

# **The ACS Response-Time Intervention Trial**

A Randomised Controlled Trial to Determine Whether an Individualised Educational Intervention Affects Response-Time in Patients who have Symptoms of Acute Coronary Syndrome.

A thesis presented to the University of Dublin, Trinity College Dublin, for the Degree of Doctor in Philosophy.

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Date: March 2014.

**Declaration**

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## Thesis Summary

**Background:** Acute coronary syndrome (ACS) refers to any constellation of clinical symptoms that are linked with acute myocardial ischaemia and includes unstable angina and myocardial infarction. These conditions are associated with varying degrees of reduced coronary perfusion, which underscores the importance of rapid diagnosis, early risk stratification and management to improve outcomes. While time is of particular importance for those who are diagnosed with ST-elevation ACS, it is also important to rapidly diagnose non-ST-elevation ACS and to differentiate the two types of ACS, in order to assign appropriate treatments. However, in ACS a differential diagnosis cannot be based on symptoms, as all categories of ACS can manifest similarly. The time from symptom onset until arrival at the emergency department (ED) is referred to as pre-hospital delay time and this should be kept to a minimum. Patient decision-delay contributes most significantly to pre-hospital delay time. A limited number of interventions have been conducted in an attempt to reduce pre-hospital delay time, most of which were unsuccessful.

**Methods:** As this was a randomised controlled trial, participants were randomly assigned to the control or intervention group. Eligible patients were recruited from five EDs in Dublin (N=1,944; control: 972, intervention: 972). Using the Acute Coronary Syndrome Response Index, pre-hospital delay time data were collected at baseline and again on participants' first subsequent readmission to an ED with ACS symptoms. Both groups received usual care from their health service provider. In addition, participants in the intervention group received a 40-minute individualised educational intervention, which was reinforced one

month later by telephone, and six months later by post. The intervention was based on Leventhal's self-regulatory model of illness behaviour.

**Results:** On admission, median baseline pre-hospital delay times were not significantly different between the groups (Mann-Whitney  $U$ ,  $p=0.34$ : intervention group 3.96 hours, 25<sup>th</sup> percentile=1.53, 75<sup>th</sup> percentile=18.51; control group 4.28 hours, 25<sup>th</sup> percentile=1.71, 75<sup>th</sup> percentile=17.37). Of the 1,944 who were recruited to the study, 314 (16.2%) were readmitted with ACS symptoms; 177 (18.2%) and 137 (14.0%) of the intervention and control groups, respectively. Pre-hospital delay times were again measured. Following the intervention, and on readmission, median pre-hospital delay time was significantly lower in the intervention group, compared to the control group ( $p<0.001$ : intervention group 1.7 hours, 25<sup>th</sup> percentile=1.1, 75<sup>th</sup> percentile=2.9; control group 7.1 hours, 25<sup>th</sup> percentile=2.7, 75<sup>th</sup> percentile=16.7). With respect to post-intervention behavioural responses to symptoms, those in the intervention group reported their symptoms more promptly to another person ( $p=0.01$ ) and fewer consulted with a GP before going to the ED ( $p=0.02$ ). There was no significant difference between the groups with respect to the use of ambulance ( $p=0.51$ ) or the use of prescribed nitrates ( $p=0.06$ ).

**Conclusion:** On readmission to the emergency department with ACS symptoms, the intervention group had a shorter pre-hospital delay time, compared to the control group. While there were some post-intervention behavioural changes noted, these could not be attributed to the impact of the intervention. This was the first RCT to effectively achieve a reduction in patient pre-hospital delay time in persons diagnosed with ACS.

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## Glossary of Terms

For the purpose of this study the following terms were interpreted as:

- **Acute Coronary Syndrome:** A diagnosis that refers to both myocardial infarction and unstable angina, as defined by the European Society of Cardiology guidelines.
- **A participant:** A person who has been recruited to the study and has been randomised to the control or intervention group.
- **A patient:** Somebody who has been admitted to hospital with acute coronary syndrome but, at the time of reference, has not been recruited to this study.
- **Interventionist:** The research nurse who collected data and delivered the educational intervention in this study.
- **Intervention manual:** The instruction book with the pictures and script that were used by the interventionist in the delivery of the intervention.
- **Interventionist training manual:** The protocol of education and instruction that was used to prepare the interventionist for recruitment, randomisation, data collection, delivery of the intervention and participant follow-up.
- **Ischaemia:** A decrease in blood and oxygen supply to an organ or tissue due to obstruction in or constriction of the blood vessels.
- **Percutaneous coronary intervention:** The insertion of a catheter that is attached to a tiny balloon into a blocked artery. When the catheter reaches the site of obstruction, the balloon is inflated. The atherosclerotic plaque within the arterial wall is flattened, thereby enlarging the vessel lumen. To maintain blood vessel patency, a small metal wire mesh called a stent can be inserted.
- **Pre-hospital delay time:** The time from acute symptom onset until the documented time of arrival at the emergency department.
- **Reperfusion:** The resumption of blood flow to an area of tissue that is deprived of oxygen or blood. This is achieved using percutaneous coronary intervention or thrombolysis.
- **Research sites:** The hospitals in which the research study took place.

- **Trial protocol:** The synopsis of the research design, methodology and research method. It also includes the step-by-step procedures to which the interventionist must adhere in order to correctly carry out the study from beginning to end.

## List of Abbreviations

- ACS – Acute coronary syndrome.
- ANOVA – Analysis of variance.
- CABG – Coronary artery bypass graft.
- CD – Compact disc
- CINAHL – Cumulative index to nursing and allied health literature.
- CONSORT – Consolidated standards of reporting trials.
- CR – Cardiac rehabilitation.
- CVA – Cerebral vascular accident.
- DVD – Digital videodisc
- ECG – Electrocardiograph.
- ED – Emergency department.
- EMS – Emergency medical services.
- EU – European Union
- GP- General practitioner.
- MI – Myocardial infarction
- NSTEMI-ACS - Non-ST segment elevation acute coronary syndrome.
- NSTEMI – Non-ST segment elevation myocardial infarction.
- PCI – Percutaneous coronary intervention.
- PhD- Doctor of Philosophy.
- PI – Principal investigator
- STE-ACS - ST segment elevation acute coronary syndrome.
- STEMI – ST segment elevation myocardial infarction.
- RCT – Randomised controlled trial.
- RM- ANOVA – Repeated measures analysis of variance.
- SD – Standard deviation.
- SPSS – Statistical package for social sciences.

# Chapter 1 Introduction and thesis outline

## 1.1 Introduction

This dissertation describes a randomised controlled trial (RCT) that was conducted to test the effectiveness of a nurse-led educational intervention in reducing patient pre-hospital delay time for persons experiencing acute coronary syndrome (ACS) symptoms. This chapter describes the clinical condition of ACS, including its significance, complications and clinical management. The relevance of patient pre-hospital delay time in the context of ACS will also be examined in this chapter. From this, the rationale for choosing to conduct a study relating to pre-hospital delay time in ACS will be presented, together with the study aim. The final section of this chapter provides the background to the study and an overview of the content, structure and organisation of the dissertation.

Acute coronary syndrome is an umbrella term for a range of undifferentiated chest pain or symptoms (Hamm *et al.* 2011, Karras *et al.* 2013). The clinical presentation of ACS can vary among individuals, but ACS is predominantly associated with atherosclerotic plaque rupture or erosion, superimposed thrombus and distal embolisation (Hamm *et al.* 2011). Myocardial hypoperfusion arises as a consequence of these pathological mechanisms. The classification of patients with ACS is determined by an electrocardiogram (ECG), which facilitates the categorisation of patients into ST-elevation ACS (STE-ACS) or non-ST-elevation ACS (NSTEMI-ACS). The majority of those who

present with STE-ACS develop an ST-segment elevation myocardial infarction (STEMI), while those with NSTEMI-ACS either develop a non-ST-segment elevation myocardial infarction (NSTEMI) or are diagnosed with and treated for unstable angina (Hamm *et al.* 2011). Accordingly, ACS includes unstable angina and myocardial infarction.

Acute myocardial infarction is the prototype of an absolute emergency. When a STEMI occurs, the infarct-related artery is normally totally occluded (Hamm *et al.* 2011, Taha *et al.* 2013). Once ischaemia begins, cell death is inevitable, but takes a finite period to develop, with hours before necrosis becomes apparent. Allowing for variations in individuals, complete necrosis of vulnerable myocardial cells takes in the region of 2-4 hours (Thygesen *et al.* 2007, Ting *et al.* 2008, Hamm *et al.* 2011). The major adverse effects of ACS-related events include fatal arrhythmias, heart failure and cardiogenic shock (Van de Werf *et al.* 2003, Anderson *et al.* 2007, Farshidi *et al.* 2013, Karras *et al.* 2013).

Ventricular fibrillation is the most lethal cardiac rhythm associated with acute myocardial infarction (MI). It accounts for approximately 50% of MI-related deaths within the first hour (Quinn 2005, Van de Werf *et al.* 2008). The most lethal rhythms can often be successfully treated with early defibrillation and cardiopulmonary resuscitation (CPR) (Finn *et al.* 2001, Coventry *et al.* 2013). Efficiency and speed are essential if maximum benefits are to be achieved from the therapeutic interventions that are available to patients (De Luca *et al.* 2004, Goldstein & Wiel 2005, Asseburg *et al.* 2007, Perkins-Porras *et al.* 2009, Mackay *et al.* 2014).

Non-ST-elevation ACS represents unstable coronary conditions that are prone to recurrent episodes of ischaemia and complications of ischaemia. These conditions can result in death or MI in the short and long term (Bassand *et al.* 2007, Hamm *et al.* 2011). There is a vast range of complications associated with NSTEMI-ACS, particularly in the early hours of symptom onset. Complications such as tachycardia, hypotension or heart failure, if present, are indicators of a poor prognosis in NSTEMI-ACS, but early management improves outcomes (Antman *et al.* 2000, Granger *et al.* 2003, Fox *et al.* 2006, Karras *et al.* 2013).

Pre-existing coronary heart disease poses the greatest risk for the development of ACS symptoms. Furthermore, symptom recurrence following an acute event, such as MI or unstable angina, is indicative of high risk and often warrants additional clinical investigations and treatments (Anderson *et al.* 2007). The symptoms of STEMI-ACS and NSTEMI-ACS are generally undifferentiated and both are associated with a reduction in coronary perfusion, which is potentially life-threatening. Once diagnosed, it is accepted that time to treatment is of less importance for patients with NSTEMI-ACS, relative to STEMI-ACS.

It is impossible for individuals to determine or stratify their category of ACS based on symptoms only (Ting *et al.* 2010). It is therefore important that all individuals with ACS symptoms present for diagnosis and treatment as soon as possible after symptom onset (Anderson *et al.* 2007, Van de Werf *et al.* 2008, Kumar & Cannon 2009, Hamm *et al.* 2011). The time from symptom onset until arrival at the ED is referred to as pre-hospital delay time (Ottesen *et al.* 2004,

Dracup *et al.* 2006, Løvlien *et al.* 2007, McKee *et al.* 2013). Patient decision delay, often referred to as patient delay, contributes most significantly to pre-hospital delay time (Ottesen *et al.* 2003, Rasmussen *et al.* 2003, Moser *et al.* 2006, McKinley *et al.* 2009, Tubaro *et al.* 2011, Garofalo *et al.* 2012). According to the European Society of Cardiology, patient pre-hospital delay time is the most critical phase in reducing ACS-related mortality and this crucial period should be kept to a minimum (Tubaro *et al.* 2011).

