Completion of primary treatment at least four weeks prior, but not more than 5 years before joining the study Diagnosis with only one cancer and no recurrence Access to the Internet Ability to read English	None specified
McCarroll et al, 2015	USA	Prospective, non-controlled, intervention study	4 weeks	Aged 18 to 75 years Women Histologically confirmed Stage I or II EC or BC within the previous 3 years without evidence of recurrence Access to a smartphone or internet with unlimited data or internet connection BMI $\geq 25\text{kg/m}^2$ Oncologist clearance for participation Performance status of 0-2 Surgical treatment > 6-months prior to study start	Non-English speaking Inability to read the consent form Lack of smartphone or Internet connection Inability to use the <i>LoseIt!</i> application Severe depression Physical or cognitive deficits Pregnancy or plan to become pregnant Breastfeeding Surgical treatment less than 6-months prior to start of the study Participation in a structured weight-loss programme in the preceding 6 months

				Endorsed desire to lose weight	
Hong et al, 2015	USA	Pilot, non-controlled intervention study	2-3 months	Aged ≥60 years Having ever been diagnosed with cancer Reporting the ability to perform physical activity Internet access	None specified
Hooke et al, 2016	USA	A within-subjects, single group, feasibility pilot study	22 days	Aged 6-18 years Diagnosis of Acute Lymphoblastic Leukemia Receiving a cycle of maintenance chemotherapy that included full doses of a corticosteroid (dexamethasone or prednisone) Normal EKG and echocardiogram Demonstrated hemodynamic stability during a pre-enrolment 6-minute walk test Ability to speak English Ability to, with their parent(s), receive and read daily emails on a home computer.	Ambulation impaired by osteonecrosis or serious neurologic toxicities
Eun Uhm et al, 2017	South Korea	Quasi RCT	12 weeks	Aged 20-70 years Histologically confirmed breast cancer Completion of primary cancer treatment including surgery, chemotherapy, and/or radiotherapy	History of treatment for accompanying severe disease (e.g., other malignancy) within one month Severe cardiovascular, pulmonary, or renal diseases that required exercise restriction

				Informed consent	Bone metastasis that caused severe pain during movement or exacerbated the risk for pathologic fracture ECOG performance status ≥ 3 Inability to perform a 2-min walk test (2MWT).
Kanera et al, 2017	Netherlands	RCT	12 months	Aged ≥ 18 years Dutch speaking cancer survivors Completed primary cancer treatment with curative intent at least 4 weeks, and up to 56 weeks prior to initial participation	Signs of cancer recurrence Signs of severe medical, psychiatric or cognitive disorders
Short et al, 2017	Australia	RCT	6 months	Aged > 18 years Proficient in English Breast cancer survivors Finished active cancer treatment No contraindications to exercise Individuals who had not participated in previous research conducted by the research team and were not already meeting PA guidelines	None specified
Sturgeon et al, 2017	USA	RCT	12 months	Aged 18–55 years BRCA1/2+ breast cancer survivors	None specified

				<p>Underwent prophylactic oophorectomy two or more years prior to study initiation</p> <p>Aged ≤ 45 at date of oophorectomy,</p> <p>Completed breast cancer treatment at least 4 months prior to study initiation</p> <p>Did not use hormone replacement therapy for 2 years prior to study initiation</p> <p>Received physician clearance to participate in the weight loss and exercise program</p> <p>Weight stable over the past year (e.g., no changes greater than 10 % in the past 12 months)</p> <p>Had a BMI ≥ 23 kg/m² when recruited</p> <p>Cancer free</p> <p>Access to the internet and a computer</p> <p>Access to basic fitness equipment (dumbbells, resistance bands) or willingness to join a fitness facility</p>	
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Key: EC - endometrial cancer, BC - breast cancer, RCT - randomized controlled trial, BMI- Body Mass Index, ECOG-Eastern Cooperative Oncology Group

Table 2.2 Participant characteristics

<i>Author, year</i>	<i>Participants (Included in final analysis)</i>	<i>Age Mean (SD)</i>	<i>Sex (Baseline)</i>	<i>Cancer: CG/IG (Baseline)</i>	<i>Patient Drop Out rate n(%)</i>
McCarroll et al, 2015	IG: 35	IG: 58.4 (10.3)	IG: Female: 50	BC: 26 EC: 19 BC & EC: 5	35(30%)
Kyung Lee et al, 2014	CG: 28 IG: 29	CG: 43.2 (5.1) IG: 41.5 (6.3)	CG: Female: 29 IG: Female: 30	CG: BC Stage 0: 2 BC Stage I: 23 BC Stage II: 28 BC Stage III: 6	Overall:2(3%) IG: 1(3%) CG: 1(3%)
Hatchett et al, 2013	CG: 36 IG: 38	Not reported	CG: Female: 42 IG: Female: 43	BC Stage I: 14/10 BC Stage II: 17/17 BC Stage III: 5/6 BC Stage IV: 2/3	Not reported
O'Carroll Bantum et al, 2014	CG: 147 IG: 156	CG: 49.3 (11.0) IG: 52.4 (11.0)	CG: Female: 148 Male: 28 IG: Female:141 Male: 35	BC: 84/83 EC/Ovarian: 23/22 Non-Hodgkins Lymphoma: 13/7 Colorectal: 11/11 Lung: 7/8 Thyroid: 6/8 Oral: 6/5	Overall:49(14%) IG: 20(11%) CG: 29(16%)
Hong et al, 2015	IG: 26	IG: *69 (Range-60-78)	IG: Female:18 Male: 8	Not reported	4(13%)

Short et al, 2017	<p>Monthly intervention: 48</p> <p>Weekly intervention: 46</p> <p>Single intervention: 61</p> <p>(Analysed at 3 month follow up)</p>	IG: ^55 (9.72)	<p>Monthly intervention: Female: 167</p> <p>Weekly intervention: Female: 168</p> <p>Single intervention: Female: 157</p>	<p>BC Stage 0: 10 (2% of whole sample)</p> <p>BC Stage 1: 108 (22% of whole sample)</p> <p>BC Stage 2: 153 (31% of whole sample)</p> <p>BC Stage 3: 103 (21% of whole sample)</p> <p>BC Stage 4: 15 (3% of whole sample)</p> <p>Unknown: 103 (21% of whole sample)</p>	336(68%)
Eun Uhm et al 2017	<p>CG: 167</p> <p>IG: 172</p>	<p>CG: 51.3 (10.7)</p> <p>IG: 49.3 (8.0)</p>	<p>CG: Female: 177</p> <p>IG: Female: 179</p>	<p>BC Stage 0: 12/9</p> <p>BC Stage 1A: 57/61</p> <p>BC Stage 1B: 5/5</p> <p>BC Stage IIA: 35/43</p> <p>BC Stage IIB: 19/17</p> <p>BC Stage IIIA: 16/13</p> <p>BC Stage IIIB: 0/5</p> <p>BC Stage IIIC: 7/5</p> <p>BC Stage IV: 1/2</p>	<p>Overall: 17 (5%)</p> <p>IG: 12(7%)</p> <p>CG: 5(3%)</p>
Sturgeon et al 2017	<p>CG: 16</p> <p>IG: 16</p>	<p>CG: 47.2 (3.8)</p>	<p>CG: Female: 16</p>	<p>Breast cancer (No stage specified)</p>	<p>Overall: 3(9%)</p> <p>IG: 3(16%)</p> <p>CG: 0(0%)</p>

		IG: 45.1 (4.0)	IG: Female: 19		
Hooke et al 2016	IG:16	IG: 8.69 (3.09)	IG: Female: 11 Male: 5	Acute Lymphoblastic Leukemia: 16	1(6.25%)
Kanera et al 2017	CG: 206 IG: 162	CG: 56.2 (11.3) IG: 55.6 (11.5)	CG: Female 186 Male 45 IG: Female 183 Male 48	CG: Breast Cancer: 164 Other cancer types: 67 IG: Breast Cancer: 162 Other cancer types: 69	Overall:81(18%) IG: 61(27%) CG: 19(8%)

IG; intervention group, CG; control group, BC; breast cancer, EC; endometrial cancer *Median data, ^Mean age for whole sample at baseline, SD; standard deviation

Study Design

A number of different study designs were employed, likely reflective of this emerging research field within cancer. Four studies investigated the effect of an eHealth intervention on the PA of cancer survivors when compared to a control group. The effectiveness of an eHealth intervention compared to current conventional programs designed to improve PA was considered in 2 studies, while the 3-arm RCT by Short et al (Short et al., 2017) investigated their eHealth intervention over varying lengths of delivery. The remaining studies, three in total, did not use a control group, but were pilot studies investigating the feasibility of their respective eHealth PA interventions, again reflecting the novelty of such strategies.

The length of interventions ranged from 14 days to 12 months. Half of the studies (n=5) reported short-term follow-up only, while maintenance was assessed in 4 studies (O'Carroll Bantum et al., 2014, Kanera et al., 2017, Sturgeon et al., 2017, Short et al., 2017), with 6-month (O'Carroll Bantum et al., 2014, Short et al., 2017) and 12-month follow up reported for two studies (Kanera et al., 2017, Sturgeon et al., 2017). Short et al (Short et al., 2017) made reference to a 6-month time-point, but data was supplied for the 12-week time-point only. The study conducted by Hooke et al (Hooke et al., 2016a) had the shortest intervention period of 2 weeks.

eHealth interventions

A variety of eHealth platforms designed to increase PA were described in these studies; web-based (n=5), web and mobile application (n=4) and e-mail-based (n=1). Features of each eHealth intervention are summarised in Table 2.3 below.

In total, of the 5 studies utilizing a web-based intervention alone, 3 of these investigated the effect of an eHealth intervention on the PA of cancer survivors when compared to a control group. All 5 studies with a web-based intervention reported an increase in self-reported PA or exercise. The composition of each web-based intervention was generally similar across the studies, with all web-based interventions including an additional educational element. This included information on PA guidelines in all studies, as well as dietary guidance in four of the studies. The study by Short et al (Short et al., 2017) focused on PA only, with no diet element included.

In contrast, the majority of the studies (3 out of 4) using mobile applications focused solely on a PA intervention, with no other element included.

PA assessment

Eight studies reported significant improvements in their respective PA and exercise outcome measurements (Lee et al., 2014, Hatchett et al., 2013, O'Carroll Bantum et al., 2014, Uhm et al.,

2017, Kanera et al., 2017, Sturgeon et al., 2017, Short et al., 2017, Hong et al., 2015). Diverse methods were employed to assess PA. One study measured PA objectively using a Fitbit to assess step count (Hooke et al., 2016a). PA was assessed using self-report methods in the other nine studies (see Table 2.4). These included six different self-report questionnaires: 7-day PA recall instrument (Hatchett et al., 2013), two forms of the Godin questionnaire (Godin Exercise Questionnaire, Godin Leisure-Time Exercise Questionnaire (Short et al., 2017, O'Carroll Bantum et al., 2014), Short-form International Physical Activity Questionnaire (Uhm et al., 2017), Short Questionnaire to Assess Health Enhancing Physical Activity (SQUASH) (Kanera et al., 2017), and Modifiable Physical Activity Questionnaire (Sturgeon et al., 2017). A self-log method was used in three studies; logging was through mobile application (McCarroll et al., 2015), completion of an exercise diary (Lee et al., 2014), or rating on a five-point scale (Hong et al., 2015).

Table 2.3 Features of E-Health intervention

Author, year	Platform for intervention				App / software	Personalisation		Behaviour change theory			PA Reporting by user			Interaction			Feedback			
	Web app	Mobile app	Email	Web		Yes	No	SCT	TTM	Theory of Goal Setting	Type	Duration	Intensity	Real-time	Automated reminders	Tel	Email	Push	SMS	
Hatchett et al, 2013	-	-	X	-		X	-	X	-	-	X	X	X	E-counsellor	Email	-	X	-	-	
Kyung Lee et al, 2014	-	-	-	X		X	-	-	X		X	X	X	-	SMS	-	-	-	X	
O'Carroll Bantum et al, 2014	X	-	-	-	<i>STC (Surviving and Thriving with Cancer)</i>	X	-	-	-	-	X	X	X	-	Message on website	-	-	-	-	
McCarroll et al, 2015	X	X	-	-	<i>Loselt!</i>	X	-	X	-	-	X	X	-	MDT	Push notifications	X	X	X	-	
Hong et al, 2015	X	X	-	-	<i>iCanFit</i>	X	-	-	-	X	X	X	X	-	Email	-	-	X	-	
Hooke et al, 2016	X	X	-	-	<i>FitBit</i>	X	-	-	X	-	X	X	-	Nurse researcher and physi		-	X	-	-	

														otherapist						
Eun Uhm et al, 2017	X	X	-	-	<i>Smart After Care</i>	-	X	-	-	-	X	X	X	-	-		-	X	-	-
Kanera et al, 2017	-	-	-	X	Kanker Nazorg Wijzer (Cancer Aftercare Guide)	X	-	X	-	-	X	X	X	-	Email		-	X	-	-
Short et al, 2017	-	-	-	X		X	-	X	-	-	X	X	X	-	Email		-	X	-	-
Sturgeon et al, 2017	-	-		X	<i>PrecisionNutrition.com</i>	X	-	X	-	X	X*			E-Counsellor	Email, phone, or video conference		-	X	-	-

Key: SCT-Social Cognitive Theory, TTM-Trans Theoretical Model

Table 2.4 Physical activity outcomes

Author, year	Intervention (IG) and control group (CG)	Physical activity outcomes and result		
		How PA recorded	Method of PA quantification	Baseline and end-intervention PA results: Mean (Standard Deviation) unless otherwise stated.
Hatchett et al, 2013	<p><i>IG</i>: Email-based intervention designed to influence PA</p> <p>Supplemented by PA e-counselling.</p> <p><i>CG</i>: Did not receive email messages and did not have access to PA e-counselling</p>	7-day physical activity recall (PAR)	Days per week achieving moderate and/or vigorous PA, <i>days/week</i>	<p>Baseline</p> <p>CG: 0 (0.00) , IG: 0 (0.00)</p> <p>6 weeks</p> <p>CG: 1.39 (1.58), IG: 1.42 (1.67)^a</p> <p>^a Significant between-group differences at 6-weeks ($p = .002$)</p> <p>12-weeks</p> <p>CG: 1.42 (1.67), IG: 3.47 (2.19)^b</p> <p>^bSignificant between-group differences at 12-weeks ($p = .001$)</p> <p><u>Moderate Intensity</u></p> <p>Baseline:</p> <p>CG: 0.00 (0.00), IG: 0.00 (0.00)</p> <p>6-weeks</p> <p>CG: 0.32 (0.62), IG: 0.50 (1.06)</p> <p>12-weeks</p> <p>CG: 0.39 (0.75), IG: 1.08 (1.05)^c</p>

				<p>Significant differences in moderate intensity between groups at 12 weeks ($p=0.002$)</p> <p><u>Vigorous Intensity</u></p> <p>Baseline:</p> <p>CG: 0.00 (0.00), IG: 0.00 (0.00)</p> <p>6-weeks</p> <p>CG: 1.08 (1.17), IG: 2.31 (1.82)^d</p> <p>12-weeks</p> <p>CG: 1.03 (1.15), IG: 2.39 (1.76)^d</p> <p>^dSignificant differences in vigorous intensity PA between groups at 6 weeks ($p=0.001$) and 12 weeks ($p<0.001$)</p>
Kyung Lee et al, 2014	<p>IG: Self-management exercise and diet intervention aimed at enhancing exercise and dietary behaviour. Included assessment, education, action planning and feedback components</p> <p>CG: 50-page educational booklet on exercise and diet</p>	<p>Self-reported exercise, logged in diary, minutes per week of at least moderate aerobic exercise that consumed at least 4 metabolic equivalents.</p>	<p>Minutes per week of moderate exercise (≥ 4 METs) reported as number of participants n (%) achieving ≥ 150min/week</p>	<p>Baseline</p> <p>CG: 10 (34.5), IG: 10 (33.3)</p> <p>12-weeks</p> <p>CG: 10 (35.7), IG: 19 (65.5)^e</p> <p>^eSignificant post-intervention between-group differences, adjusted for baseline values ($p < .0001$)</p>

<p>O'Carroll Bantum et al, 2014</p>	<p>IG: Six week online workshop, comprising of a patient education workshop designed to promote healthier diet choices and increasing exercise.</p> <p>CG: On wait list for intervention</p>	<p>Self-reported PA: Godin leisure-time exercise questionnaire.</p>	<p>Minutes per week, mean (95% CI) of exercise in the categories of (1) mild aerobic exercise, (2) moderate aerobic exercise (3) strenuous aerobic exercise.</p>	<p>Baseline</p> <p>CG: (1) 58.9 (51.5-66.2) (2) 37.0 (30.9-43.2) (3) 29.0 (22.5-35.5)</p> <p>IG: (1) 56.1 (48.9-63.3) (2) 49.0 (42.2-55.7) (3) 32.0 (25.5-38.5)^f</p> <p>6-months</p> <p>CG: (1) 65.0 (56.5-73.6) (2) 45.3 (37.5-53.0) (3) 28.9 (21.8-36.0)</p> <p>IG: (1) 74.1 (64.2-84.1) (2) 54.1 (46.5-61.7) (3) 50.8 (40.7-60.9)^f</p> <p>^fSignificant difference between intervention and control groups in increased strenuous exercise (32 to 51 min/week, p=.01)</p>
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McCarroll et al, 2015	<p>IG: Comprehensive lifestyle change programme including a nutritional component (limiting carbohydrates to <70g per day and increasing fibre intake to 30g per day), a physical activity component (to meet ACSM guidelines), and to improve eating self-efficacy</p> <p>CG: N/A</p>	Self-reported physical activity, daily exercise type and duration, logged in <i>Loselt!</i> app	Time in PA, <i>minutes. Mean (Standard Deviation)</i>	<p>Baseline: 22.7 (44.0)</p> <p>Week 4: 127.0 (185.3)</p>
Hooke et al 2016	IG: Fitbit coaching program including activity goal setting to improve physical activity	Fitbit measured steps per day	Average steps per day	<p>Baseline: 10,385</p> <p>Week -2: 10,362</p> <p>Week -1: 10,631</p> <p>Steroid Pulse: 10,324</p> <p>No significant differences in average steps per day</p>
Eun Uhm et al 2017	<p>IG: MHealth and pedometer program designed to improve physical activity and exercise.</p> <p>CG: Conventional program using brochure to promote physical activity and exercise</p>	Self-reported physical activity was assessed by the Korean version of the International Physical Activity Questionnaire-Short Form (IPAQ-SF)	<p>Total MET (Metabolic equivalent of task) per week</p> <p>Mean (Standard Deviation)</p>	<p>IG: Baseline: 2050.6 (2182.2)</p> <p>12 weeks: 3026.9 (2489.5)[§]</p> <p>CG: Baseline: 2091.5 (1811.2)</p> <p>12 weeks: 2560.4 (2354.9)[§]</p> <p>[§]Weekly physical activity was significantly increased in both groups (p<0.05), with the increment being greater in the mHealth group, but not significantly so.</p>

<p>Kanera et al 2017</p>	<p>IG: Web-based cancer aftercare intervention on moderate physical activity and vegetable consumption among early cancer survivors</p> <p>CG: They received access to the program after completing the 12-month measurement for control.</p>	<p>Self-report Short Questionnaire to Assess Health Enhancing Physical Activity (SQUASH)</p>	<p>Weekly minutes of moderate physical activity</p> <p>Mean (Standard Deviation)</p>	<p>IG: Baseline: 595.9 (620.5)</p> <p>6 months: 746.6 (676.3)</p> <p>12 months: 688.1 (570.6)^h</p> <p>CG: Baseline: 526.5 (546.5)</p> <p>6 months: 598.9 (510.7)</p> <p>12 months: 512.2 (452.1)^h</p> <p>^hThe between group differences in moderate PA after 12 months were statistically significant. (p= 0.010)</p>
<p>Short et al 2017</p>	<p>Web-based Physical activity advice for breast cancer survivors, trialling 3 separate delivery schedules.</p> <p>IG1: Monthly three-module intervention</p> <p>IG2: Weekly three-module intervention</p> <p>IG3: Single module group</p>	<p>Moderate-vigorous aerobic physical activity (mins/week) and resistance-based physical activity (resistance training score) measured using the validated Godin Leisure-Time Exercise Questionnaire (GLTEQ)</p>	<p>Aerobic exercise calculated in mins/week. Mean (SD)</p> <p>Resistance exercise calculated by training score. Mean (SD)</p>	<p>Aerobic exercise data for study completers.</p> <p>IG1: Baseline: 96.15 (119.63)</p> <p>3 months: 186.05 (172.56)</p> <p>IG2: Baseline: 97.17 (124.10)</p> <p>3 months: 186.08 (157.89)</p> <p>IG3: Baseline: 90.08 (106.63)</p> <p>3 months: 216.99 (219.99)</p> <p>Resistance exercise data for study completers.</p> <p>IG1: Baseline: 2.79 (6.45)</p> <p>3 months: 8.95 (16.24)ⁱ</p> <p>IG2: Baseline: 3.17 (7.07)</p> <p>3 months: 6.52 (9.86)</p>

				IG3: Baseline: 2.69 (7.27) 3 months: 4.5 (6.83) ⁱ ⁱ There was a significant effect of group with the incidence of resistance-training among participants allocated to the monthly three module intervention group 1.88 times higher than participants allocated to the single module intervention group ($p = 0.01$).
Sturgeon et al 2017	IG: Web-based lifestyle modification intervention to improve physical activity and exercise CG: Participants randomized to the control group were waitlisted and enrolled in the program following study activities.	Leisure time physical activity was assessed using the interviewer administered Modifiable Activity Questionnaire	Caloric expenditure (kcal/day) Mean (SD)	IG: Baseline: 483.7 (292.2) 12 months: 740.6 (330.2) ^j CG: Baseline: 559.6 (656.6) 12 months: 425.2 (325.6) ^j ^j There was a significant between group difference for daily caloric expenditure with the intervention group increasing physical activity more by the end of the intervention ($p < 0.05$).

Key: IG- Intervention Group, CG-Control Group, PA-Physical Activity. Data is presented as mean (standard deviation) unless otherwise stated

2.1.3 Discussion

This systematic review comprehensively evaluated the effect of eHealth interventions on PA in cancer survivors. Overall the review suggests that eHealth interventions may increase PA in cancer survivors, with the majority of studies (8/10) reporting improvements in PA and exercise. eHealth in general is a rapidly emerging area of healthcare, with this review showing that the challenge now is to ascertain the optimal manner in which to integrate it into clinical practice. This is true also for eHealth interventions in the area of PA promotion in cancer survivors, with the current research evaluated by this review presenting a variety of eHealth delivery methods. The use of web applications to deliver the intervention was the most popular delivery method, used in 5 of the studies as the sole delivery method, but also used in four further studies in conjunction with a mobile delivery method. Lifestyle-related mobile applications are ubiquitous in 'non clinical' settings but it appears from these results, considering the low number of studies identified, that harnessing the potential of mobile-based applications in clinical practice settings with cancer survivors lags behind. Study authors did not describe whether participants accessed web applications via mobile devices. E-mails to promote PA were only incorporated in one study (Hatchett et al., 2013), this study being the oldest study included in this review. This signals the rapid growth and progression of application-based multi-modal eHealth interventions, be it web or mobile-based, which were represented strongly in this review. It is unclear if web-only based interventions offer more potential to increase PA compared to mobile applications or email-only interventions. Future research may investigate the optimal eHealth medium to increase PA among cancer survivors.

Further variation between studies was also seen when comparing the duration of the interventions. Short-term programs such as the 14-day intervention of Hooke et al. (2016) and the 4-week program of Kyung Lee et al (Lee et al., 2014) may not have been long enough to embed behavioural change. Perhaps notably, a slightly longer 6-week programme (O'Carroll

Bantum et al., 2014) reported a significant increase in vigorous level PA. However, the short-term nature of the study still means that it is unknown whether any increases in PA behaviour translated into longer term benefits. The long-term benefits and effectiveness of an eHealth program to improve PA was, however, investigated in the two studies which had 12-month follow-up of patients (Kanera et al., 2017, Sturgeon et al., 2017). Both studies showed significant improvements in self-reported PA between intervention groups and controls at 12 months, providing valuable information on maintenance of behaviour in this patient group. It is particularly important in future studies to consider the importance of a follow up period, such as that adopted by the two aforementioned studies, especially when the outcome to be measured, PA, is behavioral in nature and the aim is to affect a lifestyle change. In the context of this review, due to a wide range of intervention durations, which varied between 14 days to 12 months, we were not able to provide any firm conclusions on optimal intervention length. This was further indication that the adoption of eHealth interventions in this patient cohort was at a relatively early stage, and thus conclusions regarding efficacy and feasibility of such interventions was difficult to decide.

No adverse effects were reported in any of the studies included in this review but caution must be applied. Such interventions could potentially cause harm if inappropriate advice is provided, desired behaviour is undermined or if data is shared inappropriately (Michie et al., 2017). All studies included were published in the last five years, again demonstrating the recent emergence of this research field within cancer. One of the difficulties or barriers that cancer researchers and clinicians may have in integrating eHealth in their practice may stem from the rapid progression of the area, where by the time a certain technology is researched the next new eHealth initiative is available. In this case, particularly in the promotion of PA, an eHealth intervention with a sound grounding in behavioral change theory may provide the foundation for an effective intervention, regardless of technology. As demonstrated in the results above,

the majority of included studies had considered behavioral change theory and had successfully implemented components of behavioural change research into their interventions, showing the flexibility of eHealth in delivering a PA intervention. In wider eHealth literature these results are mirrored, with a systematic review on PA eHealth interventions in cardiovascular disease reporting consistent use of behavior change theories in 23 studies which described PA promotion (Duff et al., 2017).

Three studies in this review (Hong et al., 2015, McCarroll et al., 2015, Hooke et al., 2016a) did not employ control groups. While ideally pragmatic RCTs would be employed to evaluate new interventions, emerging literature advocates for a more fluid cycle of development and testing in such a rapidly changing context (Michie et al., 2017), as the time taken to conduct and publish RCTs means their eventual relevance is likely to be limited (Pham et al., 2016b). Studies were analysed using traditional statistical methods, but it has been suggested that approaches such as Bayaesian analyses may be best suited to this dynamic field (Michie et al., 2017). A further sign of the infancy of this area was shown in a recent review by Harvey et al (Harvey et al., 2017) which investigated eHealth weight loss interventions in cancer survivors. The total number of eHealth studies identified was 5, with 3 of those being feasibility, pilot or single arm studies.

The underlying theme of heterogeneity between studies continued with the lack of consistency in how PA was reported in the included studies. As mentioned above, nine studies used self-report methods of assessing PA. This raises a significant likelihood of self-report bias, even if unintentional, as participants are being “cued” to think about PA. The use of direct monitoring devices (e.g. accelerometry) to measure PA could reduce this and other inherent limitations of self-report PA measurement methods (Broderick et al., 2014b).

A further consideration of the studies included in this review is the variability in baseline PA levels reported between each respective study. While some studies reported low baseline PA levels amongst their sample (Hatchett et al., 2013, Hong et al., 2015, McCarroll et al., 2015),

there were a number whose participants reported high baseline activity levels, with some exceeding PA guidelines (See Table 2.4 above). It should be borne in mind, that if PA levels are low at baseline it can typically be easier to see a significant change, with the opposite being the case when the baseline PA levels are high.

The drop-out rate, as demonstrated in Table 2.3 above, was generally low across the studies. This is an important aspect for assessing the success of an intervention, with high drop-out rate potentially indicating an intervention that may not be suitable for the chosen population. Generally across the studies, only Short et al (Short et al., 2017) and McCarroll et al (McCarroll et al., 2015) had high enough drop outs to warrant further concern regarding the efficacy and suitability of the program. The study by Short et al (Short et al., 2017), which reported a drop-out rate of 68%, conducted its study exclusively online, with the recruitment, intervention and follow-up conducted via a website and email. The results of this study may indicate that while a study, and an intervention, conducted exclusively online may present the opportunity for a high number of potential patients for recruitment, the absence of any face to face contact with a healthcare professional may become a limitation in the retention of these patients.

This review suggests a number of ways the conduct and reporting of future eHealth studies of PA in cancer survivors could be improved. Future studies should improve measurement of PA by the use of objective measures such as pedometers and accelerometers. eHealth studies should adhere to better reporting of technological interventions to ensure interventions can be replicated (Agarwal et al., 2016). If feasible and effective, eHealth interventions may be a more scalable option to improve PA than one-to-one interventions (Oosterveen et al., 2017) but unique challenges of this medium include pace of development, engagement with intervention, and regulatory, ethical and security requirements (Michie et al., 2017).

2.1.4 Conclusion

The studies discussed above may constitute the first attempts to embedding technology into the cancer rehabilitation setting. Although some studies within this review showed promising results, methodological considerations pertaining to this evolving field, largely short term follow up, heterogeneity in interventions and varying self-report PA measures all weaken the interpretability of these studies. This means the independent effect of individual programme components cannot be elucidated with any certainty. The use of a broad search criteria was necessary for such an evolving and novel area, and to reduce implicit researcher bias regarding the search criteria, however studies included were particularly varied in their approach to promoting PA, and thus drawing conclusions about eHealth efficacy in this population was difficult.

This systematic review is the first, to our knowledge, to review the effectiveness of eHealth interventions in increasing PA levels among cancer survivors. Its findings provide a contemporary and reliable research base and identify gaps in this developing area to support researchers, policy makers and other stakeholders as they design and implement effective eHealth interventions to increase PA levels in cancer survivors.

2.1.5 An update to the systematic review (2017-2019)

The systematic review detailed above was updated to highlight the studies that were conducted between March 2017 and June 2019. A search, using identical methodology as above, was performed on the 17th of June 2019. Search parameters were limited to only include studies published after March 2017. Interestingly, a further 25 studies investigating the effect of an eHealth intervention on PA in cancer survivors were extracted from the updated search (Table 2.5), which is illustrated in the PRISMA flow chart (Moher et al., 2009) below (Figure 2.2). As discussed in the original systematic review above, only 10 studies were included, a sharp contrast to the 25 studies included in this updated search. This is emphasised further when viewed in the context of the search strategy utilised in this updated search, which limited the

updated search to a span of two years between 2017 and 2019. There was no limit on the year that included studies were published in the original systematic review. Therefore, the inclusion of 25 extra studies in only two years highlights the rapid growth and development in this area of research.

Similar to the initial systematic review conducted in 2017, the majority of the studies in this updated search were RCTs (n=19), with the remaining studies being non-controlled trials (n=6). In total, 2147 participants were recruited to these studies, with 12 (48%) of these studies recruiting mixed diagnosis cancer survivors. Details regarding the composition of each study is included in below. The methods of eHealth used in the studies extracted from the new search demonstrate the progression of technology and eHealth in the promotion of PA. In total, 14 studies (56%) of the included studies in the updated search used wearable technology as part of their intervention to improve PA. This is in sharp contrast with the original systematic review conducted in 2017, which reported only 1 study (Hooke et al., 2016b) using wearable technology.

The measurement of PA also showed progression between the original systematic review and this updated search. A total of 16 studies (64%) incorporated the use of objective methods of PA measurement, such as accelerometers, pedometers and wearable trackers. This is further evidence demonstrating the progression of this area of research, with only 1 study (Hooke et al., 2016b) from the systematic review in 2017 measuring PA objectively. Overall, the key message which can be gleaned from the updated search is the rapid development and evolution of research investigating eHealth interventions to promote PA in cancer survivors. The advent of wearable technology has prompted researchers to investigate the potential of this medium to improve PA, and the results of this updated search confirm that.

Figure 2.2 PRISMA flow diagram for updated search (2017-2019)

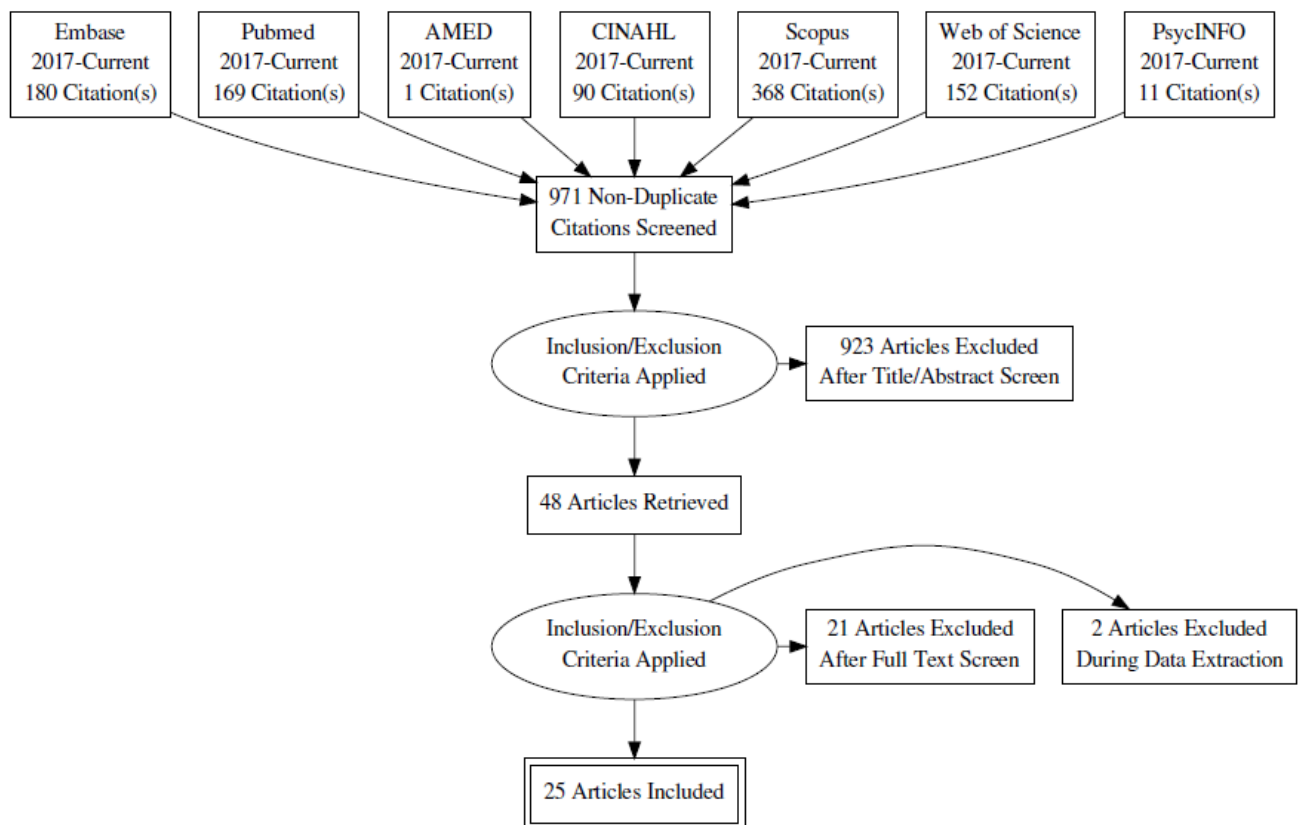


Table 2.5 Included study characteristics (n=25)

<i>Study Name</i>	<i>Study Type</i>	<i>Cancer Type</i>	<i>eHealth type</i>	<i>PA outcome</i>	<i>Recruited participants</i>
(Van Blarigan et al., 2019)	RCT	Colorectal	Wearable	Accelerometer	42
(Pope et al., 2019)	Non-controlled	Breast	Smartphone/Facebook	Accelerometer	10
(Ormel et al., 2018a)	RCT	Mixed	Smartphone	Self-report	32
(Villaron et al., 2018)	RCT	Mixed	Web-based	Pedometer	60
(Cheong et al., 2018)	Non-controlled	Colorectal	Wearable	Self-report	102
(Mayer et al., 2018)	RCT	Colon	Smartphone	Self-report	284
(Koontz et al., 2018)	Non-controlled	Mixed	Wearable	Pedometer	29
(Mendoza et al., 2017)	RCT	Mixed	Wearable/Facebook	Accelerometer	60
(Fung et al., 2017)	RCT	Testicular	Wearable	Pedometer/self-report	19
(Haggerty et al., 2017)	RCT	Endometrial	Smartphone	Self-report	41
(Lee et al., 2019)	RCT	Prostate	Smartphone	Wearable/Pedometer	100
(Kenfield et al., 2019)	RCT	Prostate	Wearable	Wearable	64
(Golsteijn et al., 2018)	RCT	Mixed	Web-based	Accelerometer	229
(Frensham et al., 2018)	RCT	Mixed	Web-based	Pedometer	91
(Park et al., 2019)	RCT	Breast	Smartphone/wearable	Self-report	356

(Howell et al., 2018)	RCT	Mixed (Paediatric)	Web-based/wearable	Accelerometer	97
(Gehring et al., 2018)	RCT	Glioma	Wearable	Self-report	34
(Short et al., 2018) (?)	Non-controlled	Mixed	Smartphone	Self-report	12
(Gell et al., 2017)	Non-controlled	Mixed	Wearable	Accelerometer	26
(Webb et al., 2019)	RCT	Mixed	Web-based	Self-report	207
(Porter et al., 2018) (video-conferencing)	RCT	Mixed	Online video conferencing	Self-report	20
(Trinh et al., 2018)	Non-controlled	Prostate	Wearable/Web-based	Accelerometer	46
(Lynch et al., 2019)	RCT	Breast	Wearable	Accelerometer	83
(Maxwell-Smith et al., 2019)	RCT	Mixed	Wearable	Accelerometer	68
(Valle et al., 2017)	RCT	Breast	Smartphone/Wearable	Wearable	35

Chapter 3 Quantitative methods and outcomes

3.1 Introduction

The content of this chapter will firstly detail and discuss quantitative study design utilised in this thesis (Study 1 and Study 3). Descriptions of the principles of reliability and validity will be detailed following this. Study endpoints for quantitative research outcomes (Study 1 and Study 3) in this thesis will then be detailed. These include PA, functional capacity, QOL, body composition and anthropometry outcome measures utilised in this thesis. Finally, a description of eHealth, and its use in this thesis, will be discussed. Specific chapters to follow in this thesis will refer back to the relevant section in this chapter when describing individual study methodologies. Qualitative methodology, which was used in study 2, will be described separately in Chapter 3.

3.2 Background research methods

3.2.1 Study Designs

There are a variety of study designs utilised in medical research and can typically be grouped into either observational or experimental studies. Study 1 was a questionnaire study and utilised a cross-sectional design. Study 2 was qualitative in design, and will be discussed in Chapter 3. Study 3 was a feasibility study and utilised a one-arm experimental design.

Study 1 used an observational study design. An observational study is defined as 'a study in which no intervention is made (in contrast with an experimental study) and which provides estimates and examines associations of events in their natural settings without recourse to experimental intervention' (Mann, 2003). Study 1 specifically used a cross-sectional questionnaire design. A cross-sectional study design characteristically measures or assesses participants at one point in time only. Cross-sectional studies are typically used to elucidate

prevalence in a population (Mann, 2003), and are often questionnaire or interview based. Advantages associated with cross-sectional studies include the low cost and low-resource requirements, while cross sectional studies also provide an insight into any potential associations between outcomes (Mann, 2003). Limitations associated with cross-sectional study design do exist however, and include the inability to differentiate between cause and effect from association (Mann, 2003), as well as the lack of guarantee that the snapshot of data gathered is representative of the population. Furthermore, cross-sectional studies can be afflicted by non-response bias, where participants who take part in the study can differ from those who chose not to, leading to further doubt over the representative nature of the study (Sedgwick, 2014).

Study 3 was a feasibility intervention study with a single-arm pre-post-test design. This study was experimental in design. The primary outcomes for this study were feasibility in nature, while secondary outcomes were efficacy in nature and consisted of the following outcomes. PA, QOL and body composition (among other outcomes) were examined as efficacy outcomes. A feasibility study is defined as a study used to estimate important parameters that are needed to design a main study (Whitehead et al., 2014). This may include estimation of willingness of patients to participate, number of people eligible, follow-up rates, response rates and adherence/ compliance rates. The aim for a feasibility study is to assess whether it is possible to perform a full-scale study in the relevant area of investigation. In this case, Study 3 was designed with the goal of exploring the potential feasibility and efficacy of a PA intervention delivered using eHealth in cancer survivors, with the ultimate goal to provide a foundation of knowledge and data to build a larger randomised control trial in the future. This goal for Study 3 aligns with the general purpose of a feasibility study design, which is designed to determine whether an intervention is appropriate for further testing (Bowen et al., 2009). A feasibility study generally has eight distinct areas of focus, described by Bowen et al.(Bowen et al., 2009). These are detailed in Table 3.1 below. The design of feasibility studies can place emphasis on any of these

areas, depending on the aim and objectives of that particular study. Feasibility outcomes in Study 3 were aligned with these areas of focus, following recommendations on suitable feasibility outcomes (Arain et al., 2010, Bowen et al., 2009).

Table 3.1. Feasibility study areas of focus. Adapted from Bowen et al., (2009)

Areas of focus	Description
<i>Acceptability</i>	Examining how individuals involved in delivering and receiving intervention respond to intervention.
<i>Demand</i>	Demand for intervention activities among the selected intervention population.
<i>Implementation</i>	The manner in which an intervention can be fully implemented as planned.
<i>Practicality</i>	This refers to the ability of the intervention to be delivered when constrained by time, commitment etc.
<i>Adaptation</i>	This investigates the changes and adaptations of the components of the intervention to accommodate a new situation.
<i>Integration</i>	This refers to an assessment of the level of change required to integrate a new intervention into an existing setting.

Expansion	This refers to the ability of a successful intervention to expand to a different setting or population.
Limited-efficacy testing	This refers to a focus on efficacy of an intervention, but in a limited way. This can take the form of a study with convenience sampling methodology and limited statistical power.

The term ‘feasibility study’ has been used interchangeably with ‘pilot study’ in various research to date (Whitehead et al., 2014), with little distinction between the terms in the MRC guidelines for designing a complex intervention (Craig et al., 2008). In a review by Whitehead et al (Whitehead et al., 2014), it was concluded that all preliminary work could be described as feasibility, with the term ‘pilot’ reserved for a study that mimics the definitive trial final trial design. As both feasibility study design and pilot study design share similarities, the limitations associated with pilot studies may also apply to feasibility studies. Pilot study design does not offer strong information on population effect size, due mainly to the small sample size inherent in pilot study design (Leon et al., 2011). This small sample size, which is often characteristic of feasibility studies also, limits the ability to confidently test the research hypothesis and efficacy of the intervention (Leon et al., 2011).

3.2.2 Validity and Reliability

Validity

Validity of an outcome measure is defined as the ‘the degree to which it measures what it is supposed to measure’ (Pallant, 2016). There are a number of types of validity, including content, criterion and construct validity. Content validity describes the ability of the outcome measure

to effectively sample and represent every single element of a construct. Criterion validity refers to the relationship or correlation between a measure and another specific criterion. In other words, criterion validity compares an outcome measure to an existing 'gold standard' measure, by examining the degree of agreement between the two measures (Stokes, 2011). Criterion validity can be divided further into two separate types of validity. Concurrent validity describes the validity of a measure when it is compared to the gold standard at the same single point in time, while, in contrast to this, predictive validity refers to the ability of a measure to predict data from another measure at some point in the future (Stokes, 2011). Construct validity refers to the testing of a measure against underlying theoretical constructs (Stokes, 2011).