There is overwhelming evidence that many people delay seeking help when they have ACS symptoms (Moser *et al.* 2006, Saczynski *et al.* 2008, McKinley *et al.* 2009, Jankowski *et al.* 2011, Farquharson *et al.* 2012). The literature indicates that of those who sustain a myocardial infarction, 30-40% delay beyond the timeframe for the most effective treatment modalities (Goldberg *et al.* 2002, Asseburg *et al.* 2007, Taha 2013). The factors that influence pre-hospital delay time have been widely researched and are especially contingent on the recognition and acknowledgement of symptoms and the person's responses to them. The published literature has highlighted the need for interventions aimed at reducing symptom appraisal time (Farquharson *et al.* 2012, McKee *et al.* 2013). However, attempts at reducing patient pre-hospital delay time over the last quarter of a century have been largely unsuccessful (Kainth *et al.* 2004, Finn *et al.* 2007, Mooney *et al.* 2012).

In the pre-hospital phase, the time taken by individuals to identify their symptoms and their transportation by the emergency medical services (EMS) to the ED is of greatest importance (Garofalo *et al.* 2012, Karras *et al.* 2013, O'



Donnell *et al.* 2013). Emergency medical service providers can deliver life-support measures and safely transfer patients with ACS symptoms to destinations where appropriate management can be initiated (Hutchings *et al.* 2004, Terkelsen *et al.* 2005, Tubaro *et al.* 2011, Health Service Executive 2012a). It has been well-recognised that a seamless system of care delivery between healthcare institutions and emergency medical services is crucial in reducing morbidity and mortality in ACS. Yet, individuals often hesitate in contacting the EMS and many are reluctant to use it as a means of transport to the ED (Pattenden *et al.* 2002, McGinn *et al.* 2005, Moser *et al.* 2005, Thuresson *et al.* 2007, Sjostrom-Strand & Fridlund 2008, Dracup *et al.* 2009). However, the EMS plays a vital role in reducing pre-hospital delay time and in the delivery of advanced life support and treatment in the presence of ACS.

Intervention in the form of primary percutaneous coronary intervention (PCI) in the shortest possible time is considered the gold standard treatment for the management of STEMI (Asseburg *et al.* 2007, Van de Werf *et al.* 2008, Tubaro *et al.* 2011, Health Service Executive 2012a). Therefore, the direct referral of patients by ambulance for treatment with primary PCI in a dedicated PCI centre is preferable (Terkelsen *et al.* 2005, Tubaro *et al.* 2011). In an effort to achieve this, primary PCI programmes have been widely implemented throughout the developed world. In Ireland, the PCI programme was established in September 2012, with the aim of increasing the percentage of patients receiving primary PCI within 90 minutes of STEMI diagnosis (Health Service Executive 2012a).

While there is a recognised need to reduce pre-hospital delay time, the means by which this can be achieved has not yet been clearly established (Ting & Bradley 2009). The time between diagnosis and treatment is vital to maximise positive prognostic outcomes in ACS and this relies heavily on patients' responses to symptoms. As patient decision delay is the greatest impediment to the timely receipt of treatment, it was considered appropriate to conduct a study focused on patient pre-hospital delay time in ACS. Using a randomised controlled trial design, this study tested the effectiveness of a nurse-led, individualised, one-to-one educational intervention in reducing patient pre-hospital delay time in the presence of ACS symptoms.

In this study, the intervention was aimed at reducing patient pre-hospital delay time through altering behaviours associated with increased delay time. Pre-hospital delay time was measured prior to the intervention and again afterwards when participants were readmitted to an ED with ACS symptoms. The intervention was a replication of one that had been previously developed and delivered elsewhere (Dracup *et al.* 2006). Consent was granted by the original authors to adopt their intervention and to use the relevant research instruments. This study had not been previously conducted in Europe and, at the time of writing, is original with respect to the sampling strategies and sample used.

## **1.2 Study background**

This study was part of a large randomised controlled trial entitled the 'ACS Response-Time Intervention Trial'. The trial was designed by the ACS research team at the School of Nursing and Midwifery, Trinity College Dublin and was

funded by the Irish Health Research Board. From the trial, two separate PhD studies were undertaken by members of the ACS team. One of these PhDs was the current study, which focused on patient pre-hospital delay time. The other PhD evaluated the impact of the intervention on participants' knowledge, attitudes and beliefs about ACS. The same educational intervention and dataset were used for both PhDs. For this current study, data were collected at baseline and on re-admission to an ED, while knowledge, attitudes and beliefs were measured at baseline and again at 3 months and 12 months following the intervention.

### **1.3 Dissertation overview**

This dissertation is divided into six chapters, including the present chapter. The content of each chapter is briefly outlined here.

Chapter 2 is entitled the Literature Review. It is divided into three parts. The first part presents an overview of pre-hospital delay time in ACS, while the second part discusses the factors that influence pre-hospital delay time. The final part examines interventions that were developed and tested to reduce pre-hospital delay time.

In Chapter 3, the study methodology is presented. The rationale for the choice of study design is discussed, together with the specifics about how a methodologically sound RCT should be conducted. The educational intervention delivered in this study was based on Leventhal's self-regulatory model of illness behaviour (Leventhal *et al.* 1980, Leventhal *et al.* 1983, Leventhal & Cameron

1987). This framework is described in Chapter 3, together with a critique of its suitability for use in the context of the current study.

Chapter 4 is entitled the operationalisation of the study. The content of the educational intervention is detailed at the outset of this chapter. This is followed by information on the study sample, the research instruments, data collection and the procedures used in the delivery of the intervention. The chapter concludes with the ethical considerations pertaining to this study.

Chapter 5 presents the results of the RCT. It includes information on the number of patients recruited, the attrition rate and the number who were readmitted with ACS symptoms. The study outcomes were determined by data obtained from those patients who were recruited prior to the intervention and subsequently readmitted to an ED with ACS symptoms following the intervention.

In Chapter 6, the study results are contextualised and discussed. The primary and secondary study hypotheses are discussed with reference to the study design and the available published literature. The limitations of this RCT are presented, together with the potential contribution of this study to health, social and economic gain. Chapter 6 concludes with recommendations from this study and the dissemination of the associated work to date.

## **Chapter 2 Literature review**

### **2.1 Introduction**

Delay in seeking treatment for acute coronary syndrome (ACS) symptoms is a well-recognised problem. While the factors that influence a person's decision to seek treatment for these symptoms have been extensively researched, consensus has not been reached with respect to this phenomenon. Delays due to transportation and in-hospital reperfusion have been documented as contributors to delayed treatment, but patient delay is the greatest impediment to early treatment for ACS. A number of strategies have been employed in an effort to reduce pre-hospital delay in the presence of ACS. These include research to determine the factors that influence pre-hospital delay and interventions aimed at raising awareness and increasing prompt action in the presence of ACS symptoms. This literature review will appraise those studies that have focused on pre-hospital delay.

This chapter is presented in three sections. In the first section, pre-hospital delay will be defined and reviewed in the context of the phases of delay and international pre-hospital delay times. Studies that have focused on pre-hospital delay will be compared and contrasted. A discussion on the factors that influence pre-hospital delay in response to ACS symptoms will be presented in the second part of this chapter, while the third section will examine the interventions that have been developed and tested to date, in an attempt to achieve a reduction in pre-hospital delay time. The chapter will conclude with a summary of the findings from the literature. It was from these findings that the aims and objectives of the current study were developed.

A search of published literature was carried out prior to conducting this review and again on completion of the study. A thorough search of relevant nursing and medical databases was conducted. These included Cumulative Index to Nursing and Allied Health Literature (CINAHL), Pubmed, Academic Search Premier, Cochrane, British Nursing Index, and Google Scholar. Three separate searches were conducted. The first search pertained to pre-hospital delay times; the second was focused on factors that influence pre-hospital delay time, while the third was centred on interventions that were conducted with a view to reducing pre-hospital delay time.

The search was limited to publications between 1986 and 2014 that were written in or translated into the English language. Time-dependant interventions, such as thrombolysis and angioplasty were introduced for the management of ACS in the mid-1980s. This explains the inclusion of studies from 1986 onwards. The following keywords were used: acute coronary syndrome, acute myocardial infarction, heart attack, chest pain, ischaemia and unstable angina. These were combined with pre-hospital delay, delay to treatment, treatment delay, prolonged delay, decision delay, transport delay, timely treatment, decision, and emergency department treatment. The core search terms used for the search of interventions included the above key words, together with intervention trials, campaigns and nursing interventions.

## **2.2 Pre-hospital delay**

### **2.2.1 Delay to the initiation of definitive treatment**

Acute coronary syndrome can manifest in a number of ways and symptoms of ACS vary between individuals. Although STE-ACS and NSTEMI-ACS are managed differently at clinical level, it is impossible to differentiate between the conditions, based on symptoms alone (Ting *et al.* 2010). Individuals with ACS symptoms should therefore present to the emergency department (ED) as soon as possible after symptom onset, to benefit from early diagnosis and appropriate treatment (Anderson *et al.* 2007, Kumar & Cannon 2009, Hamm *et al.* 2011, Tubaro *et al.* 2011). A time-delay between ACS symptom onset and the initiation of definitive treatment can result in increased mortality and morbidity (Newby *et al.* 1996, Goldberg *et al.* 2002, De Luca *et al.* 2004, Moser *et al.* 2006, Tubaro *et al.* 2011). Delays can arise from a prolongation of pre-hospital time or can result from delays within the hospital setting.

### **2.2.2 The phases of delay**

The time between acute symptom onset and the receipt of definitive treatment can be categorised into two main phases; pre-hospital delay and in-hospital delay. Pre-hospital delay is often sub-divided into decision delay and transportation delay (Moser *et al.* 2006, Finn *et al.* 2007). Decision delay is the time from symptom onset until the initial decision is made to seek professional treatment, while transportation delay is the time taken from making that decision to seek treatment until arrival at the hospital (Finn *et al.* 2007, Khraim & Carey 2009, Khraim *et al.* 2009). Pre-hospital delay is a combination of decision delay and transportation delay (Ottesen *et al.* 2004, Dracup *et al.* 2006, Løvlien *et al.* 2007). Patient decision delay contributes most significantly to pre-hospital delay

time (Ottesen *et al.* 2003, Rasmussen *et al.* 2003, Moser *et al.* 2006, O' Donnell *et al.* 2013). It is on pre-hospital delay time that this study is focused.

### **2.2.3 In-hospital treatment delay**

The initiation of definitive treatment for ACS is dependent on the rapidity of responses by the relevant staff within the ED. Any delays to executing the appropriate and necessary care constitute an in-hospital delay. This is also known as door-to-treatment time and refers to the time from arrival at the ED until the receipt of definitive treatment (Finn *et al.* 2007). It is comprised of door-to-needle time for thrombolysis and door-to-balloon inflation time for percutaneous coronary intervention (PCI).

### **2.2.4 Definitions of pre-hospital delay time**

For the purpose of this study, pre-hospital delay time refers to the time from acute symptom onset until arrival at the ED. The definition used by the majority of researchers was the time of symptom onset until arrival at the hospital (Luepker *et al.* 2000, Dracup *et al.* 2003, McKinley *et al.* 2004, Ottesen *et al.* 2004, Quinn 2005, Dracup *et al.* 2006, Moser *et al.* 2006, Thuresson *et al.* 2007, Isaksson *et al.* 2008, Perkins-Porras *et al.* 2008, Ting *et al.* 2008, Goldberg *et al.* 2009, DeVon *et al.* 2010, Mackay *et al.* 2014). While there was relative consistency among studies with respect to the definition of pre-hospital delay time, some researchers reported median decision delay and median transportation delay times separately (Birkhead *et al.* 2004, Morgan 2005, Løvlien *et al.* 2007, Perkins-Porras *et al.* 2009).

Some researchers measured the time from intense or acute symptom onset until medical care was sought (Bett *et al.* 1993, Carney *et al.* 2002, Al-Hassan &



Omran 2005, Morgan 2005, Løvlien *et al.* 2007, Walkiewicz *et al.* 2008, Fox-Wasylyshyn *et al.* 2010). Although the implication is that medical care for ACS symptoms constitutes contact with ED personnel, this was not explicit and may have included consultation with a GP. Consequently, pre-hospital delay times in some studies may have recorded only decision delay, but not transportation delay. Instead of using actual delay time, patients can be classified into early and late responders. Early responders are those who attend the ED within two hours of symptom onset. These are differentiated from late responders, who delay beyond two hours. Those who delay beyond 24 hours are categorised as prolonged delayers (Saczynski *et al.* 2008).

### **2.3 Pre-hospital delay time research**

International pre-hospital delay times have been extensively researched. The research designs included randomised controlled trial intervention studies (Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009), intervention observational studies (Ho *et al.* 1989, Moses *et al.* 1991, Bett *et al.* 1993, Blohm *et al.* 1994, Gaspoz *et al.* 1996, Naegeli *et al.* 2011), non-intervention quantitative studies (Johansson *et al.* 2004a, Thuresson *et al.* 2007, Ting *et al.* 2008, Goldberg *et al.* 2009, Vavouranakis *et al.* 2010) and non-intervention qualitative studies (Kaur *et al.* 2006, Ruston 2007, Turris & Finamore 2008). In general, these studies reported median pre-hospital delay time, although pre-hospital delay times have also been reported as discrete categories by some researchers (Løvlien *et al.* 2007, Isaksson *et al.* 2008, Smolderen *et al.* 2010). The division of time by category differed between studies, which made comparisons difficult. An overview of pre-hospital delay times will be presented below.

Median pre-hospital delay times in Europe range from two hours (Goldberg *et al.* 2009, Perkins-Porras *et al.* 2009) to four hours (Doyle *et al.* 2005). Several researchers have reported European pre-hospital delay times within these figures (Blohm *et al.* 1994, Gaspoz *et al.* 1996, Walsh *et al.* 2004, O' Donnell *et al.* 2006, Løvlien *et al.* 2007, Thuresson *et al.* 2007, Isaksson *et al.* 2008). Irish researchers reported separate median pre-hospital delay times for women and men in Dublin-based hospitals. These times were 3.1 hours for women and 1.8 hours for men (O' Donnell *et al.* 2006). However, in other parts of Ireland, median pre-hospital delay times of 7.2 hours for women and 3.3 hours for men have been reported (Walsh *et al.* 2004). Collective median pre-hospital delay times of 3 hours, 56 minutes (Doyle *et al.* 2005) and 2 hours, 15 minutes (Carney *et al.* 2002) have been reported in Ireland.

There was considerable inconsistency between studies that reported on pre-hospital delay times in Australia and New Zealand. Median pre-hospital delay times of 3.1 hours to 6.4 hours have been reported by some researchers (Dracup *et al.* 1997a, Dracup *et al.* 2003, Taylor *et al.* 2005). Yet, pre-hospital delay times of less than 2.0 hours have also been reported for these countries (Bett *et al.* 1993, Goldberg *et al.* 2009). However, these shorter pre-hospital delay times have been associated with the use of emergency services and non-consultation with a GP (Hitchcock *et al.* 2003, Taylor *et al.* 2005). Pre-hospital delay times in Asia are reported to be between 1 hour and 4.5 hours (Dracup *et al.* 2003, Al-Hassan & Omran 2005, Fukuoka *et al.* 2005, Yan *et al.* 2009, Park *et al.* 2012).

In the United States, median pre-hospital delay times ranged from 1.5 hours to 6 hours (Meischke *et al.* 1997, Luepker *et al.* 2000, Moser *et al.* 2006, Ting *et al.* 2008, Fox-Wasylyshyn *et al.* 2010, Smolderen *et al.* 2010). However, some researchers have reported pre-hospital delay times of up to 9.5 hours for women and 6.0 hours for men in the United States (DeVon *et al.* 2010). These longer pre-hospital delay times have been associated with specific influential factors, including the absence of pain or discomfort, the presence of co-existing illnesses and financial issues (Canto *et al.* 2000, DeVon *et al.* 2010, Smolderen *et al.* 2010).

It is evident that there is wide variation in pre-hospital delay time measurements within and between countries and continents. Some reports indicate that pre-hospital delay times are within desired limits, while the findings from other studies raise concerns about prolonged pre-hospital delay times. The differences between studies make it difficult to comprehensively compare pre-hospital delay times within and between countries. These issues are appraised in the next section of this chapter.

### **2.3.1 Previous research methods**

Pre-hospital delay time reports have been derived from population-based registries, large cohort single or multi-centre studies and studies based on interviews with patients or witnesses. The methodologies used in the determination of pre-hospital delay time have generally been of a quantitative nature, although some used a qualitative approach or a combination of the two. The studies that exclusively used a qualitative approach focused on issues surrounding pre-hospital delay, but did not report pre-hospital delay-times per

se. This was also the case for some of the quantitative studies. Data were difficult to compare due to differences in study designs, inclusion criteria, sample sizes, sampling methods and data collection procedures.

### **2.3.2 Study designs**

The majority of studies were prospective, cross-sectional studies (Dracup & Moser 1997, McKinley *et al.* 2004, Walsh *et al.* 2004, Al-Hassan & Omran 2005, Doyle *et al.* 2005, Fukuoka *et al.* 2005, Moser *et al.* 2005, Quinn 2005, Banks & Dracup 2006, Thuresson *et al.* 2007, Zegrean *et al.* 2009, DeVon *et al.* 2010, Naegeli *et al.* 2011). There was a smaller number of retrospective studies that reported on pre-hospital delay time (Bleeker *et al.* 1995, Johnson & King 1995, Gurwitz *et al.* 1997, Meischke *et al.* 1998, McGinn *et al.* 2005). To date, three randomised controlled trials reported on pre-hospital delay time (Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009). There was no evidence from the literature to suggest that pre-hospital delay time findings correlated in either direction with any particular type of study design. Median pre-hospital delay times varied within and between countries and studies, irrespective of the study design.

### **2.3.3 Inclusion criteria**

All of the reviewed studies included patients who attended EDs with ACS symptoms. Otherwise, inclusion criteria varied between studies. Some researchers applied age limitations (Quinn 2005, Løvlien *et al.* 2007, Isaksson *et al.* 2008, Perkins-Porras *et al.* 2008). The population-based registries and most of the research studies included data on patients diagnosed with MI only, while others included all ACS categories (Doyle *et al.* 2005, Canto *et al.* 2007,

Thuresson *et al.* 2007, Perkins-Porras *et al.* 2008, Perkins-Porras *et al.* 2009). The exclusion of one group from the ACS category rendered it difficult to comprehensively compare, contrast and discuss pre-hospital delay times in ACS. The presenting symptoms of ACS are undifferentiated in all three ACS pathologies. Therefore, the inclusion of all ACS diagnoses is important to the understanding of pre-hospital delay times, as a diagnosis is made only on arrival at the ED.

Data on patients who did not survive the cardiac event and died before admission to the ED were generally not reported. While this information might be difficult to capture empirically, it could make an important contribution to the body of information available on pre-hospital delay time, because it is estimated that about 25% of people die from myocardial infarction within the first hour of symptom onset (Finn *et al.* 2007, Mackay *et al.* 2014). Data relating to this unrepresented cohort of individuals could potentially be obtained from relatives or witnesses. However, such data collection may be difficult where a relationship has not already been formed between the researcher and the witness. Therefore, where appropriate, it may be beneficial to invite family members to be present during research meetings with patients. A follow-up call to ascertain particulars regarding an ACS event might then be more acceptable, if the researcher is known to the family. Selection bias can be minimised and findings generalised to all patients with ACS if data are captured for survivors and non-survivors of cardiac events.

### 2.3.4 Sampling and sample sizes

Sample sizes varied between the studies reviewed. The data from population-based registries included samples that ranged from 6,542 (Isaksson *et al.* 2008) to 482,327 (Ting *et al.* 2008). Many studies had relatively small sample sizes and those with smaller sample sizes tended to be reports of qualitative research approaches (Kaur *et al.* 2006, MacInnes 2006, Higginson 2008, Johansson *et al.* 2008, Turrís & Finamore 2008). Sample size appeared not to impact on the pre-hospital delay time findings between studies. However, some studies did not report a power calculation (Moses *et al.* 1991, Bett *et al.* 1993, Blohm *et al.* 1994, Gaspoz *et al.* 1996). The absence of a power calculation could preclude the verification of statistically significant differences between groups.

Where appropriate, probability sampling is desirable in prospective studies. However, probability sampling is rarely feasible where sampling involves an acutely ill population (deBoer *et al.* 2011). Non-probability sampling was generally used (Fukuoka *et al.* 2005, Moser *et al.* 2005, Zegrean *et al.* 2009, DeVon *et al.* 2010), except where population-based studies included all eligible patients (Isaksson *et al.* 2008). Some of the very large national population-based registries, among other studies (Ottesen *et al.* 1996, Dracup & Moser 1997, McKinley *et al.* 2000, Zerwic *et al.* 2003, O' Donnell *et al.* 2006, Løvlien *et al.* 2007, 2008), used more than one research site from which their samples were drawn. Otherwise, samples were mostly restricted to one specific research site. Pre-hospital delay time data from single-site studies refer to a specific cohort of individuals. This may have implications for the sample size or for the potential to generalise the results beyond that specific context.