Throughout this thesis validity will be described when discussing the rationale behind the use of specific outcome measures in the studies that were conducted. Validity coefficients are used to measure validity, and quantify the magnitude of correlation seen when examining criterion validity. These validity coefficients range from -1 to +1 (Stokes, 2011). Pearson-product moment correlation (PPMCC) is a coefficient which examines the linear relationship between data that two measures have produced. Spearman's rank order correlation is used as a non-parametric coefficient of correlation, typically in the absence of any linear relationship.

Reliability

Reliability refers to the degree that an outcome measure is free from random error (Pallant, 2016). It captures the ability of a measure to be able to produce consistent results between repeated tests, either by the same person or device (inter-rater or inter-instrument reliability) or by the same person or device over different time points (intra-rater or intra-instrument reliability). A random error has the potential to occur at any part of the measuring process, and may be due to inattention, fatigue or inaccuracy (Stokes, 2011).

Description of reliability can be categorised as relative reliability or absolute reliability. Absolute reliability is defined as the standard error of the measurement (SEM), and refers to the variation

that can be seen with outcome measure scores on repeated measurements (Stokes, 2011). Absolute reliability can be used to generate the minimal detectable change (MDC) for an outcome measure, which is the smallest score change that must occur before it can be attributed to something other than measurement error (Stratford, 2004).

Relative reliability can be expressed in 3 ways, inter-rater reliability, intra-rater reliability and internal consistency. Internal consistency measures correlation between components of the same instrument (McDowell and Newell, 1996). A measure commonly used to report relative reliability is called the intra-class correlation coefficient (ICC). ICC describes variance due to error, and a score of less than 0.5 demonstrates poor reliability. Scores of between 0.5 and 0.75 indicate moderate reliability, between 0.75 and 0.9 indicate good reliability and greater than 0.90 describes excellent reliability (Koo and Li, 2016).

3.2.3 Background to data analysis

There were a number of ways in which data collected in this thesis was analysed, with the principles of this analysis described below. Specific details pertaining to data analysis will be outlined in relevant chapters.

The first phase of data analysis commenced with the use of descriptive statistics and an assessment of data normality. Both categorical and scale (continuous) data was collected in this thesis. Categorical data is analysed by using frequencies, while in contrast, continuous data analysis will produce results showing mean, median and standard deviation (Pallant, 2016). Descriptive statistics provide further information on continuous data, with information regarding skewness and kurtosis also available. Skewness provides an indication of symmetry of the data distribution, while kurtosis indicates the peak of the distribution (Pallant, 2016).

The analysis of data normality was a mandatory preliminary step preceding statistical testing. Normal data distribution refers to a symmetrical bell shaped curve, showing the highest

frequency of score in the middle, and the smaller frequency of scores towards the outside of the curve (Pallant, 2016). Normality can be assessed in two ways, visually and statistically. Normality can be assessed by visually inspecting the normal Q-Q plots. Normally distributed data will lie on, or close, to the diagonal line in these Q-Q plots. Statistical tests of normality can also be used to assess for data normality. There are two common tests that can assess for normality, the Kolmogorov-Smirnov Test and the Shapiro-Wilk Test. The Shapiro-Wilk test was used in this thesis to assess for data normality, chosen due to its suitability at testing normality in studies with a small sample size (Ghasemi and Zahediasl, 2012). In this test, data is deemed normally distributed if the significance value is greater than 0.05 ($p > 0.05$). Data normality dictates whether a parametric or non-parametric statistical test is used to analyse the relevant data. Below is a description of the parametric and non-parametric statistical tests used in Study 3.

Friedman's test was used to compare non-normally distributed data, and one-way ANOVA (analysis of variance) repeated measures parametric test were used to compare normally distributed data at each time point with Bonferroni *post hoc* tests. Both the one-way ANOVA and Friedman's statistical tests are used when the same participants are measured at different time-points (within-subjects test). Assumptions for the one-way repeated measures ANOVA indicate that the dependent variable is measured at the continuous level, that the independent variable consists of at least two related groups, that the data is normally distributed and that variance in the data is homogenous (Pallant, 2016). Assumptions for the non-parametric Friedman's test are considerably less, but require that one group is measured on three or more occasions and that the dependent variable is also measured at the continuous level.

3.3 Quantitative outcomes

3.3.1 Physical activity (PA)

Physical activity (PA) is defined as 'any bodily movement produced by skeletal muscles that results in energy expenditure' (Caspersen et al., 1985). Exercise, which is a sub-category of PA, can be defined as 'physical activity that is planned, structured, repetitive, and purposive in the sense that improvement or maintenance of one or more components of physical fitness is an objective' (Caspersen et al., 1985). PA is a complex multi-dimensional construct which is challenging to measure accurately (Broderick et al., 2014b). PA can be measured objectively (e.g. indirect calorimetry, accelerometers, pedometers) or by using self-report methods (e.g. questionnaire, logbook). Domains of PA can be considered on a continuum from light activity (e.g. slow walking, playing most musical instruments) through to moderate level activity (e.g. brisk walking, recreational badminton) and vigorous activity (e.g. jogging, fast bicycling). Sedentary behaviour is generally referred to as low levels of activity, similar to resting levels (e.g. watching television or lying down) (Ainsworth et al., 2011). There are many different ways of quantifying PA. For the purposes of this research, quantification of PA was completed using both subjective and objective methods.

There is a growing body of evidence showing benefits of PA in patients with cancer. Therefore, the method by which PA was measured in this thesis was of great importance, particularly to accurately report this parameter. The benefits of PA and exercise in patients with cancer are numerous, with improvements in quality of life (Adamsen et al., 2009, Mutrie et al., 2007), function (Morey et al., 2009, Courneya et al., 2003) and a reduced risk of recurrence (Friedenreich et al., 2009, Holmes et al., 2005) among the established benefits. Guidelines on achieving the correct magnitude of PA each week have been established by the American Cancer Society, with 150 minutes of moderate PA recommended (Schmitz et al., 2010). Specific methods of PA measurement commonly utilised include behavioural observation, self-report methods (such as questionnaires and diaries) and physiological markers like heart rate and calorimetry (Westerterp, 2009a). The gold-standard for PA measurement is accepted as the doubly labelled water method, assessing total energy expenditure. It achieves this by enriching

the body water of a participant with heavy oxygen (^{18}O) and heavy hydrogen (^2H) and then calculating the difference in washout kinetics between both isotopes (Westerterp, 2017). This method is, however, infrequently used in research due to the expensive nature of employing it, and the high subject and time burden associated with it (Westerterp, 2009a). An outline of subjective and objective PA measurement, and its use in this thesis, is detailed below.

Subjective measurement of PA

Questionnaires and activity diaries are the primary method of obtaining a subjective assessment of PA. Questionnaires are generally regarded as a cheap method of assessing PA, can be applied to large populations and are considerably less intrusive than objective measures (Prince et al., 2008). Examples of widely used PA questionnaires are the International Physical Activity Questionnaire (IPAQ), the Godin-Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ) and the Global Physical Activity Questionnaire. Self-report methods of PA measurement are, however, characteristically afflicted by recall bias, where participants don't remember past activities or experiences accurately, and response bias (Shephard, 2003). Response bias, which may contribute to the inaccurate measurement of PA, can often be caused by respondents being influenced by their perception of what a socially desirable PA behaviour presents as, leading to over-reporting of PA (Adams et al., 2005). Furthermore, people tend to underestimate sedentary pursuits such as watching television (Shephard, 2003). Additionally, the use of PA questionnaires is typically still hampered by limited reliability and validity (Shephard, 2003).

Despite this, subjective PA measurement is an important aspect of creating a thorough and complete picture of an individual's PA behaviour, particularly when utilised alongside objective PA measurement. Study 3 in this thesis included the use of the GSLTPAQ (Godin and Shephard, 1985), which is described below and included in full in Appendix 3.

3.3.1.1 Godin-Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ) (Appendix 3)

This questionnaire was designed to measure leisure-time PA (LTPA), a sub-type of PA, defined as any 'activity undertaken in the individual's discretionary time that increases the total energy expenditure' (Amireault et al., 2015). Assessment of LTPA does not take into account occupational, household or commuting PA, and thus is often more likely to capture activity that an individual performs wilfully, and at a higher intensity (Troiano et al., 2012). The GSLTPAQ (Appendix 3) is a self-report questionnaire, entailing 4 items assessing LTPA. Items 1-3 are concerned with the quantity of strenuous, moderate and light intensity PA performed for more than 15 minutes each week. Item 4 is used to assess frequency of activity performed by the respondent that is "long enough to work up a sweat". Total score for this questionnaire (Leisure Score Index, LSI) is calculated using a formula, where quantity of PA bouts at each respective intensity (light, moderate, strenuous) is multiplied by 3, 5 and 9 respectively.

The GSLTPAQ (Appendix 3) has been shown to be a reliable and valid self-report measure of PA (Godin and Shephard, 1985). Test-retest reliability for this measure was examined in two separate studies over a two week and a 1 month period, with reported correlation coefficients of 0.81 (Sallis et al., 1993) and 0.62 (Jacobs et al., 1993) respectively. Validity for the use of the GSLTPAQ (Appendix 3) in the cancer survivor population was examined in a systematic review conducted by Amireault et al (Amireault et al., 2015), where results supported the use of the GSLTPAQ (Appendix 3) and the interpretation of the LSI for assessing relative change in PA among cancer survivors when compared to objective PA measures. Therefore, the GSLTPAQ was an appropriate measure of subjective PA in this thesis.

Objective measurement of PA

Objective measurement of PA can be performed using a variety of methods including measures of energy expenditure, physiological measures, pedometers and motion sensors. Methods to incorporate measurement of energy expenditure include indirect calorimetry and the doubly-

labelled water method. Heart rate monitoring is classified as a physiological method of measuring PA, however there are limitations to using it, particularly at low-intensity levels of activity, as heart rate can also be influenced by factors that cause sympathetic reactivity, such as caffeine consumption and temperature (Strath et al., 2013). For the purposes of this research, a detailed account of objective measurement using motion sensors is described below, focusing in particular on the Actigraph accelerometer.

Accelerometers have the ability to provide information about the amount, frequency, intensity, and the duration of PA (Westerterp, 2009b). Therefore, they provide users with considerably more information than pedometers, which are designed to measure numbers of steps only (Vanhees et al., 2005). As pedometers are capable of measuring activity in the vertical plane only, limitations exist with regard to the variety of activity that they can measure. Typically, only walking or running-related physical activities can be registered on a pedometer for this reason, thus missing activity such as cycling, upper body exercise or exercise on soft or graded terrain (Vanhees et al., 2005). In contrast to this, tri-axial accelerometers are capable of measuring activity in three planes (anteroposterior, mediolateral, and vertical planes) (Chen and Bassett, 2005). Additionally, acceleration is measured in real-time using an accelerometer, and this data can be translated to provide users with descriptions of PA volume, rate, and the time spent in different intensities of exercise (Sylvia et al., 2014). There are a variety of further advantages of using accelerometers, with ability to store large quantities of data, differentiate between intensity of PA and minute-by-minute monitoring among the strengths (Sylvia et al., 2014). These advantages are further supported by the minimal wearer burden of using an accelerometer (Broderick et al., 2014b). A study previously conducted in our research centre in 2014 reported the widespread emergence of accelerometers as a measure of objective PA in research in patients with cancer (Broderick et al., 2014b). Furthermore, a number of previous studies in our own research centre adopted the use of accelerometers to measure PA in oesophageal (Feeney et al., 2011), breast (Guinan et al., 2013) and mixed cancer populations

(Walsh et al., 2010). Thus, there was a wealth of experience in utilising this mode of objective PA measurement in this research centre.

For the reasons outlined above, it was decided that objective PA in this study would be measured using an accelerometer.

Limitations of accelerometer

A review conducted in 2005 examined and addressed a variety of issues relating to accelerometer-based assessments of PA (Trost et al., 2005). It was reported that, while there are numerous models of accelerometer available to use in research examining PA, there is no definitive evidence that shows whether one particular model of accelerometer is more valid, reliable or suitable to use than another (Trost et al., 2005). Additionally, as would transpire in Study 3 in this thesis, using an accelerometer to measure PA can introduce logistical and practical issues, with more time and effort required on the part of the participant to comply with the instructions for gathering adequate PA data. The same review mentioned above (Trost et al., 2005), also suggested that the choice of accelerometer to be used should be guided by practicality, technical support and comparability with other studies. Thus, the choice of accelerometer that was utilised in this research was influenced by the availability of the device and the wealth of knowledge, experience and support that existed in our research centre regarding its use in measuring PA. Below is a description of the accelerometer that was utilised in this research, specifically in Study 3, the ActiGraph wGT3X+ accelerometer.

3.3.1.2 Actigraph wGT3X+

The Actigraph wGT3X+ (Actigraph, LLC, Pensacola, Florida) (Figure 3.1) is a tri-axial accelerometer that was used to measure PA objectively in Study 3 of this thesis. The device itself is a small (4.6cm x 3.3cm x 1.5cm) device that can be worn on the waist, and weighs only 19 grams. The battery life for this device is approximately 25 days, and contains a memory of 2GB.

The sampling rate for this accelerometer is 30-100 Hertz. Data from the accelerometer can be processed using the appropriate companion software (Actilife 6 (Actigraph Corp, Pensacola, Florida, USA) to produce vector magnitude. Vector magnitude, which is the result of data measured from all three planes of movement being processed, is the measure by which the Actigraph indicates PA intensity.

The Actigraph accelerometer has been shown to be a valid and reliable measure of PA in healthy subjects. Inter-instrument reliability of the Actigraph wGT3X⁺ was investigated in a study conducted in 2015, where it was shown that there was no significant difference between two devices worn on contralateral hips (effect size ≤ 0.042 ; $p \geq .213$) (Aadland and Ylvisåker, 2015). Validity of the device was also demonstrated in healthy subjects when the Actigraph GT3X⁺ count/minute was significantly positively correlated with VO₂ ($r = 0.810$, $p < 0.001$) (Kelly et al., 2013), demonstrating that this device can accurately measure PA when compared to oxygen consumption. Measurement procedure for the Actigraph is detailed below.

Figure 3.1 Actigraph wGT3X⁺



The Actigraph device used for each participant was initialised using the Actilife software (Actilife 6 (Actigraph Corp, Pensacola, Florida, USA). Details for each participant were inputted, including age, study I.D., weight, height, gender, date of birth and side of placement. Start time for

recording was set, as well as a sampling frequency for recording data, which for this study was 30Hz. All participants who received the Actigraph from the lead investigator, either in-person or through the post, were instructed to wear the device for 7 days, attached to their waist via an elastic belt. Participants were instructed to ensure the micro-USB slot was always facing up, and that they should only wear the Actigraph during waking hours. The Actigraph was accompanied with an instruction leaflet (Appendix 4) detailing how to wear it, as well as those instructions detailed above. A daily log was also included to allow each participant to record when the device was put on and taken off each day. Following completion of the seven day of wear time, the participants were instructed to return the Actigraph in the stamped and addressed envelope provided to them with the Actigraph. Data analysis for the Actigraph is detailed below.

All data analysis for accelerometer data was performed on Actilife software (Version 6 13.3). Once the Actigraph was received back from the participants, wear-time validation of the data was conducted. This was performed using an algorithm developed by Choi et al (wear time > 10 hours per day and > 4 days including at least one weekend day) and an in-built wear-time algorithm in the device itself (Choi et al., 2011). Conflicts that presented following this validation were resolved using the activity log completed by the participants in conjunction with the Actigraph. The intensity of activity performed by participants during their wear-time was defined from previously validated cut-points (sedentary activity 0-99 counts per minute (CPM), light activity 100-759 CPM, moderate activity 1952 -5724 CPM, vigorous activity 5725-9498 CPM, and very vigorous activity ≥ 9499 CPM) (Freedson et al., 1998). Cut points to define moderate-vigorous PA bouts were also taken from the same publication (Freedson et al., 1998).

3.3.2 Exercise capacity

Exercise capacity is defined as maximal level of exertion an individual can sustain (Goldstein, 1990). Cardiorespiratory fitness and exercise capacity has been shown to decrease in patients with cancer, due mainly to deconditioning and the negative effects of cancer treatment on

cardiovascular, respiratory and musculoskeletal systems (Schmitz et al., 2010). The assessment of exercise capacity and performance can be achieved by performing a cardiopulmonary test (CPET) and measuring peak aerobic capacity (VO₂ peak). While adopting this method of assessing exercise capacity is regarded as the gold-standard for the measurement of exercise capacity (Ross, 2003), it is also considered time consuming, typically requires increased medical supervision and can be burdensome for patients with cancer (Schmidt et al., 2013).

Sub-maximal exercise testing provides an alternative to CPET, and can be used to predict VO₂max and assess functional performance (Noonan and Dean, 2000). Examples of sub-maximal functional performance tests include the six-minute walk test (6MWT), 12-minute walk test (12MWT) and the timed up and go test (TUG) (Noonan and Dean, 2000). Inherent advantages of sub-maximal testing include low cost, low time commitment and low equipment requirements (ACSM, 2010). The 6MWT was used in the final study of this thesis and is a measure of sub-maximal exercise performance, and involves measuring total distance covered by a participant on a flat surface in 6 minutes. Therefore, for the purposes of this research, the 6MWT was chosen as the sub-maximal functional performance test, due its characteristic as a low-burden and feasible method of exercise capacity assessment in this population. The use of the 6MWT would allow results of functional performance to be tracked throughout the entire intervention.

3.3.2.1 The Six minute walk test (6MWT)

The 6MWT was first developed in 1963 to measure functional capacity (Balke, 1963), originally targeted towards patients with pulmonary disease. The use of the 6MWT has increasingly become a popular outcome measure in oncology research (Schmidt et al., 2013), with a study conducted by Schmidt et al (Schmidt et al., 2013) demonstrating that the 6MWT is both reliable and valid for use in cancer patients when measuring functional exercise capacity. This study reported that, regarding reliability, the intra-class correlation coefficient was $r = 0.93$ (95 %CI: +

0.86; + 0.97; $p < 0.001$), demonstrating that the 6MWT is robust and reliable to change in raters (personnel conducting the 6MWT). Validity of the 6MWT was also investigated in this study, conducted by comparing various objective and subjective measures of exercise and functional capacity to distance achieved in the test (Schmidt et al., 2013). Significant correlations were observed between distance achieved on 6MWT and exercise capacity (VO_2 peak $r = 0.67$), maximum workload ($r = 0.70$) and perceived physical function ($r = 0.55$) (all $p < 0.001$). The minimal important difference (MID) for metres walked in the 6MWT for patients with lung cancer was investigated in a study by Grainger et al., where it was estimated to be between 22 metres and 42 metres, otherwise expressed as a 9.5% change (Granger et al., 2015). Prior use and practice using the 6MWT in our research centre, as well as the demonstrated reliability and validity detailed above led to the decision to use the 6MWT in this research.

Measurement procedure

Participants were screened for contraindications to performing the 6MWT, as recommended by American Thoracic Society (ATS) Guidelines (ATS, 2002). Absolute contraindications included unstable angina during the previous month and myocardial infarction during the previous month. Relative contraindications included resting heart rate of more than 120, a systolic blood pressure of more than 180 mm Hg, and a diastolic blood pressure of more than 100 mm Hg (ATS, 2002). Reasons to terminate the test, which the testers were familiar with, included the following: (1) chest pain, (2) intolerable dyspnea, (3) leg cramps, (4) staggering, (5) diaphoresis, and (6) pale or ashen appearance.

Prior to performing the 6MWT, resting heart rate, oxygen saturation, resting blood pressure and rating of perceived exertion (RPE) (BORG Scale) were measured. The BORG scale is a scale of perceived exertion which matches how hard you feel you are working to equivalent numbers. All procedures for the 6MWT were conducted with reference to ATS guidelines (ATS, 2002). Participants were instructed to wear walking shoes and comfortable clothing when attending

for their baseline assessment. The course for the 6MWT was created by placing cones along a long corridor, with a distance of 30 metres between the first and last cone, with cones placed at 3 metre intervals along the course. To monitor oxygen saturation and heart rate during the test, a portable non-invasive oximeter (Fingertip Pulse Oximeter, ChoiceMed, Beijing, China) was applied to the participant's finger. The lead investigator conducting the test required a number of pieces of equipment to correctly supervise the test, including a lap counter, timer, clipboard, Borg Scale and worksheet to input all data (Appendix 11). No warm-up was permitted for the test.

Once this preparation was complete, both the participant and the lead investigator moved to the starting cone of the test. Instructions for the test, as per the ATS guidelines (ATS, 2002), were read out by the lead investigator.

These instructions were as follows;

"The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You will probably get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but resume walking as soon as you are able. You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation."

Following these instructions the lead investigator then completed a lap of the course, ensuring that the participant understood how to turn briskly at the last cone of each lap. The lead investigator then instructed the participant further, as follows; *"Are you ready to do that? I am going to use this counter to keep track of the number of laps you complete. I will click it each time you turn around at this starting line. Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but don't run or jog. Start now, or whenever you are ready."*

The participant then commenced the test, with the tester ensuring that they were not walking with or pacing the participant. There were standardised instructions available to the tester to use throughout the test, which were spoken with an even tone. These are detailed below and corresponded to each minute completed by the participant in the test (Table 3.2). At each minute of the test, heart rate, oxygen saturation and Borg rating were recorded by the tester. Each lap was also recorded. If the participant required a break during the test, or stopped walking, the tester instructed the patient that *“You can lean against the wall if you would like; then continue walking whenever you feel able.”* The timer continued during any break. Following completion of the test the participant’s Borg rating, heart rate, oxygen saturation and the point at which they stopped walking was recorded immediately. The number of laps completed was also recorded, as well as total distance covered. The participant was then instructed to return to sitting, and the tester measured blood pressure, heart rate, oxygen saturation and rating of perceived exertion for the final 2 minutes.

Table 3.2 Standardized phrases for encouragement

Time	Standardised encouragement
1 minute	<i>“You are doing well. You have 5 minutes to go.”</i>
2 minutes	<i>“Keep up the good work. You have 4 minutes to go.”</i>
3 minutes	<i>“You are doing well. You are halfway done.”</i>
4 minutes	<i>“Keep up the good work. You have only 2 minutes left.”</i>
5 minutes	<i>“You are doing well. You have only 1 minute to go.”</i>
5 mins 45 secs	<i>“In a moment I’m going to tell you to stop. When I do, just stop right where you are and I will come to you.”</i>
6 minutes (End)	<i>“Stop”</i>

3.3.3 Body Composition and Anthropometry

Body composition is regarded as a health-related component of physical fitness (Caspersen et al., 1985) , and refers to the ratio between fat and fat free mass in the body (Lee and Gallagher,

2008). The importance of assessing body composition in patients with cancer has been highlighted in the emergent evidence demonstrating that body composition, being the distribution of fat and fat-free mass, is a risk factor for post-operative complications, overall survival in patients with cancer and chemotherapy-related toxicity (Brown et al., 2018). Anthropometry in this thesis refers to measures of BMI, height and waist circumference, detailed below.

Measurement of body composition

Laboratory techniques to measure body composition, such as computed tomography (CT), magnetic resonance imaging (MRI) and dual energy X-ray absorptiometry (DXA), have been established as the gold-standard techniques to quantify body composition (Mourtzakis et al., 2008). Such techniques are typically expensive to conduct and their use is limited to laboratory settings. Therefore, clinical measures of body composition offer more cost effective and time efficient methods of measuring this outcome (Kyle et al., 2004). One such measure utilised in a clinical setting is bioelectrical impedance analysis (BIA). This method achieves a measure of body composition by calculating the impedance to a small electrical current travelling through the body's water content (Lee and Gallagher, 2008). The use of BIA has a number of advantages including its ease of use, low cost, minimal patient burden and safety (Lee and Gallagher, 2008). The validity of BIA, using a segmental BIA analyser, was examined in a study by Verney et al. (2015), by comparing BIA and DXA results in assessing body composition in young adults. They reported that measurements of fat mass percentage (FM%) and fat-free mass (FFM) by both DXA and BIA were highly correlated. This was shown by a significant correlation between the percentage of fat mass measured by DXA and the one measured by BIA ($p < 0.001$; $r = 0.852$; ICC [IC95%]: 0.84 [0.75 – 0.90]; concordance coefficient: 0.844) and also by a significant correlation between fat-free mass measured by DXA and by BIA ($p < 0.001$; $r = 0.976$; ICC [IC95%]: 0.95 [0.93 – 0.97], concordance coefficient: 0.955) (Verney et al., 2015). Further validity testing was

performed in a study by Mourtzakis et al. (2008), where BIA measurement was compared to DXA measurement in a group of patients with cancer (Mourtzakis et al., 2008). Results from this study showed that BIA overestimated or underestimated FFM substantially when compared with DXA, with values of discrepancy ranging from -9.3 to $+7.3$ kg. Therefore, the accuracy of BIA can be disputed, and may lack the accuracy that DXA, CT and MRI offer. Despite this, BIA offers a safe and practical method of measuring body composition in a clinical setting, and thus, was the method that was performed in Study 3 of this thesis to measure body composition.

3.3.3.1 Bioelectrical impedance analysis (BIA)

Body composition in this thesis was analysed using the SECA mBCA 515 (Seca, Hamburg, Germany) body composition analyser (Figure 3.2). It is a segmental, multi-frequency bioelectrical impedance analyser, and has an integrated scale, using four pairs of electrodes at each hand and foot to allow the current to pass through the body (Ræder et al., 2018). Estimates for body composition were calculated using in-built BIA analyser software that uses impedance values measured for each segment by the SECA.

Figure 3.2 SECA mBCA 515



Procedure to measure body composition using the SECA mBCA 515 was as follows. Participants were asked to remove their shoes and socks and any jewellery they were wearing. They were then asked to step onto the SECA machine, ensuring good contact between the electrodes on the foot plate and their feet. Weight was calculated first using the inbuilt scale, and this was inputted by the tester, as well as standing height.

Participants were then screened for contraindications, as detailed by the manufacturers guidelines, and once this was complete the tester initiated the analysis. Participants were asked to place their left and right hand on the respective electrodes and to stand still while the analysis was taking place. Contact with both the electrodes at the feet and the electrodes for the hands

was required throughout the analysis. The analysis lasted approximately 20 seconds, at which stage the participants were allowed to release the electrodes and step off the machine. The tester then inputted gender, date of birth, sex and ethnicity before receiving the data output of the analysis.

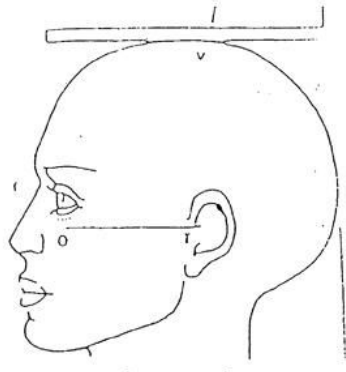
3.3.3.2 Waist circumference

Waist circumference was measured using the protocol recommended by the World Health Organisation (WHO, 2011). A stretch-resistant tape was used to achieve this measurement, placed at the approximate midpoint between the lower side of the last palpable rib and the top of the iliac crest. The tape was held parallel to the floor, and snugly against one item of light clothing, making sure that the participant was at the end of normal expiration when the circumference was measured. Participants were standing for this measure, and two measurements were taken to achieve an average. High reliability was reported for this measure, with an intra-observer ICC for waist circumference of 0.987 (95% confidence interval: 0.983-0.990), and an inter-observer ICC of 0.988 (95% confidence interval: 0.982-0.993) (Chen et al., 2001).

3.3.3.3 Standing height and Body mass index (BMI)

Standing height was measured, without shoes, using a stadiometer. Participants were instructed to stand with their feet together, back against the stadiometer. The participants head was placed in the Frankfort horizontal plane (Figure 3.3). The headboard was lowered and measurement was taken at the nearest millimetre (mm). BMI was calculated by dividing weight in kilograms by height in metres squared (kg/m^2).

Figure 3.3 Frankfort horizontal plane



ORBITALE: Lower margin of eye socket
TRAGION: Notch above tragus of ear or at upper margin of zygomatic bone at that point
FRANKFORT PLANE: Orbitale-tragion horizontal line

3.3.4 Quality of Life (QOL) and self-report physical functioning

Introduction to the measurement of QOL

Health-related quality of life (HRQOL) in patients with cancer refers to the subjective perceptions of the positive and negative aspects of the patients' symptoms, which includes their physical, emotional, social, and cognitive functions (Bottomley, 2002). Cancer treatment can have a profound effect on an individual's QOL, often manifesting as physical and psychosocial dysfunction (Hsu et al., 2017). With growing numbers of survivors from cancer, the long-term well-being, both physical and functional, are integral aspects contributing to overall QOL (Cella and Tulsky, 1990). Therefore, the assessment of HRQOL has an important role in any trial investigating efficacy of a PA intervention on patient-related outcomes. There are a number of methods of assessing QOL and well-being, and can vary between general QOL measures, and cancer-specific measures. For the purposes of this research, the questionnaires that were utilised were the FACT-G and the physical functioning component of the SF-36. The FACT-G is a cancer specific questionnaire, while the physical functioning component of the SF-36 provides

valuable information specifically on the physical component of HRQOL, complementing the information gained from the FACT-G. Both questionnaires were chosen for their low-burden nature, as well as their high reliability scores detailed below. Additionally, there was prior experience and practice using both questionnaires within the research centre that this research was conducted.

3.3.4.1 The FACT-G

The FACT-G (Version 4) (Functional Assessment of Cancer Therapy – General) is a cancer-specific questionnaire with 27 items in total, divided into 4 QOL domains (Appendix 5). These domains are physical well-being, social/family well-being, emotional wellbeing, and functional well-being. The FACT-G was first developed in 1993, and was subsequently validated in a mixed cancer population (Cella et al., 1993). There are a number of site-specific additions to the original core FACT-G questionnaire, with specific questionnaires developed for patients with breast, colon and lung cancer. Due to the sample of mixed cancer diagnoses in Study 3, the core FACT-G was chosen as the most suitable measure of QOL.

The FACT-G takes approximately 5 minutes to complete and has been written at the 6th grade level. The FACT-G is a core questionnaire from the Functional Assessment of Chronic Illness Therapy system, and licensing and the all materials required to administer the questionnaire was accessed from www.facit.org.

The four domains of the questionnaire are further divided into items to be rated. Each item on the FACT-G invites respondents to rate a specific statement on a 5-point scale, from "not at all" to "very much". The domains of physical well-being, social/family well-being and functional well-being are divided into 7 items, with a total score of 28 for each domain. The domain of emotional well-being is divided into 6 items, with a total possible score of 24. Total score for the complete FACT-G was 108.

Reliability of the FACT-G was examined in a review conducted in 2008, where it was reported that average FACT-G score reliability was 0.88, with the range of reliability for the subscales between 0.71-0.83 (Victorson et al., 2008). Interpretation of the total FACT-G score was examined alongside normative data for a sample of the general U.S. adult population and a heterogeneous sample of adult patients with cancer (Brucker et al., 2005). An interpretation of minimally important difference was detailed in this study, where it was reported that a two-point difference on the FACT-G subscale scores and a five-point difference on the FACT-G total score were representative of meaningful differences on clinical and subjective indicators.

3.3.4.3 SF-36 V2 (Physical functioning component)

In comparison to the FACT-G questionnaire, which focuses on patients with cancer, the SF-36 is a generic measure of HRQOL. There are a total of 36 items included in the SF-36. These items are categorised according to a specific facet of health, with the scales representing physical functioning (PF), role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. Support for the validity and reliability of the SF-36 has been established in cancer survivors (Reulen et al., 2006). Only the PF scale, which was reported to be the best measure of physical health in the overall scale (Ware, 2000), was utilised in Study 3 in this research. It was decided to use the PF scale alongside the FACT-G as the SF-36 would provide a more task specific measure of physical functioning than the physical well-being aspect of the FACT-G. Completing this scale requires approximately 2 minutes. This was considered an important reason for including this particular scale in this thesis as it ensured that the burden of completing QOL questionnaires would remain low. The PF scale contains 10 items, ranging from an assessment of vigorous activity function, climbing stairs, bending, kneeling and ability to walk a variety of distances. Scoring for the PF component of the SF-36 used a scoring algorithm to give scores on a 0-100 scale (Appendix 6), with higher scores for the scale indicating a higher level of functioning.

3.4 eHealth

The ultimate goal of this research was to determine the feasibility of an eHealth intervention to promote PA in cancer survivors. An eHealth intervention can be delivered through a wide variety of modalities, including the internet, computers, tablets, email, personal digital assistants (PDAs), and smartphones (Hutchesson et al., 2015). Thus, the scope and breadth of potential eHealth modalities is vast. At the commencement of this program of research, it was unclear what method of eHealth would be incorporated in the proposed feasibility study in Study 3. Initially, the use of a smartphone application which was designed to promote PA was considered for inclusion in Study 3. This was reflected in the approach of Study 1 and Study 2, which reference 'mobile technology' throughout. Mobile technology can be categorised under the umbrella of eHealth, however it generally refers to the use of smartphones and mobile phones. However, following the results from the first two studies conducted in this thesis, and an appraisal of the evidence emerging for eHealth intervention modalities, it was decided that wearable technology in the form of Fitbit would be a better fit for this research, and would offer increased opportunity to influence PA behaviours in an effective way. Study 2 in particular identified a number of key features that cancer survivors recommended for inclusion in an eHealth PA intervention (Chapter 6, Table 6.4). It was found that these recommended features aligned better with the capabilities of wearable activity trackers, and thus it was decided that wearable technology would form the basis of the eHealth component in this research.

Furthermore, a study which investigated the quality of commercially available PA apps for cancer survivors (excluding apps that required accompanying wearable technology), concluded that the mean number of behavioural change techniques integrated in these apps was only 3.96 (SD=2.09) (Martin Payo et al., 2019). In contrast to this, further evidence supporting the use of the wearable technology in this thesis was reported in an analysis conducted in 2016 (Mercer et al., 2016), where the Fitbit Flex, and its accompanying application, was found to contain a

total of 15 behavioural change techniques. This finding aligns with the emphasis this research placed on the importance of a robust grounding in behavioural change science to promote PA in cancer survivors, and supports the decision to integrate wearable technology as the chosen modality of eHealth in this thesis.

The eHealth intervention that was designed in this research (Study 3) included the use of commercially available wearable technology, as well as an accompanying application to be used on a smartphone. There is currently an abundance of wearable activity trackers available to the public, and thus choosing a model of wearable PA tracker to use in this intervention was an important consideration in the design of this research. Activity trackers such as the Jawbone tracker and the Fitbit tracker were considered for inclusion in this research. Ultimately however, the Fitbit was chosen, specifically the 'Fitbit One' and the 'Fitbit Flex 2' models. Cost, availability, specifications and inclusion of behavioural change techniques were considered in making this choice. The ubiquity of the Fitbit in Irish markets was also a reason for deciding to include the Fitbit, as it was felt that the potential familiarity of the device with participants would enhance the acceptability of the intervention. It should be noted that at the time of designing the feasibility study and its intervention, there was limited evidence to support any particular brand of wearable technology to use in PA interventions for cancer survivors, evidenced by the presence of only study in the systematic review utilising a Fitbit. Thus, the reasons above informed the decision to use Fitbit, with subsequent research and evidence strengthening the decision to use the Fitbit, particularly in relation to its inherent use of behaviour change techniques (Section 6.4.1).

Specifications for both models of Fitbit are detailed below in Table 3.3. The models of Fitbit are also shown in Figure 3.4 (Fitbit One) and Figure 3.5 (Fitbit Flex 2) below, as well as a screenshot of the Fitbit smartphone application home screen (Figure 3.6). The reason for the variance in the model of Fitbit used is described elsewhere (Chapter 6, Section 6.3.4). There is a 3-

dimensional accelerometer contained within the Fitbit which measures PA. Validity of the Fitbit for measuring PA and steps in community dwelling adults has been previously investigated, where the Fitbit One or Fitbit Zip were compared to an Actigraph accelerometer (Paul et al., 2015). Results showed that the Fitbit had excellent agreement in average steps/day over 7 days (ICC=0.94, 95% CI 0.88 to 0.97). Psychometric properties of the Fitbit was also investigated in another study, which found consistently high inter-device reliability for steps (Pearson and ICC 0.76–1.00), distance (ICC 0.90–0.99), and energy expenditure (Pearson and ICC 0.71–0.97) (Evenson et al., 2015).

Table 3.3 Specifications and features of Fitbit used in Study 3

Fitbit One	Fitbit Flex 2
<i>Clip-on device, OLED display</i>	<i>Wristband device-LED display</i>
<i>3-axis accelerometer</i>	<i>3-axis accelerometer</i>
<i>Altimeter</i>	<i>No altimeter</i>
<i>Tracks 7 days of detailed motion data – minute by minute.</i>	<i>Tracks 7 days of detailed motion data – minute by minute.</i>
<i>Wireless syncing with smartphone, or USB cable syncing with computer.</i>	<i>Wireless syncing with smartphone, or USB cable syncing with computer.</i>
<i>Stated battery life-2 weeks</i>	<i>Stated battery life-5 days</i>

<i>No auto exercise recognition. Relies on manual input</i>	<i>Auto exercise recognition</i>
<i>Cost (at time of purchase): 90 euro</i>	<i>Cost (at time of purchase): 100 euro</i>
<i>Weight: 8 grams</i>	<i>Weight: 15 grams</i>

Figure 3.4 Fitbit One



Figure 3.5 Fitbit Flex 2



Figure 3.6 Screenshot of Fitbit smartphone application home screen



3.5 Chapter 3 summary

This chapter has provided a detailed description of background quantitative methodology used in this thesis. This has included descriptions of study designs adopted, principles of reliability, validity, data analysis and an outline and rationale for the variety of outcome measures used in this thesis. Outcomes measures for PA (GSLTPAQ and Actigraph accelerometer), functional capacity (6MWT), QOL (FACT-G and PF component of SF-36), and body composition (BIA and WC) were included. Detailed description of the eHealth modality used in this thesis was also included, with the rationale for the inclusion of the Fitbit wearable tracker provided.

Chapter 4 Qualitative methodology

4.1 Introduction to qualitative methodology

Qualitative research methodology is an important and integral part of this thesis, with Study 2 employing focus groups to further the understanding of cancer survivor perceptions and experiences of the use of technology in promoting PA and exercise. This section will describe qualitative methodology in terms of the study design, sampling methodology, focus group procedures and data analysis used in Study 2 of this thesis.

Qualitative research in healthcare differs from quantitative research in the flexibility it offers both investigators and patients in exploring typically unquantifiable data, such as perspectives, thoughts and experiences about a given subject. Ultimately, qualitative research addresses questions that quantitative research cannot (Huston and Rowan, 1998). There are a wide variety of qualitative methodologies, including phenomenology, grounded theory, ethnography and narrative methodologies. Qualitative description has been suggested as a useful methodological approach to easily implement in healthcare (Neergaard et al., 2009). The aim of qualitative description is to provide a rich, straight description of an experience or an event (Neergaard et al., 2009). This differs from the aims of the other methodologies, such as a grounded theory approach which focuses on the development of a theory, or phenomenology, which focuses on the interpretation and understanding of a phenomenon. Study 2 was developed to explore and describe perceptions and barriers of cancer survivors to the potential use of technology in PA promotion, with the goal of using the data gathered to direct the eHealth intervention in Study 3. Thus, a qualitative descriptive approach, which would highlight and describe barriers, facilitators and potential features of an eHealth intervention, was chosen as the right fit for this research.

4.2 Data collection strategies

There are a variety of different data collection strategies incorporated in qualitative research, which includes focus group discussions, semi-structured interviews, in-depth interviews and analysis of texts and documents (Kirkman et al., 2016). These strategies, and indeed qualitative research in general, typically serve to provide insight into participant experiences and perspectives. Importantly, this insight is generally from the participant's point of view.

For the purposes of this thesis, a description of focus group design will be detailed below, reflecting the use of focus groups in Study 2 of this thesis. A focus group was chosen for Study 2 as it aligned with the purposes of the research, which was to explore the perceptions and beliefs of cancer survivors. The general aim of focus groups is to understand and try to explain meanings and beliefs that can influence the attitudes and behaviours of individuals (Rabiee, 2004). A focus group consists of an interviewer asking participants questions about a topic in the context of a group discussion. The novel aspect of discussion between group participants is characteristic of this form of qualitative research. This discourse between participants in the focus group is an important aspect of this study design, as it enables a greater variety of discussion topics and communication, ultimately leading to a greater sense of understanding about a given topic (Kitzinger, 1994).

4.3 Sampling

The method of sampling used in Study 2 in this thesis was convenience sampling. Convenience sampling is commonly used in qualitative research, and refers to the recruitment of participants that are readily available for study (Merriam, 2009). Convenience sampling is a type of non-random sampling where participants that meet various practical criteria, such as proximity to research centre, availability, or willingness to participate are included (Etikan Ilker et al., 2016).

Other methods of non-random sampling in qualitative research include purposive sampling and criterion sampling. Purposive sampling is also commonly used in qualitative research and allows for recruitment of participants who are deemed information-rich cases (Palinkas et al., 2015). Criterion sampling is designed to identify and recruit participants that meet specific predetermined criteria, which is central to the objectives of the research (Palinkas et al., 2015).

While the sampling methodology used in Study 2 could generally be regarded as convenience sampling, application of specific eligibility criteria for study participants may also fit in with the definition of criterion sampling. The particular specific predetermined criteria for inclusion in this focus group study was that participants had to be cancer survivors who had received chemotherapy or radiation therapy for malignancy and had finished a course of treatment or were anticipated to finish their treatment within 3 months. Therefore, included participants shared a number of characteristics and experiences. This study did not, however, utilise the strict definition of purposive sampling methodology, as no specific and deliberate selection of participants was conducted on the basis of their potential to be information rich cases (Carpenter and Suto, 2008). Criterion sampling allows a lesser amount of variation among participant perceptions, while also placing emphasis on the similarities between participants (Palinkas et al., 2015).

4.4 Sample size

In qualitative research, recruitment typically continues until data saturation has been achieved. The achievement of data saturation was described in a study by Fusch and Ness (2015) when it was indicated that saturation has been reached when there is enough information to replicate the study and when further coding is no longer feasible (Fusch and Ness, 2015). Data saturation was achieved in Study 2 in this thesis after the 7th focus group, thus recruitment ceased at this point.

4.5 Focus group procedure

The focus groups in Study 2 took place in a private room in the outpatient department of the physiotherapy department in St. James' Hospital or the exercise laboratory in the Trinity Centre for Health Sciences on the St. James' Hospital campus, depending on room availability. Participants, recruited and invited to participate as outlined above, were supplied with a date and time to meet for the focus group. The room utilised had a door for privacy and sufficient chairs and tables. As a token of appreciation to the participants, light refreshments were served at the beginning of the focus group. These refreshments also served as an ice-breaker for the group. The lead moderator (CH) carried out all the focus groups. The interview guide used in these focus group was also developed by the lead moderator (CH), and was flexible in nature. Probing questions included in the interview guide were designed to trigger further discussion between participants, but the moderator had to ensure that these probing questions were not directing the discussion (Krueger and Casey, 2000). A copy of this interview guide is included in Appendix 7. All interviews were recorded using a Philips Voice Tracer Digital Recorder DVT2000 (China). Prior to commencing the recording, participants were made aware that they were being recorded. The moderator facilitated the discussion by asking the questions. The assistant moderator took field notes and also made sure the dictaphone was running correctly throughout the focus group

4.6 Data analysis

The data analysis method used to analyse the focus groups in Study 2 was called thematic analysis. Thematic analysis is a 'method for identifying, analysing, and reporting patterns (themes) within data'(Braun and Clarke, 2006). The procedure and structure of this analysis is detailed below. Data analysis described in this thesis was conducted according to the guidelines developed by Braun and Clarke (2006).