### **2.3.5 Data collection**

The means by which data were collected varied greatly. Some data were retrieved from population-based registries that collate information on pre-hospital delay times. The registries included the Worcester Heart Attack Study (Goldberg *et al.* 2000), the National Registry of Myocardial Infarction (Rogers *et al.* 2008, Ting *et al.* 2008), the National Audit of Myocardial Infarction Project (Birkhead *et al.* 2004), the Multinational Monitoring of Trends and Determinants in Cardiovascular Disease (Isaksson *et al.* 2008), the Global Registry of Acute Coronary Events (Goldberg *et al.* 2009), the Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients' Health Status (Smolderen *et al.* 2010) and the Acute Myocardial Infarction Registry in Switzerland (Naegeli *et al.* 2011). Chart audits were used to ascertain the majority of pre-hospital delay times and trends from these registries and for many of the large and small scale studies.

Pre-hospital delay time and its associated characteristics are not always recorded in the medical records (De Von *et al.* 2004, Smolderen *et al.* 2010) and even when it is, the literature suggests that discrepancies can exist between documented medical record information and the patients' accounts of events (Fukuoka *et al.* 2005, Canto *et al.* 2007, Finn *et al.* 2007). Many researchers added to the reliability of their data collection procedures by using patient interviews in addition to chart audits (Dracup *et al.* 2003, McKinley *et al.* 2004, Ottesen *et al.* 2004, Fukuoka *et al.* 2005, Quinn 2005, O' Donnell *et al.* 2006, Perkins-Porras *et al.* 2009, Yan *et al.* 2009, O' Donnell & Moser 2012). Failure by researchers to confirm collected data, when it is possible to do so,

can have implications in terms of accuracy of data and subsequent reporting. It would appear that information acquired from charts and confirmed with the person involved, or a witness, is the most dependable means of securing reliable data.

While a prompt interview following an event is desirable, this was not always possible. Researchers who collected data at the earliest opportunity after the event reduced the potential for recall bias in their studies (Dracup *et al.* 2003, Ottesen *et al.* 2004, Walsh *et al.* 2004, Fukuoka *et al.* 2005, O' Donnell *et al.* 2006, Thuresson *et al.* 2007, Perkins-Porras *et al.* 2009, DeVon *et al.* 2010, Smolderen *et al.* 2010, O' Donnell & Moser 2012). The average time from admission to data collection was in the region of 2 to 4 days. However, there is no clear definition of what constitutes a prompt post-event interview, and no consensus on the time lapse that may lead to recall bias. One researcher (Yan *et al.* 2009) considered that recall bias was minimised in their study through the collection of data within a week of admission, yet another (Johansson *et al.* 2004a) suggested that the collection of data within 48 hours of admission may have been affected by inaccuracy or recall bias. In order to maximise accuracy, data should be collected as close to the event as possible and this should be cross-checked with the patient, witness or medical notes, as relevant.

### **2.3.6 Data collection instruments**

A variety of research instruments were used to collect data on pre-hospital delay time, including the Acute Coronary Syndrome (ACS) Response Index (Dracup & Moser 1997, McKinley *et al.* 2000, McKinley *et al.* 2004, Fukuoka *et al.* 2005, Moser *et al.* 2005), the Symptom Representation Questionnaire



(Quinn 2005), the Myocardial Infarction Symptom Survey (Rosenfeld 2004), the Incongruity of Heart Attack Symptoms Index (Morgan 2005), the Acute Myocardial Infarction in Switzerland Plus Questionnaire (Naegeli *et al.* 2011) or a bespoke questionnaire developed by the investigators (Hartford *et al.* 1993, Thuresson *et al.* 2007). The validity and reliability of the instruments were established and several had psychometric properties previously reported (Dracup & Moser 1997, McKinley *et al.* 2000, McKinley *et al.* 2004, Rosenfeld 2004, Fukuoka *et al.* 2005, Quinn 2005, O' Donnell *et al.* 2006, O' Donnell & Moser 2012).

#### **2.4 Summary of pre-hospital delay time**

Pre-hospital delay refers to the time lag between acute symptom onset and arrival at the ED. It includes decision and transportation delay. Decision delay accounts for the majority of pre-hospital delay time and is the dominant pre-hospital delay time factor, according to the literature. As the cause of ACS symptoms cannot be determined until arrival at the hospital, it is important that all individuals who have symptoms present themselves to the ED as soon as possible following symptom onset. At best, early presentation can save lives and in all cases of ACS, it permits rapid assessment, diagnosis and appropriate intervention. The clinical prognosis is better among those whose pre-hospital delay times are shortest.

International pre-hospital delay times vary and the literature indicates that in general, these times are too long. The literature provides a well-documented justification for reducing patient pre-hospital delay time. The lack of standardisation in pre-hospital delay time characteristics such as definitions,

measurements and data collection methods made comparisons difficult. While large population-based registries provide information on pre-hospital delay time trends, research studies have measured the impact of a number of independent variables on pre-hospital delay times. An understanding of the factors that influence pre-hospital delay time can provide information about the sort of interventions that are needed to target those at risk. These factors are reviewed in the next section.

## **2.5 Factors that influence pre-hospital delay time**

The factors that influence pre-hospital delay have been extensively researched. While this research has been informative about the patterns of presentation in the presence of ACS, they fail to provide a systematic account of the factors that contribute to pre-hospital delay time. There is no consistency in the literature with respect to the variables that influence pre-hospital delay time in ACS. However, predictors of pre-hospital delay time fall into the categories of clinical, socio-demographic, situational and behavioural and knowledge and beliefs. The majority of categories described in the literature include these or similar variables. Demographic and clinical factors have been the most extensively studied, although their influence on pre-hospital delay times is not consistently supported in the literature.

### **2.5.1 Clinical factors**

In this context, clinical factors refer to the severity and description of ACS symptoms and a relevant past medical history, including the presence of cardiovascular risk factors. While symptom severity is self-explanatory, a relevant past medical history and cardiovascular risk factors warrant definition. A relevant past medical history refers to a previous diagnosis of any cardiac

condition that predisposes the individual to a future ACS event. These include angina, MI, PCI and coronary artery bypass graft (CABG). Cardiovascular risks in this context refer to factors that predispose the individual to develop an ACS event. The most common modifiable risk factors are smoking, diabetes hypercholesterolaemia and hypertension. These aforementioned factors appear to impact on pre-hospital delay time, either positively or negatively, and consensus has not been achieved with respect to the extent and duration of the delay-impact of the various factors.

### **Symptom descriptors and onset**

Acute coronary syndrome symptoms that are continuous are associated with shorter pre-hospital delay times (Dracup & Moser 1997, Zerwic *et al.* 2003, Johansson *et al.* 2004a, Gartner *et al.* 2008, Rucker *et al.* 2008, Hwang *et al.* 2009, Khraim *et al.* 2009, DeVon *et al.* 2010, McKee *et al.* 2013). Furthermore, it has been suggested that the nature of symptom onset also exerts much influence over pre-hospital delay time in ACS (O' Donnell & Moser 2012, O' Donnell *et al.* 2013). Patients whose ACS symptoms are of slow onset are subject to protracted pre-hospital delay time, while those who experience fast onset symptoms have shorter pre-hospital delay times (O'Donnell *et al.* 2013). A combination of symptoms that are typical, severe and sudden in onset have been associated with shorter pre-hospital delay times (Ottesen *et al.* 2004, Foraker *et al.* 2008, Herlitz *et al.* 2010a, McKee *et al.* 2013).

Symptom descriptors associated with shorter pre-hospital delay times have varied across the spectrum of ACS categories; for example, continuous

symptoms were associated with shorter pre-hospital delay times for those diagnosed with MI, but not for those with unstable angina (McKee *et al.* 2013). The presence of atypical ACS symptoms and intermittent pain have been associated with increased pre-hospital delay time (Dracup & Moser 1997, Goldberg *et al.* 2002, McKinley *et al.* 2004, Hwang *et al.* 2006, DeVon *et al.* 2010). Overall, there is limited consensus in the literature with respect to the relationship between symptoms and pre-hospital delay time. The varied reports render it difficult to determine whether it is the actual symptoms, the nature of symptom onset, or a combination of these that contribute to increased pre-hospital delay time. It is therefore important that the complete range of ACS symptoms and their variability be disseminated to individuals to alert them to the potential seriousness of all symptoms. If this is achieved, then any ACS symptom and its onset could initiate the drive to seek treatment, as opposed to only those symptoms that are of rapid onset and cause the greatest discomfort.

### **Relevant past medical history**

Researchers have reported inconsistent results with respect to pre-hospital delay times and relevant past medical history. Extensive research has been conducted to ascertain the association between pre-hospital delay time and a past history of acute MI (Johansson *et al.* 2004a, Gartner *et al.* 2008, Saczynski *et al.* 2008, Khraim & Carey 2009, Perkins-Porras *et al.* 2009) and cardiac procedures (Sheifer *et al.* 2000, Gartner *et al.* 2008, Goldberg *et al.* 2009). While researchers reported a reduction in pre-hospital delay time among those with a past history of MI, this finding is not supported consistently in the literature (Dracup & Moser 1997, Johansson *et al.* 2004a, Quinn 2005, Banks &

Dracup 2006, McKee *et al.* 2013). However, several researchers reported shorter pre-hospital delay times among those with a history of PCI and stent insertion (Ottesen *et al.* 2004, Perkins-Porras *et al.* 2008, Ting *et al.* 2010, McKee *et al.* 2013).

The finding that a history of PCI and stent insertion is associated with shorter pre-hospital delay times warrants consideration. This finding may relate to a common misperception that PCI procedures are curative. Individuals that present sooner to the ED with ACS symptoms may do so on the premise that something has 'gone wrong' with the inserted device, as opposed to thinking that the symptoms could be ACS related. For those not previously treated with PCI, the possibility of an ACS recurrence may have prompted the use of denial mechanisms, which can prolong pre-hospital delay times. While the reasons for early presentation to the ED have not been systematically explored, the importance of disseminating realistic information about the risk of a future ACS event is worth considering. This should include those who undergo PCI, as their self-perception of future risk may differ from others. For the cohort of other individuals who seek treatment more speedily, it has been suggested that this may be related to the fact that family members and treating physicians are more sensitised by memories of previous events (Gartner *et al.* 2008). However, it is also possible that following PCI procedures, individuals receive additional information about managing ACS symptoms, although this is not supported in the literature.

## **Cardiovascular risk factors**

Cardiovascular risk factors predispose the individual to the development of ACS. While individuals cannot control their unmodifiable risk factors, those that are modifiable can be controlled, albeit to varying extents. The most common modifiable risk factors are smoking, diabetes, hypercholesterolaemia and hypertension. In general, the presence of modifiable risk factors is associated with increased pre-hospital delay time. Studies have shown a relationship between prolonged pre-hospital delay and hypertension (Sheifer *et al.* 2000, Moser *et al.* 2006, Goldberg *et al.* 2009, Khraim *et al.* 2009). Researchers have also reported an association between longer pre-hospital delay time and smoking (Goldberg *et al.* 2009, Khraim *et al.* 2009, Ting *et al.* 2010). However, with respect to smoking, a shorter pre-hospital delay time with respect to this variable has also been reported (Xanthos *et al.* 2010).

Some researchers did not report an association between hypercholesterolaemia and pre-hospital delay time (Khraim *et al.* 2009, McKee *et al.* 2013), which may be explained by the lack of an association between it and either prolonged or shortened pre-hospital delay time (Herlitz *et al.* 2010a, Park *et al.* 2012). There is consensus in the literature on the link between the condition of diabetes and increased pre-hospital delay times (Sheifer *et al.* 2000, Moser *et al.* 2006, Gartner *et al.* 2008, Goldberg *et al.* 2009, Khraim *et al.* 2009, Ting *et al.* 2010, Ängerud *et al.* 2013). This may be explained by the presence of autonomic neuropathy, which can result in silent ischaemia or the presence of atypical ACS symptoms among diabetic patients (McGinn 2005, Ryden *et al.* 2007, Tubaro *et al.* 2011). While the finding that diabetes is associated with increased

pre-hospital delay time, the suggestion that diabetics present with less typical ACS symptoms than their non-diabetic counterparts is not consistently supported in the literature (Ängerud *et al.* 2012, Ängerud *et al.* 2013).

### **2.5.2 Socio-demographic factors**

The influence of selected socio-demographic factors on pre-hospital delay time has been extensively researched in the literature. The predominant factors examined in relation to this variable were age, gender, socio-economic status, education level, health insurance and marital status. A systematic review (Nguyen *et al.* 2010), and most individual studies, focused specifically on the relationship between age and gender and pre-hospital delay time in ACS.

#### **Age**

It is widely acknowledged that the propensity to develop ACS increases with advancing age (Mandelzweig *et al.* 2006, Rogers *et al.* 2008). Whether advancing age is associated with increased patient pre-hospital delay time is, however less well-established. Studies have reported that advanced age was associated with longer pre-hospital delay times (Yarzebski *et al.* 1994, Dracup & Moser 1997, Gurwitz *et al.* 1997, McKinley *et al.* 2000, Johansson *et al.* 2004b, Moser *et al.* 2006, O' Donnell *et al.* 2006, Gartner *et al.* 2008, Nguyen *et al.* 2010, Atzema *et al.* 2011, Ängerud *et al.* 2013). This may be linked with the likelihood of pre-existing ill-health for those of advanced age. In these cases, the symptoms of ill health may inhibit the individual's ability to decipher cardiac symptoms from those of a different pathology. Therefore, the potential for ambiguity of symptoms could interfere with an understanding of the significance of the threat to health and delay the time to seeking treatment (Dracup *et al.*

2006). However, the correlation between longer pre-hospital delay times and age was not consistently reported in the literature, with some studies reporting little or no relationship between advancing age and patient pre-hospital delay time (Burnett *et al.* 1995, Zerwic *et al.* 2003, Moser *et al.* 2005, Løvlien *et al.* 2007, Goldberg *et al.* 2009, Herlitz *et al.* 2010a, McKee *et al.* 2013, Qian *et al.* 2013). As ACS disease pathology advances with age, the presence of symptoms may be more severe, and this has been shown to reduce patient pre-hospital delay. This may explain the differences between studies with respect to this variable.

### **Gender**

Whether women have longer pre-hospital delay times than men remains unconfirmed. As women develop cardiovascular disease at a more advanced age than men (Schoenberg *et al.* 2003, Lefler & Bondy 2004), the presence of co-existing conditions may interfere with their responses to symptoms and with pre-hospital delay time. It is therefore difficult to discern the extent to which each variable contributes to pre-hospital delay time. While the majority of investigators support the proposition that female gender is a significant variable in predicting increased pre-hospital delay time (Sheifer *et al.* 2000, Johansson *et al.* 2004a, Walsh *et al.* 2004, O' Donnell *et al.* 2006, Ting *et al.* 2008, Goldberg *et al.* 2009), this is not consistently reported (Dracup & Moser 1997, McKinley *et al.* 2000, Moser *et al.* 2005, Løvlien *et al.* 2007, Isaksson *et al.* 2008, McKee *et al.* 2013, O' Donnell *et al.* 2013). Consequently, the evidence is equivocal as to whether gender in itself is a predictor of pre-hospital delay times.



Compared to men, women can experience less of the “classic” ACS symptoms (Albarran *et al.* 2007, De Von *et al.* 2008, Zbierajewski-Eischeid & Loeb 2009). One suggested reason for increased delay by women is their failure to identify with the occurrence of atypical ACS symptoms. Chest pain is the most commonly recognised ACS symptom, but it occurs less frequently in women than in men (Patel *et al.* 2004, Arslanian-Engoren *et al.* 2006, Zbierajewski-Eischeid & Loeb 2009). This relative absence of chest pain among women has been identified internationally (DeVon & Zerwic 2003, Brieger *et al.* 2004, Milner *et al.* 2004, Hwang *et al.* 2009). In addition, compared to reports of male symptoms, some women’s ACS symptoms have been described as non-severe and intermittent (Canto *et al.* 2007).

Prolongation of pre-hospital delay time is further compounded by the notion that heart disease has traditionally been considered a male problem. It has been suggested that knowledge of ACS symptoms has been derived predominantly from male samples and that the ‘male norm’ became the accepted benchmark for ACS symptoms (Milner *et al.* 2002, Lefler & Bondy 2004, O'Donnell *et al.* 2004a, Higginson 2008). Women can experience prodromal symptoms for weeks before an event occurs (McSweeney *et al.* 2003, O' Donnell *et al.* 2006, Sjostrom-Strand & Fridlund 2008). Consequently, more women than men can have an ACS event without an awareness of it. Under these circumstances, pre-hospital delay times are extended, with a consequent and inadvertent loss of opportunity to avail of emergency treatments.

Research findings in relation to concerns over increased pre-hospital delay times among women in Ireland have been disseminated through academic discourse and the media since 2007 (O' Donnell *et al.* 2004b, O' Donnell *et al.* 2006). This may have had a mediating effect in reducing the gender-time delay gap that has been identified in the literature. While there are suggestions that the gender-time delay difference may be narrowing (Gartner *et al.* 2008), an ongoing emphasis must be placed on educating women about their risk status for ACS. This is important, as researchers have reported that women have difficulty with interpreting ACS and perceiving themselves to be vulnerable to the development of heart disease or MI (Zerwic *et al.* 2003, Lockyer 2005, Sjostrom-Strand & Fridlund 2008). If women are informed about typical and atypical symptoms and assisted with symptom identification, then delayed pre-hospital delay time may be averted.

### **Health insurance, socio-economic status and education**

Having health insurance, a high socio-economic status and the highest educational level attained are viewed as inter-dependent. Those with higher education status are more likely to be of higher socio-economic status and are therefore more likely to have the capacity to afford health insurance. Higher education and income are enabling factors for better healthcare access and choices (Lefler & Bondy 2004). Conversely, low socioeconomic status and limited social support have been independently associated with an increased risk of cardiovascular disease (Graham *et al.* 2007). As with the other variables, researchers have not reached consensus on the extent of influence exerted by these factors on pre-hospital delay time.

Some researchers reported no relationship between pre-hospital delay and socio-economic status (Horne *et al.* 2000, Fukuoka *et al.* 2005, Moser *et al.* 2005, Quinn 2005, McKee *et al.* 2013). However, this finding was refuted in other studies where this relationship was reported (Dracup & Moser 1997, McKinley *et al.* 2000, Zerwic *et al.* 2003, Smolderen *et al.* 2010, Atzema *et al.* 2011). Ireland, among other EU countries, has suffered from an economic downturn. This may have altered the economic status of individuals and impacted on their willingness to attend the ED, which has a cost implication. Consequently, this may be a factor in delayed pre-hospital delay times in Ireland as well as other countries.

Smolderen *et al.* (2010) identified that those who were uninsured and those with financial concerns had increased pre-hospital delay times when compared with those who were insured and without financial concerns. As with the majority of factors associated with pre-hospital delay time, consensus has not been reached with respect to this variable. The possession of health insurance has been associated with reduced pre-hospital delay times (Meischke *et al.* 1998, Gibler *et al.* 2002, Banks & Dracup 2006, O' Donnell *et al.* 2006, Tubaro *et al.* 2011). Other researchers, however, contest this finding and have reported no difference in pre-hospital delays times between those with and those without health insurance cover (Morgan 2005, Moser *et al.* 2005, McKee *et al.* 2013).

The majority of the studies relating to health insurance, socio-economic status and education were conducted in the United States, where health insurance

premiums are considered high and unaffordable for many (Smolderen *et al.* 2010). In addition, two of the studies were conducted with minority groups using small samples (Banks & Dracup 2006, McSweeney *et al.* 2007). For example, there were 52 uninsured and 9 insured individuals in one study (Banks & Dracup 2006). Studies differed in their measurement of pre-hospital delay time. One study measured delay to treatment (McSweeney *et al.* 2007), which includes in-hospital delay, while the majority did not include in-hospital delay in their measurements. In terms of education, Lefler and Bondy (2004) advocate that education serves to increase knowledge, which in turn can influence lifestyle behaviours and enhance problem-solving abilities. Perhaps owing to this, those with higher education levels have been shown to have shorter pre-hospital delay times (Dracup & Moser 1997, McGinn *et al.* 2005). In summary, there is very limited empirical evidence to support a relationship between health insurance, socio-economic status or education and patient pre-hospital delay time.

### **Marital status**

There is no evidence to support the suggestion that marital status influences pre-hospital delay time. Researchers found no difference in pre-hospital delay times between those who were married and those who were not (Dracup & Moser 1997, Nouredine *et al.* 2006, McKee *et al.* 2013). However, being married or in a common law relationship was reported as a factor in reducing pre-hospital delay in other studies (Gurwitz *et al.* 1997, McKinley *et al.* 2000, Banks & Dracup 2006, Atzema *et al.* 2011). In these circumstances, it may have been the communication of symptoms to the other person in the relationship that reduced pre-hospital delay times, where consultation may have prompted

treatment seeking behaviours. Although marital status is referred to in the literature, it is perhaps not the state of marriage itself that influences patient pre-hospital delay time but the presence and support of another during an event. The presence of another person at the time of symptom onset, or an obligation to notify somebody about symptoms might be one means by which pre-hospital delay could be reduced, as treatment may be sought out faster by those not experiencing the symptoms. The delegation of responsibility to another person in the presence of ACS symptoms has been recommended (Yarzebski *et al.* 1994, Horne *et al.* 2000, Gartner *et al.* 2008).

### **2.5.3 Situational and behavioural factors**

Situational and behavioural factors are concerned with the time of symptom onset and the location of the individual when symptoms began. It also includes the individual's responses to the presence of symptoms, whether symptom onset was witnessed and, if so, by whom. Responses to symptoms include the notification of another individual that symptoms are present, whether time was taken to consult with a GP and whether the person used an ambulance to access the ED to seek treatment for symptoms. These responses to symptoms are of extreme importance, as these behaviours, which are known to influence patient pre-hospital delay time, are amenable to change.

#### **Time of symptom onset and location of the individual**

Studies have demonstrated that the majority of people are at home when their symptoms begin (Dracup & Moser 1997, McKinley *et al.* 2004, Moser *et al.* 2005). However, symptom onset outside the home tends to be linked with shorter pre-hospital delay time (Khraim & Carey 2009, Perkins-Porras *et al.*

2009, Herlitz *et al.* 2010a). Consequently, when symptoms arise at home, pre-hospital delay time is longer. According to Moser *et al.* (2006), social commitments can overshadow the incentive to seek care for heart warning symptoms, as behaviour is often constrained by the value placed by individuals on social situations. A link has been identified between individuals' locations and times of symptom onset as well as the presence or absence of a witness, all of which support the suggestion that social factors are significant predictors of pre-hospital delay (Goldberg *et al.* 2002, Perkins-Porras *et al.* 2009, Herlitz *et al.* 2010a).