The first step in analysing the data that was produced by the focus groups was familiarisation of the data itself, whereby the lead investigator (CH) listened back to each focus group recording and read through the field notes attached to each focus group. As the focus groups were in audio form, the lead investigator (CH) transcribed all the focus groups into word documents using Microsoft Word and Windows Media Player (Version 12). Transcription of the data is regarded as an important step in thematic data analysis, not only for organising and preparing the data for coding, but also as a further method of familiarisation for the lead investigator (Braun and Clarke, 2006). The focus group audio was transcribed verbatim, and included silences, laughter and interruptions that were present in the audio. Once the focus groups had been transcribed, the text was checked for accuracy by listening to the audio once more. In addition to this, a second researcher also checked the transcripts for accuracy.

Once the transcription of all the focus groups had been completed the next step in the process of data analysis was the generation of the initial codes from the transcripts. This process involves the organisation of the data into categories (Dey, 1993). To aid in the generation of codes and data analysis in general, a qualitative software program called Nvivo 12 for Windows (QSR International Pty Ltd, Victoria, Australia) was utilised. Coding is the identification of a part of the data (a code) that is of interest to the researcher (Braun and Clarke, 2006). Coding the data is merely the first step of the analysis procedure, and the outcome of this stage of analysis was the organisation and collection of categories highlighted from the text. Two independent researchers (CH and JM) systematically coded the transcribed data from the focus groups, and produced a collection of codes that they deemed to have meaning in the context of the stated objectives of these focus groups. This coding stage precedes the interpretive aspect of thematic analysis, which will be described below.

The generation and identification of themes was the next step of thematic analysis of the focus group data. Using the list of codes developed in the coding process, the process of organising

these codes into potential themes was undertaken. This step involves establishing relationships between codes, themes and subthemes (Braun and Clarke, 2006). The result of this step in the analysis process is a collection of potential themes, subthemes and the assignment of all important codes to these themes.

The next step in thematic analysis was the refinement of these initial themes and subthemes. Where subthemes could be combined to provide greater meaning to a section of data, this was done so. The goal of this stage of thematic analysis was to ensure that the themes that were generated gave meaning to the whole data set, and any additional themes or subthemes that emerged as the analysis continued, were accounted for and included in the final iteration of the analysis. This was again a collaborative effort undertaken by the two independent researchers involved in the coding stage of this analysis (CH and JM). Phase 5 and Phase 6 of the process of thematic analysis according to the guidelines published by Braun and Clarke (2006) involve the naming of the final themes decided upon, and the production of the final analysis. A detailed analysis of each individual theme and subtheme accompanies the title of each theme, an analysis which should attempt to encapsulate the story of the theme within the data, and one which provides context into how each individual theme fits into the aims of the research. This detailed analysis is described in Chapter 4, where results of the focus group study is provided. A summary of the stages required for thematic analysis is detailed below in Table 4.1, and is adapted from the guidelines referred to throughout this qualitative methodology (Braun and Clarke, 2006).

Table 4.1 Phases of Thematic analysis (Braun and Clarke, 2006)

Phase	Description of the process
1. Familiarising yourself with your data:	<ul style="list-style-type: none"> • Transcribing data (if necessary), reading and rereading the data, noting down initial ideas.
2. Generating initial codes:	<ul style="list-style-type: none"> • Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	<ul style="list-style-type: none"> • Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	<ul style="list-style-type: none"> • Checking in the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes:	<ul style="list-style-type: none"> • Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells; generating clear definitions and names for each theme.
6. Producing the report:	<ul style="list-style-type: none"> • The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

4.7 Reliability and validity

Validity of qualitative research, such as focus group interviews, is commonly conducted by using 'member checking', also referred to as respondent validation (Mays and Pope, 2000). Respondent validation is the process of reducing errors that may exist between the investigators account and the participants (Mays and Pope, 2000). With regard to focus group studies, this can involve sending transcripts of relevant focus groups to the participants that were involved in them, and allowing them to check the content, and ensure that their input was accurately portrayed and transcribed. In Study 2 of this thesis member checking was not utilised, however a synopsis of the main points was given at the conclusion of each focus group whereby participants were questioned whether it was an accurate portrayal of what had been discussed. This type of 'member check' allows for participants to establish and amend any errors in topics discussed (Neuman, 2006).

Reliability in qualitative research can be referred to as replicability of results gained from analysis and of processes utilised (Leung, 2015). In order to improve reliability of qualitative research and analysis, it is recommended that triangulation be performed (Patton, 1999). There are a variety of methods of triangulation which can be adopted in qualitative research. These include method triangulation, investigator triangulation, theory triangulation and data source triangulation. Method triangulation involves the use of multiple methods of data collection about the same phenomenon (Polit and Beck, 2012). Theory triangulation uses different theories to analyze and interpret data, usually using more than one hypotheses when investigating a phenomenon (Carter et al., 2014). Data source triangulation involves the collection of data from a variety of individuals, groups and stakeholders in order to gain varied perspectives on a particular topic.

Investigator triangulation was utilised in Study 2 of this thesis. Investigator triangulation involves the use of multiple analysts, as opposed to one investigator analysing the entirety of the data.

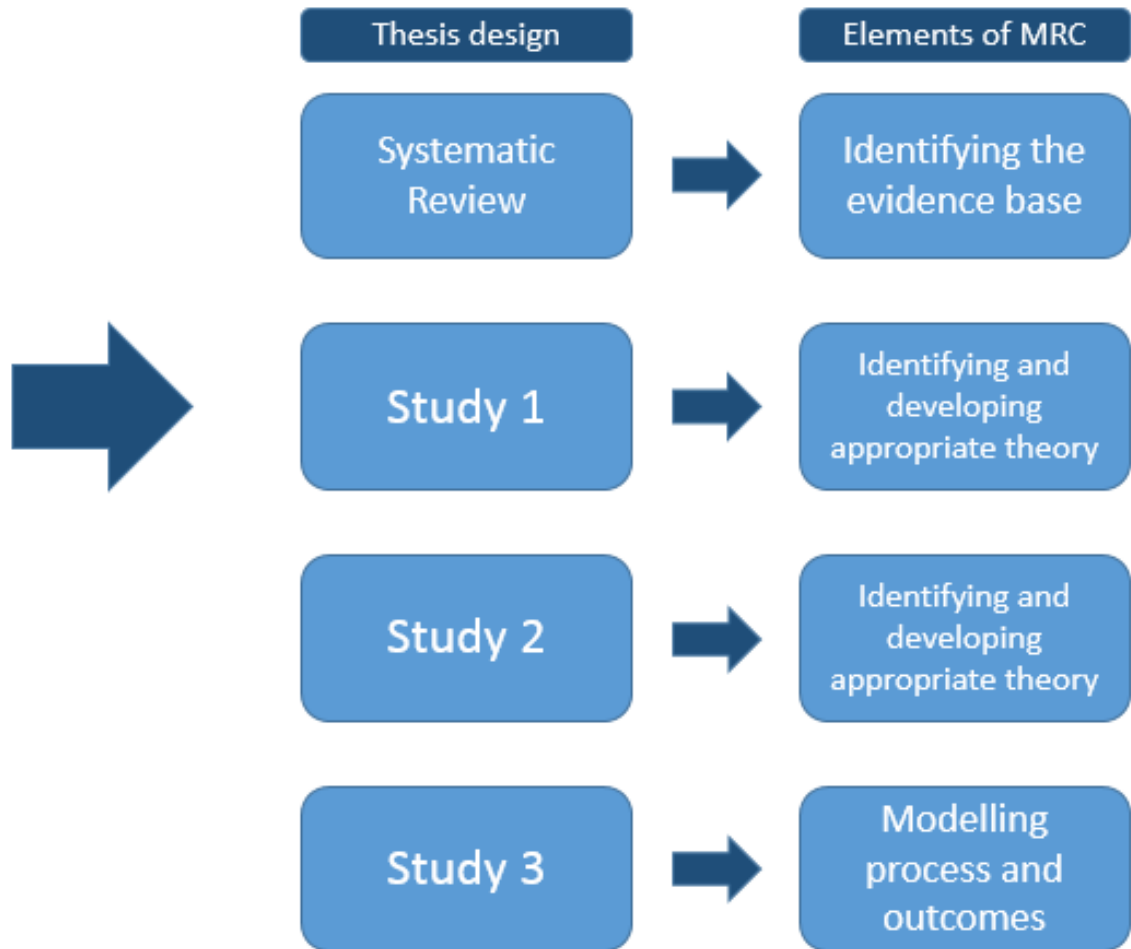
This approach minimises the potential of bias with data analysis. In Study 2 of this thesis, transcripts were coded independently by two investigators. Following independent data analysis, both investigators met and compared data analysis, ultimately producing coherent and agreed themes and subthemes, comprised of aspects of both sets of data analysis combined. Further triangulation that could have been adopted in this study, on retrospective analysis, was data source triangulation. In the context of the focus group study that was conducted, additional focus groups could have been conducted to include cancer survivor's families, or physiotherapists that worked in the area. Within the scope of this research however, investigator triangulation was viewed as the most important form of triangulation to include.

4.8 Summary of Chapter 4

This chapter has described and detailed the methodology behind Study 2 in this thesis, a focus group study exploring cancer survivor perceptions to using technology for PA promotion. This has included a description of study design, sampling methodology, focus group procedure, data analysis and reliability and validity.

Chapter 5 Study 1-Questionnaire

Figure 5.1 Progression of thesis related to MRC guidelines for developing a complex intervention



5.1 Introduction

The completion of the systematic review described in Chapter 1 provided initial guidance to inform the design of an evidence-based PA intervention using eHealth. Further to the information gained by the completion of the review, it was decided that additional preparatory research was required before addressing the design of Study 3, a feasibility study examining the

effectiveness of an eHealth PA intervention. The rationale behind organising and conducting both Study 1 and Study 2, a questionnaire and focus group-based study respectively, was primarily to align with the Medical Research Council (MRC) recommendations on designing and conducting a complex intervention (Craig et al., 2008). It recommends that before any intervention study be conducted, it should be developed to the point where it could be reasonably expected to have a worthwhile effect (Craig et al., 2008).

This questionnaire based study was designed to fit in with this approach (visually represented in Figure 5.1), and would allow us to supplement knowledge gleaned from the systematic review previously conducted (Haberlin et al., 2018), as well as further the understanding of the role of technology and PA in the lives of cancer survivors, in anticipation of developing an intervention incorporating eHealth methods.

5.2 Aim of study and objectives

The overall aim of this PhD was to establish the feasibility of using eHealth for physical activity promotion in patients with cancer. It was decided that the first step in examining this, after an appraisal of the literature, was to conduct a questionnaire with cancer survivors. Therefore, an initial scoping questionnaire-based study was designed to fulfil the following objectives;

1. To ascertain awareness and knowledge of physical activity (PA) guidelines.
2. To establish adherence to PA guidelines and to establish levels of daily sedentary behaviour.
3. To quantify smart phone penetration, mobile phone application use and use of PA/exercise applications.
4. To establish the number of patients who would be prepared to take part in a focus group discussion about PA and the possible use of technology to promote it (Study 2, Chapter 5).

5. To establish the proportion of patients who might be interested in taking part in a future intervention study to explore the effect of mobile technology to increase physical activity/decrease sedentary behaviour (Study 3, Chapter 5).

5.3 Methods

5.3.1 Study Design

A cross-sectional questionnaire design was used for this study. The conduct and reporting of this study was guided by elements of STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (von Elm et al., 2007).

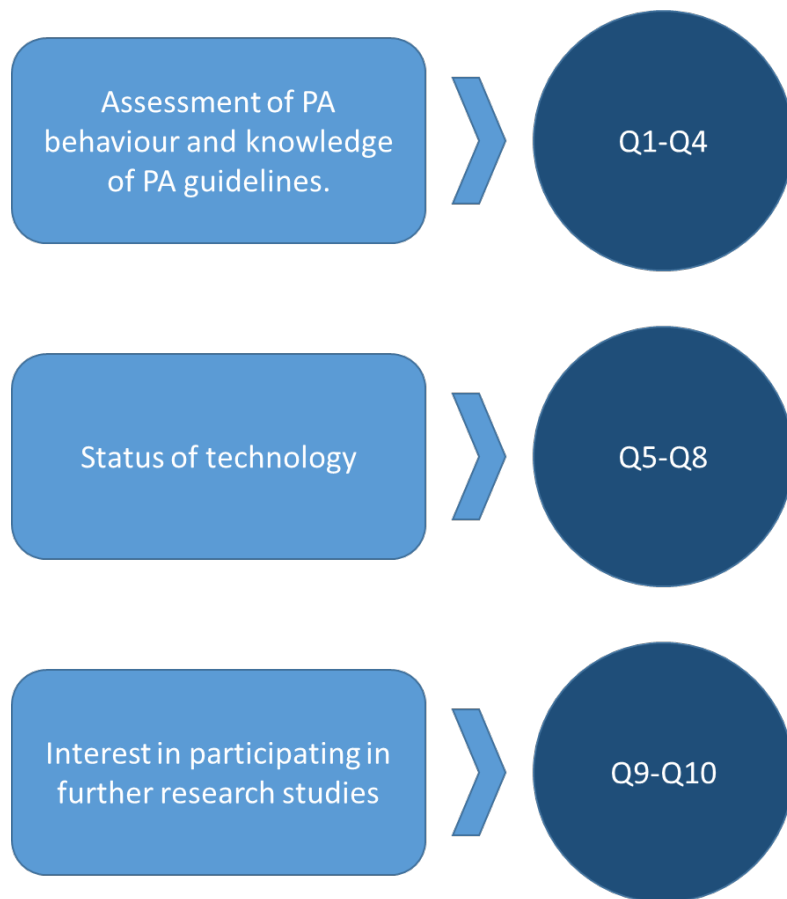
5.3.2 Questionnaire development

The development of this questionnaire was informed by the need to gain more information about the role of technology in the cancer survivor population, while also beginning to indicate the potential composition of an intervention promoting PA in cancer survivors. The results of this questionnaire were intended to advance the understanding of technology use in cancer survivors, but also ensure that the questions posed in the focus groups of the second study of this thesis, would be appropriate, focused and specific to the sample population and the aims of this thesis.

Specifically, the questions included in the questionnaire could be separated into three distinct areas of investigation. Those areas of investigation were physical activity (PA), technology and willingness to participate in further studies. This structure is illustrated in Figure 5.2 below. Below, the method by which these questions were developed has been detailed, including what the intended outcomes of each question was. No prior questionnaire existed that explored the use of technology in PA interventions for cancer survivors, therefore the questionnaire that was developed was based on an existing PA assessment questionnaire (Godin and Shephard, 1985)

and the specific objectives of this study, particularly with regard to technology. The questionnaire was designed to take approximately 5 minutes to conduct. The full questionnaire is detailed in Appendix 8.

Figure 5.2 Structure of questionnaire



Question 1 to 4 were based generally around PA behaviours of the participant. The first and second questions were designed to assess participant knowledge of the PA guidelines prescribed by the American Cancer Society (ACS) (Rock et al., 2012). In these questions, the participant was asked to write down how many days of PA were recommended per week, as well as how many minutes of PA were recommended. Answers to these questions were compared to the ACS guidelines published for PA in cancer survivors (Rock et al., 2012). The purpose of these first two questions was to establish the awareness and knowledge of PA

guidelines, which would indicate how well informed cancer survivors were of their recommended activity levels.

Question 3 and 4 assessed the participant's current habitual PA levels. These questions were framed in the context of achieving the guidelines mentioned above, and were developed and adapted from the GSLTPAQ (Godin and Shephard, 1985) (Appendix 3). Sedentary behaviour was also assessed in these questions, with participants posed the question 'During waking hours, how many hours per day do you spend sitting or lying? The current self-report PA and sedentary behaviour status of participants was established within these questions.

Questions 5 to 8 were generally centred on the status of technology in our participant's lives, particularly their use of smartphones. Using technology can present as problematic for some, particularly those of the population who may not have grown up using smartphones. Advancing the knowledge of the degree of familiarity cancer survivors have with smartphone technology would allow an insight into barriers and areas where participants may need more support.

Question 5 simply asked if the participant owned or had access to or owned a smartphone. This question was developed with consideration given to the fact that in order to test the feasibility of a PA intervention using smartphone technology, participants would be required to use a smartphone. The remaining questions (Q6-Q8), enquired about the use of smartphone applications among the participants, in particular if they used any PA applications currently. This was again to ascertain the familiarity of the sample population with using smartphone technology, but also highlighting whether they were using PA and exercise applications. Question 9 and question 10 provided an insight into the level of interest of the sample population of cancer survivors to participate in further studies within this program of research.

5.3.3 Ethical Approval

Ethical approval for this study was granted by St. James's Hospital/Tallaght University Hospital Research Ethics Committee (Reference: 2015-05 Chairman's Action 15). Informed consent, in writing, was required from all participants to be included in this study.

5.3.4 Sampling and recruitment

There is no accurate sample size calculation for a cross sectional questionnaire based study but it was envisaged that at least 100 participants would be an adequate sample size to explore the objectives outlined above. Therefore the aim for this study was to recruit between 100-120 participants. The recruitment process for this study is outlined below, including the inclusion and exclusion criteria for the study.

Inclusion criteria;

- a. Adult population: (≥ 18 years)*
- b. Current outpatients (at the time of the study) in the St. James Oncology Service.*
- c. Capable of understanding an English language questionnaire.*
- d. Absence of cognitive disabilities that would hinder following instructions.*
- e. Patients who had received chemotherapy or radiation therapy for malignancy and had finished a course of treatment or were anticipated to finish their treatment within 3 months.*

Exclusion criteria;

- a. Participants <18 years of age.*
- b. Unable to understand English language questionnaire*
- c. Cognitive impairments which would hinder participation.*
- d. Patients whom the physician or specialist nurse felt should not be approached for the study.*
- e. Patients waiting to start their cancer treatment*

Recruitment for this study was based in St. James's Hospital, Dublin. Cancer clinics were targeted starting from August 2015. Due to the heterogeneous nature of cancer and its treatment there were a large number of cancer clinics in St. James's Hospital Oncology service. These included the oncology day ward and follow up clinics. The lead investigator (CH) liaised with the relevant medical and nursing staff in advance of the study. The treating physician performed initial eligibility screening and advised whether each patient could be approached for study participation at the patient's outpatient appointment. The lead investigator then approached the patient at this outpatient clinic, provided information about the study, and advised patients that their participation was voluntary and would not affect medical services they were accessing. Written informed consent was obtained from all the participants following this if they were agreeable to participation.

5.3.5 Procedure for completing questionnaire

The questionnaire required patients to sit and answer written questions, on paper, while they were waiting for an outpatient appointment. The lead investigator was on hand to explain any questions which the patient's had difficulty understanding.

5.3.6 Statistical analysis

Data in this study was analysed using SPSS version 25.0 software (SPSS, Inc, Evanston Illinois, USA). Baseline characteristics were expressed using descriptive statistics, using mean (SD) for continuous data and number (%) for categorical data. Questionnaire results were also assessed by frequencies for categorical answers, and using mean and standard deviation for scale data.

5.4 Results

5.4.1 Recruitment and response rate

This study took place between August 2015 and January 2016. In total 102 participants completed the questionnaire and were included in the final analysis. Due to the nature of our

method of recruitment there were no refusals to participate once the patients were referred to the lead investigator from their treating physician. As mentioned above, the lead investigator would only have contact with the potential participant once the physician had cleared them to take part. Therefore, patients presenting to the lead investigator had already been screened by the physician, and had expressed an interest in taking the questionnaire. A further likely reason for the absence of refusals to complete the questionnaire was the non-burdensome nature of this short questionnaire, which was completed while patients were waiting for their outpatient appointment, and thus did not require additional time commitment.

5.4.2 Participant characteristics

Described below is a breakdown of the participant demographics who were included in the study (Table 5.1). There were slightly more female participants included in the study (n=54), with men accounting for 47% of the total participants (n=48). The most well represented cancer type among the included participants was rectal cancer, with 29.4% (n=30) of participants presenting with this diagnosis. Mean age of the included participants was 65.5 years, with a standard deviation of 14.3 years. Demographic data was collected using the electronic patient record system for St. James' Hospital.

Table 5.1 Participant demographics

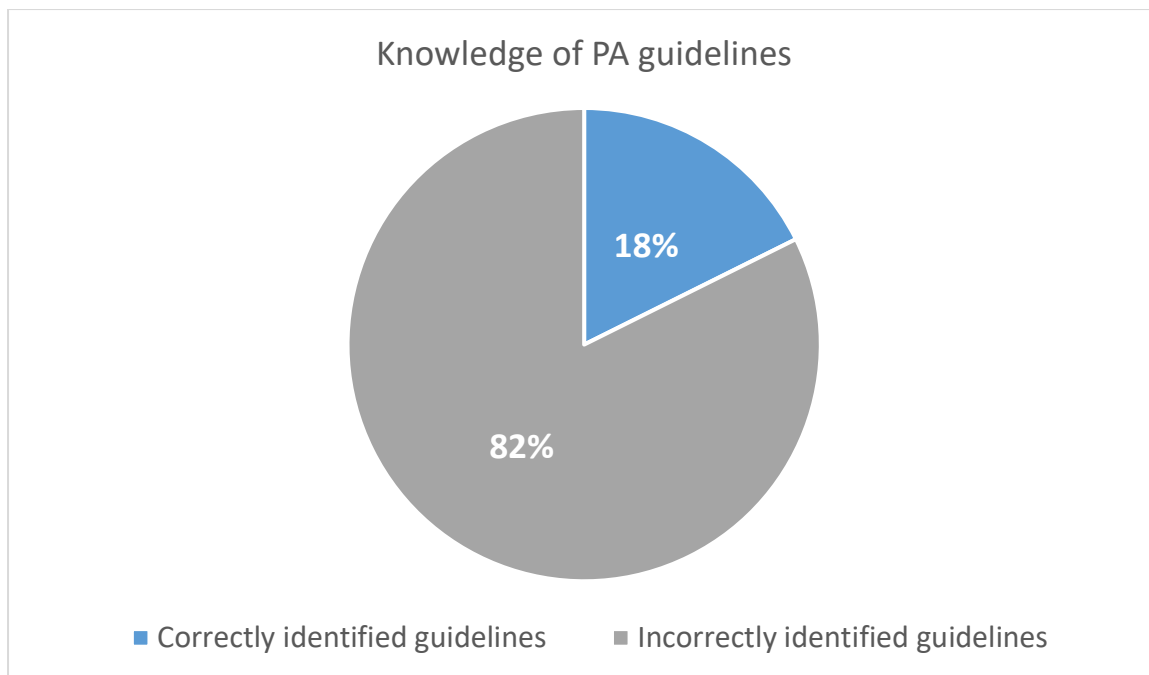
Demographic characteristic	Total sample (n=102)
Gender	
Male, n(%)	48 (47%)
Female, n(%)	54 (53%)
Age, M(SD)	65.5(14.3)
Cancer-related characteristics	
Breast cancer, n(%)	13 (12.7%)
Colon cancer, n(%)	22 (21.5%)
Rectal cancer, n(%)	30 (29.4%)

Ovarian cancer, n(%)	13 (12.7%)
Uterine cancer, n(%)	5 (4.9%)
Lung cancer, n(%)	5 (4.9%)
Testicular cancer, n(%)	6 (5.8%)
Oesophageal, n(%)	1 (.9%)
Other, n(%)	7 (6.8%)
Treatment, n(%)	
Chemotherapy, radiation therapy	27 (26%)
Chemotherapy only	72 (71%)
Radiation therapy only	3 (3%)
Surgery	102 (100%)
Marital status, n(%)	
Married	62 (61%)
Single	34 (33%)
Unknown	6 (6%)

5.4.3 Questionnaire responses

In the first two questions of this questionnaire, which asked the participants to state the recommended PA guidelines for cancer survivors, only 17.6% (n=18) of participants correctly answered and identified these recommended guidelines (Figure 5.3), as defined by the American Cancer Society (Rock et al., 2012). There were 64% of participants (n=65) that overestimated the recommended weekly PA, while just over 18% (n=19) underestimated the guideline for weekly PA.

Figure 5.3 Knowledge of PA guidelines



Question 3: In the past week, on how many days have you done a total of 30 minutes or more of physical activity, which was enough to raise your breathing rate. This may include sport, exercise, and brisk walking or cycling for recreation or to get to and from places, but should not include housework or physical activity that may be part of your job

Results from this question indicated the current PA status of the participants included in this study, with 46 (45%) participants reporting to be either achieving or exceeding the guidelines, while 56 (55%) participants reported their current PA status as below the guideline amount. This is represented in Figure 5.4 below. A further breakdown and illustration of these results is provided in Figure 5.5, showing the high percentage of participants (29%) reporting seven days of exercise for at least 30 minutes.

Figure 5.4 Reported PA status of participants

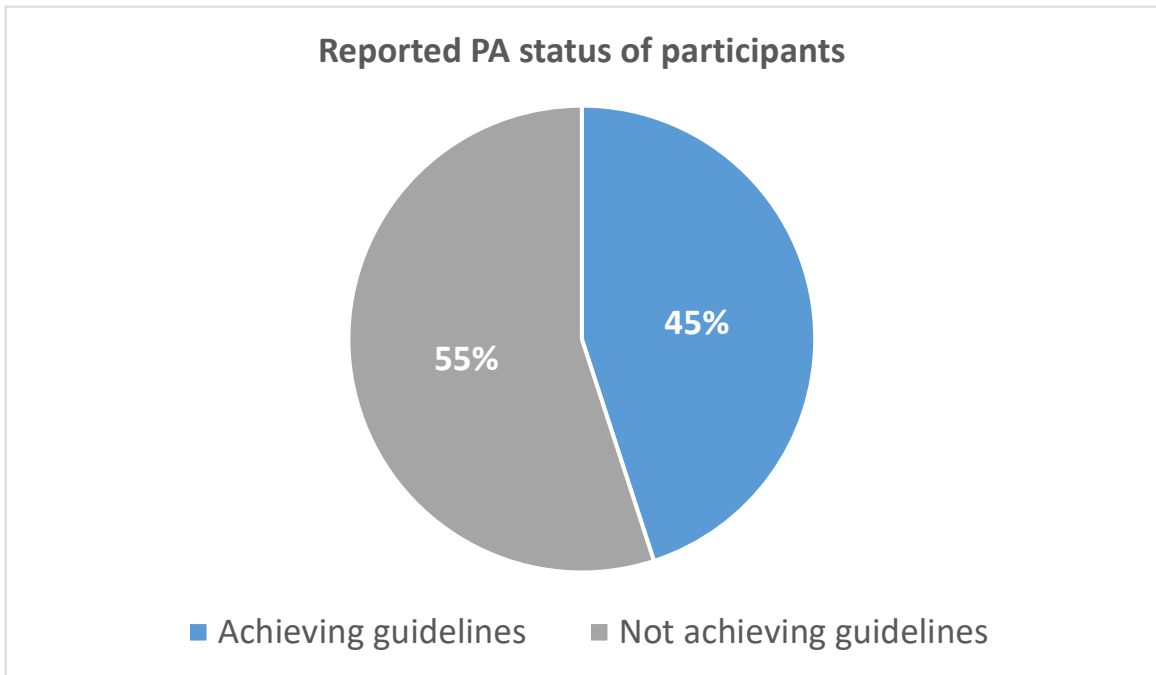
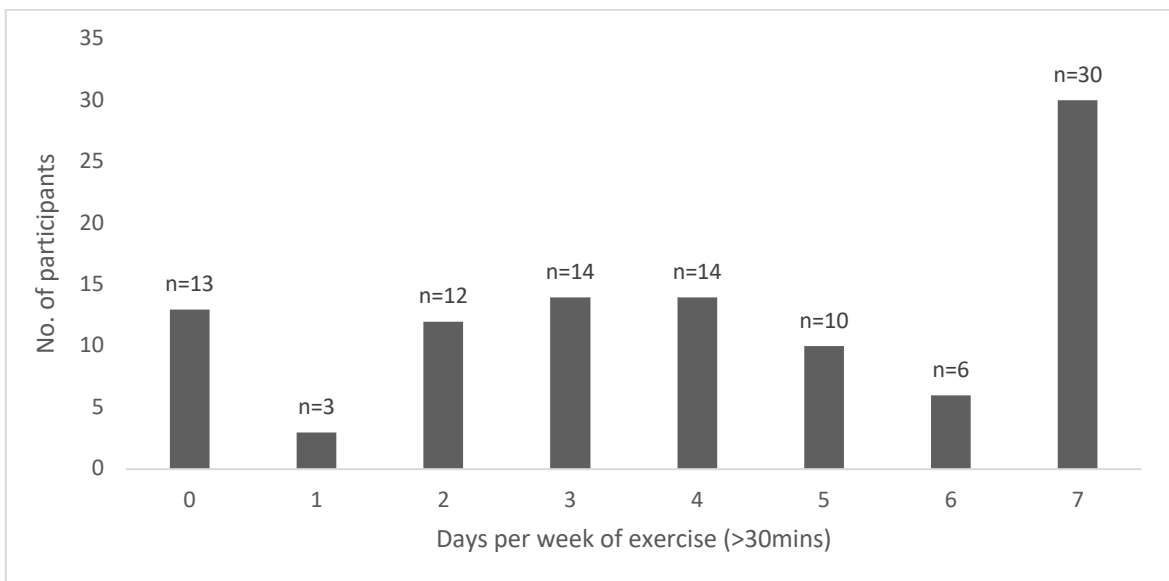


Figure 5.5 Days per week of exercise

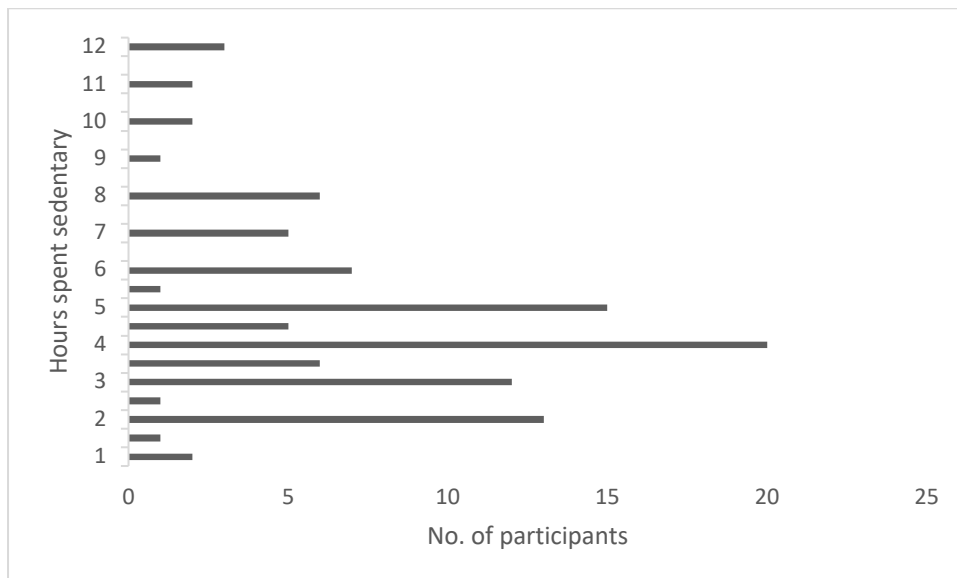


Question 4: On average how many hours per day do you spend sitting or lying during waking hours?

The range of answers for the amount of time spent sedentary by each participant spanned between 1 and 12 hours. An illustration of this variety can be seen below in Figure 5.6, where it

can be clearly seen that the most commonly identified number of sedentary hours was 4 hours, accounting for approximately 20% (n=20) of all participants. Analysis also revealed that the mean hours spent sedentary was 4.7 hours, with a standard deviation of 2.5 hours.

Figure 5.6 Sedentary behaviour of participants



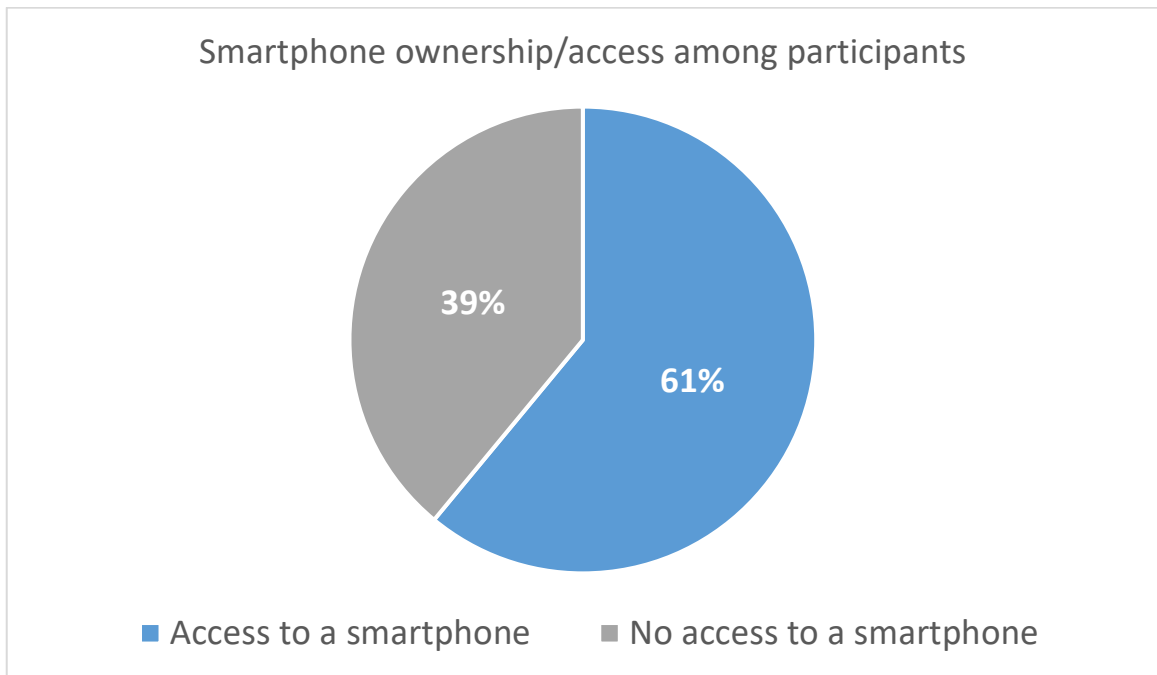
Question 5. Do you own or have access to a smartphone?

This question was designed to ascertain the availability of smartphones in this cohort of patients. The majority of patients reported that they had access to a smartphone (n=62, 61%), illustrated in 5.7 below. The mean (SD) age of those that did not own or have access to a smartphone was 73.9 (10) years of age. In contrast, the mean (SD) age of those that owned or had access to a smartphone was considerably younger, at 60.1 (14) years of age.

Question 6. Do you use smartphone applications?

This question was posed to survey the number of people who utilised the application functions of their smartphone. Results showed that overall, approximately 53% (n=54) of participants reported using smartphone applications. It was also identified that this represented 87% (n=54) of those that had access to smartphones (n=62).

Figure 5.7 Smartphone ownership/access among participants



Question 7. What is your most commonly used application?

In total, 54 participants provided the name of their most commonly used application. 48 participants responded to this question with 'N/A'. Of the participants who provided a name of an application, the most commonly provided answer was Facebook (n=14), with Whatsapp (n=9) the second most common answer. Beyond this, participants reported that Google (n=7) and their native email application (n=6) were their most commonly used application. Other applications that featured in answers, as well as the frequency of appearance are listed below. Skype (n=1), Yotsi (n=1), Samsung Health (n=1), Viber (n=2), Netflix (n=1), Bus Éireann (n=1), Wish (n=1), Ryanair (n=1), Kindle (n=1), Sudoku (n=1), Irish Independent (n=1), Pinterest (n=1), Irish Times (n=2), Paddy Power (n=1), banking application (n=1).

Question 8. Do you use any physical activity or exercise applications on your smartphone?

In total, only 10 participants reported using PA or exercise applications on their smartphone, although these applications were not specified. This represented approximately 16% of participants who reported owning or having access to a smartphone.

Question 9. Would you be interested in taking part in a group discussion about improving your physical activity using a smartphone application?

Results showed that 45% of participants (n=46) expressed interest in participating in a follow-up focus group. In total, 54% of participants (n=55) expressed no interest in participating in a focus group study, while 1 participant answered this question as 'Maybe'. Interest in participating in this follow up focus group was expressed by 60% (n=37) of participants who owned or had access to a smartphone.

Question 10. Would you be interested in taking part in a research study which will investigate the effect of smartphone applications on your daily physical activity?

Interest in participating in an eHealth intervention was expressed by 56.9% of all participants (n=58) and by 75.8% (n=47) of those with access to a smartphone.

5.5 Discussion

This study demonstrated a number of important factors relating to PA promotion in cancer survivors. It highlighted the lack of knowledge that participants had of PA guidelines, their self-reported PA and sedentary behaviour, smartphone penetration and current usage of apps. These factors were of paramount importance to the development of future studies described in this thesis, and showed that the information gained from conducting this scoping questionnaire was worthwhile in developing a greater understanding of the potential benefit that incorporating technology in a PA intervention would have on cancer survivors.

Establishing knowledge of PA was the focus of the opening two questions in the questionnaire. Only 17.6% (n=18) of participants correctly answered and identified the recommended PA guidelines, perhaps highlighting the considerable education that this cohort requires to improve awareness of guidelines for PA following a diagnosis of cancer. It is difficult to expect cancer survivors to be more active if they are not aware of the quantity or intensity of PA they should be performing each week. This finding also presents further questions regarding what the optimal delivery method of this important health information to cancer survivors is, as well as how this education can be integrated into their clinical care.

The PA status of participants was also examined and produced results that indicated, despite the lack of knowledge regarding PA guidelines, that almost half of participants reported they were achieving or exceeding these guidelines (n=46, 45%). Equally so, over 54% (n=56) reported their current PA and exercise as being below recommended guidelines. This finding, demonstrating the insufficient levels of PA among cancer survivors, has been previously elucidated throughout the literature on PA levels in cancer survivors (DeNysschen et al., 2014, Blanchard et al., 2008, Bourke et al., 2013). Sedentary behaviour was also assessed in this study, with participants reporting a mean (SD) of 4.7 (2.5) hours spent sedentary. Sedentary behaviour is characterised by prolonged sitting or reclining and activities of low (≤ 1.5 metabolic equivalents) energy expenditure (Lynch, 2010). Studies have shown that sedentary behaviour, in conjunction with low activity levels, is associated with lower QOL, poorer body composition and increased mortality in a variety of cancer survivor populations (Phillips et al., 2015). High levels of sedentary behaviour have been shown in cancer survivors (Lynch et al., 2010, Phillips et al., 2015), indicating an unfortunate trend when viewed in the context of the aforementioned associations with lower QOL and mortality. In this study, 25% (n=26) of participants reported greater than or equal to 6 hours of sedentary time each day, mirroring aspects of the literature referenced above.

While results from this study demonstrate a high percentage of participants reporting achieving PA guidelines, it must be noted that the method of assessment used may be susceptible to self-report bias, a consideration that must warrant further merit when viewed in conjunction with the limited knowledge among participants as to what the guidelines were. Self-report measures of PA are often subject to limitations which can lead to overestimation and indeed underestimation of PA when compared to direct measures of PA, such as accelerometry (Prince et al., 2008). Overall, these results have shown that cancer survivors may have difficulty in adhering to healthy PA behaviours, thus emphasising the importance of delivering an effective PA intervention to cancer survivors.

The role of technology, and the potential integration of eHealth into PA promotion for cancer survivors was the focus of the latter half of the questionnaire in Study 1. It was important to begin to investigate the place of technology in the lives of the cancer population, particularly in preparation for the design of an eHealth intervention, which was the ultimate intention for this thesis.

In this questionnaire, there were 62 participants who reported having access to or owning a smartphone, representing smartphone penetration in over 60% of the sample of cancer survivors surveyed. This particular result was especially important for us as we commenced development on a technological intervention in this population. The feasibility of delivering an eHealth intervention to cancer survivors relied on the availability of the required technology (smartphone) to participants. There is a global trend of increasing smartphone ownership and usage, with a study from 2015 estimating that roughly 68% of Americans own at least one smartphone device, a statistic which is increased from 35% of Americans owning a mobile device in 2011 (Anderson, 2015).

Further information on the characteristics of those with smartphone ownership was elucidated in the questionnaire described above also. The mean (SD) age of those that did not own or have

access to a smartphone was 73.9 (10) years of age, compared to a mean (SD) age of 60.1 (14) years in smartphone owners in this study. This highlights the increased penetration of smartphone technology in a younger demographic, and thus highlights a potential limitation to utilising eHealth interventions for older cancer survivors. Despite this, the majority of the sample surveyed in this study did have access to smartphones, therefore the results are also indicative of an opportunity to embed technology in PA interventions in this cohort. Additionally, as this questionnaire was conducted in 2015, the trend of increasing smartphone usage and ownership described above (Anderson, 2015), would indicate that the statistics regarding smartphone penetration in cancer survivors reported in this study would have increased further in 2019.

Establishing use of smartphone applications, and focusing on the use of exercise and applications, allowed for an insight into familiarity of cancer survivors to the use of mobile technology in promoting healthy behaviours. In total, only 10 participants reported using exercise applications on their smartphones, representing 16% of participants who reported having access to a smartphone. While this statistic is low in this study, accessing health information, which includes PA and exercise information, through the internet and smartphones is a growing trend in healthcare. An estimated 70% of Americans turn to the Internet to address their healthcare information-seeking behaviours (Rainie and Fox, 2000), while 62% of American smartphone users have reported using their mobile devices in particular to obtain health information (Smith, 2015). The use of smartphone health applications in particular was the focus of another study by Bhuyan et al. (Bhuyan et al., 2016) where it was reported that 36% of adult owners of smartphones had health applications on their smartphone. This evidence is further indication of the increased role of smartphones in providing information and strategies to promote healthy behaviours.

Certainly the uptake and integration of exercise applications in this population was low, and is a pertinent consideration when designing an intervention which would have an exercise

application at its core. This result was an indication that, should an exercise application, or indeed the principles of one, be utilised in an eHealth PA intervention for cancer survivors, it should not be presumed that participants would be adept at navigating exercise applications. It was also an important finding for the development of Study 2 in this thesis, where it was possible to expand on this topic, and further investigate the experience and barriers participants may have with exercise applications.