The relationship between the time of symptom onset and patient pre-hospital delay time is less well established. Some researchers found no relationship between these variables (Yarzebski *et al.* 1994, Burnett *et al.* 1995, Fukuoka *et al.* 2005, Løvlien *et al.* 2007, McKee *et al.* 2013), while others have reported shorter delay times with nocturnal symptom onset (Sheifer *et al.* 2000, Ting *et al.* 2008). There have been additional reports of longer pre-hospital delays at night and at the weekend (Gurwitz *et al.* 1997, Goldberg *et al.* 2002, Pattenden *et al.* 2002).

### **Symptom witnesses and the notification of others**

The duration of pre-hospital delay has also been correlated with the presence or absence of a witness. While the majority of people are with someone when symptoms develop, those who are alone have longer pre-hospital delay times (Perry *et al.* 2001, Moser *et al.* 2006, Perkins-Porras *et al.* 2009, Herlitz *et al.* 2010a). Additionally, those who do not share the information with a third party

have increased pre-hospital delay times (Johansson *et al.* 2004a). While the rationale for these findings is not fully elucidated, the literature suggests that people who are alone when symptoms begin forego the influence of others who may encourage them to take appropriate action (Alonzo 2007, Herlitz *et al.* 2010a). Again, this highlights the importance of encouraging individuals to disclose the presence of symptoms to another person, with a view to increasing the rapidity of treatment-seeking action.

While disclosure of symptoms to another individual is an important component of decision-delay reduction, the relationship between the patient and those to whom symptoms are disclosed can influence the responses to symptoms. It has been suggested that those who consult with a spouse or family member (Alonzo 1986, Rasmussen *et al.* 2003, Kaur *et al.* 2006, Johansson *et al.* 2008, Sjostrom-Strand & Fridlund 2008), may delay longer than if they consulted with a stranger, co-worker or friend (Alonzo 1986, Dracup *et al.* 2006, Herlitz *et al.* 2010a). This may be because family members deny or fail to acknowledge the possibility of a health threat, and in doing so may incorrectly label symptoms. It is therefore important to consider the role of denial in the provision of education to patients and relatives or lay individuals. The disclosure of symptoms to another individual is a potentially modifiable behaviour, which could result in reduced pre-hospital delay time in the presence of ACS symptoms.

### **Consultation with a general practitioner (GP)**

While seeking advice from another individual can reduce decision delay, it only reduces total pre-hospital delay time if the individual seeks medical assistance directly from the ED; not from a GP. However, in the face of ACS symptoms, lay

individuals generally recommend that the person with symptoms should consult with a GP (Alonzo 2007), which can contribute to an increase in pre-hospital delay time (Johansson *et al.* 2004a, Johansson *et al.* 2004b, Ottesen *et al.* 2004, Alonzo 2007, Løvlien *et al.* 2007, Gartner *et al.* 2008, Hwang *et al.* 2009, Mosley *et al.* 2011, Tubaro *et al.* 2011, McKee *et al.* 2013). When the literature was reviewed, the reasons for consultation with a GP varied between countries. The reasons ranged from local regulation (Vavouranakis *et al.* 2010) to not feeling sufficiently unwell to go directly to the ED and so, the approval of the GP was sought before attending the ED (Hartford *et al.* 1993, Pattenden *et al.* 2002). Total pre-hospital delay time may not be prolonged with GP consultation in countries that regulate against direct or self-referral to the ED, as pre-hospital diagnostics may be available to these patients. However, in countries like Ireland where diagnosis and medical intervention are ED-dependant, direct and rapid transport to the ED in the presence of ACS symptoms is advocated. The avoidance of consultation with a GP in the presence of symptoms is a modifiable behaviour which could be targeted to reduce pre-hospital delay time.

### **Ambulance use**

The association between emergency medical services (ambulance) use and patient pre-hospital delay has been studied. It has been reported that less than half of all individuals with ACS symptoms call an ambulance initially (Gurwitz *et al.* 1997, Lozzi *et al.* 2005, Løvlien *et al.* 2007, Gartner *et al.* 2008, McKee *et al.* 2013). Yet, failure to use an ambulance increases pre-hospital delay time (Johansson *et al.* 2004b, McKinley *et al.* 2004, Foraker *et al.* 2008, Hwang *et al.* 2009, Khraim *et al.* 2009). The greatest benefits of a reduction in pre-hospital delay time with ambulance use is among those who are diagnosed with MI, with



less time-benefit for those diagnosed with unstable angina (Johansson *et al.* 2004b, Garofalo *et al.* 2012, McKee *et al.* 2013). While it is not the case in all countries, ambulance use in Ireland is available to everybody and it is cost-free. As ambulance use has been shown to reduce pre-hospital delay time, it is important that the public develop an appreciation of the role and value of ambulance services. This is a potential area for inclusion in the education of individuals to modify behaviour and, in doing so target a reduction in pre-hospital delay time.

#### **2.5.4 Knowledge and beliefs**

Knowledge and beliefs about an ACS event include the thoughts, actions and coping strategies that are employed to deal with the situation. Accurate knowledge, coupled with appropriate and well-balanced beliefs, can help determine how the individual understands symptoms, correctly attributes them to an ACS origin and, based on this understanding, responds appropriately to their presence. These contribute towards the determination of patient pre-hospital delay time.

Correct attribution of ACS symptoms to the heart has been identified as the most influential of all in reducing pre-hospital delay time (Fukuoka *et al.* 2005, Quinn 2005, McSweeney *et al.* 2007, McKee *et al.* 2013). Several investigators have identified that longer pre-hospital delays are associated with those who fail to attribute ACS symptoms to their cardiac origin (Banks & Dracup 2006, Perkins-Porras *et al.* 2009, Fox-Wasylyshyn *et al.* 2010). Consequently, it has been reported that patients who attribute their symptoms to the heart have an

increased likelihood of seeking care within an hour of symptom onset, relative to those who do not.

Despite the highlighted benefits of symptom recognition, up to 50% of individuals who experience an MI fail to attribute ACS symptoms to the heart (Meischke *et al.* 1995a, Johansson *et al.* 2004a, Kaur *et al.* 2006, Perkins-Porras *et al.* 2009). An understanding of the seriousness and threat posed by symptoms is important to the decision-making process and to the reduction of pre-hospital delay. This highlights the importance of informing patients about the symptoms of ACS and the actions to take in their presence (Khraim & Carey 2009). Knowledge of ACS symptoms has been linked with shorter pre-hospital delay times (Bleeker *et al.* 1995, Ruston *et al.* 1998, Finnegan *et al.* 2000). Failure to recognise ACS symptoms is associated with increased delay, which is linked with a knowledge deficit (Ryan & Zerwic 2004).

## **2.6 Appraisal of literature on factors influencing pre-hospital delay**

From the literature reviewed, there is evidence of extensive variation with respect to the variables that are reported to influence pre-hospital delay time and the categories into which these variables fit. Consequently, it is difficult to assimilate conclusive evidence that is grounded in the literature. Researchers used a variety of research approaches, across various cultures, to collect data. Some of the larger studies, including registry and large epidemiological studies examined only socio-demographic and clinical variables, while others examined selected variables of interest. Furthermore, the subdivision of the factors that influence pre-hospital delay time by ACS category added to the identified inconsistencies. The use of univariate, bivariate and multivariate analyses by

various researchers contributed further to the heterogeneous data and the associated reported results.

## **2.7 Summary of factors influencing pre-hospital delay**

Prolonged pre-hospital delay time poses the greatest barrier to effecting timely treatments for ACS. Pre-hospital delay time is influenced by a number of factors. These include clinical, socio-demographic, situational and behavioural and knowledge and beliefs. While these variables have been extensively researched, a consistent picture of their influence on pre-hospital delay time does not emerge. It would seem that no factor in isolation has primacy in the decision-making process on time to treatment. Despite the inconsistency across studies, this review provided insights into important issues that warrant consideration when developing an intervention aimed at reducing patient pre-hospital delay time in ACS.

While the requirement for improved knowledge and beliefs are self-evident, so too is the provision of accurate information about symptoms and their variability. Furthermore, information on the potential for a risk of another ACS event in the future should be disseminated to all relevant individuals, including those who may perceive themselves to be no longer at risk. This review provided insights into some of the means by which pre-hospital delay time could be reduced. The targeting of modifiable behaviours could contribute to a reduction in pre-hospital delay. These behaviours include: the notification of another person about the presence of ACS symptoms; non-consultation with a GP in the presence of ACS symptoms and; direct access to the ED by ambulance in the presence of ACS symptoms. The potency and limitations of the studies reviewed here have

contributed towards the refinement of the current study, which is aimed at reducing patient pre-hospital delay time and delay-related behaviours.

## **2.8 Interventions aimed at reducing pre-hospital delay time**

This section of the literature review examines interventions that have been carried out to date and their effectiveness in reducing pre-hospital delay time. A total of nine published interventions were conducted between 1986 and 2014 and all were aimed at reducing pre-hospital delay time. Of the nine interventions, six were before-and-after studies (Ho *et al.* 1989, Moses *et al.* 1991, Bett *et al.* 1993, Blohm *et al.* 1994, Gaspoz *et al.* 1996, Naegeli *et al.* 2011) and three were randomised controlled trials (Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009). The majority of interventions were mass media interventions (Ho *et al.* 1989, Moses *et al.* 1991, Bett *et al.* 1993, Blohm *et al.* 1994, Gaspoz *et al.* 1996, Meischke *et al.* 1997, Luepker *et al.* 2000, Naegeli *et al.* 2011). As the factors that influence responses to ACS symptoms are complex and ambiguous, it is not known whether media influences alone are sufficient to bring about the necessary behavioural changes. Efforts to reduce delay time have been largely unsuccessful to date (Kainth *et al.* 2004, Mooney *et al.* 2012), with only three studies reporting a reduction in pre-hospital delay times (Blohm *et al.* 1994, Gaspoz *et al.* 1996, Naegeli *et al.* 2011). The key points of the intervention studies conducted between 1986 and March 2014 and aimed at reducing pre-hospital delay are outlined in Table 1.