The final two questions in this questionnaire-based study were particularly important and addressed the feasibility of recruiting cancer survivors to two further studies in this thesis. Interest in participating in an eHealth PA intervention was high among current smartphone users in this study, with 75.8% (n=47) expressing interest. This showed that participants were receptive to engaging in a PA intervention which would involve the use of technology. Considering the aims and objectives of this study, which was the exploration of the feasibility of using technology to promote PA, this was a particularly positive result and provided valuable knowledge that would be built on in Study 2.

5.5.1 Strengths and limitations

This study represents an exploratory analysis of PA knowledge, PA behaviour and smartphone use and engagement in cancer survivors. Sample size for this study was reasonable (n=102) and can potentially be regarded as a strength of this study. There is a paucity of research into eHealth interventions for PA promotion in cancer survivors and this study offers a foundation of knowledge imperative to the progression towards the development of an optimal PA intervention utilizing eHealth methodology. A further strength of this study is that the knowledge gleaned from this study aligns closely with the MRC guidelines for developing a complex intervention (Craig et al., 2008), and thus can form an important part of the development of a future study that will investigate further the effectiveness of an eHealth-based PA intervention.

Convenience sampling was used in this study, and may be regarded as a limitation of this methodology. This questionnaire, which was developed by the research team according to the specific objectives of this study, was not piloted prior to implementation in this study. A further limitation of this study was that work status and job type was not collected while gathering demographic information on participants, which may have provided further insight and context into the question on sedentary behaviours of participants in this study. Additionally, it should be considered that participants already active, or interested in exercise, may have been more likely to take part in this research, leading to a selection bias of active participants.

The rate of recruitment was also slow, with a total of 102 participants recruited over approximately 6 months. A potential reason for this may relate to the method of recruitment, with the lead investigator only having contact with the potential participant once the physician had cleared them to take part, while practically it may be that the added task of screening the participant for the physician, on top of their existing multitude of responsibilities, may have led to a number of eligible participants being missed. Refining this process, to allow the research physiotherapist to take on the responsibility of screening each participant for eligibility may have improved this rate.

It should also be noted that refining the process in this way, where a research physiotherapist not involved in the direct care of the patient would present the research to the patient, would eliminate any potential element of coercion that may apply when the physician presents the research to their patient.

5.5.2 Conclusion

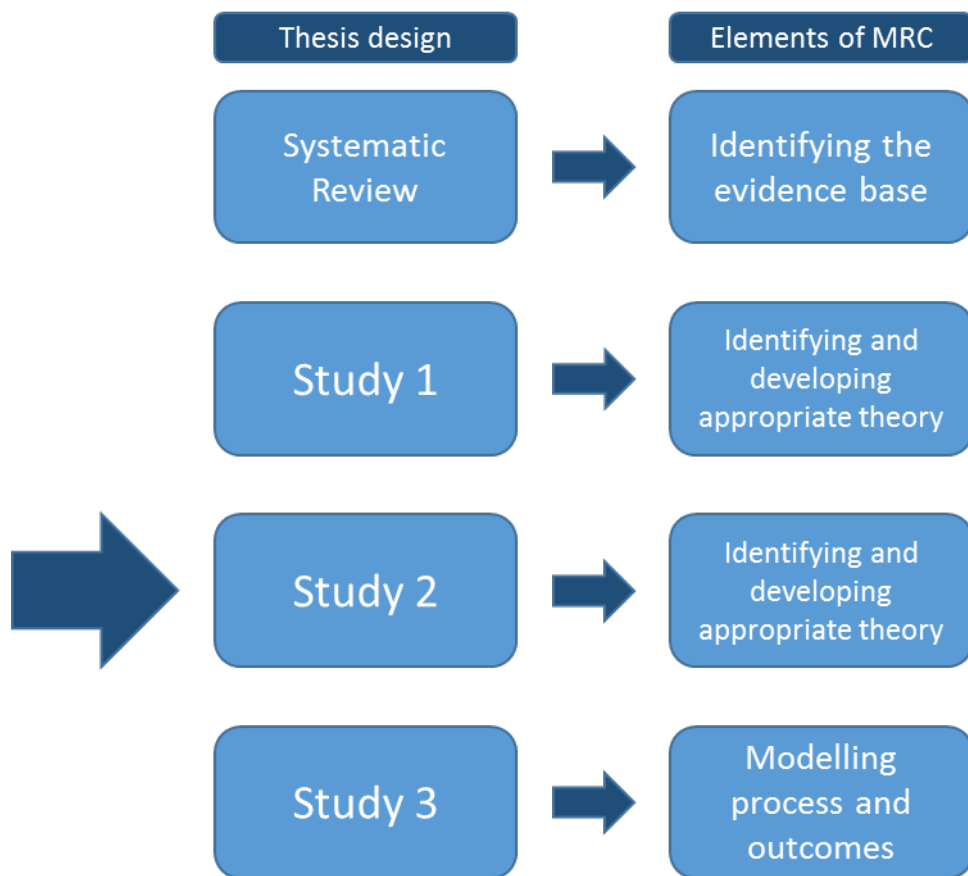
This study forms an important part of the emerging literature into PA promotion in cancer survivors through the use of technology. Advances in technology, and the integration of technology in healthcare present us with novel and potentially effective methods of changing a patient's behaviour. As with any burgeoning area of medical research involving development of

an intervention to patients, a systematic and careful patient-centred approach to study development will ensure that any intervention developed is a specific and caters optimally for the patient's needs.

In summary, this study has shown that smartphone penetration in this sample was 60.8% overall. Of those participants that owned or had access to a smartphone, the majority expressed interest in a future study incorporating eHealth to promote PA. Notably, less than 1 in 5 participants had knowledge of the recommended PA guidelines. The findings from this study laid the foundations for the future studies within this thesis.

Chapter 6 Study 2-Focus Group

Figure 6.1 Progression of thesis related to MRC guidelines for developing a complex intervention



6.1 Introduction

Chapter 4 has described the initial preparatory research that was conducted in order to align with the MRC recommendations on designing and conducting a complex intervention (Craig et al., 2008). This initial preparatory study took the form of a questionnaire, and explored the role of technology in the lives of cancer survivors, while also indicating the potential composition of an intervention promoting physical activity in cancer survivors. Study 2, a focus group-based study will be described below, and represents the final scoping study of this thesis. The design of Study 2 was qualitative in nature and provided an investigation into the barriers and facilitators that cancer survivors faced using technology. It was hoped that the results of the focus group would inform the development of an effective and appropriate eHealth-based intervention for cancer survivors.

Focus groups present an opportunity for a researcher to gain an understanding of a patient's perspective on a specific topic that is chosen to be discussed (Wong, 2008). In this case, the chosen topic to be discussed was the use of technology as a tool to improve PA behaviours in patients with cancer. A focus group would allow a further exploration of patient perceptions about using technology to improve their PA, with the intention to concentrate findings from Study 1 and ultimately refine our understanding of what components an eHealth intervention should include. Considering the results of the systematic review, detailed in Chapter 2, which showed how little research had been conducted thus far in the area of PA promotion using eHealth in cancer survivors, an approach incorporating patient perception to a topic which is relatively unexplored is justified. The addition of a focus group, alongside the questionnaire detailed in Chapter 3, was important as it could reveal additional relevant information for the design of the final intervention study.

Establishing barriers and facilitators to using eHealth, while identifying patient-centred preferences for components of the intervention served as the rationale for conducting the focus

groups. Successful focus groups have the unique power to extract information about their topic that is typically left untapped by other forms of data collection (Kitzinger, 1995). Furthermore, integrating qualitative research can optimize the robustness of intervention materials (O'Cathain et al., 2013), and has been utilized within a number of complex interventions in the pre-trial design phase (Corrigan et al., 2006, Hoddinott et al., 2013, Bradley et al., 1999).

Although previous studies have explored perspectives of cancer survivors towards exercise, these studies have generally been conducted after completion of a structured exercise program (Spence et al., 2011, Midtgaard et al., 2006, Emslie et al., 2007, Korstjens et al., 2008). One of the disadvantages of gaining participant perspectives after completion of an intervention are that preferences are influenced by their direct experience of the program itself (Spence et al., 2011). It would appear that no prior study has integrated personalized insights of eHealth-based PA interventions at the pre-trial phase to inform the design of such an intervention.

6.2 Study Aims and Objectives

The overall aim of the study was to establish cancer survivor perceptions to using mobile technology for PA promotion.

Specific objectives of focus group:

- Explore perceptions of the possible use of mobile technology to increase PA.
- Map barriers to the possible use of mobile technology to increase PA.
- Identify methods to overcome barriers to the use of mobile technology to increase PA.
- Map facilitators to the use of mobile technology to increase PA.

6.3 Methods

The methods, results and analysis of this study are reported using the guidance of the 'Consolidated criteria for reporting qualitative research (COREQ)' (Tong et al., 2007).

6.3.1 Study Design

A qualitative methodology was used in this study, involving the organisation of a number of focus groups in patients with cancer. Focus groups were chosen for their strength in generating new ideas and diverse opinions in a way which would be less accessible in a one to one interview (Kitzinger, 1995). A further advantage of focus group design is that participants can build on each other's ideas, through facilitated discussion in a group setting (Leung and Savithiri, 2009). The design and reporting of research methods used in this study was informed by the 'Consolidated criteria for reporting qualitative research' (COREQ) standardised reporting guidelines (Tong et al., 2007).

6.3.2 Ethical Approval

Ethical approval for this study was granted by St. James's Hospital/Tallaght University Hospital Research Ethics Committee (Reference: 2015-05). Informed consent, in writing, was required from all participants to be included in this study.

6.3.3 Sampling and Recruitment

Convenience sampling was utilised for the purpose of this study. The sampling approach in this study is explained in detail in Chapter 3 (Section 3.3) in this thesis. Criteria for inclusion in this study were as follows; adult population (≥ 18 years of age), patients that were attending outpatient clinics of the oncology and haematology day services of St. James's Hospital at the time of recruitment, fluent in the English language, absence of cognitive disabilities which may hinder following instructions and patients who had received chemotherapy or radiation therapy for malignancy and had finished a course of treatment or were anticipated to finish their treatment within 3 months.

Participants for this focus group were recruited from Study 1, the questionnaire study, with recruitment taking place between August 2015 and January 2016. The recruitment process of this questionnaire study is detailed in Chapter 4 (Section 4.3.3). In the questionnaire study, participants were given the option to express their interest in taking part in a further focus group study. That focus group study is the current study (Study 2). The participants who expressed a willingness to be contacted for the focus group were invited to participate in the focus group by a phone call. Those still willing to participate in the focus group study were posted out a consent form and information leaflet about the focus group. Once consented, participants were added to a database and contacted by phone regarding the date and location of the focus group. It should be noted that even following consent, participants were assured that withdrawal at any timepoint would not impact their cancer care in any way, and that participation was voluntary.

6.3.4 Interview Guide

The interview guide, presented in full in Table 6.1 below, for the focus groups was developed by the lead investigator (CH). The interview guide contained questions about potential barriers that cancer survivors may have in adopting mobile technology when trying to become physically active. Questions regarding potential solutions to these barriers were also included, as well as facilitating factors that could help patients with cancer improve their PA using technology. Development of the interview guide was directed by results from the systematic review (Haberlin et al., 2018) that was described in Chapter 1 of this thesis, and discussion among the research team based on pre-stated study objectives (detailed above in Section 5.2). Development was also influenced by literature on qualitative research in healthcare (Neergaard et al., 2009). Based on this research by Neergaard et al. (2009), the interview guide was semi-structured and flexible, allowing for more in-depth questioning as themes emerged from each of the focus groups. This approach also encouraged a free flow of conversation (Marks, 2003). The interview guide was not pilot tested prior to the first focus group. The composition of the

interview guide was structured so that initial questions focused on general aspects of PA motivations and barriers, with the latter questions in the interview guide focusing specifically on important aspects of the design of an eHealth intervention.

Table 6.1 Interview Guide

<p>Q: What motivates you to exercise? <i>Probing question: Is there anything in particular that could help?</i></p> <p>Q: Do you think a smartphone application could help you to increase your daily physical activity? <i>Probing Question: In what way could it do this? What features would be useful? Why would it not help?</i></p> <p>Q: Would anything stop you from using mobile technology to help you to exercise more? <i>Probing question: Can you explain these barriers?</i></p> <p>Q: Can you think of any ways you could overcome these difficulties? <i>Probing questions: How would these solutions work to make mobile technology effective in helping you exercise?</i></p> <p>Q: Is there anything that would make it easier to use mobile technology? <i>Probing questions: What support/help do you think would facilitate you to use a smartphone application in physical promotion?</i></p> <p>Q: Are there any smartphone app features that you think would help you to exercise more?</p>

6.3.5 Data collection and setting

Demographic data for the patients included in this study were obtained from electronic patient records in St. James' Hospital, Dublin. A dictaphone (Philips Voice Tracer Digital Recorder DVT2000, China) was used to record the audio of the focus group. The complete methodology of the qualitative data collection used for this study is detailed in Chapter 3. Data collection continued until saturation was reached, a stage where no new ideas or themes were emerging (Guest et al., 2006).

The focus groups took place in two locations, the outpatient department of the physiotherapy department in St. James' Hospital and the exercise laboratory in the Trinity Centre for Health Sciences on the St. James' Hospital campus, based on room availability. The lead moderator (CH) of all the focus groups was a male doctoral researcher, but also a qualified physiotherapist with a bachelors degree. While the assistant moderator varied between the focus groups (JB/JM), each of these was a post-doctoral researcher or academic, as well as a qualified physiotherapist with additional training and experience in qualitative methodology. During the focus groups, only the participants and researchers were present in the room. At the start of each focus group, brief study information was provided, and ground rules about confidentiality and respect of others opinions were discussed and agreed.

The lead moderator had previous experience of post-graduate qualitative methodology training as well as consultation with an expert in qualitative research methodology from the School of Nursing in Trinity College Dublin. The lead moderator was also the lead investigator on this study, and was in charge of recruitment for this study, therefore the participants were familiar with him. The assistant moderator (JB/JM) present in each focus group acted as a note taker during the discussion, recording potential themes that emerged that the lead moderator may have missed, as well as general observations. No incentive was provided to participants.

6.3.6 Data analysis

In view of the emergent nature of this area, data analysis was performed using thematic analysis following the phased approach outlined by Braun and Clarke (2006), further described in Chapter 3 (Section 3.6). Recordings were transcribed verbatim (names were replaced by participant numbers) by CH and double checked for accuracy by JB. All transcripts were read multiple times by CH, JM and JB. Focus group transcripts were coded into meaningful clusters using NVivo qualitative data analysis software (QSR International PTY Ltd. Version 9). The data was examined to establish recurring patterns of meaning (Braun and Clarke, 2006). Codes and

themes were discussed, refined and agreed by authors and then checked and compared to ensure grouped data was contextually meaningful. Any differences in coding were discussed by researchers until a consensus was achieved with the final themes. Smaller sections of participant text were selected to illustrate subthemes. Following the 6th and 7th focus groups, where consensus was achieved that no new codes or themes were being drawn from the data, the focus groups were concluded.

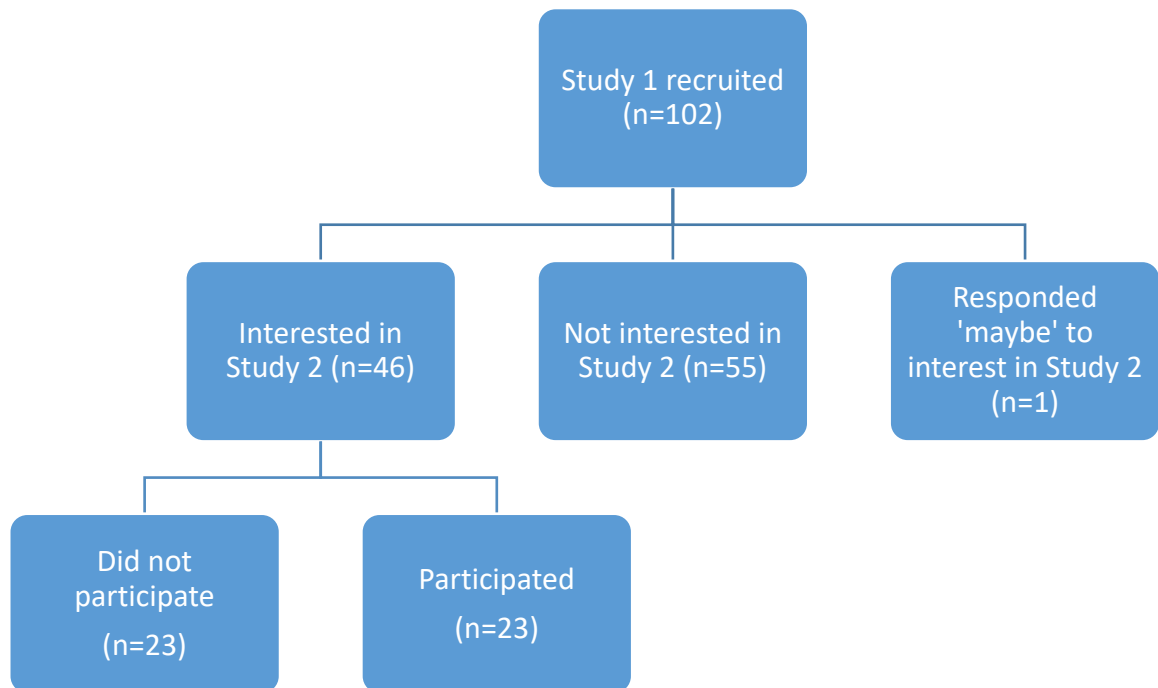
6.4 Results

6.4.1 Participant selection and data saturation

Question 9 of the questionnaire (Study 1) established interest in participating in a follow-up focus group. Following the completion and analysis of results from this questionnaire, it was revealed that 45% (n=46) of participants expressed interest in participating in this focus group. Inclusion criteria for this study were the same as Study 1 (Chapter 4, Section 4.3.3) and therefore participants did not require further screening. The flow diagram for study recruitment and participation is illustrated below in Figure 6.2.

Data saturation was achieved after the 7th focus group, when no new knowledge regarding the aims of the study was established. This resulted in conclusion of the study after the 7th focus group, with a final sample size of 23 participants (n=23). Reasons for non-participation included; no response (n=10), unable to participate (n=7) and declining on contact (n=6). All focus groups took place between November 2015 and April 2016. If data saturation had not been achieved at this point, further focus groups would have been conducted using the same methodology, recruiting from the pool of participants that were unable to participate in the first 7 focus groups.

Figure 6.2 Flow diagram of study participation and recruitment



6.4.2 Participant characteristics

Demographic details of all included participants are collated in Table 6.2 below. The focus groups ranged from 23 - 34 minutes and the mean (SD) length of the focus groups was 28.74 (3.39) minutes. In total, 36428 words were transcribed verbatim by the lead investigator (CH). Seventeen participants were female and 6 were male, with a mix of cancer diagnoses. The age range was 34-82 years. 11 participants were ≥ 65 years old and 12 participants were < 65 years. In total, 19 participants (83%) owned or had access to a smartphone, with 4 participants not owning or having access to a smartphone. There were only 6 participants who reported using PA or exercise applications. A breakdown of the composition of each individual focus group is provided in Table 6.3 below.

Table 6.2 Demographic details of all included participants

<i>Variable</i>	<i>Frequency (%) / Mean (SD)</i>
Gender	
<i>Male</i>	6(26%)
<i>Female</i>	17(74%)
Age (at study enrolment)	61.34 (12.6)
Cancer Type	
<i>Breast</i>	4(17%)
<i>Colorectal</i>	6(26%)
<i>Ovarian</i>	5(22%)
<i>Testicular</i>	2(9%)
<i>Endometrial</i>	3(13%)
<i>Other*</i>	3(13%)
Treatment	
<i>Chemotherapy only</i>	15 (65%)
<i>Chemotherapy and Radiotherapy</i>	8 (35%)
<i>Surgery</i>	23(100%)
Marital Status	
<i>Married</i>	14(61%)
<i>Single</i>	9(39%)

*Other cancer types: Mandibular (n=1), Oesophageal (n=1), Appendiceal (n=1)

Table 6.3 Composition of each focus group

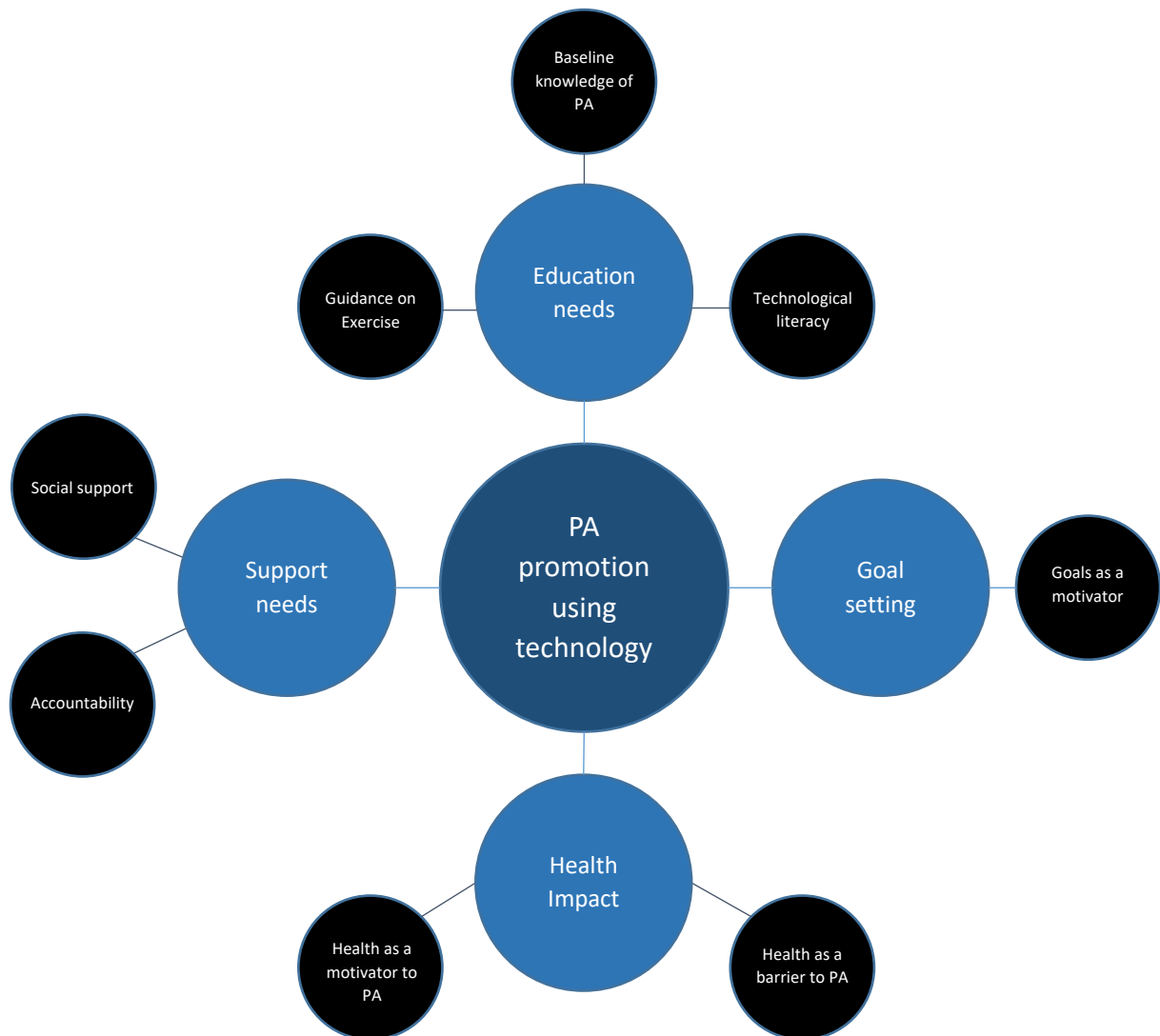
	<i>Gender</i>	<i>Mean age (SD)</i>	<i>Cancer Type</i>
Focus Group 1 (n=3)	2 male	42.6 (9)	<i>Testicular (n=2)</i>
	1 female		<i>Breast (n=1)</i>
Focus Group 2 (n=3)	3 female	68 (2.6)	<i>Rectal (n=1)</i>
			<i>Endometrial (n=1)</i>
			<i>Ovarian (n=1)</i>
Focus Group 3 (n=5)	1 male	65.2 (12.3)	<i>Rectal (n=2)</i>
	4 female		<i>Colon (n=1)</i>
			<i>Appendix (n=1)</i>
			<i>Endometrial (n=1)</i>
Focus Group 4 (n=3)	1 male	67 (11.5)	<i>Ovarian (n=2)</i>
	2 female		<i>Rectal (n=1)</i>
Focus Group 5 (n=3)	1 male	65.6 (9.6)	<i>Endometrial (n=1)</i>
	2 female		<i>Ovarian (n=1)</i>
			<i>Oesophageal (n=1)</i>
Focus Group 6 (n=3)	3 female	66.6 (8.1)	<i>Colon (n=1)</i>
			<i>Breast (n=1)</i>
			<i>Ovarian (n=1)</i>
Focus Group 7 (n=3)	1 male	51.6 (13.3)	<i>Mandibular (n=1)</i>
	2 female		<i>Breast (n=1)</i>
			<i>Breast (n=1)</i>

6.4.3 Results of thematic analysis

Following analysis and coding of the transcripts, a number of themes and subthemes were extracted from the data, these are detailed below in Figure 6.3. There were 4 main themes in total, which had accompanying subthemes. Additionally, there were two minor themes that emerged from the data, 'User-friendly' and 'Weather', and are detailed following the results of the main themes and subthemes. Detailed descriptions of each theme, with accompanying

supporting quotations extracted from the transcription of the focus groups, are detailed below. These themes reflect the perceptions of our sample to adopting positive PA behaviours, with the help of mobile technology.

Figure 6.3 Themes and subthemes from focus groups



6.4.3.1 Theme 1: Education needs

There were a number of subthemes that fell under the main theme of education, these will be discussed below.

Subtheme 1: Baseline knowledge of PA

Throughout the focus groups, there was a prevailing pattern of participants reporting the absence of education regarding the importance of PA following a cancer diagnosis. Quotes will be labelled and assigned with the participant code, gender and age in years (Code, Gender, Age).

'But after the treatment I was never really told exercise was important' (P56, Female, 53),

'Nobody said anything, do anything when you're finished' (P49, Female, 82)

'I probably wouldn't been aware on, like P69 and P57 of the importance of exercise, ah, post cancer, I have never been told anything about it.' (P12, Female, 54)

'I didn't hear anything about it at all, until I met you (speaking to lead investigator)' (P57, Female, 71), 'Even if you got a leaflet, even if there was something, or the book recommend, a book to read, but there was nothing' (P69, Male, 76).

There were some participants who also admitted to their lack of knowledge regarding the importance and benefits of PA and exercise

'Oh god, you really don't know what, it's hard, you don't know what you're meant to be doing' (P84, Female, 64).

Subtheme 2: Technological literacy

The data extracted from the focus groups also indicated the level of technological literacy that was present in this sample, with many indicating that for technology to be introduced to their healthcare program, they would require education on how to use it.

'I like to, someone to sit down and show me and make sure I listen, and it was my grandson, and my little granddaughter of 5 that taught me how to use my phone!' (P87, Female, 74).

'To be shown yeah, to get a demonstration on how to use it' (P85, Female, 58).

'But someone just to sit there with you, for just a certain amount of time, till you sort of grasp it' (P87, Female, 74).

'Well I think I agree with P60 really, with the app yeah, so that you're shown how to use it, follow up, to make sure you're doing it right you know correctly and helping yourself.' (P85, Female, 58)

'But you'd have to show me how to work it on that, I know nothing about this phone but it is a smartphone' (P90, female, 63)

There was also an awareness among some participants that they were not entirely comfortable using technology currently, but similarly agreed that support and education would make it possible to try using technology;

'Yeah I think there is, now I'm personally not into phones, so I you know don't be on anything like that so, you know I probably need a trainer' (P04, Female, 52).

'There's no point saying to somebody that's never been, I don't mean, that's never used an app before, switch on that app and away you go, you know it's not as easy as that, you know you need to download it and all, if that handover was there'(P12, Female, 54).

Subtheme 3: Guidance on exercise

The focus groups also highlighted the level of importance that participants placed on PA and exercise education, with demonstration and direction equally as important as when learning technology.

'I'd need somebody to show me what I'm doing and what do to do, how to exercise because I don't exercise and I don't know' (P04, Female, 52).

'When you're going through the treatment, that maybe on a regular basis somebody comes in and talks to you... say how much exercise did you get and did you get' (P56, Female, 53).

Indeed one participant referenced the value of this direction and education coming from a professional

'If there was a link in, if I did have a specific question to physiotherapy and exercise... that I had a particular question about exercise that I can get an answer back from a professional, that would be good (P12, Female, 54).

'I think it has to start from when we're discharged from our treatment, by having a sit-down chat with the physiotherapist or given a leaflet or given the app, there, that missing link is there, it should start from there'.

This sentiment was echoed in another focus group, when one participant warned against the danger of limited education on how much exercise to perform;

'I don't know you see, I think they're, I think those things you have to be very careful about, that's why people go to gyms and hopefully a person tells you what to do' (P84, Female, 64).

Further value was placed on professional support and guidance from a professional in another focus group;

'I think I'd want a bit of feedback from the like of you (speaking to lead investigator, a physiotherapist), somebody like you, you know even to keep, contact maybe every two weeks, something like that, even ring you up every 2 weeks' (P38, female, 69).

6.4.3.2 Theme 2: Goal setting

One of the main themes to emerge from the data extracted from the focus groups was the concept of goals. The importance of goals was expressed in a number of different ways, these are detailed below.

Subtheme 4: Goals as a motivator

Understanding the motivators and barriers to exercise that patients with cancer had was an important part of this qualitative research. At the conclusion of the final focus group it was clear that goal setting would act as a motivator for these participants

'I'll say hey that's not good enough now, I'm going to, I'm definitely going to go 2 km and then I'll get to 2 and I'll think ah sure I'm at 2 now, I don't feel so bad, maybe I'll go to 3 and then it actually motivated me every day to beat my previous record' (P12, Female, 54).

This sentiment was expressed again when one participant told how having a goal ahead of them was a motivator *'And that motivates us as well, because we know exactly what we've done and what we want to do ye... Because, we're doing a challenge you see, for Slimming World, you know it's to do 6 kilometres 3 times a week' (P85, Female, 58).*

When posed the question whether having a smartphone application could help improve PA, another participant who had been using an application mentioned that *'Yeah, it did, because I had a target, tell you exactly what you've done, if you've hit that target, well not every day, but maybe once a week, trying to beat that target' (P81, Male, 57)*, again highlighting the presence of a target or goal as a motivator.

The sense of achievement from reaching a goal was mentioned throughout the focus groups also.

'Well I'm going back to what I used to do in the park and every so often she would time us all, you know, and it really made you want to do this thing quicker... timing the mile you really felt good and it was like going back to getting your reward or your goal' (P38, Female, 69).

'I would like to look back and say, awh yeah I've achieved, and you know I'd say that was great, I suppose a bit like the park run, the, the, the couch to 5K' (P56, Female, 53).

The phenomenon of achievement acting as a motivator was also mentioned by one participant when speaking about knowing their goal;

'So that's what motivated me, the fact that you know, I oh and then I got very proud of myself' (P12, Female, 54).

6.4.3.3 Theme 3: Health impact

The theme of health had two distinct subthemes emerge from the focus groups analysed in this study. The first was the role of health as a barrier to PA, with the second subtheme being the role of improving health as a motivator for PA.

Subtheme 5: Health as a barrier to PA

There were a number of participants who signalled that side-effects of cancer treatment, or their health in general were primary barriers to exercise or PA, with tiredness or fatigue consistently mentioned.

'But ever since the chemo I've lost interest, planning things around, but just get up get out, I've lost interest, got so tired' (P80, Female, 76)

'I've always been a bit active I think, but I'm very stiff so I don't exercise, I just get stiff' (P84, Female, 64).

'It's like I hope when I start all this that this tiredness will gradually ease off' (P80, Female, 76).

'And that's why I was attending the hospital, because I was getting this feeling in my chest all the time, just say what stopped me from walking' (P87, Female, 74).

'I'm on me feet in the house, doing housework and stuff, so me back starts at me so that's what prevents me sometimes from going out. Like when I walked for the hour on, eh Sunday, I think it might have been too much, and irritated the back' (P90, Female, 63).

Subtheme 6: Health as a motivator

In contrast to those expressions detailed above, where participants indicated how their health and well-being acted as barrier to their engagement in PA, the following quotes demonstrate how some participants viewed good health and feeling better as a motivator for improving PA.

'When I was going through the treatment I felt like going out for a walk, not matter how tired I was, I felt better after the walk you know, even though I used to walk very slow but it helped you know kinda, and I think it helped me through the treatment you know, and helped me overall you know?' (P19, Female, 65).

'I felt that walking before I got sick helped me, kinda get strong you know, helped me you know, physically, helped me through the treatment as well, you know' (P19, Female, 65).

'Bit of a steep hill to get up, when you get up, coming back down then it's all downhill, you feel better when you do go up, you do feel better after being out' (P38, Female, 69).

The feeling of improving well-being being a motivator was echoed throughout the focus groups.

'I suppose I feel very tired and because of that I just think that once I get the bit of exercise done it makes me feel better, so it's to get out and get a bit of air, it helps (Inaudible), otherwise I'm just slouching around and I feel more tired' (P56, Female, 53).

'Yeah you go out and you meet people and you're out in the air, kind of it's very good for you' (P49, Female, 82)

'It's just the feeling of well -being, I personally love to get up and get out, hail, rain or snow I love it' (P80, Female, 76)

'There's definitely benefits to the exercise, you you feel better, you eat a lot better, and you sleep a lot better.' (P81, Male, 57)

'to make you feel better I think, because people always say like if you get out in the air, and you walk, ok you're tired, but do as much as you can then get back, you do feel better for it, I do.'
(P87, Female, 74).

Losing weight, and improving health in that manner, served as motivation for a number of participants

'I suppose to get out in the fresh air, keep my weight down I suppose' (P38, Female, 69)

'Get rid of the weight...I'm nearly 20 stone, I have to try and get it down, I only became like this after the chemo, so I don't know, that's about it' (P37, Male, 69).

'To get my weight down...I joined weight-watchers, and I'm doing relatively well' (P46, Female, 69)

'Yeah, putting weight on, probably would, anyway, yeah' (P57, Female, 71), *'And another motivation would be to try and get the weight down'* (P87, Female, 74).

'Well mine is to lose weight, and to just get a bit fitter' (P85, Female, 58).

Getting fitter, similar to the quote above, was a motivating factor for many participants.

'Just to be healthy and keep fit like, em that's it' (P49, Female, 82).

'Just to keep fit, and it's great social aspect to it as well, to get out and about and forget about what else is going on or' (P13, Female, 53).

'Well, I like to be physically fit, so that's my motivation.' (P69, Male, 76).

'My motivation is purely fitness, before I, before I got into this, I used to sit on the sofa day in day out doing nothing, and then I was told, a bit of exercise you'll feel 10 times better, so I started exercising and I'm now doing 7, 8 miles a day' (P81, Male, 57).

'Trying to make yourself feel fit, because the more you stay in, and the more you sit, the more you feel you're tired' (P87, Female, 74).

There were also a number of participants that reported that the positive effect that exercise and PA had on their pain, and stiffness was a motivating factor to engage in exercise

'My knees are really really bad, but it all, it does really seem to help the bike and the stiffness so contrary to what I thought, actually it's good to be moving' (P84, Female, 64)

'My knees yeah, and I need to do that because if I'm still at home, after a few hours I couldn't do nothing, absolutely nothing, and it's because that, and and I to myself, 'A little bit more, a little bit more', and I motivate myself' (P89, Female, 55).

6.4.3.4 Theme 4: Support needs

The theme of support featured heavily throughout all the focus groups, and was heavily discussed. It will be detailed below in terms of the two subthemes that emerged from analysis, accountability and social support.

Subtheme 7: Accountability

The importance of accountability for exercise performance and volume of PA achieved was seen in many focus groups in this study. The presence of a trainer, or someone to direct the exercise and PA was mentioned.

'But a trainer will be like, 'come on, get up, get going, you know that kind of way' (P01, Male, 34),

'You know I probably need a trainer' (P04, Female, 52).

'Well even just to sit, and talk to somebody like yourself, and to feel like there is somebody there, that you care if we do exercise or not' (P87, Female, 74)

'That maybe on a regular basis somebody comes in and talks to you, I don't mean to put anyone under pressure but, say how much exercise did you get and did you get, and try a little bit this week' (P56, Female, 53).

Personalisation, feedback and the provision of PA prescription specific to each individual participant also emerged from the focus groups and can be classified under the theme of support.

'I think each person is an individual, so no-one app, do you know, it has to be adaptable to every single person not just one type of person, so like P11 said, you input your information there and then that app is for you not an app for 50 other people or 60, or thousands of other people, it's specifically for you, so I think that's important.' (P01, Male, 34)

'Yeah I'd say if if you felt this wasn't some generic thing, that that like eh marathon runners are also doing the same thing, actually it's designed with you in mind or some some basic fitness test is done at the beginning...and you actually feel this is clued into my life' (P11, Male, 42)

'If there's someone there to say well this is probably what you need, and just to start it' (P87, Female, 74)

'Well, I think em, I'm only guessing, but I say ideally, the ideal thing for everybody would to have somebody personalising some regime for yourself so they know what you're capable of, or whats your, things you shouldn't be doing' (P11, Male, 42).

Subtheme 8: Social support

In contrast to the professional, prescriptive support that participants mentioned as important, the majority of participants also described motivation stemming from family, friends and peers

'Yeah, my friends and family more so, kind of influence in a way, they say 'I'm going for a walk, do you want to go for a walk?' I'll say yeah, sure why not, you know that kind of way' (P01, Male, 34).

When mentioning potential eHealth features, *'Even if it had a social aspect, where if people with the same app could, I don't know, say what they're doing, if they're nearby could they join them, you know it's always better in groups than on your own'* (P01, Male, 34).

Returning to the importance of social support from friends *'Someone to say, come on we're going, where if you're looking out and the weather is bad, you won't, I won't go out anyway, but if she was there I'd drop myself up and go out'* (P38, Female, 69).

The following themes were minor themes that emerged from the focus groups, and relate to barriers and facilitators to adopting good PA behaviours.

Theme 5: User-friendly

This theme was discussed generally in terms of how participants could adapt to the use of technology as a potential tool to PA. Many of the participants primarily recommended that any technology utilised be easy and easy to use

'Keep it basic, don't go fancy with it, simple' (P81, Male, 57).

'Is it easy to use? That's all I want to know' (P87, Female, 74),

'...simplified app that works kind of, all the time' (P13, Female, 53).

Clarity was also mentioned in this context, *'I think, I think if I had it, if I had it and it was clear and made sense I would use it.'* (P11, Male, 42).

Theme 6: Weather

This particular theme that emerged from the data analysis offers insight into a significant barrier for a lot of participants that took part in the focus groups.

'The weather, I suppose, you could mention the weather as well, when you get home and it's dark you don't necessarily want to go out for a walk' (P01, Male, 34),

'I find that if you've nobody with you, you're not inclined to, unless the weather is good, then I'd get out and walk' (P38, Female, 69).

When responding to the question exploring potential barriers to exercise, one participant said *'maybe the bad weather, weather, you know maybe the pouring rain or something like that' (P19, Female, 65).*

Weather also had the opposite effect for a number of participants, as opposed to it acting as a barrier to exercise, it acted as a motivator. When asked to detail motivation for exercise, these participants replied

'Weather, ye the weather, if the weather is good you can get out and go walking ye, that's the main motivation for me.' (P60, Female, 68)

'If it's nice it gives you the motivation to get out and you say awh that's great I'd love to go for a walk, or get out and do your garden, you know all these things, it is, it's the weather' (P87, Female, 74)

6.4.3.5 Application of findings to intervention design

Below is a table of features (Table 6.4) mentioned by participants in this study that were considered for inclusion in the design of the final study in this thesis, Study 3, a feasibility study investigating the effectiveness of a PA eHealth intervention in cancer survivors..

Table 6.4 Key design features of eHealth based PA intervention

Key design features eHealth intervention
<ul style="list-style-type: none">• Personalised instruction to upskill technical literacy• Integrated education about PA• Integrated goal setting• Tailored programme – individually prescribed• Blended programme including technology and human interaction/personalized professional guidance throughout programme• Supervision for initial session

- Feedback on behaviour
 - User-friendly
-

6.5 Discussion

eHealth-based PA interventions are an emerging type of intervention for cancer survivors. While receptivity to the concept of an eHealth-based intervention was positive, this study indicated that participants need education about the role of PA, technological up-skilling to enable engagement with this medium and some face-to-face interaction with a health professional in tandem with an eHealth program. The major themes from this study will be each discussed below, concluding with a brief discussion on the importance of conducting research which invites patient perspectives in the development of a future intervention.

Education and support needs

It was clear that adequate training, education and support in both using technology, and adopting good PA behaviours, was an important factor for participants. The paucity of knowledge regarding optimal and recommended weekly PA amongst participants was highlighted in these focus groups, with numerous participants indicating a lack of information on exercise and PA provided to them after their cancer diagnosis.

'Well I, it was never emphasised to me the importance of exercise either while on the treatment'
(P69)

This finding aligns with the low levels of PA prevalent among cancer survivors reported in current literature (Broderick et al., 2014b, Courneya et al., 2008, Smith and Chagpar, 2010). Certainly, the emergence of this lack of knowledge among cancer survivors from these focus groups could be regarded as one of the many potential reasons for the insufficient levels of PA

in this cohort. Interestingly, the previous study detailed in Chapter 3 in this thesis, highlighted this lack of knowledge, with only 17.6% (n=18) of participants correctly identifying the recommended PA guidelines, as defined by the American Cancer Society (Rock et al., 2012). Overall, Study 1 and Study 2 in this thesis show poor health literacy in cancer survivors regarding recommended PA levels after cancer. Creating an opportunity for health professionals to bring up the topic of PA and revisit it is needed. Exercises preferences were not explored in this study but it was implicitly stated throughout that walking was the most preferable form of exercise which mirrors similar research in cancer survivors (Roberts et al., 2019). Building strength and flexibility in cancer survivors is also valuable (Schmitz et al., 2010) and it would be important to incorporate other modes of exercise in an eHealth based PA programme.

The subtheme of guidance on exercise was a logical topic to emerge following the admission of lack of knowledge from participants. The majority of participants reported that they felt it was important that, in any attempt to improve their PA behaviour, guidance and support from someone would be available. This was elaborated on further by some participants, with professional healthcare input referred to when discussing support for PA. Typically the cornerstone of most PA interventions in healthcare is the facilitation of behaviour change through professional support.

Goal setting

The identification of goal setting as a major theme, which participants regarded as a motivation, could serve as a complement to the professional support mentioned above, and improve the effectiveness of any intervention that utilises both. Goal setting has also previously been identified in a focus group study of cancer survivors as important in helping promote increased PA levels (Boland et al., 2018b) and is underpinned by a well-recognized theoretical framework (Michie, 2016). Indeed, the effectiveness of goal setting as a feature of behavioural change interventions was examined in a systematic review (Huisman-de Waal et al., 2010), which

reported that over 40% of behavioural change interventions that used goal-setting techniques reported significant positive results. In summary, the results achieved by Study 2, coupled with the additional evidence detailed above, indicate that cancer survivors value the importance of goal setting when trying to change their PA behaviour, and is thus an important feature of a PA intervention in this population.

Health impact

Health presented as both a barrier and a facilitator to exercise in this group of cancer survivors. One particular side effect of treatment that participants discussed as limiting their involvement in exercise and PA was tiredness or fatigue. Fatigue, as a result of cancer treatment, can be defined as a 'persistent, subjective sense of tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning' (Mock, 2007). The appearance of fatigue in this cohort was not surprising, with a survey conducted in 2008 reporting that from a sample of 1569 patients with cancer, 80% of these participants reported suffering from cancer –related fatigue (Henry et al., 2008). The results from this focus group showed that for this sample of patients, not only was fatigue present, but more importantly it was affecting the degree to which these participants engaged in good PA and exercise behaviours. The emergence of this phenomenon under the theme of health highlighted the role of fatigue in acting as a barrier to these patients.

Technological literacy

Among the objectives of this study was to establish barriers and facilitators to using mobile technology for PA promotion cancer survivors. Throughout this focus group there were a number of subthemes that emerged regarding mobile technology that are discussed below. One of these was the clear emergence of the opinion that for technology to be adopted by this cohort, education and training prior to its utilisation was necessary. Several participants identified a technological training need to up-skill sufficiently to enable engagement with an

eHealth-based intervention due to low confidence in their computer literacy. It is interesting also to note that a number of participants referenced this education taking the form of face to face training, indicating the value that participants placed on their patient-health care provider relationship. The value of a trusted patient-healthcare provider relationship was also highlighted in two separate studies which evaluated perspectives of eHealth interventions in cancer survivors (Roberts et al., 2019) and in patients with rheumatoid arthritis (Mathijssen et al., 2018). It would appear from these results that a fully automated eHealth program may not be attractive to potential users. Instead, a blended program with personalized and formalized face-to-face human interaction integrated with eHealth may be optimal.

These considerations were important in the goal to design an effective PA intervention using technology in this population. The expression of sentiments from the participants in this study that advocated for the personalisation, feedback and the provision of PA prescription was insightful, and interestingly aligns closely with the capabilities and potential of technology. The suggested benefits of using technology in healthcare includes the ease of updating information and ability to provide personalized feedback (Griffiths et al., 2006a). These characteristics provide the opportunity and means for healthcare professionals to deliver the components that are mentioned by the participants in these focus groups, namely personalisation and feedback.

Implication of results for development of Study 3

This study describes the process and results of exploring perceptions to using mobile technology for PA promotion in cancer survivors. One of the objectives of this study was to ensure that the features that would be included in the final intervention (Study 3) were based on patient perspectives. This focus group study elucidated and explored these features, providing the research team with intervention elements that could be incorporated in a technological intervention for improving PA in patients with cancer (Table 6.4). These features included personalised technological instruction, integrated PA education, goal setting, specific PA

prescription and feedback on behaviour. While the systematic review that was detailed in Chapter 1 highlighted the evidence-based components of an effective PA intervention currently described in the literature, the following two studies (Study 1 and Study 2), presented potential components of an effective intervention from the perspective of the people who would be taking part in the intervention, cancer survivors. Furthermore, as previously mentioned in Chapter 2 (Section 2.4), following the results of this focus group, and in particular the potential intervention features recommended by participants (Table 6.4), the focus on what type of eHealth modality to use in Study 3 was directed towards wearable technology. It was found that participant perspectives regarding the optimal eHealth PA intervention would be better aligned with the capabilities of wearable activity trackers. Qualitative research can often be difficult to generalise to a larger population, however results can be grounded in the context of other research in the area (Anderson, 2010). The collated recommendations detailed in Table 6.4 were considered in the context of the other preparatory research conducted in this thesis, including the systematic review and questionnaire study in order to direct the content of our final feasibility study.

Patient perspectives

Incorporating the perspective of patients in designing a behavioural change intervention aligns with the ethos of patient-centred care, which refers to an individualized and holistic approach to treatment, including the patient as an empowered and active part of their own treatment strategy (Leplege et al., 2007). Patient-centred care describes the process of including the patient in clinical decisions, and ensuring an alliance between healthcare professional and patient is present when designing treatment and self-management plans (Thompson and McCabe, 2012). This can be summarised by the main objective of patient-centred care, which is

to achieve a working partnership between patients and families in relation to the delivery of health care services (Delaney, 2018). Incorporating the principles of patient-centred care provides numerous benefits (Delaney, 2018), however possibly the most important of these benefits, particularly in the context of this thesis, is the improvement in patient adherence. This was detailed in a systematic review which examined the effect of patient-centred care on the adherence of patients to a mental health treatment plan (Thompson and McCabe, 2012). The results indicated an association between patient-centred care and more favourable patient adherence.

It is clear then, how important it was to ensure that patient-centred care was incorporated into the development of the intervention described in this thesis (Study 3). This focus group was a significant factor in making sure that this occurred. The results from the focus group above demonstrated the variety and depth of information that cancer survivors provided with regard to incorporating technology in a PA intervention.

6.5.1 Strengths and limitations

A number of strengths pertained to this study. Participants were not biased by a pre-determined program. This study involved gaining end users needs and preferences to co-design the technological aspects of the intervention described in Chapter 5 (Greenhalgh, 2018), and this knowledge can now also be applied to the design of future interventions. This study provided valuable information on acceptability of the intervention in principal as well as components, perceived value and benefits of the intervention (O'Cathain et al., 2013). Employing focus groups also allowed the ability to drill down and generated a depth of information not found in the preceding cross-sectional questionnaire (Chapter 3). There was a small number of participants in each focus group which was less intimidating (Saywell and Taylor, 2015) and encouraged interaction. Participants were diverse in terms of age and cancer diagnoses.

Future qualitative work should include other stakeholder perspectives as well as evaluation of user experience after completion of the eHealth interventions. There was a notable absence of issues relating to privacy and data security in the focus groups. Other behavioral change techniques such as prompts/cues to exercise as well as incentives/rewards and gamification were not raised by participants, but response to these behavioral change techniques may be mixed (Roberts et al., 2019). Future studies should nonetheless explore these pertinent topics.

Resource constraints meant the research could be conducted in only one centre in Dublin, Ireland, although a geographical spread of participants was noted, with 26% (n=6) of participants rural dwelling. Despite this, findings may be contextually and culturally aligned to this setting. The generalizability of results to other settings is not known, although we have no evidence to suggest perspectives of this cohort are at odds with other locations. Naturally 'one size does not fit all' in a heterogeneous disease such as cancer, and it is likely that design of an eHealth PA intervention in cancer survivors should be nuanced with a need for different considerations such as increased supervision for people with advanced/metastatic diseases and those with a range of co-morbidities. Ideally a suite of exercise and PA options should be available to cancer survivors, of which eHealth appears to be an acceptable option.

The interview guide for the focus group was not piloted prior to the first focus group, presenting a potential limitation of this study. Piloting interview questions can be useful to address practical issues that may arise in using the questions (van Teijlingen and Hundley, 2002). Consequently, the absence of a pilot of the interview guide in this study may have taken away the opportunity to adjust and tailor the interview guide prior to data collection.

A further limitation of this study was the low number of participants in a number of the focus groups, with 6 focus groups having a total of 3 participants, a result of a number of participants being unavailable for participation on the day of the group. Reasons for this included inclement weather and being unwell on the day of the focus group. Ideally, focus groups should aim to

have between 6-8 participants (Krueger and Casey, 2000). It is also recommended that each focus group should be over-recruited (Rabiee, 2004), which may combat drop-off of participants, a pertinent consideration for future research using focus group study design. Potential limitations to the lower number of participants in the groups would be the reduced ability to gain a variety of perspectives within the focus group. Despite this, data saturation was achieved in these focus groups, when no further codes or themes were drawn from the data after the 7th focus group.

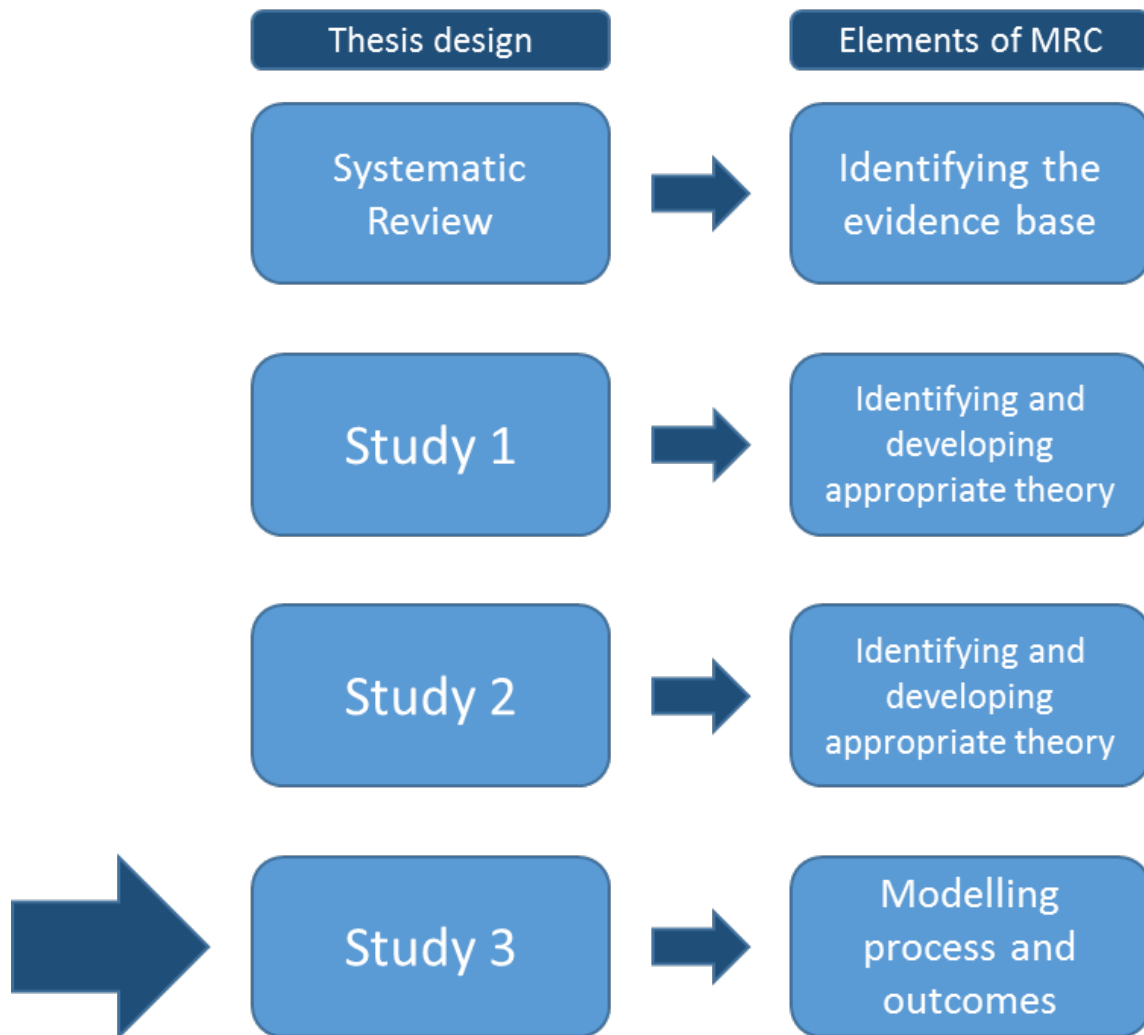
6.6 Conclusion

Given recent advancements which offer more technologically enhanced PA programmes, this type of research is warranted to tailor design features and optimise their acceptability to cancer survivors. Even though some participants reported low levels of technological literacy it would appear that an eHealth enabled PA intervention would be acceptable to cancer survivors. Clear findings were that eHealth should work in tandem with traditional delivery methods but not fully replace them.

Additionally, the results from this study provide an insight into features of technology that cancer survivors find most important, and the potential methods of implementation in a behavioural change intervention targeting PA promotion. The identification of these themes provided the foundation for the design of the feasibility trial detailed in Chapter 5, and may help design and reconfigure future interventions incorporating this new and exciting medium.

Chapter 7 Study 3-Feasibility study

Figure 7.1 Progression of thesis related to MRC guidelines for developing a complex intervention



7.1 Introduction

The final study in this program of research, which investigated the potential role of eHealth to increase PA in patients with cancer, was a feasibility study, called the 'IMPETUS' trial [Improving Physical Activity and Exercise with Technology Use in Survivors (of Cancer)].

The development of this study was heavily influenced by the preceding studies presented in this thesis. The systematic review that was conducted (Haberlin et al., 2018) in Chapter 1 identified a number of eHealth-based PA interventions for patients with cancer, and highlighted the potential efficacy of this modality in promoting PA. This was followed up by two further studies, a questionnaire-based study and a focus group study, which provided both insight into the status of technology in the lives of cancer survivors, and perspectives of cancer survivors regarding the optimal PA intervention incorporating eHealth.

These particular studies culminated in the feasibility study described below. An eHealth intervention was designed, harnessing Fitbit technology, to promote improved PA behaviours in people with cancer. This study was devised to investigate the feasibility and preliminary efficacy of the intervention, relating to various outcome measures described below. The lead investigator (CH) was responsible for recruitment, assessment at all time-points, calling participants throughout the intervention and support for any issues participants had during the intervention. A research assistant (SK), fully trained and initialised to the study procedures assisted with data collection, although the main proportion of all duties was carried out by the lead investigator.

The protocol for this study has been published in BMJ open (Appendix 14)

HABERLIN, C., O'DWYER, T., MOCKLER, D., MORAN, J., O'DONNELL, D. M. & BRODERICK, J. 2018. The use of eHealth to promote physical activity in cancer survivors: a systematic review. Supportive Care Cancer.

This study combined both remote personal healthcare professional input and Fitbit technology in an intervention designed to improve PA in cancer survivors. The study's overall aim was to explore the initial feasibility of that intervention, which would ultimately provide data required to design a definitive future RCT. It was hypothesized that this blended approach to the promotion of PA would result in improved PA behaviors in patients with cancer.

The objectives of this study were;

- To investigate the acceptability to participants of a remotely delivered, individualised PA intervention utilising Fitbit technology.
- To provide information needed to design a full-scale RCT including a) number of participants recruited and drop-out rates, b) suitability of data collection procedures, c) compliance of participants, d) resource availability and e) participant response to the intervention.
- To assess the preliminary efficacy of this intervention to increase PA, quality of life and aerobic capacity and to improve body composition.

7.2 Methods and measures

7.2.1 Study Design

This study adopted a single arm longitudinal pre-post test design, and was principally a feasibility study. This design was reflected in the primary outcome measures for this study, which were feasibility in nature. Further outcome measures, which investigated the efficacy of the study, were regarded as secondary outcome measures. These are detailed below. Measurements for these outcomes were performed at three separate time points, T1 (Baseline), T2(12 weeks post baseline), T3(12 weeks post intervention end).

7.2.2 Ethical approval

Ethical approval for this trial was granted by the St. James's Hospital/AMNCH joint ethics committee (Reference number: 2016/05/02). Amendment to the ethics application, of which the approvals are detailed in Appendix 9, included minor refinement to the phone call schedule of the intervention and minor alterations to the language used in the patient information leaflet.

Written, informed consent was obtained from each participant prior to taking part in the study. Additionally, all participants required agreement from their treating oncology clinician to take part. This study was registered as a clinical trial on clinicaltrials.gov (NCT03036436).

7.2.3 Sampling and recruitment

Participants were identified and recruited from cancer clinics in St. James's Hospital (Dublin, Ireland), a major teaching hospital and the National Bone Marrow Transplant Centre. Clinics included the oncology day ward, haematology day ward, and follow up outpatient services, from where a heterogeneous sample of participants was recruited.

Oncology clinicians were provided with the eligibility criteria for study participation prior to each outpatient clinic, which they used to review their patient list and identify suitable candidates for participation. Inclusion criteria and exclusion criteria are detailed in Table 7.1 below.

Table 7.1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ol style="list-style-type: none">1. Agreement of the participant's treating clinician that he/she can participate, including medical clearance to exercise and interest in taking part.2. Aged ≥ 18 years.3. Completed chemotherapy or radiotherapy with curative intent within	<ol style="list-style-type: none">1. Diagnosis of prostate cancer or upper gastro-intestinal cancer (to avoid cross-contamination between simultaneously ongoing exercise studies in the study site).2. Chronic medical and orthopaedic conditions that precluded exercise (e.g

<p>the preceding 3 years. Participants may have had chemotherapy or radiotherapy as the sole treatment for cancer, with adjunctive surgery, but not surgery alone. Participants who were still on adjuvant hormone therapy and/or adjuvant Her2-directed therapy were also eligible (with physician agreement as above).</p> <ol style="list-style-type: none"> 4. Ability to understand English. 5. Owns or had access to a device which is compatible with the Fitbit app i.e. smartphone, tablet or computer. 	<p>uncontrolled congestive heart failure or angina, myocardial infarction within 6 months, pulmonary embolism within 3 months, breathing difficulties requiring oxygen use or hospitalization or osteoarthritis causing significant mobility impairment).</p> <ol style="list-style-type: none"> 3. Confirmed pregnancy. 4. Dementia, cognitive impairment or psychiatric illness that would preclude ability to participate in the study. 5. Incomplete haematological recovery after chemotherapy (WCC < 3, Hb < 10 or Platelets < 100). 6. Patients \leq18 years 7. Evidence of active cancer.
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The lead investigator then liaised with the treating oncology clinicians, and approached those potential participants who were deemed eligible for inclusion by the clinician, and had expressed an interest to these clinicians. Only participants that were deemed eligible for inclusion by the oncology clinicians were approached by the lead investigator.

The lead investigator (CH) provided full details of the study to these potential participants, answered any questions that presented and commenced the process of consenting and recruiting these suitable candidates into the study if suitable. This involved providing potential participants with a consent form, participant information leaflet and a verbal explanation of the study. Participants who were willing to take part in the study at that point signed a consent form and were instructed that after a cooling off period of two days the lead investigator would contact them by phone to confirm their involvement, and then post the Actigraph monitor to their home if applicable. Participants were instructed to wear the Actigraph for 7 days.

Potential participants who did not sign the consent form at the first meeting, but indicated that they would consider participation, were given the option to bring the consent form and information leaflet home, and instructed to send the signed or unsigned consent form back to the lead researcher when they had sufficient time to consider the study. Those participants were sent the Actigraph activity monitor (in a padded envelope using the national postal service) once the signed consent form had been received by the researcher, prior to their baseline session.

The difficulties of generating accurate sample size calculation for feasibility studies are well known. For feasibility studies, sample sizes between 24 and 50 have been recommended (Sim and Lewis, 2012). Based on this, it was proposed that a sample size goal of 60 be recruited, which would allow for 20% drop-out.

7.2.4 Outcome measures and testing protocol

Assessments were conducted at three time-points in this study, T1 (Baseline), T2 (12 weeks, +/- 2 weeks) and also T3 (24 weeks, +/- 2 weeks). Assessments took place at the Clinical Research Facility (CRF) in St.James' Hospital, Dublin. Participants were asked to attend St.James' in person for these assessments. At each time point (T1, T2, T3), participants completed the efficacy outcomes listed below. The baseline assessment at T1 also included the introduction and provision of the eHealth component of this study. Below is a graphical representation of the assessment timeline (Figure 7.2).

Figure 7.2 'IMPETUS' study assessment timeline



Study outcomes and their associated measures are listed below, and are described in greater detail in Chapter 2 (Section 2.3) with validity, reliability and background described there also. As this study was primarily a feasibility study, primary outcome measures for this study were feasibility in nature, these are listed below. This evaluation of feasibility was designed and developed to align with recommended outcomes such as acceptability, implementation and practicality (Arain et al., 2010, Bowen et al., 2009). All participants recruited to this study received usual care provided by their treating clinician, which did not include routine exercise or PA advice or physiotherapy input.

7.2.4.1 Feasibility outcomes

Feasibility outcomes were assessed at intervention completion (T3).

- Evaluation of recruitment capability and resulting sample characteristics
- Evaluation and refinement of data collection procedures and outcome measures
- Evaluation of the adherence and compliance of the intervention and study procedures
- Evaluation of the resources and ability to manage and implement the study and intervention
- Preliminary evaluation of participant responses to intervention

7.2.4.2 Efficacy outcomes

Secondary outcomes evaluated preliminary efficacy of the intervention.

- PA: The modified version of the GSLTPAQ (Godin and Shephard, 1985) (Appendix 3) was used to measure self-report PA. The Actigraph GT3X⁺ triaxial accelerometer was used to objectively monitor 7 days of activity at time-points T1, T2 and T3. (Section 2.3.1)

- Quality of life: The FACT-G scale (general) (Cella et al., 1993) and the physical functioning measure of the SF-36 (Ware JE, 1993) were used as two measures of quality of life. (Section 2.3.4)
- Exercise capacity: This was measured using the six minute walk test (6MWT) (ATS, 2002) at T1, T2 and T3. (Section 2.3.2)
- Body Mass Index (BMI): This was measured using a standardised digital scales to measure body weight. Standing height was measured, without shoes, to the nearest millimetre (mm) using a stadiometer. BMI was calculated by dividing weight in kilograms by height in metres squared (kg/m²). (Section 2.3.3.3)
- Body composition: Bioelectrical impedance analysis was conducted using a Seca device. (Section 2.3.3)
- Waist Circumference: This was measured using a non-stretch flexible measuring tape. (Section 2.3.3.2)

7.2.5 Baseline session

Eligible participants attended the baseline session (T1) with the lead investigator (CH), who is a chartered physiotherapist. The content of this baseline session is detailed below.

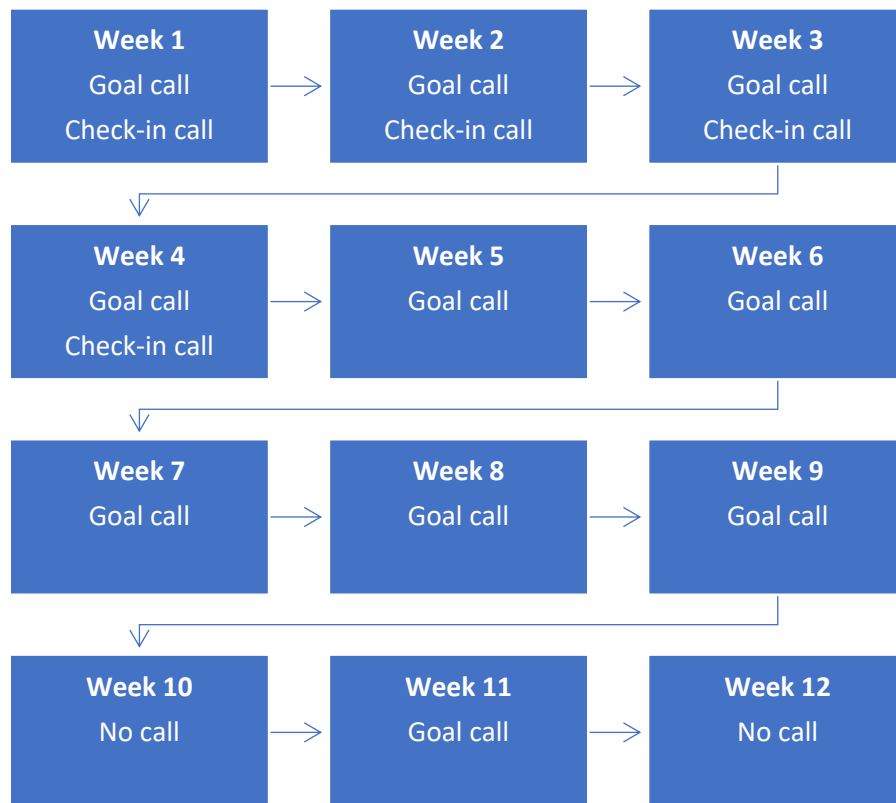
This session consisted of 3 components; baseline study measurements, participant evaluation and setting of appropriate individual PA goals, and education. The lead investigator designed and set appropriate, individualised PA goals for the start of the 12-week intervention using a subjective assessment of the participant's current PA level, as gleaned by the Godin leisure time questionnaire, and a subjective evaluation on interview of the participant's goals and PA preferences. The educational component of this baseline session included advice and information on PA and exercise following cancer treatment. Participants were also introduced to the technological component of the study. Each participant was provided with a Fitbit and

verbal instructions on how to download the paired smartphone application. If a participant was unfamiliar with this type of technology, a family member was also invited to receive the training. Participants were instructed to wear the Fitbit on their waist, bra, pocket or wrist, depending on their preference. They were also instructed to wear the Fitbit at all times during their waking hours, apart from when it was not appropriate, such as when going for a shower.

7.2.6 eHealth intervention

The educational component of the intervention was delivered at the baseline assessment, prior to outcome measurement. This involved a presentation of the benefits of PA in patients with cancer, current PA and exercise guidelines and potential contraindications to exercise. The structure of the study and the intervention was also reiterated. This educational component was delivered by the lead investigator via a Microsoft PowerPoint presentation, and lasted approximately 10 minutes. Following the baseline session, participants were instructed to wear the Fitbit and upload their PA data each week. The lead investigator (CH) and the participant both had shared access to a study-specific Fitbit account, with log-in details shared. This review of the data allowed the physiotherapist to monitor the participant's progress towards their goals, specifically their daily step count and their weekly moderate intensity exercise bouts. Participants each received scheduled calls, the frequency of which were tapered on a phased basis throughout the intervention. Participants received 2 calls each week until week 4, one call a week for the next four weeks and a call once every fortnight in the last 4-week period (Figure 7.3).

Figure 7.3 Phone call schedule



The content of the calls was individualised and designed to support and motivate participants, by introducing specific PA goals. Phone calls in the first four weeks were divided into a ‘Goal’ phone call and a ‘Check-in’ call, as illustrated in Figure 7.3 above. The ‘Goal’ phone call involved the lead investigator discussing the past week of PA with the participant, and providing feedback on their performance. The participant was also invited to provide feedback to the lead investigator regarding their perceived progress. This phone call also provided the participant with their updated PA goal, which was prescribed using FITT (frequency, intensity, type, time) principles. The goals prescribed by the physiotherapist were collaborative in nature, with participants encouraged to provide feedback about their ability to achieve their goals and any changes they would like to these goals moving forward. For this study, with consideration for the cancer population, PA goals were individually prescribed by the lead investigator using the American Cancer Society (ACS) guidelines (Rock et al., 2012). Goals for this study included daily step goals and also weekly moderate intensity exercise goals, and were tailored to each

participant. An example of a weekly goal for a patient would be, “8,000 daily steps, 3 days of 15 mins moderate intensity walking”. Goals would then be progressed as deemed appropriate by the physiotherapist.

The delivery of the goal phone call by the physiotherapist was underpinned by key elements of motivational interviewing, of which the lead investigator had previous training. Motivational interviewing is an approach to behavioural change which is patient-centred, collaborative and focuses on the promotion of autonomy in an individual to enable them to evoke their own change (Shingleton and Palfai, 2016).

The ‘Check-in’ phone calls were designed as a means to provide advice and a reminder on uploading Fitbit data. Ongoing technological support regarding the Fitbit was also provided to participants in phone calls if required. Content for the phone call was summarised in Figure 7.4 below. If participants informed the study team that they would be uncontactable by telephone e.g. abroad, for some of these scheduled phone calls, we requested permission from the participants to contact them during those times via a secure messaging service, to allow for an uninterrupted schedule of reminders. If a participant was unwilling to complete the intervention, and requested to be discontinued, the lead researcher terminated the intervention for this particular participant.

Figure 7.4 Content for phone calls

Goal Phone Call	Check-in Phone Call
<ul style="list-style-type: none">•Physiotherapist providing feedback on participant's past week of PA.•Participant given opportunity to feedback on their progress.•Goal update provided by physiotherapist-Step goal and activity goal (FITT).	<ul style="list-style-type: none">•Physiotherapist providing reminder on uploading activity data and synchronising Fitbit.•Physiotherapist providing technological support if required.•Participants given opportunity to raise any difficulties with technology.

This study used the commercially available Fitbit wearable technology with its paired smartphone application. The two components worked in tandem to measure PA and to motivate participants to become more physically active. The 'Fitbit One' and the 'Fitbit Flex 2' were chosen, with both containing a three-dimensional accelerometer which can track daily activity including steps taken, distance travelled and active minutes. Details regarding each device are provided in Chapter 2 (Section 2.4). Goal-setting is also an important feature of this device, as the paired smartphone application allows participants to view their progress, record their workouts and log food intake. It also wirelessly uploads data to a website that provides graphical visualizations of daily activity patterns for participants to view. Participants were instructed to use the Fitbit and its paired application for the 12 weeks of the intervention. They were instructed to return the Fitbit at 12 weeks post baseline.

7.2.7 Statistical approach

Baseline characteristics and adherence were expressed using descriptive statistics, using mean (95% confidence interval) for parametric data, median (Inter-quartile range) for non-parametric data and number (%) for categorical data. Feasibility outcomes were assessed using descriptive

statistics where appropriate. Data was analysed at the T1, T2 and T3 time-points. Only within-subject changes were considered as there was no control group.

Data was tested for normality using the Shapiro-Wilk normality test and Q-Q plots. Homogeneity of variance was tested using Mauchly's Test of Sphericity. Friedman's test was used to compare non-normally distributed data, and one-way ANOVA (analysis of variance) repeated measures parametric tests were used to compare normally distributed data at each time point with Bonferroni *post hoc* tests. A complete case analysis was carried out because of the feasibility focus of the study. Statistical Package for the Social Sciences Version 22 (IBM Corp., Armonk, NY, USA) was used for all analysis and the significance level was set at 0.05.

7.2.8 Participant withdrawal from study and/or from follow-up

Non-retention rate, when participants withdrew consent or were lost to follow up so outcome data could not be obtained, was recorded. If participants were happy to give a reason for their withdrawal from the study, this was documented. Non-adherence, when participants deviated from the intervention but provided follow-up assessment was also recorded, as were adverse events that occurred throughout the intervention.

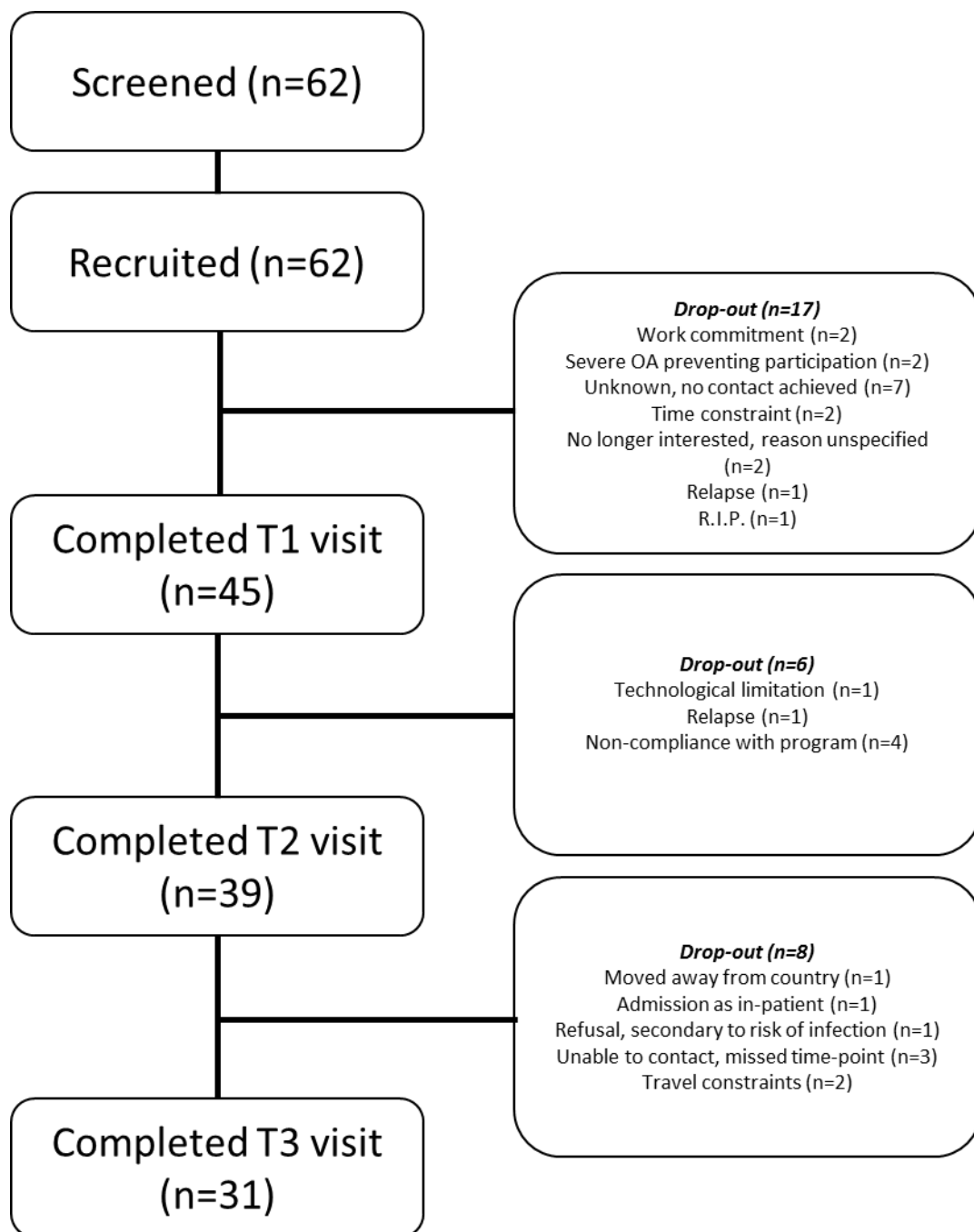
7.3 Results

7.3.1 Participant characteristics

In total, 62 participants were recruited to the study. The start date for this study was January 2017, with the final participant concluding the study in March 2019. Descriptive characteristics for participants who commenced the study are detailed below in Table 7.2. A flow chart of study recruitment and compliance is detailed below in Figure 7.5, with detailed reasons for drop-out at each stage of the intervention period also illustrated. Overall, drop outs throughout the study could be grouped into the following categories; declined (n=9), withdrawal by research team

(n=8) and lost to follow-up (n=14). At the outset of the trial, a recruitment goal of 60 participants was set, which included a consideration for a 20% drop out rate. A drop-out rate of 20% for a sample of 60 would mean that 48 participants commenced the program, therefore the final recruitment and drop-out rate in this study (62 recruited, 45 commenced) was close to the expected level.

Figure 7.5 Flow diagram of participants through the IMPETUS Trial



1 participant (n=1) was recruited to the study within 3 years of their last treatment, as per the eligibility criteria, however by the time she had commenced the study it was 6 weeks past the 3 year cut-off. Refer to Section 7.3.4 below.

Table 7.2 Participant characteristics (n=45)

	Overall (n=45)
Sex n(%)	
Male	10 (22%)
Female	35 (78%)
Age (years)	
Mean (SD)	50.7 (11.8)
BMI (kg/m²)	
Mean (SD)	27.1 (5.3)
Range	18-41
Cancer Type n(%)	
Haematological	16 (35%)
Breast	9 (20%)
Gynaecological	12 (27%)
Colorectal	7 (16%)
Testicular	1 (2%)
Treatment n(%)	
Chemotherapy and radiation therapy	10 (22%)
Chemotherapy only	34 (76%)
Radiation therapy only	1 (2%)
Hormonal therapy ^a	6 (13%)
Herceptin ^b	7 (16%)
Chemotherapy regimen n(%)	
Allogeneic BMT conditioning	14 (32%)
Paclitaxel/Carboplatin	11 (25%)
AC-Paclitaxel	8 (19%)
FOLFOX	7 (16%)
Methotrexate	1 (2%)
Bleomycin, etoposide, and cisplatin	1 (2%)
High-dose chemotherapy with autologous stem cell rescue	1 (2%)
ABVD x3, AVD x 3	1 (2%)
Time since diagnosis (years) n (%)	
<1	4 (9%)
1-2	25 (56%)
>2	16 (35%)
Marriage Status n (%)	
Married	33 (73%)
Unmarried	10 (22%)
Unknown	2 (5%)

^aParticipants on hormonal therapy during intervention, ^b 5 participants were receiving Herceptin at commencement of intervention (n=5).

Abbreviations: BMT (Bone marrow transplant); AC-Paclitaxel (Adriamycin, Cyclophosphamide, Paclitaxel); FOLFOX (Folinic acid, Fluorouracil, Oxaliplatin); ABVD (Adriamycin, Bleomycin, Vinblastine, Dacarbazine); AVD (Doxorubicin, Vinblastine, Dacarbazine)

7.3.2 Adverse events

No adverse events occurred during either the assessments or throughout the intervention period.

7.3.3 Data normality

Data was normally distributed at all three points (T1, T2, T3) for the measures of BMI, waist circumference and 6MWT.

Data for the FACT-G quality of life questionnaire was normally distributed at T1 and T3, but was not normally distributed at T2. Data for the Godin PA self-report questionnaire was not normally distributed at all 3 time points, as was data for body fat percentage. This was mirrored by data for the SF-36 quality of life scale which was not normally distributed at all three time points.

The total time spent in various states of activity was also measured using the Actigraph, including time spent sedentary and in MVPA (Moderate-Vigorous Physical activity). Complete data for participants who completed and returned the Actigraph at all three-points was normally distributed at T1 for time spent sedentary, but not normally distributed for at T2 and T3. Data for time spent in MVPA was not normally distributed at all three time-points.

Data for mean daily steps, as recorded by the Fitbit, at week 1, week 6 and week 12 of the intervention was also not normally distributed. Appropriate statistical tests were conducted on each outcome depending on data normality (Section 5.2.6).

7.3.4 Feasibility outcomes

Evaluation of recruitment capability and resulting sample characteristics: In total, 62 participants were recruited from outpatient clinics in St. James's Hospital. A variety of cancer types were represented in this study, with patients with haematological cancers representing 37% (n=23) of all participants recruited. Patients with breast cancer represented 18% (n=11) of the sample recruited, while patients with gynaecological cancer made up 23% (n=14) of the sample. The mean age (standard deviation) of the participants who commenced this feasibility trial was 50.7 (11.80) years, with an age range of 20-71 years. As detailed in Figure 7.5, 1 participant (n=1) was recruited to the study within 3 years of their last chemotherapy treatment, as per the eligibility criteria, however by the time she had commenced the study it was 6 weeks past the 3 year cut-off. Due to the pragmatic nature of this feasibility trial, a decision was taken to include this participant in this analysis.

Evaluation and refinement of data collection procedures and outcome measures: Duration of outcome measure testing at each time point (T1, T2, and T3) was approximately 45 minutes. Each assessment was scheduled flexibly during the working day. At the baseline session, only one participant (n=1) opted to invite a family member to attend for support with the Fitbit technology.

Evaluation of the adherence and compliance of the intervention and study procedures: There was a 69% (n=31) compliance rate for all three testing time points (T1, T2, T3) among the 45 participants who completed evaluation at T1. There was an 87% (n=39) compliance rate for attending T1 and T2 among those same 45 participants. Mean adherence to the phone call schedule among the participants was 89.7% (n=44). Over 86% (n=38) of participants who commenced the study complied with $\geq 70\%$ of all phone calls. Phone calls were <10 minutes in length. In total, 36 participants synchronised and recorded Fitbit data spanning the entire intervention. Mean daily wear and synchronisation compliance for these participants was high at 92.6%.

Variance in the model of Fitbit used was related to particular hardware issues associated with the Fitbit One which presented during this trial. This study was commenced with the Fitbit One device being the exclusive wearable option for participants. However, issues with the clip-on function of the Fitbit One, which enabled it to be worn on a belt or bra, caused a number of participants to lose the Fitbit. In total, 4 participants lost the Fitbit provided to them, with all reasons related to the security of the clip-on function of the Fitbit One device. It was decided following this, that an alternative model of Fitbit would be provided to participants, with the Fitbit Flex 2 chosen for its enhanced security as a device that could be worn on the wrist. Following this adaptation to the model of Fitbit device provided to participants, no further loss of the device occurred.

Preliminary evaluation of participant responses to intervention: The patient satisfaction questionnaire used in this study was not pilot tested, which may present as a limitation, however a template from previous research in our research centre was utilised to develop the questionnaire. Additionally, considering the novel nature of the intervention, questions chosen were designed to be specific to the goals of the intervention, particularly in relation to the eHealth component of the intervention. An analysis of the patient satisfaction questionnaire was performed. Answers to open questions included in this questionnaire were analysed by grouping similar answers and quotes into themes, detailed below. In total 36 participants completed the patient satisfaction questionnaire, representing 92% of all participants that attended for T2 assessment.

Q1: I found this intervention helpful in improving my physical activity:

Possible answer: *strongly agree* *agree* *neither agree nor disagree* *disagree* *strongly disagree*

In total, 75% (n=27) of participants answered 'strongly agree' to this question. Eight participants (n=8) answered 'agree', while the remaining participants answered 'strongly disagree' (n=1).

Q2: Were there any aspects of this programme which you enjoyed?

Responses from participants were grouped into 7 themes as detailed in Table 7.3 below.

Examples themes and their corresponding participant quotes are described below also.

Table 7.3 Question 2: Patient satisfaction questionnaire themes

<i>Themes</i>	<i>Quotes</i>
<i>Goals and achievements</i>	<ul style="list-style-type: none"> • “reaching goals gave me a sense of achievement.” • “setting goals made me more aware and wanting to increase activity” • “achievement factor” • “I enjoyed the challenge of increasing my steps and activity”
<i>Motivation via Fitbit</i>	<ul style="list-style-type: none"> • “I enjoyed the motivation having the fitbit encouraged” • “the fitbit - definitely encouraged me to move more” • “and the push the fitbit gave me to get out and walk” • “fitbit gameification” • “Initially the fitbit and the app were great for motivating me to get out and try to achieve daily steps goal.”
<i>Improvement of fitness</i>	<ul style="list-style-type: none"> • “getting fitter” • “I enjoyed the exercise programme and having the help to increase my fitness”
<i>Creating good habits</i>	<ul style="list-style-type: none"> • “creating new habits- making me think how far I've come since being sick” • “yes I never believed that I could go for a walk every day”
<i>Monitoring</i>	<ul style="list-style-type: none"> • “Liked being able to track my steps and see how I was doing” • “yes, it gave a really good insight into my level of activity and how often I was active on a daily basis”

	<ul style="list-style-type: none"> • "I found it interesting to monitor my daily steps and exercise and sleep patterns on the fitbit." • "enjoyed seeing how many steps I was doing" • "achievement factor, monitoring progress, feel good factor"
<i>Support and feedback</i>	<ul style="list-style-type: none"> • "the contact with Ciarán keeping me on track and the push the fitbit gave me to get out and walk" • "Yes, good to get phone support each week to create a goal!" • "the motivational phone calls- they gave me a reason to make sure I got up and moved" • "I liked the phone calls because it kept me on my toes" • "Getting feedback was great, it reinforced my exercise programme" • "Talking to Ciarán and Sinéad and getting positive feedback also good."
<i>Development of PA knowledge</i>	<ul style="list-style-type: none"> • "yes, it gave a really good insight into my level of activity and how often I was active on a daily basis"

Q3: Were there any aspects of this programme which you did not enjoy?