**Table 1. Key points of intervention studies aimed at reducing pre-hospital delay time**

Study background	Duration	Intervention type & sample size	The messages	Results
Ho <i>et al.</i> (1989) United States in 1986 /1987.	2 months.	A 2 month public media education intervention comprising newspaper inserts, radio & television announcements.  <b>Sample size</b> (N=890).	Symptoms of acute MI and the importance of acting quickly.	Time from onset of chest pain to receipt of definitive care.  <b>No significant earlier presentation time noted.</b>
Moses <i>et al.</i> (1991) United States.  Study date not stated.	2 years.	Public education intervention comprising patient education brochures, television & radio advertising, public talks & posters.  <b>Sample size</b> (N=1,793).	The warning signs of a heart attack and the need to seek prompt medical attention were disseminated.	Time from onset of symptoms until hospital presentation.  <b>No significant earlier presentation time noted.</b>
Bett <i>et al.</i> (1993) Australia in 1989.	1 week	An intensive media intervention.  <b>Sample size</b> (N=809).	The need to respond urgently to symptoms of suspected MI and the positive benefits of thrombolytic therapy.	Time interval from symptom onset until first seeking help.  <b>No significant earlier presentation time noted.</b>
Blohm <i>et al.</i> (1994) Sweden in 1986/1987.	1 year	A 3-week intensive media intervention followed by a 9 month maintenance period.  <b>Sample size</b> (N=2,317)	If pain lasts beyond 15 minutes, dial immediately for ambulance transport to hospital. It may indicate MI.	Time from onset of symptoms until hospital admission.  <b>Median delay time reduced significantly (<math>p&lt;0.001</math>)</b>

<b>Study background</b>	<b>Duration</b>	<b>Intervention type &amp; sample size</b>	<b>The messages</b>	<b>Results</b>
Gaspoz <i>et al.</i> (1996) Switzerland in 1992.	1 year.	Multimedia intervention.  <b>Sample size</b> (N=2,395).	Information about chest pain, acute MI and thrombolysis was disseminated.	Pre hospital delay was from onset of symptoms until arrival at the hospital. <b>Median delay time reduced by 25 minutes during the intervention (<math>p&lt;0.002</math>).</b>
Meischke <i>et al.</i> (1997) United States in 1991.	2 years.	Mass media intervention. <b>Sample size</b> (N=5,444).  <b>Control</b> (N=1,343) <b>Intervention</b> (N=4,101)	Information about acute MI symptoms, the importance of fast action and curability of acute MI. Also, the relevance of the emergency services in diagnosis and treatment.	Defined as time from acute symptom onset to emergency department arrival.  <b>No significant earlier presentation time noted.</b>
Luepker <i>et al.</i> (2000) United States in 1995.	18 months.	Mass media intervention. <b>Sample size</b> (N=9,633)  <b>Control</b> (N=5,051) <b>Intervention</b> (N=4,582)	Symptom recognition and the need to act fast.	From symptom onset until emergency department arrival.  <b>No significant earlier presentation time noted.</b>
Dracup <i>et al.</i> (2009) United States/New Zealand in 2002 – 2004.	2 years.	Individualised educational intervention - randomised 2-group experimental design. <b>Sample size</b> (N=3,522).  <b>Control</b> (N=1745) <b>Intervention</b> (N=1777)	Symptom information and emphasis on seeking care fast.	Time from symptom onset to hospital presentation.  <b>No significant earlier presentation time noted.</b>
Naegeli <i>et al.</i> (2011) Switzerland in 2007.	15 weeks – divided into 9 weeks & 6 weeks.	Multimedia intervention.  <b>Sample size</b> (N=5006).	Information about ACS symptoms, importance of rapid intervention including the emergency numbers, instructions for resuscitation and automated external defibrillator use.	Pre hospital delay was from the onset of symptoms until hospital admission.  <b>Median delay time reduced by 17 minutes during the intervention (<math>p&lt;0.001</math>).</b>

## **2.9 Previous interventions**

The purpose of all the interventions was to reduce the time from ACS symptom onset until arrival at the hospital. The interventions were designed to educate people about the potential dangers of ACS symptoms and the benefits of early treatments. They focused on acute myocardial infarction symptoms and the importance of rapid access to care. All interventions were aimed at the general public or at individuals at risk of developing ACS. The primary outcome measurement in all cases was the duration of pre-hospital delay in the presence of ACS symptoms. In all studies the term pre-hospital delay represented the time from symptom onset until arrival at the ED or until the receipt of definitive care.

Ho *et al.* (1989) conducted one of the earliest intervention studies following the era of angioplasty and thrombolysis. Data were collected for four and a half months either side of this two-month media intervention. Pre-hospital delay times were compared before, during and after the intervention with no significant changes noted between the time periods. Subsequently, a two-year public education media intervention was conducted in the State of Illinois (Moses *et al.* 1991). Pre-hospital delay times were measured before and during the intervention, using chart reviews. The sample comprised patients who presented to the ED with at least one acute MI symptom, from a pre-defined list of symptoms. Pre-hospital delay time was unchanged when the study was concluded.

The importance of mortality prevention through rapid responses and use of emergency services was the thrust of an Australian National Heart Foundation intervention launched in 1989 (Bett *et al.* 1993). The benefits of new and pre-existing therapies for MI management were widely publicised, with a view to reducing pre-hospital delay time. Median pre-hospital delay times were measured at three time-points; twice before and once after the intervention. No significant earlier presentation was noted following the intervention.

Blohm *et al.* (1994) carried out a successful one-year media intervention. The intervention used by these researchers was underpinned by motivational techniques, which were aimed at decreasing denial and increasing help-seeking behaviour and myocardial infarction symptom evaluation. These investigators reported a sustained forty minute reduction in pre-hospital delay time for three years beyond completion of the study. While the same levels of sustained success were not reported by Gaspoz *et al.* (1996), their media intervention also demonstrated an overall reduction in median pre-hospital delay times of twenty-five minutes following the intervention. On sub-group analysis, pre-hospital delay time was significantly reduced among men, but not among women in this study (Gaspoz *et al.* 1996). Following a nationwide public intervention initiated by the Swiss Heart Foundation in 2008, median pre-hospital delay times were reduced by 17 minutes (Naegeli *et al.* 2011).

Three randomised controlled trials were reported (Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009). The three differed significantly in terms of their design. Two were mass media interventions concerned with educating



the general public (Meischke *et al.* 1997, Luepker *et al.* 2000). The third was an individualised educational intervention aimed at individuals who were considered to be at risk of developing ACS symptoms (Dracup *et al.* 2009). These researchers sought to increase patients' knowledge about symptoms and improve attitudes and beliefs about seeking care in the presence of ACS symptoms.

The earliest reported randomised controlled trial (Meischke *et al.* 1997) involved a brief mass media and direct mail intervention, which was targeted at those over 50 years of age. Following the intervention, median delay time between each of the three intervention groups and the control group was not statistically significant. The Rapid Early Action for Coronary Treatment Trial (Luepker *et al.* 2000) was one of the largest intervention studies to date. This multi-site randomised controlled trial involved a community intervention in which twenty cities in the United States were paired with each other. Ten cities were randomised to intervention communities and ten to control or comparisons. The intervention cities were targeted with educational strategies. These included mass media, community organisations and public, professional and direct patient education. Post-intervention median delay times were reduced in both groups, with no significant difference in delay time reported between them.

The RCT reported by Dracup *et al.* (2009) differed from the other studies in that all recruits to this study had documented ischaemic heart disease. The sample was recruited from the United States (56%), Australia and New Zealand (44%). In this study, the control and intervention groups received usual care from their

healthcare provider. In addition, those randomised to the intervention group received an individualised education and counselling intervention, using motivational techniques. These investigators reported no significant pre-hospital delay time difference between the experimental and control groups at the end of the study.

The outcomes of the various interventions on pre-hospital delay times have provided inconsistent results. Three interventions reported successful outcomes, while the remainder had no effect on pre-hospital delay time. The reasons for these differences are not immediately apparent. A collective appraisal of the interventions will provide insight into their strengths and limitations. Issues surrounding the intervention designs, messages, objectives and durations may offer explanations as to why so few interventions to date have successfully reduced pre-hospital delay time.

### **2.9.1 Intervention designs, delivery and outcomes**

One of the primary objectives of all interventions was to evaluate their effectiveness on pre-hospital delay time in ACS. All were multi-media public education interventions, except the intervention by Dracup *et al.* (2009), which exclusively used an individualised approach to reduce pre-hospital delay time (Dracup *et al.* 2006). The three researchers that reported a reduction in pre-hospital delay following their interventions were Naegeli *et al.* (2011), Blohm *et al.* (1994) and Gaspoz *et al.* (1996).

The target population differed in some cases, with target groups ranging from whole communities (Ho *et al.* 1989, Moses *et al.* 1991, Bett *et al.* 1993, Blohm

*et al.* 1994, Gaspoz *et al.* 1996, Luepker *et al.* 2000, Naegeli *et al.* 2011) to subgroups within communities (Meischke *et al.* 1997) and individuals (Dracup *et al.* 2009). Two of the randomised controlled trials included individualised teaching for those assigned to their intervention groups (Luepker *et al.* 2000, Dracup *et al.* 2009). This individualisation of intervention delivery was unique to these researchers. The third RCT involved a brief mass media promotion followed by a direct mailing system, which was aimed at households where dwellers were fifty years and older (Meischke *et al.* 1997).

The randomised controlled trial is the most reliable guide to providing research evidence about what works in practice (Torgerson & Torgerson 2008). However, attempts at conducting mass media interventions using randomised controlled trials have been met with unsuccessful outcomes (Meischke *et al.* 1997, Luepker *et al.* 2000). This may be because with mass media interventions, individuals assigned to control groups have greater potential to be exposed to some or all of the intervention messages and consequently, may respond in accordance with the intervention to which they are exposed. Evidence to this effect was reported in anti-smoking interventions, where high recognition of messages was identified in areas where interventions had not been broadcast (Brown *et al.* 1990). Consequently, with respect to the interventions aimed at reducing pre-hospital delay, any media exposure to intervention messages could have impacted on pre-hospital delay time in both groups. This risk of contamination between groups cannot be controlled for and is impossible to measure when media messages are used in individual

communities as part of a randomised controlled trial. The inclusion of true control groups in mass media evaluations is almost impossible.

The successful mass media interventions were observational designs with consecutive phases (Blohm *et al.* 1994, Gaspoz *et al.* 1996, Naegeli *et al.* 2011). However, it has been acknowledged that an alternative design would have been preferable, as a concurrent observation of two groups, with only one group exposed to the message would provide more reliable evidence (Gaspoz *et al.* 1996, Naegeli *et al.* 2011). Studies without true control groups are limited in so far as it cannot be ascertained whether their success was attributable to the interventions alone, or to other confounding variables. Moreover, Torgerson & Torgerson (2008) contend that inferring causality from non RCTs can lead to the implementation of ineffective or harmful interventions. While these studies indicate that media interventions have the potential to reduce pre-hospital delay times, clear inferences cannot be drawn from them.

The individualised intervention design offers an alternative to that of mass media designs. To date, this approach has not been widely used as an intervention. Luepker *et al.* (2000) partially used direct patient education by confining it to those who attended clinics and had a history or risk factors for coronary heart disease. Dracup *et al.* (2009) focused exclusively on an individualised intervention. The intervention by Dracup *et al.* (2009) was aimed specifically at individuals who were known to have ischaemic heart disease. The individualised intervention design provides a forum for the inclusion of family or other relevant individuals. This is significant because research has

demonstrated that people generally consult with another person before seeking assistance when they develop symptoms of ACS (McKinley *et al.* 2004).