The majority of participants (n=26, 72%) responded that they had no aspects of the programme that they did not enjoy. The remainder of responses are detailed below, with failure to achieve goals, practical issues with Fitbit and guilt associated with low PA among the aspects that participants did not enjoy.

Table 7.4 Question 3: Patient satisfaction questionnaire themes

Responses to Q3
" not reaching goals was sometimes disappointing, however this was very rare"
" not really. Wearing actigraph can be a pain, hard to hide it"
" Trying to mind the fitbit!"

“ taking off fitbit while swimming”

“ yes, wet weather”

“ Not reaching my goals”

“ original get out but once I was out I enjoyed been out”

“ the guilt on myself for not making myself get up and walk”

“ remembering to recharge battery or keeping an eye on charge level”

“ feeling guilty when CH phoned (not really)”

Q4: Did any aspects of this programme help you increase your physical activity level?

Yes/No

In total, 94% (n=34) of participants responded ‘Yes’. One participant left this question blank, with one participant responding “no but it helped regularise it”.

Q5: If yes-please specify what aspects in particular helped you increase your physical activity level

Themes for the responses to this question are described below in Table 7.5.

Table 7.5 Question 5: Patient satisfaction questionnaire themes

<i>Themes</i>	<i>Quotes</i>
<i>Fitbit use</i>	<ul style="list-style-type: none"> • “The fitbit reminds you of goals everyday which helped me walking.” • “I think that the fitbit and the motivational phone calls worked to increase my activity” • “using the fitbit”

	<ul style="list-style-type: none"> • The notification on the fitbit if you hadn't moved in an hour...was good motivation" • "using the fitbit gradually increasing steps and activity" • "the fitbit feedback" • "Checking Fitbit app"
<i>Goals</i>	<ul style="list-style-type: none"> • "the goals set by Ciarán and his phone call keeping me on track." • "setting goals" • "daily goals and knowledge of what exact activity I was doing" • " hitting targets" • "just the fact that you had something to record your activity and satisfaction achieving goals" • "Being given the target each week. This gave motivation to get up and exercise. Having a goal - had a target amount of exercise per week and step target per day" • 'trying to hit step goal"
<i>Benefits of regular PA</i>	<ul style="list-style-type: none"> • "I am much more motivated now and I can definitely feel the benefits of extra regular exercise" • " I feel fitter" • "walking better" • "being conscious of needing to walk and do moderate levels of exercise regularly"
<i>Support</i>	<ul style="list-style-type: none"> • "the goals set by Ciarán and his phone call keeping me on track" • "encouragement" • "as above having to wear fitbit and know that a phone call every wk" • "... phone calls from Ciarán was good motivation if I had been slacking a little" • " Calls from physios" • " support from physio (phonecall)"
<i>Monitoring of PA</i>	<ul style="list-style-type: none"> • " Being monitored helped motivate me"

	<ul style="list-style-type: none"> • “Being able to see if I needed to go for a walk and trying to get the right amount of walks in per week” • “ knowledge of what exact activity I was doing” • “ just the fact that you had something to record your activity” • “ Seeing the steps counted is really useful and helps to set goals for my activity” • “ having the fitbit and knowing that my activity would be monitored many times motivated me to wak home from work or get out of the house when I might not have bothered”
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Q6: How did you find using the Fitbit device and application?

Participants generally responded that using the Fitbit and its application was easy, with the majority of participants 89% (n=32) reporting that using the Fitbit was a positive experience. A selection of quotes are included below, and are segregated between positive and negative experiences. In total, only two participants reported any issues using the Fitbit, these are detailed below.

Table 7.6 Question 6: Patient satisfaction questionnaire themes

Experience	Quotes
<i>Positive experience</i>	<ul style="list-style-type: none"> • “very easy. I could clip it on my belt and forget about it for the day” • “great for measuring my activities, I was able to check my goals to see if I met them on my phone” • “Great. It kept me on track and made me feel good when I did well and bad when I didn’t” • “very easy”
<i>Negative experience</i>	<ul style="list-style-type: none"> • “easy to use but the clip was awkward for catching in straps/clothes. Lost fitbit while out walking. Popped off my tracksuit”

	<ul style="list-style-type: none"> • “Fell off easily”
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Q7: What was the most useful part of using the technology?

In general, responses to what the most useful part of using the Fitbit technology concerned the ability to monitor PA, the step counter function and the ability to track PA goals. A selection of responses and the themes identifies within these is described below.

Table 7.7 Question 7: Patient satisfaction questionnaire themes

Themes	Quotes
<i>Tracking PA</i>	<ul style="list-style-type: none"> • “being able to check if I met my goals. Keeping me focused” • “it is motivating to see what you have walked in a day and encourages you to increase” • “ Be able to track my progress” • “ being able to see how close you were to the target” • “keeping a record of activity over the week” • “ the monitoring/timing of exercise sessions and sleep patterns” • “monitoring the extent of my exercises” • “ easy to track activity while using it, motivational!”
<i>Step Counter</i>	<ul style="list-style-type: none"> • “ Recording walking/steps etc.” • “ fitbit- monitoring steps” • “ showing the number of steps” • “ Step counter. Encouraged me to try reach a goal” • “ counting steps on a daily basis” • “step count • “seeing my steps improve each day”
<i>Miscellaneous</i>	<ul style="list-style-type: none"> • “ using the GPS to map your walk/exercise route” • “ couldn't lie to myself about what I was doing”

	<ul style="list-style-type: none"> • “ making me think more about my activity”
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Q8: Did you have any difficulty using the Fitbit or the application?

In total, 77% (n=27) of participants responded to this question (n=35) that they did not have any difficulty using the Fitbit or the application. More detailed responses and issues that presented are listed below.

Table 7.8 Question 8: Patient satisfaction questionnaire themes

Difficulties using Fitbit/Application	<ul style="list-style-type: none"> • “ a little a first but well supported with technical glitches” • “ Not good at recording the walk on my Ipad” • “ fitbit power on phone but battery dead” • “ sometimes forget to track exercise or unable to switch on correctly” • “ not really just one day it didn't sync correctly” • “No. though I was never sure did it measure my steps accurately. I sometimes had the impression it may overcount (compared to pedometer app on my phone) • “ Remembering to charge Fitbit (and wear it)” • “ it took me a while to learn to use the phone app and log activities”
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Q9: Do you have any suggestions as to how this program could be improved?

In total, 34 participants provided an answer to this question. There were 12 participants (35%) who responded with either ‘No’ or a variety of this. Three participants (9%) responded that they would not improve the program at all, and it was fine as it was, “ it’s a very well structured programmed and is very easy to follow. I couldn't improve it”, “no great as it is”, “ no,

programme was perfect for me". The remainder of the suggestions are listed below, with the introduction of dietary input appearing in 4 responses.

Table 7.9 Question 9: Patient satisfaction questionnaire themes

Themes	Quotes
<i>Diet</i>	<ul style="list-style-type: none"> • " maybe to include a dietician and perhaps I could have lost weight as well!!" • "maybe incorporate and look at people's diets" • " Maybe add in a diet programme as well" • " widen research to involved dietician and lymphedema specialist"
<i>Miscellaneous</i>	<ul style="list-style-type: none"> • " adding a training exercise" • "More secure fitbit" • "maybe include heart rate in fitbit" • "A text message with goals for week as well as phone call as I'm a very visual person." • "award a fitbit as a prize to the most improved candidate" • "The fitbit stopped communicating with the phone app. Had to go into "help" to find restart. Maybe explain as start of program" • "possibly some group sessions maybe for people who live alone and wouldn't have the support of someone living with them, may make a walk or phone/msg buddy to keep them going" • " Not sure. There's something around getting people to keep motivating themselves to move." • " to do it for longer than the 12 weeks" • "maybe use fitbit on watch rather than the clip on" • "maybe on receipt of fitbit given a manual to explain different prospects of it"

	<ul style="list-style-type: none"> • “I would suggest incorporating the monitoring of sleep into the study as this data is available on the fitbit and some patients struggle with either disturbed sleep or oversleeping” • “help with muscle strength” • “ extending it to Co. Clare”
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Q10: Any other comments

Responses to this question are listed and detailed in Appendix 10.

7.3.5 Efficacy outcomes

Results for normally distributed variables (Table 7.11) and non-normally distributed variables (Table 7.12) are detailed below.

7.3.5.1 PA results

Self-report PA

Self-report PA was measured using the GSLTPAQ (Godin and Shephard, 1985) (Appendix 3). At baseline, participants reported a median (IQR) score of 28 (25) on the Godin PA questionnaire, increasing at T2 to a median score of 58.0 (40), and reporting a median score of 51.0 (45) at T3. Results, using a non-parametric Friedman’s test, showed that these scores, representing self-report PA, increased significantly over the course of the intervention ($p < 0.0005$). (Table 7.12)

Post hoc analysis with Wilcoxon signed-rank tests was conducted with a Bonferroni correction applied, which resulted in a significance level of $p < 0.017$. Conducting this post hoc test showed that there was a statistically significant increase in PA score between T1 and T2 ($Z = 4.170$, $p < 0.017$), and a statistically significant increase in score between T1 and T3 ($Z = 2.736$, $p = 0.006$). Results showed that there was no significant difference between Godin PA scores at T2 vs. T3 ($Z = 1.059$, $p = 0.289$).

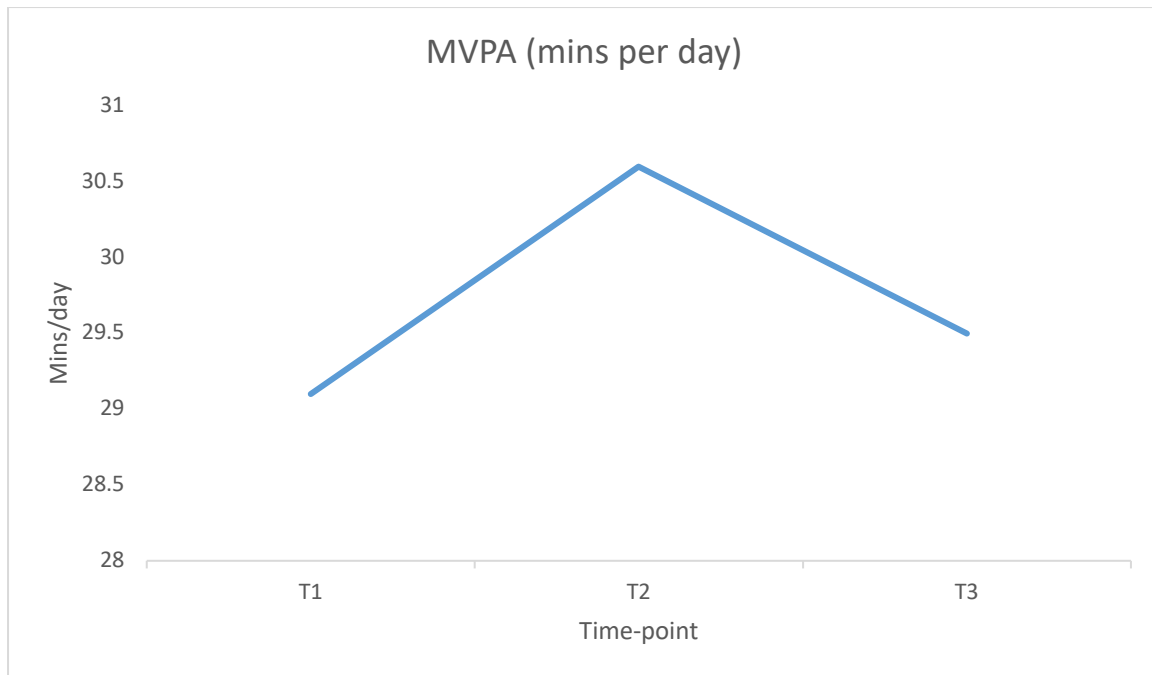
Objective PA assessment

Data from the assessment of PA by Actigraph is presented below. Non-compliance with Actigraph assessment was high, particularly at T3, where only 58% (n=18) of participants who attended T3 assessments returned the Actigraph with valid data. This was attributable to corrupt or inadequate data (n=5) and failure to wear and return Actigraph within the correct time period (n=8). In total, Actigraph data for 43 participants was suitable for analysis at T1, data for 34 participants was available at T2, and finally data for 18 participants was available and suitable for analysis at T3.

Results for time spent sedentary and in MVPA is detailed in Table 7.12 below. At baseline, participants spent a median (IQR) of 8.3 (2.4) hours sedentary per day and 29.1 (28.9) minutes in MVPA per day. Median time spent in MVPA increased slightly at T2 (30.6 minutes), and decreased slightly again at T3 (29.5 minutes). At baseline, 36% (n=16) participants were below the recommended level of 150 minutes per week of moderate activity (Rock et al., 2012). Therefore, the majority of participants (64%, n=29) were above or on the recommended level of weekly moderate intensity PA, indicating that the recruited participants were considered sufficiently active at baseline.

Friedman's test of non-parametric data was used to analyse time spent sedentary and in MVPA. Analysis of daily time spent sedentary showed no significant difference between all three time-points ($p=0.79$). Similarly, no significant difference was detected between all three points for daily time spent in MVPA ($p=0.662$). Figure 7.6 below charts the time spent in MVPA throughout the study period.

Figure 7.6 Chart of median time spent in MVPA (minutes)

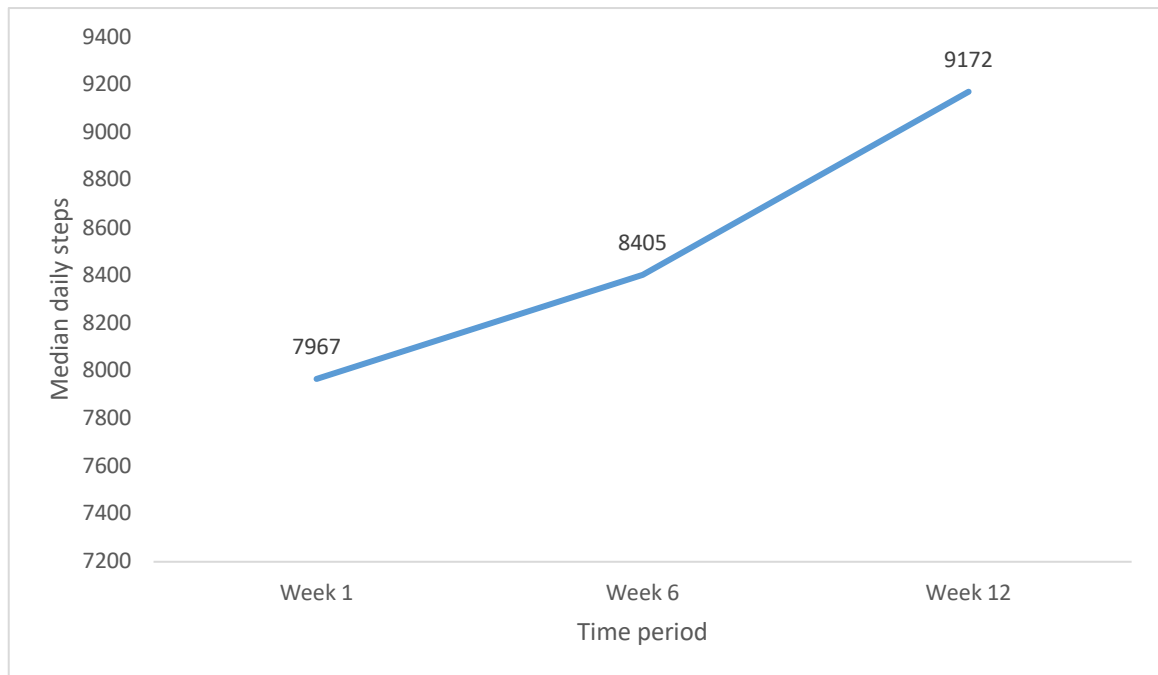


Fitbit steps results: At baseline, participants recorded 7967 median daily steps, increasing to 8405 steps by week 6, and 9172 steps by week 12 (Table 7.10). While there was a steady increase in steps at each time point, overall there was no significant difference between the median weekly steps when analysed using Friedman’s non-parametric test ($p=0.368$). Difference in median steps is illustrated below in Figure 7.7, where a trend of increasing steps throughout the intervention is shown.

Table 7.10 Results from analysis of Fitbit Steps throughout intervention (n=37)

	Median(IQR)	Median(IQR)	Median(IQR)	
Median daily steps recorded by Fitbit	7967 (4247)	8405 (4799)	9172 (5843)	0.368

Figure 7.7 Chart of daily median steps recorded by Fitbit



7.3.5.2 Six-minute walk test (6MWT) results

Results for the 6MWT are detailed below. A general linear model analysis was conducted to analyse results between all time-points. Baseline results showed that participants walked a mean distance of 557.4 metres, which increased at T2 (577.1 metres) and continued to increase at T3 (597.2). Results showed that there was an overall significant difference demonstrated ($p=0.002$), with a significant difference between T1 and T3 ($p=0.002$) for distance walked also shown. No significant difference was demonstrated between any of the other time points (Table 7.11).

7.3.5.3 Quality of Life results

SF-36: Friedmans test was performed on data for the SF-36 physical functioning questionnaire. Results showed that there was an overall statistically significant difference in physical functioning between the three time points ($p = 0.035$). Post-hoc testing revealed that there was

a significant difference between T1-T2 ($p=0.001$) Median scores for SF-36 for all three time-points are detailed below in Table 7.12. Differences demonstrated were positive in nature.

FACT-G: Friedman's test was also conducted for the FACT-G data. Results showed there was an overall statistically significant difference between the three time-points ($p=0.02$). Post-hoc tests revealed the significant positive difference to be between T1-T2 ($p=0.001$) and also between T1-T3 ($p=0.004$). Median scores for the FACT-G for all three time-points are detailed below in Table 7.12.

7.3.5.4 Body composition results

At T1, only 1 participant ($n=1$) in this trial was categorised as underweight according to BMI, while 34% ($n=15$) were normal, 36% ($n=16$) were overweight and 27% ($n=12$) were categorised as obese. Results for body mass index (BMI), waist circumference and body fat percentage are detailed below. There was no significant difference between any time-points for BMI ($p=0.07$). Waist circumference was overall significantly increased ($p=0.002$), with further testing indicating a significant difference between T1-T3 ($p=0.008$) (Table 7.11). Otherwise, no significant differences were evident between time-points for waist circumference. There was no significant difference in body fat percentage at any time-points ($p=0.08$) (Table 7.12).

Table 7.11 Effects of exercise intervention on normally distributed variables

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6-minute walk test result (m)	557.4 (70.5)	45	577.1 (75.0)	39	597.2 (67.7)	31	21.3 (0.7-42.7)	29.9 (-10.1-49.6)	0.002*
Waist circumference (cm)	87.6 (15.4)	45	89.6 (15.8)	39	90 (14.1)	31	1.6 (-3.4- 0.37)	2.8 (-0.6- 5.1)	0.002**
Body mass index (kg.m ⁻²)	27.1(5.3)	45	27.5 (5.7)	39	27.8 (5.5)	31	0.2 (0.2- 0.6)	0.5 (0.03- 0.9)	0.07

mod moderate, *vig* vigorous, *CI* confidence interval, *difference between T1 and T3 (p=0.002), **difference between T1 and T3 (p=0.008)

Table 7.12 Effects of exercise intervention on non-normally distributed variables

Self-report physical activity (arbitrary units)	28 (25)	45	58.0 (40)	39	51.0 (45)	30	< 0.0005*
Objective mod/vig time (min.day ⁻¹)	29.1 (28.9)	43	30.6 (26.4)	34	29.5 (25.6)	18	0.66
Objective sed time (hr.day ⁻¹)	8.3 (2.4)	43	8.2 (2.6)	34	8 (2.7)	18	0.79
Body Fat (%)	37 (10)	45	38.0 (13)	39	40.5 (14.5)	30	0.08
Fact-G (total score)	87.5 (22)	45	92 (18.2)	39	94.0 (18.7)	31	0.02**
SF-36 (Physical functioning measure)	85 (27.5)	45	90 (15)	39	90 (15)	31	0.035***

*mod moderate, sed sedentary, vig vigorous, CI confidence interval, *difference between T1 and T2 (p=0.005) and T1 and T3 (p=0.006), **difference between T1-T2 (p=0.001), *** difference between T1-T2 (p=0.001) and T1-T3 (p=0.004)*

7.4 Discussion

Study 3 demonstrates the preliminary feasibility and acceptability of this remotely-delivered technology-enhanced PA intervention in a heterogeneous cancer survivor population. This study has established an important basis of knowledge regarding the implementation of an eHealth intervention targeting PA behaviour in patients with cancer. Overall, this study has been shown to be safe and feasible in cancer survivors, with high acceptability demonstrated also. Recruitment rates in this study indicate that such an intervention is feasible in the cancer survivor population, however the rate of drop-out from commencing the study, and particularly at T3 warrants further investigation and consideration. This study has been shown to improve efficacy parameters such as self-report PA, functional capacity. Therefore, this study has shown initial efficacy of an eHealth intervention to impact PA and HRQOL in cancer survivors, however there is further need for a randomised control trial to be conducted with similar aims and objectives in order to progress this examination of efficacy.

The novel nature of this intervention, whereby wearable technology was utilised as a tool to motivate and influence PA behaviours of patients with cancer, is one of the core areas of investigation in this thesis. At the outset, particularly considering the results detailed in Chapter 3 and Chapter 4 in this thesis, it was recognised that cancer survivors would have unique requirements and needs when embarking on an intervention designed to improve their PA. It is clear, from both the extensive evidence base investigating PA behaviours in cancer survivors, and the qualitative investigation performed in Study 2 in this thesis, that support and guidance from healthcare professionals would be required for any intervention designed to influence PA. In this study, it was hypothesised that this support could defer from the traditional, high frequency face-to-face support that exercise programs adopted, and emphasise more on the ability of technology

to bridge the support gap between patient and healthcare professional by providing remote guidance. Indeed, results above show that the mean percentage of wear time for participants who completed the 12-week intervention was 92.6% (n=36), demonstrating a high level of engagement with the technology. The utilisation of wearable technology in this study enabled an insight into the PA behaviours of participants through the data gleaned from the use of the Fitbit by the participants. Results indicated that there was an increase in mean steps walked from T1 to T2, however this increase was not statistically significant.

Acceptability of this intervention, and of the technology used throughout, was high among participants. Acceptability was a primary marker for the overall feasibility of this intervention. This was primarily assessed using the patient satisfaction questionnaire which was completed by 36 participants following their T2 appointment, resulting in a 92% completion rate. The majority of these participants (n=35, 97%) reported that they found the intervention helpful in improving their PA. Further evidence of acceptability of this intervention was shown through the 77% of participants who indicated that they did not have any difficulty using the Fitbit or the application, a further corroboration of the acceptability of this intervention. Indeed, the high compliance with Fitbit wear time (92.26%) was another indicator of high acceptability with the intervention, in this case specifically with the technological component.

Compliance with the extensive phone call schedule, which included 14 phone calls in total, was high, with over 86% (n=38) of participants who commenced the study complying with $\geq 70\%$ of all phone calls. In a similar study conducted recently (Lynch et al., 2019), which also examined the effect of a wearable technology-based intervention on PA in cancer survivors, a high compliance with the respective phone call schedule was also reported, with 27 participants undergoing the intervention (68%) receiving all 5 calls and 10 participants (25%) receiving 4 calls. There was a total of 5 calls in this particular intervention (Lynch et al., 2019), considerably less than the total of 14 calls included

in this study described in this chapter. It can be seen that even with the high number of phone calls provided to participants in this trial, there was high engagement with the schedule, indicating that participants appreciated and valued the human interaction accompanying each phone call. This would reinforce findings from Study 2 in this thesis, which signalled the value which was placed by participants on human interaction and support. This accumulation of evidence shows that, regardless of frequency and number of phone calls, cancer survivors have high compliance with support provided through phone calls.

There were indications from the rate of drop-out before T2 however (n=6), that while technology showed promise in engaging some participants, there were others where technology may have presented as a barrier more than a facilitator. In one participant, who commenced the program and received a Fitbit, the model of smartphone that she was using did not have the ability to support running the Fitbit application. Similarly, a number (n=4) of these drop outs did not synchronise their Fitbit throughout the program, and were not compliant with their weekly phone calls, and therefore were considered drop-outs. It is clear that technology offers great potential in healthcare, and particularly in PA interventions where wearable trackers can be incorporated, however there must be a consideration for technology presenting as a barrier for certain patients also.

Adherence to attendance at the intervention time points was high, particularly for T1 and T2. In total, 45 participants commenced the intervention at T1, of these 39 participants completed their assessment at T2, representing an 87% adherence rate. Adherence at the third time point, 6 months after commencing the intervention was slightly lower, with 69% (n=31) of participants completing their T3 visit. The high rate of adherence to the second time point, compared to the follow-up at the third time-point may be explained by the design of the study, which tapered contact and support after the intervention. There were three (n=3) participants for which there was no reply to the invitation to attend T3, and consequently they missed their T3 assessment. As detailed above, at T2

the intervention concluded and all participants were instructed to return the Fitbits, and were informed that no further contact would be provided by study personnel until T3, when they would be invited for their follow-up appointment. This lack of contact, compared with the extensive contact throughout the PA intervention may have resulted in a lack of interest from a number of participants, who may then not have been as inclined to fulfil the third time point.

There was a significant increase in self-report physical activity from baseline to the 12 week time point ($p < 0.005$), which was preserved till the conclusion of the maintenance phase at T3. There was no significant improvement in score between T2 and T3, demonstrating the maintenance of the participants with the activity levels they achieved throughout the supported 12-week intervention. These results demonstrate a rise in perceived PA levels. Interestingly, these results also demonstrate that even following the conclusion of the supported intervention, participants were able to maintain their improved PA level when the Fitbit and professional support were withdrawn.

This study was designed to include both subjective and objective PA measurement, with the Godin PA questionnaire fulfilling the subjective PA measurement, and the Actigraph accelerometer fulfilling the objective PA measurement.

In contrast to the statistically significant difference seen in the Godin PA score above, no statistically significant difference was seen in any aspect of objective PA measured by Actigraph. There may be a number of reasons for this discrepancy. Self-report PA assessment can typically be afflicted by over-reporting or under-reporting. This is not to say that self-report PA is not a useful outcome of measurement, however the use of objective accelerometers is widely regarded as a more precise method of PA assessment, eliminating the potential of recall bias. Objective measurement using the Actigraph negates the potential of self-report bias, thus self-report results for weekly PA detailed above must be interpreted with caution. Additionally, the accelerometer cannot capture all activity,

such as swimming or activity undertaken without wearing the technology, providing another potential reason for the discrepancy noted between subjective PA results in this study and objective. Additionally, emerging literature investigating the efficacy of wearable technology in improving PA levels in cancer survivors has mirrored objective PA results obtained in this trial. In a study by Gell et al (Gell et al., 2017), where a Fitbit was used to target PA post a supervised exercise intervention, participants did not demonstrate any increase in PA, expressed as MVPA measured by accelerometer, resulting from its use. Similarly, a study by Pope et al (Pope et al., 2018), which had a goal of investigating the effect of a wearable technology based intervention on increasing PA, did not demonstrate any significant improvements between intervention and control groups in MVPA or light PA as measured by accelerometer.

The requirement for caution when interpreting self-report PA results has been advised by several studies, where the potential for exaggeration of PA has been highlighted (Shephard, 2003, Prince et al., 2008). There can be a multitude of reasons for this overestimation of PA, with social desirability and poor memory affecting accuracy (Prince et al., 2008). Limitations to self-report methods of PA assessment can also stem from the design of the questionnaire itself. The chosen questionnaire in this study, the Godin PA questionnaire, asked participants to categorise their PA intensity as vigorous, moderate and light. This method of assessing PA in particular has been shown to lead to problems with participant interpretation and recall, especially at capturing higher intensity PA (Prince et al., 2008). Perception of intensity can also vary greatly between participants, another issue affecting self-report accuracy, and can possibly be attributed to the wide variety of participant experience of PA (Sallis and Saelens, 2000). It must also be borne into consideration, however, that in previous studies which utilised technology as part of a PA intervention, there were significant improvements in subjective PA also demonstrated. This trend can clearly be seen in the results of the systematic review that was conducted at the beginning of this program of research (Haberlin et

al., 2018), detailed in Chapter 1. In this systematic review, 8/10 studies included reported significant improvements in PA, with all studies measuring PA subjectively using a variety of questionnaires and self-log diaries. Therefore, while it is sensible to apply caution to interpreting subjective PA results produced by this intervention, it is a result which has been shown numerous times in the growing body of evidence investigating the effect of technological PA interventions in cancer survivors.

Despite the limitations of self-report PA assessment highlighted above, there are a number of benefits of utilising this form of PA measurement. Self-report questionnaires are typically easy to administer, cost-effective and exact a low burden on patients who complete them (Ndahimana and Kim, 2017). The use of accelerometers in measuring PA, while regarded as a more robust measure of PA than self-report questionnaires, may have proved to be more burdensome for the population in this study. As described above, non-compliance with Actigraph assessment was high. Only 49% (n=19) of participants who completed T2 assessments returned the Actigraph with valid data at T3. The experience of correctly using an Actigraph accelerometer requires considerably more effort and attention from a participant than a questionnaire. Valid accelerometer data requires strict adherence of the user to the correct method of wearing it and consistent wear time over a week. Furthermore, the method of delivery of the Actigraph to participants in this study was through the postal service, and introduced further responsibility and effort for participants to return the completed Actigraph. This elevated responsibility for participants, coupled with the greater time-burden and degree of intrusion may have contributed to the drop in adherence at T3, considering participants had completed the process twice already at this point, and had not received support or contact from the study team since the conclusion of the intervention, 3 months prior. Additionally, participants may have suffered from technology fatigue by T3, with the Actigraph at this time-point proving burdensome on top of all the previous use of technology in the study. In contrast to this, as

detailed above, compliance and engagement with the Fitbit was markedly higher among participants than compliance with the Actigraph. The reasons for this discrepancy in compliance between the two technologies may be a further area of investigation for future research.

Results for the two separate quality of life (QOL) questionnaires used in this study demonstrated statistically significant improvements in both, and represented encouraging signs for the efficacy of this PA intervention for having positive effects on health-related quality of life. There was a significant improvement in scores of the SF-36 questionnaire, a questionnaire designed to assess the often impaired physical functioning of cancer survivors. Deficits in physical functioning are common in cancer survivors (Schmitz et al., 2010). Morbidity caused by the effect of cancer, and indeed cancer treatment, can ultimately result in impaired ability to execute daily tasks and to participate in social tasks (Campbell et al., 2012), as well as cause physical limitations, cognitive limitations, depression/anxiety, sleep problems, fatigue and pain (Harrington et al., 2010). The improvements detailed in this study are therefore an important consideration for interpreting the overall efficacy of this intervention. Consideration for the QOL of cancer survivors has established itself as an integral component in any intervention in the cancer survivor population (Gilchrist et al., 2009). Improvements in FACT-G scores, the second QOL measure used in this study, also demonstrated statistically significant differences, and is an indication that this PA intervention is effective in improving patient reported HRQOL. It should be noted that no dedicated measure of fatigue or mood was included in this feasibility study, despite being established side-effects of cancer treatment, and side-effects which can be impacted by PA and exercise. It was decided, however, that to ease the burden of questionnaires and outcome measures on participants, efficacy outcomes would centre mainly on PA and general QOL. Certainly, it may be pertinent in future research to include dedicated measures of fatigue and mood.

The physical functioning component of the SF-36 is an important patient-reported outcome of functioning, however physical functioning was also assessed objectively in this study. The six-minute walk test provided an objective measure of functional capacity, and similar to the positive, and significant, improvements seen in the SF-36, there was a statistically significant improvement in 6MWT score ($p=0.002$), evident between T1 and T3, although the corresponding change (+29.9m) may have limited clinical relevance(Granger et al., 2015). Therefore, these results indicate an improvement in not only subjectively assessed physical functioning, but also an improvement in objectively measured exercise capacity, showing that this eHealth intervention using Fitbit technology was effective in improving both HRQOL and exercise capacity.

Waist circumference of higher than 102cm for men and 88cm for women places individuals at an increased obesity-related health risk (WHO, 2011). In this study at baseline, the majority of participants ($n=29$, 64%) were below these cut-off points, with the remainder ($n=16$, 36%) above the cut-off points and at an increased obesity related health risk. Contrary to expectation, waist circumference increased significantly from T1 to T3 ($p=0.008$) in this study. There was no change to other anthropometric measures noted. The reason for the increase is difficult to conclude, particularly with no significant difference seen in BMI or body fat percentage. Potential reasons for this increase in waist circumference may be relate to the reliability of the measurement used. The protocol recommended by the WHO indicates that the measuring tape should be held snugly against one item of light clothing, making sure that the participant is at the end of normal expiration when the circumference is measured (WHO, 2011). Potential variety in the thickness and definition of 'light clothing' may have contributed to this finding.

7.4.1 Strengths and Limitations

Strengths

There were several unique strengths associated with this study. The intervention used in this trial was designed using the perspectives of the user to guide the content included. This patient-centred approach was achieved by the completion of Study 1 and Study 2, a questionnaire and a focus group study respectively. Results and information from these two preparatory studies ensured that the intervention designed in this study accounted for and prioritised components and content which were valued most by cancer survivors, allowing for a balance between an evidence-based approach and a patient-centred approach.

A further strength of this study was this evidence based approach taken during the design of this behavioural change intervention. There was an emphasis on the inclusion of evidence-based behavioural change components in this intervention, manifesting as a variety of effective behavioural change techniques (BCT) adopted throughout the intervention. BCTs in the intervention included 'self-monitoring of behaviour', 'goal-setting', 'feedback on behaviour' and 'information about health consequences', among others (Michie et al., 2013). Evidence suggests that successful and sustainable PA interventions are underpinned by behavioural change theory (Husebo et al., 2013, Turner et al., 2018). A study which also utilised wearable technology to promote PA in cancer survivors, and demonstrated significant improvements in activity, hypothesised that the inherent presence of BCTs in Fitbit software was a contributory factor towards the improvements shown (Maxwell-Smith et al., 2019), further strengthening the rationale for wearable technology use in interventions that target PA in cancer survivors.

Thirdly, the remotely delivered nature of the intervention which incorporated new technology may have greater reach compared to traditionally delivered programmes. This trial also included a heterogeneous cancer population and included robust measures such as accelerometer to measure physical activity, which can be regarded as further strengths.

Limitations

Recruitment for this trial was slow, despite the low-threshold nature of this intervention, with recruitment averaging about 4 participants per month, similar to a recent study using smart scales and activity trackers in African American breast cancer survivors (Valle et al., 2017). This slow rate of recruitment was similarly reported in a study which incorporated a PA smartphone application (Ormel et al., 2018b), and another which incorporated PA wearables (Lynch et al., 2019).

Potential reasons for this slow rate of recruitment may be due to the recruitment strategy utilised in this trial. The recruitment strategy for this trial was designed so that oncology clinicians were provided with the eligibility criteria for study participation prior to each outpatient clinic, which they used to review the patient list and identify suitable candidates for participation. It was the oncology clinicians themselves who first presented the study to participants, and if they showed interest and were eligible, the clinician then referred them to the lead investigator who was present in another room at the clinic. Thus, all patients who presented to the lead investigator had already expressed an interest in participation, and inevitably showed desire to take part and consent to participation. This method of recruitment was adopted throughout this study, and brought with it certain advantages as well as disadvantages. A significant advantage of this method of recruitment was that all patients who would participate in this trial had been screened by their clinician, and thus carried explicit permission from them to participate, as well as ensuring that all patients who took part were safe to do so. However, in retrospect, there were disadvantages to this method of recruitment. Due

to the extremely busy nature of the oncology clinics, and the prioritisation of the patients care before exploring participation in this trial, a number of patients may have been missed due to the clinicians forgetting to raise the study with the patients. Furthermore, an accurate analysis of the number of patients screened was impossible to ascertain, due to the high number of patients attending the clinic each week, and the screening process being performed by the clinician themselves who had little chance to record patients screened. This process was certainly one of the reasons why recruitment for this study was somewhat slow.

A further consideration which must be applied to the discussion on the slow rate of recruitment in this study is the stringency of the eligibility criteria. Only patients who were 3 years or less post treatment were eligible to participate, ruling out a significant proportion of patients who were beyond this cut-point. In comparison to this, a similar study which examined the effect of an eHealth-based PA intervention in breast cancer survivors had initially set inclusion criteria which stated that only women that had been diagnosed within the past 5 years were eligible (Lynch et al., 2019). This criteria was then dropped later in the trial period as recruitment had been slow, allowing for cancer survivors who were any number of years post diagnosis to participate, facilitating the rate of recruitment. Indeed, this particular study also utilised a variety of channels from which to recruit patients from, with a country-wide cancer registry, promoted Facebook advertisements and national cancer council distributed newsletters used. This multi-faceted approach to recruitment may be an effective way of maximising potential recruitment numbers, and is in contrast to the recruitment capability of Study 3, which was limited to one recruitment site.

The emergence of the concept of fidelity of delivery is a worthwhile consideration that can be applied to this study, and indeed any complex behavioural change intervention. Fidelity of delivery has been defined as the extent to which an intervention is delivered as intended (Gearing et al., 2011). The assessment of fidelity may involve an assessment of a multitude of intervention

components, particularly in complex behavioural change interventions, such as this study described above. The aim of assessing and considering fidelity of delivery is to ensure that any results achieved following an intervention can be attributed to this intervention itself, and not due to inconsistency or quality of its delivery, allowing for accurate interpretation of treatment or intervention effects (Perepletchikova and Kazdin, 2005). Fidelity of delivery was not assessed in this study, and thus may be regarded as a potential limitation, but also an area of future research and growth. An assessment of fidelity is often recommended in the developmental and piloting stage of research (Gearing et al., 2011), and thus would be an appropriate approach for a feasibility study like Study 3. Indeed, this approach was adopted in a study published in 2017, which assessed fidelity of delivery of a complex self-management intervention for people with osteoarthritis and low back pain (Toomey et al., 2017). This assessment of fidelity was conducted in the context of determining the feasibility of progressing to a full scale trial, mirroring efforts of this study (Study 3) to align with MRC guidelines (Craig et al., 2008). Therefore, a future iteration of Study 3 may include fidelity of delivery as an assessment to accurately elucidate the effects of the eHealth intervention conducted.

7.5 Conclusion

This study demonstrated that an eHealth based PA intervention, using Fitbit technology, is acceptable and feasible in the cancer survivor population. Improvements in subjective PA, functional capacity and HRQOL were seen after this intervention, with participants reporting positive feedback regarding the content of this study. This feasibility trial has established a foundation of knowledge and insight regarding the acceptance and feasibility of technology-driven PA interventions in cancer survivors, and thus enables further research to continue to explore the optimum eHealth intervention to promote PA in this population.

Chapter 8 Discussion

8.1 Introduction

The field of research which examines the effect of exercise and PA on patients with cancer is ever growing, and has come a long way from the pioneering research conducted in the 1980s. That landmark work showed that interval, aerobic training was safe, feasible, and that it improved the aerobic capacity, body composition, and symptoms of patients with cancer (Winningham and MacVicar, 1988, MacVicar et al., 1989, Winningham et al., 1989). It also paved the way for the abundance of research currently available which reports a multitude of benefits of PA and exercise for patients with cancer. PA is associated with improvements in quality of life (Adamsen et al., 2009, Mutrie et al., 2007), function (Morey et al., 2009, Courneya et al., 2003) and, in some cancers, with a reduced risk of recurrence (Friedenreich et al., 2009, Holmes et al., 2005). Recovery from cancer treatment, and its associated side-effects, has also been shown to be improved with exercise and PA (Schmitz et al., 2010). There is also a growing body of research examining the effects of exercise and PA on tumour physiology, with alterations in hypoxia, vascular normalisation and immune cell mobilisation leading to potentially improved responses to tumour therapy (Ashcraft et al., 2019).

Traditional strategies to promote PA and exercise in the cancer survivor population focused mainly on supervised and group-based sessions in a clinical setting. A systematic review conducted in 2010 indicated that such approaches produce safe and feasible interventions, and demonstrated that they can produce significant improvements in a variety of measures that may have been affected by cancer and its treatment, such as aerobic capacity, QOL, fatigue, muscle strength and mood (Speck et al., 2010). While these traditional interventions can bring exercise and PA-related benefits to cancer survivors, they present a number of key limitations. Supervised sessions can be costly, are limited by availability and can be difficult to access due to geographical location (Hardcastle et al., 2018). They may also not align with the PA or exercise preferences of the individual participant

(Hardcastle et al., 2018). Thus, the substantial evidence which exists to support the integration of PA and exercise in the care of cancer survivors has prompted care providers to enter a new era of exercise oncology research. We are challenged to formulate strategies and interventions which can take advantage of the benefits, while also progressing beyond the traditional methods of exercise and PA prescription and treatment.

The design of such strategies or interventions, which should be efficacious, feasible and safe, has become an important aspect of PA research in the cancer survivor population. The genesis for the work reported in this thesis was the substantial benefits PA could impart to cancer survivors discussed above and the opportunity for an exploration into how best these benefits could be delivered. The starting point was the recognition of the emergence of technology in healthcare, specifically the application of eHealth in behavioural change interventions targeting the improvement or adoption of healthy behaviours. A detailed exploration of this area was seen as particularly relevant for research in the cancer survivor population, as research had shown that the majority of cancer survivors have difficulty in adhering to healthy lifestyle behaviours, including healthy PA behaviours (DeNysschen et al., 2014, Blanchard et al., 2008).

The advent of technology as a component of PA interventions can be charted across a variety of populations, from healthy community-dwelling adults, paediatric and elderly population groups (Norman et al., 2007, Krebs et al., 2010, Davies et al., 2012, Foster et al., 2013, Aalbers et al., 2011, Oosterveen et al., 2017), as well as clinical populations, such as in patients with Type II diabetes (Connelly et al., 2013). The suggested benefits of using internet technology in healthcare include convenience for users, easy storage of large amounts of information, ease of updating information and ability to provide personalized feedback (Griffiths et al., 2006a). The paucity of research exploring the potential of eHealth in addressing poor PA behaviours specifically in cancer survivors served as the impetus for the research which was described in this thesis. The ultimate goal for this

research was to progress towards the design and implementation of an eHealth intervention targeting improvements in PA in cancer survivors. The path to arrive at this goal, as previously mentioned throughout the thesis, was influenced by guidelines published by the Medical Research Council on designing and conducting a complex intervention (Craig et al., 2008). Those recommendations guided each component of this research. Additional importance in our research was given to the perspective of the cancer survivor population; reflected in the several consultations with patients on their recommendations and the incorporation of formalised patient-centred outcome measures in the final feasibility study. Thus, this thesis has presented the evolution of a body of research aimed at exploring the feasibility and efficacy of a newly-designed eHealth-based PA intervention in cancer survivors. This chapter will discuss the pertinent issues which emerged from this research, including their implications for the future of research in this area.

8.2 Systematic review

Following the structure recommended by the MRC guidelines for the development of a complex intervention (Craig et al., 2008), the first step in this program of research was to examine and appraise the current evidence base investigating technology-based PA interventions for cancer survivors. A systematic review was conducted in March 2017 to appraise the evidence base fully (Haberlin et al., 2018). Its results were pivotal in the progression of this research, and the subsequent intervention that was developed. That review, which ultimately included 10 studies in total, showed that the majority of studies (8/10) reported that eHealth PA interventions improved PA and exercise. Equally as important in the context of this research was the finding that most studies (9/10) included in the review used only subjective means of measuring PA and exercise, highlighting an area of development for any further research in this area. Furthermore, use of wearable technology in the included studies was very low, with only one study incorporating

wearable technology (Hooke et al., 2016b). Ultimately, it was found that consensus is lacking in terms of the optimal eHealth-based intervention design in the cancer setting.

8.3 Study 1

Study 1 was designed to ensure that the perspectives of the intervention user, in this case cancer survivors, were taken into account for the development of the final intervention study in this thesis. The questionnaire was to supplement knowledge gleaned from the systematic review previously conducted, as well as furthering the understanding of the role of technology and PA in the lives of cancer survivors in Ireland. The main findings from this study were to show that the majority of the sample population owned or had access to a smartphone (n=62, 60%), and to highlight the inadequate knowledge of recommended PA guidelines among the sample of cancer survivors included in the study. The insights afforded by the results of the questionnaire study were developed in Study 2, where further analysis of patient perspectives, focusing on barriers and facilitators to eHealth was conducted.

8.4 Study 2

Through a number of focus groups, Study 2 elicited the personalized views of cancer survivors about a potential eHealth-based PA intervention. As Study 2 was conducted at the pre-trial phase of this thesis, results were applied directly to the development of Study 3. Major insights gleaned from Study 2 showed that adequate training, education and support in both using technology, and adopting good PA behaviours, would be an important factor for participants in a future eHealth cancer intervention. Lack of information and advice on exercise and PA guidance, particularly after their cancer treatment had concluded, was also highlighted by participants. The desire for professional support by a physiotherapist, in the form of specific PA goals and monitoring, was also

widely referenced throughout the focus groups, and hence it was ensured that this feature was part of the intervention designed and implemented in Study 3.

8.5 Study 3

The culmination of the systematic review, Study 1 and Study 2 was the feasibility study – “Study 3” - described in Chapter 5. Study 3 study also aligns with the MRC guidelines, where it is recommended that a feasibility study be performed to examine an intervention for its acceptability prior to a full-scale randomised controlled trial. That process also provided information regarding the feasibility and preliminary efficacy of the intervention in cancer survivors. Results of Study 3 showed that the intervention was safe, feasible and acceptable in the cohort of Irish cancer survivors who participated. Statistically significant improvements in self-report PA, functional capacity and HRQOL were demonstrated. Objective PA as measured by accelerometer was not significantly improved, however; this is further discussed below. Ultimately, this study showed that the eHealth based PA intervention designed and implemented in this thesis was acceptable and feasible in the cancer survivor population. The key points of discussion emanating from this thesis will be detailed in the remainder of this discussion, including strengths and limitations of the research, and what this thesis has added to the growing body of evidence in the area of PA promotion in cancer survivors using eHealth.

8.6 Analysis of key points

8.6.1 eHealth/Technology

eHealth and technology are at the very centre of all the research conducted in this thesis, from the exploration of its use in trials promoting PA in cancer survivors in the systematic review, the investigation of its role in the lives of the cancer survivor population in Study 1, the consideration

of cancer survivor perceptions in Study 2 and the investigation of the feasibility and efficacy of an eHealth PA intervention in Study 3. The presence of eHealth in research investigating PA interventions in cancer survivors has increased exponentially since the commencement of this program of research in 2015. The systematic review described in Chapter 1 was based on a literature search conducted in March 2017. In total, the review described 10 studies which employed eHealth to promote PA in cancer survivors. For completeness, the same search was repeated in June 2019. By then, 25 studies that met the same criteria were identified. This considerable increase in studies meeting eligibility criteria is a clear indication of the rapid development of this area of research. The results of the systematic review conducted in 2017 also provided a valuable insight and snapshot into the methods of eHealth used in PA interventions designed for cancer survivors up to that point in time. There was a large contrast between eHealth modalities used between both searches, with the majority (n=16) of the 25 studies extracted from the updated search utilising wearable technology, compared to just one study in the original review.

Therefore eHealth is clearly a rapidly developing area of research, and, in particular, the advent of wearable technology raises numerous possibilities for exploring its potential use in cancer survivors. However, the path from technologies now in common use among healthy individuals to set and monitor individual PA goals to the implementation of an acceptable and effective eHealth PA intervention for cancer survivors cannot be based upon assumptions. This thesis has taken a systematic approach building upon and adding to current knowledge regarding the role of technology in this population. Study 1 showed that over 60% of our sample surveyed owned or had access to a smartphone. This approaches the level of usage shown by the general population, where statistics indicate approximately 68% of the total Irish population were smartphone users in 2016, projected to rise to over 79% in 2022 (O'Dea, 2017). The ubiquity of smartphones is a key result to consider when examining the feasibility of delivering an eHealth intervention to cancer survivors,

as it ensures that such an intervention is accessible for the majority, and does not present a barrier to patients. It remains to be determined, however, what the future demographic coverage will be. It must be acknowledged that there will remain some people for whom an eHealth intervention based on smartphone usage will not be feasible or acceptable.

Further evidence which adds support to the utilisation of eHealth in PA interventions for cancer survivors was the acceptability of the Fitbit in this research, specifically in Study 3. Results showed that mean adherence to daily wearing and synchronising of the Fitbit throughout the intervention was 92.6%. Participant satisfaction questionnaire results post-intervention showed that several aspects of Fitbit use were positive experiences for participants. Participants reported that motivation for PA gained from using the Fitbit was an aspect of the intervention they enjoyed. Similarly, use of the Fitbit was referenced throughout as something that helped participants increase their PA. In total, 77% (n=27) of participants who provided an answer to this particular question in the patient satisfaction questionnaire responded that they had no difficulty using the Fitbit. A similar study, which also used Fitbits as part of a PA intervention, reported similar positive results of acceptability for the technology. In that study, 87% reported satisfaction with the Fitbit, with further acceptability shown with the majority of participants indicating that the Fitbit and text message support employed in the intervention having a positive impact on motivation performing PA (Gell et al., 2017). There have been a number of similar studies emerging, investigating the use of wearable technology, such as a Fitbit activity tracker, to promote PA in cancer survivors, and results from these trials generally recommend the safety, feasibility and efficacy of using wearable technology as part of a PA intervention. A recent randomised controlled trial investigated the effect of a 12-week eHealth intervention using Fitbit on PA in cancer survivors (Maxwell-Smith et al., 2019). Results from this study reported excellent adherence to the intervention time points, as well

as high engagement with the Fitbit itself. These findings support and mirror the results obtained from Study 3 in this thesis.

All these positive results, including our own, must be interpreted in the light of one important fact; namely that participants who consented to these studies, were, by definition, motivated to explore the use of wearable technology and eHealth. They should be extrapolated only with caution to the cancer survivor population as a whole. Furthermore, a substantial minority in our study (23%) did indicate some difficulty using the Fitbit, suggesting that support for technology use will likely be necessary for eHealth interventions in even a motivated group who have access to a smartphone or tablet. Ultimately, the examination of technology and eHealth in this thesis concluded that the methods used, specifically the Fitbit and its accompanying application, were acceptable and enjoyable to most participants.

8.6.2 Efficacy of Study 3

Study 3 also showed that measures of self-report PA, QOL and functional exercise capacity were better at the end of the intervention. However, no statistically significant improvement in PA over time, as objectively measured by accelerometer, was found. As previously mentioned, most PA studies in cancer survivors have relied on self-report PA; our study deliberately incorporated accelerometry measurements. A prior observational study of breast cancer survivors showed that while self-report PA increased over the first survivorship period, there was no increase in objectively measured PA (Broderick et al., 2014a). That suggests that cancer survivors, like many others, overestimate PA. An increase in self-report PA without objective confirmation may call into question the efficacy of the intervention. However, it should be noted that large population-based studies which showed an association between more PA and improved survival in certain cancers relied on self-report PA (Friedenreich et al., 2009, Holmes et al., 2005). Therefore, self-report PA may be a

construct which incorporates subtle levels of activity and other changes not immediately apparent on objective testing.

However, the small randomised controlled trial conducted by Maxwell-Smith et al. (2019) did report that objectively measured PA was significantly improved in participants who were in their intervention group, with a significant between group net difference of 66 min/wk of MVPA in favour of the intervention group. Our study, as a single-arm feasibility intervention, used PA over time rather than between-group differences. This highlights that further research must be conducted to gain an understanding into the optimum composition of an eHealth PA intervention.

8.6.3 Behavioural Change

An appreciation and consideration of behavioural change theory has embedded itself as a necessary step in designing an intervention seeking to change an individual's behaviour. Application of behavioural change theory has been shown to increase the efficacy of PA interventions in cancer survivors (Short et al., 2013), while also increasing the likelihood of cancer survivors making and sustaining a positive change in exercise and PA behaviours (Loprinzi et al., 2012). The development of Study 3 was heavily influenced by behavioural change techniques (BCT), defined by Michie et al. (2011). This involved including techniques such as 'self-monitoring of behaviour', 'goal-setting', 'feedback on behaviour' and 'information about health consequences' (Michie et al., 2011). Interestingly, use of the Fitbit in Study 3 also contributed to the presence of BCT in the eHealth intervention, through the inherent presence of BCTs in activity trackers and their accompanying applications (Lyons et al., 2014). Therefore, the presence of BCT throughout was as a result of both study design, which provided goal setting, feedback on performance and information of health consequence through the supportive role of the lead investigator, but also the use of the Fitbit tracker and its application. While it is difficult to attribute the effects of this intervention to any

particular BCT, feedback from participants regarding the acceptability of the intervention in Study 3 referenced a number of these BCTs that were incorporated in the intervention, with numerous participants praising the ability to self-monitor their PA progress, and the goal setting by the lead investigator.

8.6.4 Delivery of PA prescription

This research described in this thesis has culminated in a presentation of a PA intervention which utilises a remote approach to PA prescription and monitoring. Technology has enabled this movement away from the more traditional, face to face format of PA prescription. However, this research has also shown that despite the capabilities of technology to facilitate a remote intervention, participants valued the presence and support of the physiotherapist throughout the program, reflecting the findings in Study 2 which influenced that component of the design.

A major theme that emerged from the focus groups in Study 2 concerned the importance and value that participants placed on the role of a healthcare professional to guide and support their PA and exercise, but also to instil a sense of accountability to complete their PA goal. This knowledge was confirmation that inclusion of physiotherapist support for goal and monitoring of PA would be an integral part of the intervention designed in Study 3. Ultimately these results from Study 2 were mirrored in feedback provided by participants in Study 3. An analysis of the patient satisfaction questionnaire in Study 3 specifically highlighted that the support and guidance received from the lead investigator throughout the intervention was an aspect of the programme which participants enjoyed. Furthermore, this support was referenced as a contributory factor to increasing the participants PA level. These results can be viewed as an indication that, despite the wide and varied capabilities of technology, the presence or inclusion of a healthcare professional in an intervention targeting improved PA is important to cancer survivors.

An article published in 2018 reported that using wearables in isolation to promote behaviour change may not be sufficient to result in meaningful, sustained behaviour change (Phillips et al., 2018). They recommended that if wearables are integrated into a behavioural change intervention, they should be accompanied by other behavioural theory-based components and supports. This corroborates the results gleaned from this thesis, in which participants explicitly referenced the support and feedback of the physiotherapist as an important factor alongside the use of the Fitbit. This also emphasises the importance of viewing technology not as a panacea for promoting PA, but as a tool to facilitate it. Indeed, Patel et al. (2015) described wearable technology as a facilitator of behaviour change, but also warned against the opinion that wearable devices alone would significantly impact an individual's health behaviour. Instead, it was hypothesised that the potential benefits associated with the use of wearable devices would occur only if the use of a device was accompanied by a variety of 'engagement strategies'. These engagement strategies could take the form of individual encouragement, feedback and social support (Patel et al., 2015).

Therefore, despite the capabilities of technology, the presence of healthcare professional support is an important aspect of an effective and acceptable PA intervention. This is supported further by a systematic review conducted in 2018 (Wong et al., 2018), which examined the preferred composition of a PA intervention in adult cancer survivors. Results from this systematic review showed that the majority of cancer survivors would prefer to receive PA prescription and guidance from a PA specialist associated with a cancer centre, adding further weight to the argument that the inclusion of healthcare professional support is absolutely integral to a PA intervention in this population. Furthermore, cancer survivors are such a heterogeneous group that realistic and specific goal-setting is crucial to effective PA improvement. A professional assessment at the start of an intervention is likely to entail goal-setting of this nature, and may result in safer and more achievable PA interventions. The format and composition of an optimal eHealth PA intervention has

yet to be discovered. It is likely that it will never be “one size fits all” and that the support of a physiotherapist and other HCP will remain an important aspect of any intervention, especially one involving cancer survivors after therapy with known significant and long-lasting physiological effects.

8.6.5 Research limitations

There were some general limitations associated with the research conducted in this thesis and these will be discussed below.

First, agreement to participate in the focus groups of Study 2 may have reflected an interest in PA and technology greater than among other cancer survivors with low PA. It must be recognised that a PA intervention based on eHealth will not suit all cancer survivors; the work reported in this thesis by definition was aimed at improving PA in those who were open to such an intervention. The design of Study 3 in this thesis was a one-arm trial, as it aimed to establish the feasibility and initial efficacy of a novel, under-investigated method of promoting PA in cancer survivors. Therefore, the results of the intervention could not be compared with a control group, but were compared over time.

The generalisation of results from these studies are limited somewhat by the method of sampling used in this thesis. Convenience sampling was used to recruit participants to each study, with recruitment occurring at one site only, St. James’ Hospital, Dublin. Convenience sampling is often afflicted with a variety of biases, such as over-representation of a particular group in a sample, or bias in the recruitment of a group from a specific location. In Study 2 and Study 3, patients capable of easily accessing the research centre may have been more likely to commit to participation, even though the design of the remote aspect of Study 3 was intended to offset access issues as far as possible, with participants having the opportunity to participate in this study while only attending the research centre three times in 6 months.

8.7 Future research directions and clinical implications

At the outset of this research the ultimate intention was to investigate the potential feasibility and efficacy of a novel eHealth intervention to promote PA in cancer survivors. The progression through each study highlighted the areas of further development and research to be undertaken in order to approach a consensus on optimal composition and format of PA promotion in cancer survivors using eHealth. The results of this thesis have provided an important base of knowledge on the initial feasibility of an eHealth approach to PA promotion, and thus findings from this thesis can be built and developed on in future research. The potential future directions and clinical implications of this research are discussed below.

8.7.1 Future research

Considering the burgeoning and novel nature of research in the field of eHealth and PA promotion in cancer survivors, the potential and scope for future research in this area is significant. Results from this thesis have shown that an eHealth intervention incorporating Fitbit devices is safe and feasible in cancer survivors. Furthermore, positive changes in QOL, self-report PA and functional capacity were shown following a 12-week PA intervention. Study 1 and Study 2 also provide a considerable amount of information regarding cancer survivor's perspectives, barriers and facilitators to using technology for PA promotion. Future research should focus on a refinement of these methods, with the goal of developing an optimal intervention, influenced by user-perspectives, and efficacious in cancer survivors. This future research may take the form of a full-scale, definitive efficacy trial. The design of this would be a RCT, with one arm adopting the use of a Fitbit as part of an eHealth intervention, and a control arm where participants would receive an adapted PA intervention without the use of the Fitbit or any aspect of eHealth. This trial would

investigate and compare the efficacy of an eHealth intervention against a more traditional PA intervention to improve PA behaviour and adherence.

For many cancer interventions, such as systemic therapy or radiation, the concept of “responders” and “non-responders” is important. If a single-arm study identifies a proportion of patients who respond favourably to an intervention, analyses are frequently undertaken to identify clinical and/or biological characteristics which may predict the likelihood of benefit. Subsequent RCTs of that intervention may then include groups or strata known to be most likely to benefit, and/or exclude those who are unlikely to respond or where additional interventions may be more appropriate. In the field of PA, exercise and behavioural interventions, such analysis is not standard and has not been reported in this work. However, given the heterogeneity of the cancer survivor population, it may be worth analysing the results of Study 3 and others in the light of that approach.

Dosage of PA prescription should be investigated further, with exploration on the required intensity, frequency and type of PA to produce significant changes in weekly PA. Dosage and frequency of physiotherapy support should also be investigated for acceptability and efficacy. In Study 3, remote phone call support was extensive, with a total of 14 calls provided to participants on a tapered schedule. A similar study, which also investigated an eHealth intervention in cancer survivors, included a phone call support schedule with 5 calls only (Lynch et al., 2019), and reported significant changes in MVPA. Further research should explore the effect of increasing or decreasing professional support on acceptability and objective PA. Future studies should also build upon the qualitative results obtained in this thesis, ensuring that cancer survivors are retained as an integral component of the development, and post-trial evaluation, of a PA intervention.

This research has also highlighted additional components of an intervention which may be efficacious for promoting healthy behaviours in patients with cancer. Participants in Study 3 were

invited to give suggestions as to how the intervention they had completed could be improved, and one of the themes which emerged from analysis of this question was the potential inclusion of a dietary component. Although the association of obesity with cancer is undisputed (Lauby-Secretan et al, 2016) the relationships between survival, weight loss and weight gain after treatment are much more complex (El-Safadi et al., 2012, Caan et al., 2012). The inclusion of a dietary component in an eHealth intervention could be an important area of investigation, but would require rigorous monitoring and analysis that could also introduce many confounding factors into a trial of a PA intervention.

The potential role of self-management in the promotion of PA using eHealth in patients with cancer is an area that further research may also address. The aim of self-management is to empower and enable patients to manage their own condition, with efficacious self-management defined as an individual's 'ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition' (Barlow et al., 2002). A recent systematic review examined the impact of self-management interventions for cancer survivors on health outcomes such as activity participation, self-efficacy and quality of life (Boland et al., 2018a). Interestingly, there were statistically significant differences in PA reported in two studies included in this review, with one of these studies, which also featured in the systematic review detailed in Chapter 1, incorporating self-management strategies through a web-based intervention (Lee et al., 2014). Considering results from this thesis, which show an eHealth PA intervention as being safe and feasible in cancer survivors, the potential integration of well-defined self-management strategies in an intervention of this nature should be examined in future research to investigate further efficacy.

The results from the updated search of the literature in Chapter 1, where 25 additional studies were identified, highlight an important consideration for the use of eHealth moving forward. Technology

and software is characteristically quick to evolve and progress beyond one static form (Pham et al., 2016a). The burgeoning nature of eHealth-based PA interventions in cancer survivors evident in this updated search reflects this characteristic, and highlights both the enhanced technological capabilities potentially available for use, and the difficulty this rapid progression means for evaluating particular eHealth interventions. This difficulty may manifest in an increased risk of an eHealth intervention becoming obsolete before its efficacy or feasibility can be investigated fully. Attenuating this risk will become an important aspect of the development of future eHealth PA interventions, and a robust grounding in behavioural change principles and application of patient perspectives in the development of an intervention, such as that adopted throughout this thesis, may assist in this endeavor.

A further consideration regarding the future of this research is the importance of maintaining data protection and privacy. The recent General Data Protection Regulations (GDPR) that came into effect provide for higher standards of data protection, and will require considerable diligence and attention when designing an intervention which includes technology capable of storing large amounts of information.

8.7.2 Clinical implications

Bridging the gap between research and clinical care is often a challenging task. The results from this research have shown the potential positive effects of an eHealth intervention targeting PA in cancer survivors. Due to the novel nature of this research, considerable further work, such as that suggested above regarding refinement of the intervention and its testing in an RCT, is still required before widespread implementation in a clinical setting can be recommended.

Consideration of implementation science, despite the novel and early nature of the research described in this thesis, is an important aspect of ensuring that future research arising from this

thesis is optimally designed for integration in routine clinical practice. Implementation science describes the uptake of research findings into routine practice (Greenhalgh and Papoutsis, 2019), and has recently transitioned from a highly structured and restrictive approach, to a more flexible approach which introduces qualitative methods to explore potential implementation of an intervention. Again, while the clinical implementation of the intervention described in this thesis still requires further testing and exploration, the process that testing will undergo should be rooted in implementation science.

8.8 Conclusion

The focus of this thesis was to develop the evidence base in the area of PA promotion in cancer survivors, with a specific exploration of the feasibility and efficacy of using an eHealth intervention to achieve this. The emergence of eHealth, and the potential it offers to PA behavioural change programs for cancer survivors, prompted the need for robust, developmental research to assess the safety, feasibility and efficacy of this medium. The research in this thesis achieves this, offering preliminary results showing that an eHealth intervention, designed to impact PA through the use of Fitbit technology, was safe, acceptable and produced positive improvements in HRQOL, subjective PA and exercise capacity. Moreover, the results from this thesis provide researchers and clinicians with a further base of knowledge and insight into a burgeoning area of research. There is rationale for a future randomised control trial investigating an eHealth PA intervention in this population, where the focus should be on the optimal composition of an intervention, including the study on dosage of PA, method of eHealth technology used and how to identify those survivors most likely to benefit.

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Appendix 1 Published Systematic review

Review Article | Published: 16 June 2018

The use of eHealth to promote physical activity in cancer survivors: a systematic review

[Ciarán Haberlin](#) , [Tom O'Dwyer](#), [David Mockler](#), [Jonathan Moran](#), [Dearbhaile M. O'Donnell](#) & [Julie Broderick](#)

[Supportive Care in Cancer](#) **26**, 3323–3336(2018) | [Cite this article](#)

1322 Accesses | 24 Citations | 20 Altmetric | [Metrics](#)

Abstract

Purpose: Achieving adequate levels of physical activity (PA) and avoiding sedentary behaviour are particularly important in cancer survivors. eHealth, which includes, but is not limited to, the delivery of health information through Internet and mobile technologies, is an emerging concept in healthcare which may present opportunities to improve PA in cancer survivors. The aim of this systematic review was to explore the effects of eHealth in the promotion of PA among cancer survivors.

Methods: Suitable articles were searched using PubMed, CINAHL, EMBASE, PsychInfo, Web of Science and SCOPUS databases using a combination of keywords and medical subject headings. Articles were included if they described an eHealth intervention designed to improve PA in cancer survivors. Two reviewers screened studies for inclusion.

Results: In total, 1065 articles were considered. Ten studies met eligibility criteria. A variety of platforms designed to increase PA were described in these studies: web application (app) (n = 5), web and mobile application (n = 2), mobile app (n = 1), website only (n = 1), e-mail based (n = 1). All studies measured PA using self-report outcome measures with the

exception of one study which measured steps using a Fitbit. Meta-analysis was not performed because of variations in study design and interventions. All studies reported improvements in PA, with 8/10 studies reporting statistically significant changes.

Conclusion: The use of eHealth to promote PA in cancer survivors is a relatively new concept, which is supported by the recent emergent evidence described in this review. eHealth shows promise as a means of promoting and increasing daily PA, but further high-quality, longer term studies are needed to establish the feasibility and effectiveness of eHealth platforms aimed at that goal.

Keywords: Cancer; Cancer rehabilitation; Physical activity; Technology; eHealth.

Appendix 2 Search strategy for systematic review

Search strategy for systematic review

EMBASE

- 1 'neoplasm'/exp OR 'cancer patient'/exp OR 'cancer rehabilitation'/exp
- 2 ((cancer OR tumor* OR tumour*) NEAR/3 (surviv* OR patient*)):ab,ti
- 3 1 OR 2
- 4 'telehealth'/exp OR 'mobile application'/exp OR 'telemetry'/exp
- 5 (telerehabilitation OR telehealth OR telemedicine OR telehealthcare OR telemetry OR 'e-medicine' OR 'mobile health' OR mhealth OR 'e-health' OR 'mobile technology' OR 'mobile apps' OR apps OR smartphone OR 'cell phone'):ti,ab
- 6 4 OR 5
- 7 'exercise'/exp OR 'kinesiotherapy'/exp OR 'physical activity, capacity and performance'/exp OR 'physiotherapy'/exp OR 'sport'/exp
- 8 (Exercise OR 'physical activity' OR endurance OR physiotherap*):ti,ab
- 9 (Exercis* NEAR/3 (therap* OR protocol* OR intervention)):ti,ab
- 10 7 OR 8 OR 9
- 11 3 AND 6 AND 10

PubMed

- 1 "Neoplasms"[Mesh]
- 2 cancer[tiab] OR neoplasm*[tiab]
- 3 #1 OR #2
- 4 "Telemedicine"[Mesh] OR "Telemetry"[Mesh] OR "Mobile Applications"[Mesh] OR "Cell Phones"[Mesh]
- 5 telerehabilitation[tiab] OR telehealth[tiab] OR telemedicine[tiab] OR telehealthcare[tiab] OR telemetry[tiab] OR e-medicine[tiab] OR mobile health[tiab] OR mhealth[tiab] OR e-health[tiab] OR mobile technology[tiab] OR mobile apps[tiab] OR apps[tiab] OR smartphone[tiab] OR telerehabilitation[tiab] OR web-based[tiab] OR cell phone[tiab]
- 6 #4 OR #5
- 7 "Physical Exertion"[Mesh] OR "Physical Education and Training"[Mesh] OR "Exercise Therapy"[Mesh] OR "Exercise Movement Techniques"[Mesh] OR "Physical Endurance"[Mesh] OR "Motor Activity"[Mesh:NoExp]
- 8 exercise therapy[tiab] OR exercis*[tiab] OR physical education[tiab] OR training[tiab] OR kinesiotherapy[tiab] OR physical education[tiab] OR kinesiotherapy[tiab] OR physical rehabilitation[tiab] OR physical fitness[tiab] OR physiotherapy*[tiab] OR physical therap*[tiab]
- 9 #7 OR #8
- 10 #3 AND #6 AND #9

CINAHL

- 1 (MH "Neoplasms+") OR (MH "Rehabilitation, Cancer") OR (MH "Cancer Patients")
- 2 TI (((cancer OR tumor* OR tumour*) N3 (surviv* OR patient*))) OR AB (((cancer OR tumor* OR tumour*) N3 (surviv* OR patient*)))
- 3 1 OR 2
- 4 (MH "Electronic Mail") OR (MH "Instant Messaging") OR (MH "Interactive Voice Response Systems") OR (MH "Internet") OR (MH "Telehealth+") OR (MH "Telephone") OR (MH "Text Messaging") OR (MH "Videoconferencing") OR (MH "Voice Mail") OR (MH "Mobile Applications") OR (MH "Telemetry")
- 5 TI (telerehabilitation OR telehealth OR telemedicine OR telehealthcare OR telemetry OR 'e-medicine' OR 'mobile health' OR mhealth OR 'e-health' OR 'mobile technology' OR 'mobile apps' OR apps OR smartphone OR 'cell phone') OR AB (telerehabilitation OR telehealth OR telemedicine

OR telehealthcare OR telemetry OR 'e-medicine' OR 'mobile health' OR mhealth OR 'e-health' OR 'mobile technology' OR 'mobile apps' OR apps OR smartphone OR 'cell phone')

6 4 OR 5

7 (MH "Physical Fitness+") OR (MH "Physical Activity") OR (MH "Physical Performance") OR (MH "Sports+") OR (MH "Physical Therapy+") OR (MH "Therapeutic Exercise+") OR (MH "Exercise Test, Cardiopulmonary") OR (MH "Exercise Test, Muscular") OR (MH "Exertion+")

8 TI (Exercise OR 'physical activity' OR endurance OR physiotherap*) OR AB (Exercise OR 'physical activity' OR endurance OR physiotherap*)

9 TI (Exercis* N3 (therap* OR protocol* OR intervention OR treatment)) OR AB (Exercis* N3 (therap* OR protocol* OR intervention OR treatment))

10 7 OR 8 OR 9

11 3 AND 6 AND 10

AMED

1 (DE "NEOPLASMS")

2 TI (((cancer OR tumor* OR tumour*) N3 (surviv* OR patient*))) OR AB (((cancer OR tumor* OR tumour*) N3 (surviv* OR patient*)))

3 1 OR 2

4 (DE "TELEMEDICINE") OR (DE "TELEPHONE")

5 TI (telerehabilitation OR telehealth OR telemedicine OR telehealthcare OR telemetry OR 'e-medicine' OR 'mobile health' OR mhealth OR 'e-health' OR 'mobile technology' OR 'mobile apps' OR apps OR smartphone OR 'cell phone') OR AB (telerehabilitation OR telehealth OR telemedicine OR telehealthcare OR telemetry OR 'e-medicine' OR 'mobile health' OR mhealth OR 'e-health' OR 'mobile technology' OR 'mobile apps' OR apps OR smartphone OR 'cell phone')

6 4 OR 5

7 (DE "PHYSICAL FITNESS") OR (DE "PHYSICAL FITNESS,") OR (DE "PHYSICAL THERAPY MODALITIES") OR (DE "PHYSICAL THERAPY SPECIALITY") OR (DE "PHYSICAL THERAPY TECHNIQUES") OR (DE "PHYSIOTHERAPISTS") OR (DE "PHYSIOTHERAPY") OR (DE "PHYSIOTHERAPY METHODS") OR (DE "EXERCISE") OR (DE "EXERCISE MOVEMENT TECHNIQUES") OR (DE "EXERCISE TESTING") OR (DE "EXERCISE THERAPY") OR (DE "EXERCISE TOLERANCE") OR (DE "SPORTS") OR (DE "MOTOR ACTIVITY")

8 TI (Exercise OR 'physical activity' OR endurance OR physiotherap*) OR AB (Exercise OR 'physical activity' OR endurance OR physiotherap*)

9 TI (Exercis* N3 (therap* OR protocol* OR intervention OR treatment)) OR AB (Exercis* N3 (therap* OR protocol* OR intervention OR treatment))

10 7 OR 8 OR 9

11 3 AND 6 AND 10

SCOPUS

Advanced search

ABS(telerehabilitation OR telehealth OR telemedicine OR telehealthcare OR telemetry OR 'e-medicine' OR 'mobile health' OR mhealth OR 'e-health' OR 'mobile technology' OR 'mobile apps' OR apps OR smartphone)

Search for cancer 'within results'

Web of Science

(telerehabilitation OR telehealth OR telemedicine OR telehealthcare OR telemetry OR 'e-medicine' OR 'mobile health' OR mhealth OR 'e-health' OR 'mobile technology' OR 'mobile apps' OR apps OR smartphone) AND ('cancer patient' OR 'cancer survivor') AND ('exercise' OR physical activity')

PSYCHinfo

(telerehabilitation OR telehealth OR telemedicine OR telehealthcare OR telemetry OR 'e-medicine' OR 'mobile health' OR mhealth OR 'e-health' OR 'mobile technology' OR 'mobile apps' OR apps OR smartphone) AND ('cancer patient' OR 'cancer survivor') AND ('exercise' OR physical activity')

Appendix 3 GLTPAQ

Godin Leisure-Time Exercise Questionnaire

INSTRUCTIONS

In this excerpt from the Godin Leisure-Time Exercise Questionnaire, the individual is asked to complete a self-explanatory, brief four-item query of usual leisure-time exercise habits.

CALCULATIONS

For the first question, weekly frequencies of strenuous, moderate, and light activities are multiplied by nine, five, and three, respectively. Total weekly leisure activity is calculated in arbitrary units by summing the products of the separate components, as shown in the following formula:

$$\text{Weekly leisure activity score} = (9 \times \text{Strenuous}) + (5 \times \text{Moderate}) + (3 \times \text{Light})$$

The second question is used to calculate the frequency of weekly leisure-time activities pursued “long enough to work up a sweat” (see questionnaire).

EXAMPLE

Strenuous = 3 times/wk

Moderate = 6 times/wk

Light = 14 times/wk

Total leisure activity score = $(9 \times 3) + (5 \times 6) + (3 \times 14) = 27 + 30 + 42 = 99$

Godin Leisure-Time Exercise Questionnaire

During a typical **7-Day period** (a week), how many times on the average do you do the following kinds of exercise for **more than 15 minutes** during your free time (write on each line the appropriate number).

Times Per

Week

a) STRENUOUS EXERCISE

(HEART BEATS RAPIDLY)

(e.g., running, jogging, hockey, football, soccer,

squash, basketball, cross country skiing, judo,

roller skating, vigorous swimming,

vigorous long distance bicycling)

b) MODERATE EXERCISE

(NOT EXHAUSTING)

(e.g., fast walking, baseball, tennis, easy bicycling,
volleyball, badminton, easy swimming, alpine skiing,
popular and folk dancing)

c) MILD EXERCISE

(MINIMAL EFFORT)

(e.g., yoga, archery, fishing from river bank, bowling,
horseshoes, golf, snow-mobiling, easy walking)

* During a typical **7-Day period** (a week), in your leisure time, how often do you engage in any regular activity **long enough to work up a sweat** (heart beats rapidly)?

OFTEN

1.

SOMETIMES

2.

NEVER/RARELY

3

Appendix 4 Actigraph Participant leaflet

Participant Information Leaflet

ActiGraph Activity Monitor

Thank you for agreeing to wear the ActiGraph Activity Monitor. The ActiGraph measures your physical activity levels and provides us with information on the amount of time you spend engaging in different intensities of activity. The following information leaflet addresses some frequently asked questions. Should you have any queries please contact the Physiotherapy Postgraduate and Research Room at the Trinity Centre for Health Sciences, St. James's Hospital on 01-8963613.

1. How many days do I wear the monitor?

You are requested to wear the activity monitor for one week (7 days) during waking hours.

2. Do I wear the monitor to bed?

No. You put the monitor on first thing in the morning and take it off last thing at night. You are requested to record the time you put the monitor on in the morning and the time you take it off at night in the activity diary provided.

3. Do I wear the monitor in the shower?

No. You should remove the monitor during any water-based activity such as showering, bathing or swimming. You are requested to record these activities, including the times you take the monitor on and off in the activity diary provided.

4. Do I need to press any button to start / finish the monitor?

No. The monitor is set-up by the researcher leading your study. You do not have to press any button to activate or stop the monitor.

5. Where on my body is the monitor worn?

The monitor is connected to a flexible strap with a clip. The strap should be worn like a belt around your waist with the monitor sitting at hip level on the right side of your body (see picture). Ensure the black disk on the side of the monitor is pointing towards your head. The strap should not be too tight or too loose. You can adjust the strap size if necessary. You may wear the monitor under or over your clothes.



6. Do I need to charge the monitor during the week?

No. Do not plug the monitor into any power source or connect to any USB cable during the week and this may wipe the data collected.

7. I forgot to wear the monitor – what should I do?

If you forget to wear the activity monitor on a particular day don't worry. Please write down clearly in the activity diary which day you forgot to wear the monitor and just carry on wearing it as normal the following day.

8. What should I do when I finish wearing the activity monitor?

When you finish wearing the monitor please return it to us in the stamped addressed envelope provided. Please return the monitor to us as soon as possible to ensure that the battery does not die before we receive it.

Try not to change your activity levels while wearing the monitor as our aim is to get an idea of normal activity patterns

Thank you very much for recording your physical activity

Physical Activity Diary

You are requested to wear your ActiGraph Activity Monitor during **all waking hours**. You will have to remove the activity monitor when you are going to bed or during water-based activities such as showering or swimming. Please record the time you put the activity monitor and the time you take it off in the following activity diary. If you forget to wear the monitor for a day please record this clearly in the activity diary. This record will help us to analyse your physical activity data as accurately as possible.

Should you have any queries please contact the Physiotherapy Postgraduate and Research Room at the Trinity Centre for Health Sciences, St. James's Hospital on 01-8963613. The following example outlines the details required.

Example:

On Date	On Time	Off Date	Off Time	Activity completed while not wearing the monitor
04.10.2013	8.20am	04.10.2013	7.10pm	Shower

Thank you for taking the time to record your physical activity.

Appendix 5 FACT-G Questionnaire

FACT-G (Version 4)

Below is a list of statements that other people with your illness have said are important. **Please circle or mark one number per line to indicate your response as it applies to the past 7 days.**

<u>PHYSICAL WELL-BEING</u>		Not at all	A little bit	Some- what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

<u>SOCIAL/FAMILY WELL-BEING</u>		Not at all	A little bit	Some- what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	<i>Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box <input type="checkbox"/> and go to the next section.</i>					
GS7	I am satisfied with my sex life	0	1	2	3	4

FACT-G (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

EMOTIONAL WELL-BEING

		Not at all	A little bit	Some- what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness.....	0	1	2	3	4
GE3	I am losing hope in the fight against my illness.....	0	1	2	3	4
GE4	I feel nervous.....	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

FUNCTIONAL WELL-BEING

		Not at all	A little bit	Some- what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling.....	0	1	2	3	4
GF3	I am able to enjoy life.....	0	1	2	3	4
GF4	I have accepted my illness.....	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now.....	0	1	2	3	4

FACT-G Scoring Guidelines (Version 4)

- Instructions:*
1. Record answers in "item response" column. If missing, mark with an X
 2. Perform reversals as indicated, and sum individual items to obtain a score.
 3. Multiply the sum of the item scores by the number of items in the subscale, then divide by the number of items answered. This produces the subscale score.
 4. Add subscale scores to derive total FACT-G score. *The higher the score, the better the QOL.*

<u>Subscale</u>	<u>Item Code</u>	<u>Reverse item?</u>	<u>Item response</u>	<u>Item Score</u>
PHYSICAL WELL-BEING (PWB)	GP1	4 -	_____	= _____
	GP2	4 -	_____	= _____
	GP3	4 -	_____	= _____
	GP4	4 -	_____	= _____
	GP5	4 -	_____	= _____
	GP6	4 -	_____	= _____
	GP7	4 -	_____	= _____
Score range: 0-28				

Sum individual item scores: _____
Multiply by 7: _____
Divide by number of items answered: _____ = **PWB subscale score**

SOCIAL/FAMILY WELL-BEING (SWB)	GS1	0 +	_____	= _____
	GS2	0 +	_____	= _____
	GS3	0 +	_____	= _____
	GS4	0 +	_____	= _____
	GS5	0 +	_____	= _____
	GS6	0 +	_____	= _____
	GS7	0 +	_____	= _____
Score range: 0-28				

Sum individual item scores: _____
Multiply by 7: _____
Divide by number of items answered: _____ = **SWB subscale score**

EMOTIONAL WELL-BEING (EWB)	GE1	4 -	_____	= _____
	GE2	0 +	_____	= _____
	GE3	4 -	_____	= _____
	GE4	4 -	_____	= _____
	GE5	4 -	_____	= _____
	GE6	4 -	_____	= _____
Score range: 0-24				

Sum individual item scores: _____
Multiply by 6: _____
Divide by number of items answered: _____ = **EWB subscale score**

FUNCTIONAL WELL-BEING (FWB)	GF1	0 +	_____	= _____
	GF2	0 +	_____	= _____
	GF3	0 +	_____	= _____
	GF4	0 +	_____	= _____
	GF5	0 +	_____	= _____
	GF6	0 +	_____	= _____
	GF7	0 +	_____	= _____
Score range: 0-28				

Sum individual item scores: _____
Multiply by 7: _____
Divide by number of items answered: _____ = **FWB subscale score**

TOTAL SCORE:

Score range: 0-108

_____ + _____ + _____ + _____ = _____ = **FACT-G Total score**
 (PWB score) (SWB score) (EWB score) (FWB score)

*For additional guidelines please refer to the Administration and Scoring Guidelines in the manual or at www.facit.org.

Appendix 6 SF-36 Physical Functioning Component

Study I.D. #: _____ MRN #: _____ Time: _____

Name: _____ Date: ____/____/____

The following questions are about activities you might do during a typical day.

Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <u>Vigorous activities</u> , such as running, lifting heavy objects, participating in strenuous sports			
b. <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf			
c. Lifting or carrying groceries			
d. Climbing several flights of stairs			
e. Climbing one flight of stairs			
f. Bending, kneeling or stooping			
g. Walking <u>more than a mile</u>			
h. Walking <u>several hundred yards</u>			
i. Walking <u>one hundred yards</u>			
j. Bathing or dressing yourself			

Scoring the SF-36

The process for scoring the SF-36 can be broken down into 7 steps

1. Enter item response data
2. Recode item response data
3. Determine health domain raw scores
4. Transform health domain raw scores to 0-100 scores
5. Transform health domain scale 0-100 to T-scores
6. Score component summary measures (if required)
7. Score response consistency index (optional)

Precoded and final values for items 3a-3j (PF component)

Response choice	Precoded item value	Final item value
Yes, limited a lot	1	1
Yes, limited a little	2	2
No, not limited at all	3	3

Formula for scoring: $\text{Transformed Scale} = (\text{Actual raw score} - \text{lowest possible raw score} / \text{Possible raw score range}) \times 100$

Appendix 7 Detailed Interview Guide for Study 2

Interview Guide

Introduction:

Participants will be welcomed and the purpose of the focus group will be explained again. Light refreshments will be served at this point. This will act as an ice-breaker. The moderator and the co-moderator will be introduced.

'I'd like to welcome you all to this focus group discussion. Thanks for agreeing to be part of the focus group. My name is Ciaran Haberlin and I will be leading the discussion, my supervisor Julie Broderick will be taking notes throughout. We appreciate your willingness to participate in this discussion today'.

Our topic is the promotion of physical activity using mobile technology/smartphones. What we are trying to find out, is if there is a way to encourage people to exercise more using smartphones.

Ground rules

No right or wrong answers

We are tape recording- one person to speak at a time

First name basis

You don't need to agree, but listen respectfully to each other

Phones to be turned off, or if you must take a call please do so quietly, away from the group.

My job will be to guide the discussion

Start recording

This is focus group number 1

Subject Questions:

What motivates you to exercise?

Probing question: Is there anything in particular that could help?

Do you think a smartphone application could help you to increase your daily physical activity?

Probing Question: In what way could it do this? What features would be useful? Why would it not help?

Would anything stop you from using mobile technology to help you to exercise more?

Probing question: Can you explain these barriers?

Can you think of any ways you could overcome these difficulties?

Probing questions: How would these solutions work to make mobile technology effective in helping you exercise?

Is there anything that would make it easier to use mobile technology?

Probing questions: What support/help do you think would facilitate you to use a smartphone application in physical promotion?

Are there any smartphone app features that you think would help you to exercise more?

Clarifying Questions:

Can you expand a little on this? Can you give some examples?

Note taker question/observation

Any theme that was not elaborated sufficiently, any question that could be asked.

Closing Questions

Asked of each participant: Of everything we talked about today, what to you is the most important part?

Is there any other information regarding your experience with mobile technology and exercise that you think would be useful for me to know?

Appendix 8 Study 1 Questionnaire

Questionnaire

Title: Exploration of the possible use of mobile technology to promote physical activity in patients with cancer.

This questionnaire will only take 5 to 10 minutes to complete. Most of the questions ask you to answer YES or NO next to your question. All questionnaires will be treated with the strictest confidence.

There is a research physiotherapist available if you have any questions or would prefer someone to fill the form in with you.

More information on this questionnaire is available in the information leaflet you have been given. You may also contact Ciaran Haberlin if you have further queries. Email: haberlic@tcd.ie
Phone: 0852432679

Questionnaire

1. How many days a week of physical activity or exercise are recommended for the average adult to stay healthy?

_____ (number of days)

2. On those days, how long should the average adult be physically active to stay healthy?

_____ (minutes or hours)

3. In the past week, on how many days have you done a total of 30 minutes or more of physical activity, which was enough to raise your breathing rate. This may include sport, exercise, and brisk walking or cycling for recreation or to get to and from places, but should not include housework or physical activity that may be part of your job

- 0 days
- 1 day
- 2 days
- 3 days
- 4 days
- 5 days
- 6 days
- 7 days

4. On average how many hours per day do you spend sitting or lying during waking hours?

9. Would you be interested in taking part in a group discussion about improving your physical activity using a smartphone application?

10. Would you be interested in taking part in a research study which will investigate the effect of smartphone applications on your daily physical activity?

Appendix 9 Letters of ethics approval

THIS DOCUMENT MUST NOT BE USED FOR
PROMOTION OR MARKETING PURPOSES



SJH/AMNCH Research Ethics Committee Secretariat
Claire Hartin Ph: 4142159
email: claire.hartin@amnch.ie

**THE ADELAIDE & MEATH
HOSPITAL, DUBLIN**
INCORPORATING
THE NATIONAL CHILDREN'S HOSPITAL

TALLAGHT, DUBLIN 24, IRELAND
TELEPHONE: +353 1 4142000

Mr. Ciaran Haberlin
Discipline of Physiotherapy
Trinity Centre for Health Sciences
St. James Hospital
James's Street
Dublin 8

18 July 2017

Re: Investigating the feasibility and acceptability of a technology-delivered physical activity intervention in cancer: The IMPETUS study

REC Reference: 2017-07 List 25 (7)
(Please quote reference on all correspondence)

Dear Mr. Haberlin,

Thank you for your recent correspondence to SJH/AMNCH Research Ethics Committee in which you requested an amendment in relation to the above referenced study.

The Chairman, Dr. Peter Lavin, on behalf of the Research Ethics Committee, has reviewed this request and grants permission for this amendment.

Yours sincerely,

Claire Hartin
Secretary
SJH/AMNCH Research Ethics Committee

The SJH/AMNCH Joint Research and Ethics Committee operates in compliance with and is constituted in accordance with the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 & ICH GCP guidelines.

THIS NOTE/PAPER MUST NOT BE USED FOR
PRESCRIPTIONS OR MEDICINE PURPOSES



**THE ADELAIDE & MEATH
HOSPITAL, DUBLIN**
INCORPORATING
THE NATIONAL CHILDREN'S HOSPITAL

TALLAGHT, DUBLIN 24, IRELAND
TELEPHONE +353 1 4142000

SJH/AMNCH Research Ethics Committee Secretariat
Claire Hartin, Ph: 4142199
email: claire.hartin@amnch.ie

Dr. Dearbhaile O'Donnell
Consultant Medical Oncologist
St. James's Hospital
James's Street
Dublin 8

14th July 2016

Re: Investigating the feasibility and acceptability of a technology delivered physical activity (PA) intervention in cancer; The IMPETus Cancer Trial

REC Reference: 2016-07 List 27 (1)

Please quote REC reference on all correspondence

Dear Dr. O'Donnell,

Thank you for your recent correspondence in which you responded to the conditions as requested by SJH/AMNCH Research Ethics Committee.

The Chairman of the Committee has reviewed this correspondence, is satisfied with the response and advises that full ethical approval is in place for this study.

Yours sincerely,

Claire Hartin
Secretary
SJH/AMNCH Research Ethics Committee

The SJH/AMNCH Joint Research and Ethics Committee operates in compliance with and is constituted in accordance with the European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations 2004 & ICH GCP guidelines.

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PRESCRIPTIONS OR ANY OTHER PURPOSES



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HOSPITAL, DUBLIN**
INCORPORATING
THE NATIONAL CHILDREN'S HOSPITAL

TALLAGHT, DUBLIN 24, IRELAND
TELEPHONE +353 1 4142000

SJH/AMNCH Research Ethics Committee Secretariat
Claire Hartin Ph: 4142199
email: claire.hartin@amcnh.ie

Mr. Ciaran Haberlin
Discipline of Physiotherapy
Trinity Centre for Health Sciences
St. James's Hospital
James's Street
Dublin 8

30th September 2016

Re: Investigating the feasibility and a acceptability of a technology-delivered physical activity intervention in cancer: The IMPETUS study

REC Reference: 2016/07/List 27 (1) 2016-09 List 33 (10)
(Please quote reference on all correspondence)

Dear Mr. Haberlin,

Thank you for your correspondence to SJH/AMNCH Research Ethics Committee, in which you requested an amendment in relation to the above referenced study.

The Chairman, Dr. Peter Lavin, on behalf of the Research Ethics Committee, has reviewed this request and grants permission for this amendment.

The following documents were reviewed:

- Amended Ethics Form
- Amended Patient Information Leaflet
- Cover letter explaining changes

Yours sincerely,

Claire Hartin
Secretary
SJH/AMNCH Research Ethics Committee

The SJH/AMNCH Joint Research and Ethics Committee operates in compliance with and is constituted in accordance with the European Commission (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 & ICH GCP guidelines.

Appendix 10 Question 10-Patient satisfaction questionnaire results

<ul style="list-style-type: none"> Getting out of the house in order to reach goals had made me happier over the course of the programme. I feel more motivated to get my strength back in order to return to my previous lifestyle.
<ul style="list-style-type: none"> The twelve weeks have been <u>VERY</u> beneficial and I feel stronger/fitter and healthier now and determined to continue with regular exercise. I have really enjoyed the experience
<ul style="list-style-type: none"> Very good experience which I felt I needed to get me motivated, now I hope I can keep it up without my fitbit. I feel that I might have benefitted from this type of programme sooner post-chemotherapy/radiation (3 years post)
<ul style="list-style-type: none"> thank you
<ul style="list-style-type: none"> no
<ul style="list-style-type: none"> Following treatment I suffered fatigue, so was not doing any exercise- some days was not sure if it was laziness or fatigue- my family would encourage rest. So this programme helped me to get back walking and normality- felt more confident that I was being monitored. Illness causes you to lose confidence with yourself and your body. Thank you.
<ul style="list-style-type: none"> nil comments
<ul style="list-style-type: none"> Really found it helped me exercise and kept me focused on the routine. Also made me watch my weight.
<ul style="list-style-type: none"> Thanks
<ul style="list-style-type: none"> Thanks :)
<ul style="list-style-type: none"> nil comments
<ul style="list-style-type: none"> Really enjoyed taking part. Found it a great motivator
<ul style="list-style-type: none"> Without the encouragement from Ciaran I wouldn't have made it on my own
<ul style="list-style-type: none"> I feel there needs to be a lot more emphasis on physical health during and after bone marrow transplant and cancer treatments. That if I felt I wanted to exercise a bike would have been available throughout the process. Getting back physical health takes a lot longer because this isn't encouraged.
<ul style="list-style-type: none"> Having the fitbit made me more conscious of my idle time. Sometimes rather than waiting for luas for example, if I had time I would walk to the next stop or walk around while on the phone

<ul style="list-style-type: none"> • nil comments
<ul style="list-style-type: none"> • I enjoyed taking part
<ul style="list-style-type: none"> • nil comments
<ul style="list-style-type: none"> • no
<ul style="list-style-type: none"> • Really enjoyed taking part in the research. Has given me an interest in exercising and trying to improve my physical well-being. When I reached my goal and I felt I slept better and it improved my general well-being. It's amazing how a phone call once a week can motivate a person to do more exercise, to shift things a bit. The next bit is how to keep going once the intervention stops. That's my challenge. Thanks! I learned how fast I need to walk for getting the benefits of walking from Ciarán at the start of the programme. Otherwise I tended to walk a bit slower.
<ul style="list-style-type: none"> • no
<ul style="list-style-type: none"> • being in touch all through the programme helped me to push myself
<ul style="list-style-type: none"> • nil comments
<ul style="list-style-type: none"> • Really enjoyed the 12 weeks hoping it helped in the study. Ciaran amazing with phone calls and helped in everyway. Thanks :)
<ul style="list-style-type: none"> • I liked the idea that everything was all contained in 1 app- exercise, steps, water and food but unfortunately I didn't utilise the water and food intake as much as I should have. Might be an idea to bring this more into study as I do feel if I'm eating healthy it does spur me on to exercise more.
<ul style="list-style-type: none"> • Ultimate goal/target for participants
<ul style="list-style-type: none"> • nil comments
<ul style="list-style-type: none"> • nope
<ul style="list-style-type: none"> • nil comments
<ul style="list-style-type: none"> • I just found it very beneficial, it gives me confidence in being able to do it.
<ul style="list-style-type: none"> • blank
<ul style="list-style-type: none"> • I thank you. I feel this programme has helped me in many ways e.g. getting fitter, losing weight and has given me a more positive outlook
<ul style="list-style-type: none"> • ?if I would have been as good in winter. Sleep function wasn't great.
<ul style="list-style-type: none"> • just a big "thank you" for the opportunity to take part
<ul style="list-style-type: none"> • nil comments

Appendix 11

Data entry forms for outcome assessment in Study 3

Body Composition

Study I.D: _____

Bioelectrical Impedance Analysis

O Void before measure	O Fast >3hours	Time:
Age:years	Height:cm
Weight:kg	BMI:kg/m ²
FMkg	FM% %
FFMkg	FMIkg/m ²
FFMIkg/m ²	SMMkg
LST L armkg	LST R armkg
LST L legkg	LST R legkg
TBWL	ECWL
Hydration%		

Vector Analysis:

Xc Ω R Ω

Health Risk:

Phase Angle Ψ

Waist Circumference

WC 1:cm WC 2:cm

Average WC:cm

Six Minute Walk Test

Study I.D: _____

Pre-Testing

Resting Heart Rate

Resting heart rate: bpm

Resting Blood Pressure

Resting BP (i): mm Hg

Resting BP (ii): mm Hg

Resting BP (iii): mm Hg

BORG

Oxygenation Saturation

Resting BORG RPE: SpO₂: %

During Testing

Lap Counter (Note: 1 lap = 60m)

Time (mins)	HR	BORG	Rests
1			
2			
3			
4			

5			
6			

Recovery

Time (mins)	HR	BORG	BP	SpO₂
1				
2				

Total Distance:m

Appendix 12 Consent, patient information leaflets for Study 1,2,3.

Patient Consent Form

Title of research

Exploration of the possible use of mobile technology to promote physical activity in patients with cancer.

This study and this consent form have been explained to me. The investigator has answered all of my questions to my satisfaction. I believe I understand what will happen if I agree to be part of this study. I will be filling out a questionnaire on the subject of physical activity and smartphone technology. The results from the test will be used to find out current physical activity and mobile technology behaviours in patients with cancer.

I agree to allow the investigator in this study to access my medical chart in order to check my suitability for this study. I consent to the publication of data from this study and I understand that my identity will remain confidential.

I have read, or have been read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement and I understand that, if there is a sponsoring company, a signed copy will be sent to that sponsor.

Participant's Name _____

Participant's Signature _____

Date _____

[Date on which form was first furnished: _____]

Statement of investigator's responsibility

I have explained the nature, purpose, procedures, benefits and risks of this research study. I have offered to answer any questions and fully answered such questions. I believe that the participants understands my explanation and has freely given informed consent.

Investigator's signature _____

Date _____

Patient Consent Form

Title of research

Exploration of the possible use of mobile technology to promote physical activity in patients with cancer: A Focus group study.

This study and this consent form have been explained to me. The investigator has answered all of my questions to my satisfaction. I believe I understand what will happen if I agree to be part of this study.

I will be taking part in a focus group discussion on the subject of physical activity and smartphone technology. The study results will be used to find out attitudes and opinions to physical activity and mobile technology in patients with cancer. I will not be asked to disclose anything about my cancer or its treatment. Only information that I volunteer about my cancer will be discussed.

I agree to allow the investigators in this study to access my medical records in St.James's Hospital in order to check my suitability for this study and to obtain data about my treatment in order to analyse the results of the study. I understand that data will be only be kept by the investigators in a form where I cannot be identified. I understand that the focus group conversation will be recorded, but that recording will be destroyed once my answers have been written down. When my answers are written down, that document will not identify me. I understand that my identity will remain confidential.

I consent to the publication of data from this study.

I have read, or have been read, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I have received a copy of this agreement and I understand that, if there is a sponsoring company, a signed copy will be sent to that sponsor.

Participant's Name _____

Participant's Signature _____

Date _____

[Date on which form was first furnished: _____]

Statement of investigator's responsibility

I have explained the nature, purpose, procedures, benefits and risks of this research study. I have offered to answer any questions and fully answered such questions. I believe that the participants understands my explanation and has freely given informed consent.

Patient Consent Form

Title of research

Investigating the feasibility and efficacy of a technology delivered physical activity (PA) intervention in cancer survivors: The IMPETUS Trial

This study and this consent form have been explained to me. The investigator has answered all of my questions to my satisfaction. I believe I understand what will happen if I agree to be part of this study. I will be taking part in a 12 week programme, with follow up at 24 weeks, to evaluate the effect of support and motivation from a qualified physiotherapist combined with using physical activity tracker [Fitbit device, (Fitbit, Inc.)] which will be lent to me for the duration of the study. The results from the study will be used to find out if the use of technology can increase physical activity in patients with cancer.

I agree to take part in a series of tests, as described in the information leaflet attached, supervised by a chartered physiotherapist. I agree to allow the investigator in this study to access my medical chart in order to check my suitability for this study. I consent to the publication of data from this study and I understand that my identity will remain confidential. I agree to allow the investigator access to my physical activity data recorded by the Fitbit device in order to prescribe and monitor physical activity goals during the study.

I have read, or have had read to me, this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.

Participant's Name _____

Participant's Signature _____

Date _____

[Date on which form was first furnished: _____]

Statement of investigator's responsibility

I have explained the nature, purpose, procedures, benefits and risks of this research study. I have offered to answer any questions and fully answered such questions. I believe that the participants understands my explanation and has freely given informed consent.

Investigator's signature _____

Date _____

The copy this form will be kept in the medical record, one copy will be given to the participant and the original stored in the investigator records.

Patient Information Leaflet Study 1

Title of Study

Exploration of the possible use of mobile technology to promote physical activity in patients with cancer.

Introduction

The importance of keeping physically active is particularly important in patients with cancer. Many cancer survivors are unfit or are not as active as is recommended for good general health. The use of mobile phone technology and smartphone apps may provide the tools necessary to help patients stay physically active and may also help motivate patients to engage in exercise every day.

This study will involve the administration of a questionnaire to patients currently attending the outpatient oncology service in St. James's Hospital. The aim of this questionnaire is to find out the current physical activity (and exercise) behaviours of this population. The questionnaire will also find out how many of these patients are using smartphones in their daily life. We are also seeking information as to the number of patients meeting the physical activity guidelines recommended for patients with cancer.

The information gained from this study will be helpful to find out the best way for clinicians to recommend exercise, and whether using a smartphone application will actually help patients achieve more physical activity every-day.

Participation in this study will not affect your medical or surgical treatments.

If you choose to participate, you will be requested to complete a questionnaire which will ask questions about your current physical activity and if you use technology and smartphones in your daily life.

Who is being asked to participate

1. Adult population (at least 18 years of age)
2. Patients currently attending outpatient clinics of the oncology and haematology day services of St.James's.
3. Capable of understanding an English language questionnaire.
4. Absence of cognitive disabilities that may hinder following instructions.
5. Patients who have received chemotherapy or radiation therapy for malignancy and have finished a course of treatment or are anticipated to finish their treatment within 3 months.

What do I have to do

If you choose to participate, you will have to fill in a 10- item questionnaire, which will take approximately 10 minutes. The questionnaire can be completed on paper or on a tablet computer.

The questionnaire contains questions about your current physical activity and if/how you use smartphones.

What are the benefits to me

The completion of this study will inform you of how much physical activity you should be doing every day to promote good general health.

Are there any risks to me?

There is extremely low possibilities of risks involved when performing the assessments. You will only be required to fill in a questionnaire either on a sheet of paper or on a tablet computer.

Who cannot participate in this study?

You may not participate in this study if you are unable to give informed consent or if you have the following condition

- Participants <18 years of age.
- Unable to understand English language questionnaire
- Cognitive impairments which hinder participation.
- Patients whom the physician or specialist nurse feels should not be approached for this study.
- Patients waiting to start their cancer treatment.

Will my information be confidential

Your identity will remain confidential. Your name will not be published or disclosed to anyone outside the Discipline of Physiotherapy, Trinity College Dublin or St James's Hospital.

Compensation

Your doctors are covered by standard medical indemnity insurance. Nothing in this document restricts or curtails your rights.

What if I change my mind

If you have volunteered to participate in this study, you may quit at any time. If you decide not to participate or if you quit, you will not be penalised and will not give up any benefits which you had before entering the study. Participation in this study will not affect your treatment in any way.

Stopping the Study

You understand that your doctor or investigator in this study may stop your participation in the study at any time without your consent.

Permission

This study is conducted under the approval of ____ Research Ethics committee

I have more questions, who will I ask?

You can get more information or answers to your questions about the study, your participation in the study and your rights, from Ciaran Haberlin (lead investigator) who can be telephoned at 0852432679. If there is any important information that might affect your desire to remain in the study, he will tell you.

Patient Information Leaflet Study 2

Title of Study

Exploration of the possible use of mobile technology to promote physical activity in patients with cancer: A focus group study.

Introduction

Keeping physically active is particularly important in people who have cancer. Many cancer survivors are unfit or are not as active as is recommended for good general health.

We would like to know how cancer patients feel about using mobile technology to help them achieve physical activity goals. We want to hear what they think could be barriers or problems with using mobile technology for physical activity promotion. We will use that information to decide if it is worthwhile developing a physical activity programme for cancer patients and survivors which includes a smartphone application or some other mobile technology.

This study involves taking part in a focus group discussion with patients currently attending the outpatient oncology or haematology service in St. James's Hospital. A focus group is an open discussion among a group of people about a specific topic. Participants are invited to share their feelings, ideas and attitudes about a certain topic in the company of others.

Participation in this study will not affect your medical or surgical treatments.

If you choose to participate, you will be asked to attend a focus group which will ask questions about your opinions and thoughts about the use of technology and smartphones in encouraging physical activity.

Who is being asked to participate?

6. Adults (at least 18 years of age)
7. Patients currently attending outpatient clinics of the oncology and haematology services of St. James's Hospital.
8. Patients who speak fluent English. (Members of the research team will be available to read through the information leaflet with participants if needed).
9. Patients who have received chemotherapy or radiation therapy for cancer or leukemia and have finished a course of treatment or are anticipated to finish their treatment within 3 months.

What do I have to do?

If you choose to be a part of this study, you will have to take part in one group discussion with other cancer patients and survivors on the subject of mobile technology and physical activity. Two members of the research team will be present, as well as your fellow participants. There will be 4-6 people in each group, and the discussion will last between 60-90 minutes. The discussion will last no longer than 90 minutes.

Before the start of the focus group, light refreshments will be served as a token of appreciation for taking part in the study.

You will be invited to respond to various questions the investigator has and to share your thoughts on the subject of mobile technology and exercise.

Will I have to discuss my cancer and its treatment with the other patients?

No. We will only be asking questions about physical activity and mobile technology. However, because everyone will have signed the same consent form, all those taking part in the group will know that everyone else in the group is going through or has recently finished cancer treatment. Beyond that, there will be no obligation to discuss anything specific. In fact, the researcher leading the group will try to steer people away from discussing anything other than mobile technology and physical activity. This focus group is not a support group for cancer patients.

What are the benefits to me?

Taking part in this study will allow you to think about and discuss issues surrounding mobile technology and physical activity with other participants who may be in similar situations as yourself. It may help your awareness of how much you should be exercising every week to stay healthy.

Are there any risks to me?

There is an extremely low possibility of any risks involved when taking part in this study. You will only be required to sit and speak about your experiences of mobile technology in your life and your thoughts about it.

Who cannot participate in this study?

You may not participate in this study if you are unable to give informed consent or if you have the following condition

- You are less than <18 years of age.
- You are non-fluent in spoken English.
- You have other difficulties (for example hearing impairment) which could stop you taking part.
- Your doctor or specialist nurse feels you should not take part in this study.
- You have not yet started cancer treatment.

Will my information be confidential?

Yes. The conversations will be recorded at the time so that the researchers can write down afterwards what everyone says. As soon as it is written down, the tape will be destroyed so your voice is not identifiable. When it is written down, you will only be identified by a letter or number. Only the researchers will know the identity of each individual. Your identity will remain confidential. Your name will not be published or disclosed to anyone outside the Discipline of Physiotherapy, Trinity College Dublin or St James's Hospital. If the results of this research are published, there will be no way of identifying anyone who took part.

Compensation

Your doctors are covered by standard medical indemnity insurance. Nothing in this document restricts or curtails your rights.

What if I change my mind

If you have volunteered to participate in this study, you may quit at any time. If you decide not to participate or if you quit, you will not be penalised and will not give up any benefits which you had before entering the study. Participation in this study will not affect your treatment in any way.

Stopping the Study

You understand that your doctor or investigator in this study may stop your participation in the study at any time without your consent.

Permission

This study is conducted under the approval of ____ Research Ethics committee

I have more questions, who will I ask?

You can get more information or answers to your questions about the study, your participation in the study and your rights, from Ciaran Haberlin (lead investigator) who can be telephoned at 0852432679. If there is any important information that might affect your wish to remain in the study, he will tell you.

Patient Information Leaflet Study 3

Title of Study

Investigating the feasibility and acceptability of a technology-delivered physical activity intervention in cancer: The IMPETUS study

Introduction

Keeping active physically is very important in people who have been treated for cancer. Many people who have had chemotherapy or radiotherapy for cancer are unfit or are not as active as is recommended for good general health.

This study will investigate if it is feasible (possible) to set up a programme using devices to track physical activity with support from qualified physiotherapists to help people who have been treated for cancer in the recent past to improve their daily physical activity.

This study will invite people to take part in a 12-week study, with follow up at around 24 weeks after the first appointment. If you decide to take part, a qualified physiotherapist will give you goals and support aimed at improving your physical activity. We will also lend you a commercially available physical activity tracking device (Fitbit, Fitbit, Inc.) and teach you how to use it. That physical activity tracker will also include an application for use with a smartphone or tablet or with a computer connected to the internet. You will be able to upload your daily activity from the tracker and keep up to date with your goals using your smartphone or tablet, or by logging on to a computer. If you are not familiar with this type of technology, we will provide extra training and support to you. A partner or family member is also welcome to take part in this training, so they can support you at home if you wish. The aim of the study is to find out how useful and effective this technology might be in helping people treated for cancer to become more active physically

This study will measure your usual physical activity levels at the start of the study and at the end to see if the programme had any effects on your physical activity levels. We will also find out your views on the programme. Taking part in this study will not affect your usual medical or surgical care.

If you choose to take part, you will be asked to attend St. James Hospital for this study on four separate occasions over 6 months. We have explained exactly what will happen on each of those visits below.

Who is being asked to take part in this study?

- People aged 18 to 75 years
- People who finished chemotherapy or radiotherapy for treatment of cancer up to 3 years before the start of the study.
- People able to understand English

- People whose cancer doctor (medical oncologist, haematologist, radiation oncologist or surgeon) has agreed they can take part
- People who own or who have access to a device which works with the Fitbit activity tracker, i.e. a smartphone, a tablet, or a computer with an internet connection.

What do I have to do?

If you choose to be a part of this study, you will wear a Fitbit (Fitbit Inc.) physical activity tracker (Picture 1) for 12 weeks of the study. As well as wearing the Fitbit, you will be asked to wear an additional physical activity monitor (The Actigraph accelerometer) (Picture 2.) for even more precise activity measurement for one week at a time at three time points. Those time points are Week 1, Week 12 and Week 24.

(Picture 1) Fitbit (Fitbit Inc.)



(Picture 2) Actigraph Accelerometer



(These are both actual size)

You will meet the lead researcher on 4 occasions in St.James' Hospital, the details of which are described below.

Appointment 1 (Consent)

The lead researcher Ciaran Haberlin will provide you with a consent form and this leaflet at your routine outpatient oncology appointment in St. James' Hospital. If you wish to participate in the study he will provide you with an Actigraph, which is a special research physical activity tracker. You do not have to do anything with that device except post it back to St. James's after that time. If you wish to take more time to consider your participation in the study, you can bring home the consent form and this information leaflet, and send back the signed consent form in the post, if you decide to participate.

Appointment 2 (called the "Baseline" session):

You will attend an educational session, delivered by the lead researcher Ciaran Haberlin, a chartered physiotherapist. This will consist of a group information session on physical activity following cancer treatment. In this session you will learn about current physical activity guidelines and the benefits of avoiding a sedentary lifestyle. You will be given a Fitbit for the study and shown how to download the paired application. The lead investigator, Ciaran Haberlin, will be on hand to explain all features of the smartphone application and the Fitbit.

You will also have a one-to-one session on that day with a physiotherapist, to have your weight, height and body composition measured, to do a walking test and to fill out a questionnaire on your current physical activity and quality of life.

If you feel unfamiliar with the Fitbit or internet technology, you can have another one-to-one session after your fitness test to ensure you are completely happy with using it. A family member can also come along to receive the Fitbit training if you wish.

We expect that first visit will take about an hour to an hour and a half.

Phone calls: Following that Baseline session, you will receive scheduled phone calls related to the study over the next 12 weeks. During these phone calls you will be reminded and advised about uploading data from the Fitbit and study personnel will also provide you with feedback and an update on your goals. You will receive 2 calls a week for the first 4 weeks, 1 call a week for the next four weeks and a call every fortnight in the last 4-week period.

Appointment 3 (approximately 12 weeks after first appointment):

You will return to St. James's Hospital to have your weight, height and body composition measured again, to repeat the walking test and to fill out another questionnaire on your current physical activity and quality of life. You will again get the Actigraph accelerometer (Physical activity tracker) to wear for a week and to post it back to St. James's.

Appointment 4 (approximately 24 weeks (a bit less than 6 months) after the Baseline):

You will return to St. James's Hospital to have your weight, height and body composition measured again, to repeat the walking test and to fill out another questionnaire on your current physical activity and quality of life. You will again get the Actigraph accelerometer (Physical activity tracker) to wear for a week and to post it back to St. James's. That is the end of the main study. You may be asked at that visit if you would be prepared to be contacted in a further 3 months' time, but there will be no obligation to do that.

What are the benefits to me?

Taking part in this study will allow you to participate in a program which is designed to motivate and support you to increase your physical activity. It also gives you an opportunity to have a chartered physiotherapist help you set and achieve physical activity goals. It may help your awareness of how much you should be exercising every week to stay healthy. You should be aware that this physiotherapist can only see you in relation to this study. For any health concerns you will be asked to contact your cancer care team, usually your liaison nurse in the first instance, for advice.

Are there any risks to me?

There is an extremely low possibility of any risks involved when taking part in this study. All assessments including the walking test will be closely supervised by a qualified physiotherapist. The physical assessments are not taxing in this study. The physical assessments will be stopped immediately if any risk is identified. The physical activity goals in this study will be small and gradual and you will not be asked to do any strenuous physical activity as part of this study.

Who cannot take part in this study?

You may not take part if you cannot give informed consent or if any of the following apply:

- You are under 18 years of age or aged over 75 years.
- You are not able to understand English instructions
- Your doctor or specialist nurse thinks you should not take part in this study
- You are still receiving active anti-cancer treatment (except hormone therapy and Herceptin)

- You have a medical condition, for example, severe lung or heart disease or severe arthritis which prevents you being active physically
- You do not have access to a smartphone, tablet or to a computer with an internet connection

Will my information be confidential?

Yes. Only the researchers will know the identity of each individual. Your identity will remain confidential. Your name will not be published or disclosed to anyone outside the Discipline of Physiotherapy, Trinity College Dublin or St James's Hospital. If the results of this research are published, there will be no way of identifying anyone who took part. The information from the Fitbit will be uploaded by you using a special email address and password for the study, so it can only be seen by you and by the physiotherapist(s) monitoring your physical activity and won't show your identity at all.

Compensation

Your doctors are covered by standard medical indemnity insurance. Nothing in this document restricts or curtails your rights.

What if I change my mind?

If you have volunteered to take part in this study, you may quit at any time. If you decide not to take part or if you quit, you will not be penalised and will not give up any benefits which you had before entering the study. Taking part in the study will not affect your usual medical or surgical care in any way.

Stopping the Study

Your doctor or the investigator(s) in this study may stop your participation in the study at any time without your consent.

Permission

This study is conducted under the approval of the AMNCH/St. James's Hospital Research Ethics committee. Data will be retained for a maximum of 7 years and you will be given an opportunity to consent to this period of retention.

I have more questions; whom should I ask?

You can get more information or answers to your questions about the study, your participation in the study and your rights, from Ciaran Haberlin (lead investigator) who can be telephoned at (01) 8962110. If there is any important information that might affect your wish to remain in the study, he will tell you.

Appendix 13 Downs and Black Risk of bias tool

Appendix

Checklist for measuring study quality

Reporting

1. *Is the hypothesis/aim/objective of the study clearly described?*

yes	1
no	0

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*

If the main outcomes are first mentioned in the Results section, the question should be answered no.

yes	1
no	0

3. *Are the characteristics of the patients included in the study clearly described ?*

In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

yes	1
no	0

4. *Are the interventions of interest clearly described?*

Treatments and placebo (where relevant) that are to be compared should be clearly described.

yes	1
no	0

5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*

A list of principal confounders is provided.

yes	2
partially	1
no	0

6. *Are the main findings of the study clearly described?*

Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

yes	1
no	0

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*

In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0

8. *Have all important adverse events that may be a consequence of the intervention been reported?*

This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

yes	1
no	0

9. *Have the characteristics of patients lost to follow-up been described?*

This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

yes	1
no	0

10. *Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?*

yes	1
no	0

External validity

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*

The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant

population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*
 The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

yes	1
no	0
unable to determine	0

13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*
 For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

yes	1
no	0
unable to determine	0

Internal validity - bias

14. *Was an attempt made to blind study subjects to the intervention they have received?*
 For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

yes	1
no	0
unable to determine	0

15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

yes	1
no	0
unable to determine	0

16. *If any of the results of the study were based on "data dredging", was this made clear?*

Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

yes	1
no	0
unable to determine	0

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?*

Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

yes	1
no	0
unable to determine	0

18. *Were the statistical tests used to assess the main outcomes appropriate?*

The statistical techniques used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0
unable to determine	0

19. *Was compliance with the intervention/s reliable?*

Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

yes	1
no	0
unable to determine	0

20. *Were the main outcome measures used accurate (valid and reliable)?*

For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

yes	1
no	0
unable to determine	0

Internal validity - confounding (selection bias)

21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?*

For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

yes	1
no	0
unable to determine	0

22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?*

For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

23. *Were study subjects randomised to intervention groups?*

Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.

yes	1
no	0
unable to determine	0

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*

All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

yes	1
no	0
unable to determine	0

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*

This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

yes	1
no	0
unable to determine	0

26. *Were losses of patients to follow-up taken into account?*

If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

yes	1
no	0
unable to determine	0

Power

27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?*

Sample sizes have been calculated to detect a difference of x% and y%.

	Size of smallest intervention group	
A	<n ₁	0
B	n ₁ -n ₂	1
C	n ₃ -n ₄	2
D	n ₅ -n ₆	3
E	n ₇ -n ₈	4
F	n ₈ +	5

BMJ Open eHealth-based intervention to increase physical activity levels in people with cancer: protocol of a feasibility trial in an Irish acute hospital setting

Ciarán Haberlin,¹ Julie Broderick,¹ Emer M Guinan,² Catherine Darker,³ Juliette Hussey,¹ Dearbhaile M O'Donnell⁴

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¹Department of Physiotherapy, University of Dublin Trinity College, Dublin, Ireland

²School of Medicine, University of Dublin Trinity College, Dublin, Ireland

³Discipline of Public Health & Primary Care, University of Dublin Trinity College, Dublin, Ireland

⁴Department of Medical Oncology, St. James's Hospital, Dublin, Ireland

Correspondence to
Ciarán Haberlin; haberlic@tcd.ie

ABSTRACT

Introduction Exercise and physical activity (PA) are established and effective treatment options for various side effects of cancer treatments such as surgery, chemotherapy and radiotherapy. The advent of eHealth brings new opportunities to influence healthy behaviours, using interactive and novel approaches. Influencing PA behaviours in people with cancer presents a potential application of this. The aim of this study is to evaluate the feasibility and preliminary efficacy of an intervention, using eHealth, for increasing PA in cancer survivors.

Methods and analysis This will be a single-arm pre-post feasibility study. We aim to recruit a heterogeneous sample of 60 participants from cancer clinics in St. James's Hospital, Dublin, Ireland. Eligibility criteria will include patients who have completed chemotherapy and/or radiotherapy with curative intent between 3 and 36 months prior to enrolment. The intervention will include the delivery of a 12-week PA programme. The eHealth aspect of the intervention will involve the provision of a Fitbit activity tracker, which will be used in conjunction with specific PA goals remotely prescribed and monitored by a physiotherapist. Primary outcomes will be feasibility measures related to the study (recruitment capability, data collection procedures, adherence and compliance, evaluation of the resources to implement the study and evaluation of participant responses to the intervention). Secondary measures will evaluate preliminary efficacy of the intervention in terms of clinical outcomes (body composition, PA (objective and self-report), quality of life and aerobic capacity). Primary and secondary outcomes will be assessed at baseline (as appropriate), at conclusion of the intervention and at a 6-month follow-up.

Ethics and dissemination Ethical approval has been granted by the St. James's Hospital/AMNCH Joint Ethics Committee (2016/05/02). Results from this study will be submitted for publication in peer-reviewed journals, as well as for presentation and dissemination at conferences in the field of oncology and survivorship.

Trial registration NCT03036436; Pre-results.

INTRODUCTION

Early detection and increasingly effective treatments have led to improved survival rates for cancer. Data from Cancer Research UK

Strengths and limitations of this study

- This study will use an eHealth-focused physical activity (PA) intervention, using commercial Fitbit technology to examine its effectiveness to improve PA behaviours in a clinical population.
- Professional input and support, from a chartered physiotherapist, will be used as a key component of this study.
- Objectively measured PA will be used as an outcome to assess the effectiveness of an eHealth intervention, setting it apart from the current research base in eHealth PA interventions in cancer which have generally adopted self-report PA outcome measures.
- The PA intervention in this study will be grounded in behavioural change science, with a number of behavioural change techniques such as 'self-monitoring of behaviour', 'goal-setting' and 'feedback on behaviour' included in the design of the intervention.
- A limitation is that this study will use a feasibility design, and will therefore not include a control or other comparator arm.

show that half of those diagnosed with cancer in England and Wales survive their disease for 10 years or more (2010–2011).¹ This reflects a global trend of increasing survival after cancer treatment. The benefits of physical activity (PA) and exercise in patients with cancer have been well documented, with improvements in quality of life (QOL),^{2,3} function^{4,5} and some association with a reduced risk of recurrence.^{6,7} Many cancer treatments, including radiation therapy and chemotherapy, can have long-term effects, which may be ameliorated by exercise.⁸ In spite of these reported benefits, it has been shown that the majority of cancer survivors have difficulty in adhering to healthy lifestyle behaviours, including recommended PA behaviours.^{9,10} So far, no single method of exercise promotion has been demonstrated to increase and maintain PA levels in cancer survivors. eHealth, defined by the WHO as

Appendix 15 Cochrane Collaboration's tool for assessing risk of bias

Domain	Support for judgement	Review authors' judgement
<i>Selection bias.</i>		
Random sequence generation.	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.
Allocation concealment.	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.
<i>Performance bias.</i>		
Blinding of participants and personnel <i>Assessments should be made for each main outcome (or class of outcomes).</i>	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.
<i>Detection bias.</i>		
Blinding of outcome assessment <i>Assessments should be made for each main outcome (or class of outcomes).</i>	Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessors.
<i>Attrition bias.</i>		
Incomplete outcome data <i>Assessments should be made for each main outcome (or class of outcomes).</i>	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Attrition bias due to amount, nature or handling of incomplete outcome data.
<i>Reporting bias.</i>		
Selective reporting.	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Reporting bias due to selective outcome reporting.
<i>Other bias.</i>		
Other sources of bias.	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol,	Bias due to problems not covered elsewhere in the table.

	responses should be provided for each question/entry.
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Criteria for judging risk of bias in the ‘Risk of bias’ assessment tool

RANDOM SEQUENCE GENERATION	
Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.	
Criteria for a judgement of ‘Low risk’ of bias.	<p>The investigators describe a random component in the sequence generation process such as:</p> <ul style="list-style-type: none"> • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. <p>*Minimization may be implemented without a random element, and this is considered to be equivalent to being random.</p>
Criteria for the judgement of ‘High risk’ of bias.	<p>The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:</p> <ul style="list-style-type: none"> • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. <p>Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example:</p> <ul style="list-style-type: none"> • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.

Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.
ALLOCATION CONCEALMENT	
Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.	
Criteria for a judgement of 'Low risk' of bias.	<p>Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:</p> <ul style="list-style-type: none"> • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgement of 'High risk' of bias.	<p>Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:</p> <ul style="list-style-type: none"> • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
Criteria for the judgement of 'Unclear risk' of bias.	<p>Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.</p>
BLINDING OF PARTICIPANTS AND PERSONNEL	
Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	
Criteria for a judgement of 'Low risk' of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; • Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; • Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	<p>Any one of the following:</p>

	<ul style="list-style-type: none"> • Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’; • The study did not address this outcome.
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BLINDING OF OUTCOME ASSESSMENT

Detection bias due to knowledge of the allocated interventions by outcome assessors.

Criteria for a judgement of ‘Low risk’ of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
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Criteria for the judgement of ‘High risk’ of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; • Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.
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Criteria for the judgement of ‘Unclear risk’ of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’; • The study did not address this outcome.
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INCOMPLETE OUTCOME DATA

Attrition bias due to amount, nature or handling of incomplete outcome data.

Criteria for a judgement of ‘Low risk’ of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; • Missing data have been imputed using appropriate methods.
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Criteria for the judgement of ‘High risk’ of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;
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	<ul style="list-style-type: none"> • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • ‘As-treated’ analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.
Criteria for the judgement of ‘Unclear risk’ of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • Insufficient reporting of attrition/exclusions to permit judgement of ‘Low risk’ or ‘High risk’ (e.g. number randomized not stated, no reasons for missing data provided); • The study did not address this outcome.
<p>SELECTIVE REPORTING</p> <p>Reporting bias due to selective outcome reporting.</p>	
Criteria for a judgement of ‘Low risk’ of bias.	<p>Any of the following:</p> <ul style="list-style-type: none"> • The study protocol is available and all of the study’s pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; • The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgement of ‘High risk’ of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • Not all of the study’s pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; • One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of ‘Unclear risk’ of bias.	Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’. It is likely that the majority of studies will fall into this category.
<p>OTHER BIAS</p> <p>Bias due to problems not covered elsewhere in the table.</p>	
Criteria for a judgement of ‘Low risk’ of bias.	The study appears to be free of other sources of bias.
Criteria for the judgement of ‘High risk’ of bias.	There is at least one important risk of bias. For example, the study:

	<ul style="list-style-type: none"> • Had a potential source of bias related to the specific study design used; or • Has been claimed to have been fraudulent; or • Had some other problem.
Criteria for the judgement of 'Unclear risk' of bias.	<p>There may be a risk of bias, but there is either:</p> <ul style="list-style-type: none"> • Insufficient information to assess whether an important risk of bias exists; or • Insufficient rationale or evidence that an identified problem will introduce bias.

Appendix 16 Patient Satisfaction Questionnaire

Patient Satisfaction Questionnaire

This questionnaire will only take 5 to 10 minutes to complete. All questionnaires will be treated with the strictest confidence.

There is a research physiotherapist available if you have any questions.

Questionnaire

1. I found this intervention helpful in improving my physical activity:
strongly agree agree neither agree nor disagree disagree strongly disagree

2. Were there any aspects of this programme which you enjoyed?

3. Were there any aspects of this programme which you did not enjoy?

4. Did any aspects of this programme help you increase your physical activity level?

Yes/No

5. If yes-please specify what aspects in particular helped you increase your physical activity level

6. How did you find using the Fitbit device and application?

7. What was the most useful part of using the technology?

8. Did you have any difficulty using the Fitbit or the application?

9. Do you have any suggestions as to how this program could be improved?

10. Any other comments

Appendix 17 Data Extraction form

Review title or ID

General Information

Date form completed <i>(dd/mm/yyyy)</i>	
Name/ID of person extracting data	
Report title <i>(title of paper/ abstract/ report that data are extracted from)</i>	
Reference details	
Publication type <i>(e.g. full report, abstract, letter)</i>	

Type of study	
Participants	
Types of intervention	
Types of outcome measures	

Population and setting

	<p>Description</p> <p><i>Include comparative information for each group (i.e. intervention and controls) if available</i></p>
<p>Population description</p> <p><i>(from which study participants are drawn)</i></p>	
<p>Setting</p> <p><i>(including location and social context)</i></p>	
<p>Inclusion criteria</p>	
<p>Exclusion criteria</p>	
<p>Method/s of recruitment of participants</p>	

Methods

	<p>Descriptions as stated in report/paper</p>
<p>Aim of study</p>	
<p>Design</p> <p><i>(e.g. parallel, crossover, non-RCT)</i></p>	
<p>Unit of allocation</p> <p><i>(by individuals, cluster/ groups or body parts)</i></p>	
<p>Start date</p>	
<p>End date</p>	
<p>Duration of participation</p> <p><i>(from recruitment to last follow-up)</i></p>	

Participants

	Description as stated in report/paper
Total no. randomised <i>(or total pop. at start of study for NRCTs)</i>	
Baseline imbalances	
Withdrawals and exclusions <i>(if not provided below by outcome)</i>	
Age	
Sex	
Diagnosis	

Intervention Group 1

	Description as stated in report/paper
Group name	
No. randomised to group <i>(specify whether no. people or clusters)</i>	
Description <i>(include sufficient detail for replication, e.g. content, dose, components; if it is a natural experiment, describe the pre-intervention)</i>	
Duration of treatment period	
Timing <i>(e.g. frequency, duration of each episode)</i>	

	Description as stated in report/paper
Delivery <i>(e.g. mechanism, medium, intensity, fidelity)</i>	

Outcomes

Copy and paste table for each outcome.

Outcome (Physical Activity)

	Description as stated in report/paper
Outcome name	Physical activity
Time points measured <i>(specify whether from start or end of intervention)</i>	
Outcome definition <i>(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)</i>	
Unit of measurement <i>(if relevant)</i>	

Results

	Description as stated in report/paper	
Reported Results in Physical Activity Outcome		
Reported Results in Secondary Outcomes		
Timepoint <i>(specify whether from start or end of intervention)</i>		
Post-intervention or change from baseline?		
No. participants	Intervention	Control
No. missing participants and reasons		
Statistical methods used		

Other information

	Description as stated in report/paper
Key conclusions of study authors	