The individuals that were originally recruited by Dracup *et al.* (2009) were the same people whose post-intervention pre-hospital delay times were measured. However, there were no baseline data measurements available. While the sample size was large and randomisation took place, the availability of baseline data would have provided an opportunity to demonstrate that the randomisation procedure was effective in producing groups that were similar in all characteristics. If a pre-intervention difference existed between the groups, this would need to be controlled for during data analysis to prevent a threat to the study's internal validity. Therefore, the collection of baseline and post-intervention data would have strengthened the design of this intervention.

### **2.9.2 The key intervention messages**

A variety of media methods including television, radio shows and advertising was used in addition to billboard signs, public transport announcements and printed material. The intervention messages were centred on the necessity to access care promptly in the presence of ACS symptoms. Some also incorporated messages about ACS symptom recognition (Ho *et al.* 1989, Moses *et al.* 1991, Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009, Naegeli *et al.* 2011). The remainder either excluded references to symptoms or placed less emphasis on them (Bett *et al.* 1993, Blohm *et al.* 1994, Gaspoz *et al.* 1996). The only intervention that offered direct and clear advice about non-consultation with a GP and about disclosing the presence of symptoms to another person was Dracup *et al.* (2009). However, among the other eight

interventions, the avoidance of consultation with a GP was implied through their recommendation to phone directly for an ambulance in the presence of ACS symptoms.

Some researchers also used slogans to complement their message (Ho *et al.* 1989, Bett *et al.* 1993, Blohm *et al.* 1994, Gaspoz *et al.* 1996, Meischke *et al.* 1997, Naegeli *et al.* 2011). The slogans used by the studies reporting successful outcomes were very short. The slogans were: “Hjarta-Smarta-90 000”, which translates into “Heart-Pain-90000”, was used by Blohm *et al.* (1994), while “Heart attack? Every minute counts! Call 144!, was the slogan adopted by Gaspoz *et al.* (1996). The slogan “HELP: Act Correctly-Saving Lives”, was used in the Swiss Heart Foundation intervention (Naegeli *et al.* 2011). The slogans used by Bett *et al.* (1993) and Meischke *et al.* (1997) were of similar content to those of Blohm *et al.* (1994), Gaspoz *et al.* (1996) and Naegeli *et al.* (2011).

Despite their suggestion that television is the most effective form of media in Sweden, the intervention by Blohm *et al.* (1994) was the only mass media intervention not delivered through the medium of television. Yet, in contrast to the majority of those that used television promotion, these researchers reported successful outcomes. The media interventions in the Swiss studies were particularly targeted at men (Gaspoz *et al.* 1996, Naegeli *et al.* 2011), and it was among men that the noted effects of the intervention were most pronounced. A message directed at men in this way can reinforce the notion that heart disease is a male problem and consequently the intervention may have had little impact

on women. It is important that all individuals who are at risk of ACS be informed about their predisposition to it.

The message conveyed by Blohm *et al.* (1994) emphasised the presence of denial associated with ACS symptoms. These researchers used motivational techniques to reduce denial, teach self-evaluation of symptoms and teach the steps to take to get help. These may have been factors in its success. However, other studies generated similar types of messages, yet these were met with limited success (Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009). Moreover, the relationship between denial and pre-hospital delay has not been well researched or established empirically. Some authors suggest that there is a positive correlation between denial and pre-hospital delay time (Dracup *et al.* 1995, Alonzo & Reynolds 1997, Perkins-Porras *et al.* 2008), while others dispute this association (Kenyon *et al.* 1991, Theisen *et al.* 1995). However, as Caldwell & Miaskowski (2002) suggest, the content of mass media intervention messages is one variable that may influence their outcomes. In conclusion, there is no evidence to suggest that the slogans or message content alone influenced the study outcomes.

### **2.9.3 Duration of Interventions**

Intervention durations varied between studies. The shortest intervention lasted one week (Bett *et al.* 1993) and the longest was two years (Moses *et al.* 1991, Meischke *et al.* 1997). Two of the successful interventions were of twelve month duration (Blohm *et al.* 1994, Gaspoz *et al.* 1996), while the other was fifteen weeks (Naegeli *et al.* 2011). The fifteen-week intervention was divided into two stages. This meant that six months after the initial exposure to the intervention,

the messages were reinforced again. It has been suggested that the reinforcement and repetition of information has the potential to increase the saliency of intervention messages (Dracup *et al.* 2009).

The intervention by Blohm *et al.* (1994) began with an intensive phase which was followed by a maintenance phase for a more prolonged period. This was also the case for other studies (Moses *et al.* 1991, Meischke *et al.* 1997). While Blohm *et al.* (1994) suggest that their systematic sustained year of public media information may have been a factor in the success of their study, the intensity and focus of their intervention was not dissimilar to those that were of equal or greater duration (Moses *et al.* 1991, Meischke *et al.* 1997). The duration of interventions was not in itself reflective of success or failure and there was no rationale given by the researchers for their intervention durations.

## **2.10 Samples and sampling**

### **2.10.1 Sample size**

Pre-intervention sample sizes ranged from 401 (Ho *et al.* 1989) to 9,633 (Luepker *et al.* 2000). Post-intervention sample sizes ranged between 489 (Ho *et al.* 1989) and 51,410 (Luepker *et al.* 2000). The sample sizes among the studies that reported successful outcomes ranged from 2,126 (Blohm *et al.* 1994) to 5,006 (Naegeli *et al.* 2011). Sample size therefore, does not appear to be a factor in determining study successes, as no clear trend was noted between successful outcomes and sample sizes. The only researchers that referred to their power calculations in their statistical analyses were those who conducted RCTs (Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009).



### 2.10.2 Population characteristics

The use of various approaches to participant recruitment and reporting of data makes it difficult to compare studies. Inclusion criteria were generally broad and were inconsistent between the studies. While some researchers had younger age as an exclusion criterion (Ho *et al.* 1989, Meischke *et al.* 1997, Luepker *et al.* 2000, Naegeli *et al.* 2011), the remainder did not exclude individuals based on their age (Moses *et al.* 1991, Blohm *et al.* 1994, Gaspoz *et al.* 1996, Dracup *et al.* 2009). Four interventions were targeted at specific age groups (Ho *et al.* 1989, Meischke *et al.* 1997, Luepker *et al.* 2000, Naegeli *et al.* 2011). Although data for the entire population were included, Meischke *et al.* (1997) targeted households where the head of house was at least 50 years of age, while Naegeli *et al.* (2011) stated that their intervention was aimed at younger patients and included anyone less than 75 years. Luepker *et al.* (2000) and Ho *et al.* (1989) targeted those over 30 and 35 years, respectively. The targeting of interventions at those over a particular age could result in the message being overlooked by a potentially high-risk younger group. The risk of developing heart disease at a younger age is increased for individuals who have a family history of heart disease (Graham *et al.* 2007). Therefore, it may be more beneficial to target interventions at individuals who are at greatest risk of an ACS event, irrespective of age.

Although the interventions reviewed here were concerned with acute myocardial infarction (MI) symptoms and rapid access to care, many studies did not confine their samples to those diagnosed with ACS or acute MI (Ho *et al.* 1989, Moses *et al.* 1991, Bett *et al.* 1993, Gaspoz *et al.* 1996, Meischke *et al.* 1997, Luepker

*et al.* 2000, Dracup *et al.* 2009). Most samples comprised those admitted with chest pain or those with suspected acute MI. This makes it difficult to draw conclusions, as some study samples were diagnosed with ACS (Naegeli *et al.* 2011), others were at high risk of ACS (Blohm *et al.* 1994, Gaspoz *et al.* 1996, Dracup *et al.* 2009), while others had the potential to be at low or high risk of MI (Moses *et al.* 1991). The studies that reported successful reductions in pre-hospital delay times had samples that were definitively diagnosed with ACS or at risk of its development.

The studies that demonstrated effectiveness of interventions in reducing delay times were carried out in Sweden and Switzerland. These countries have universal health insurance schemes, which entitle all citizens to healthcare services (Commonwealth Fund 2010). Conversely, the issue of medical insurance and costs of seeking care are known barriers to health-seeking behaviour in the United States (Smolderen *et al.* 2010). Five of the nine interventions comprised samples from the United States (Ho *et al.* 1989, Moses *et al.* 1991, Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009). This may account for the differences found between studies within and outside the United States. According to Randolph & Viswanath (2004), mass media intervention success is dependent on the nature of the environment that facilitates the behavioural change being promoted. If healthcare facilities in Sweden and Switzerland are readily accessed, then this may have been a factor in the outcomes of all three studies that reported a reduction in pre-hospital delay time.

### **2.10.3 Recruitment**

Only two researchers (Ho *et al.* 1989, Dracup *et al.* 2009) referred to the issue of informed consent in their studies. It was unclear from the majority of interventions whether recruits were aware or notified that their data were included. In addition to approaching potential recruits and inviting them to participate, Dracup *et al.* (2009) also advertised the study in strategic locations where it would be seen and noticed by prospective participants who then made contact with the researchers to volunteer their willingness to participate. It is unclear how many people were recruited through this voluntary mechanism and how many were approached and invited to participate by the researchers. While it is accepted that participation in research is always voluntary, the recruitment through advertising has the potential to exclude the less gregarious in society. Accordingly, from a statistical perspective, the exclusion of a particular cohort could have implications for the study's results in terms of representation. On the other hand, the sample size was large and randomisation took place.

### **2.11 Data collection**

The method of data collection varied between studies. Chart audits and interviews were the predominant methods used. In some studies, data were collected directly from patients or witnesses by designated research assistants or hospital staff. This information was then cross-referenced against the documented information in the medical or nursing notes (Ho *et al.* 1989, Blohm *et al.* 1994, Gaspoz *et al.* 1996, Luepker *et al.* 2000, Dracup *et al.* 2009). Others confined data collection to face to face interviews only (Bett *et al.* 1993). The remainder obtained their pre-hospital delay time data from registries, hospital

records or medical charts (Moses *et al.* 1991, Meischke *et al.* 1997, Naegeli *et al.* 2011). The preparation of the data collectors in advance of data collection was referred to by some researchers (Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009). Where more than one data collector is assigned to a study, equivalence should be ascertained by performing inter-rater reliability testing. However, this was not referred to in some studies (Ho *et al.* 1989, Moses *et al.* 1991, Bett *et al.* 1993, Blohm *et al.* 1994). The two studies that reported a reduction in pre-hospital delay time collected data directly from patients and cross checked the findings against the medical notes (Blohm *et al.* 1994, Gaspoz *et al.* 1996).

Some studies had dedicated staff assigned to the collection of information on pre-hospital delay time (Gaspoz *et al.* 1996, Meischke *et al.* 1997, Dracup *et al.* 2009). Others combined designated research staff with hospital staff (Blohm *et al.* 1994, Luepker *et al.* 2000). Coronary care nurses collected data for Bett *et al.* (1993). Sampling details were not explicit in all studies (Ho *et al.* 1989, Moses *et al.* 1991, Naegeli *et al.* 2011). Two studies that reported reductions in pre-hospital delay times referred to the collection of data by research personnel (Blohm *et al.* 1994, Gaspoz *et al.* 1996). While it was not stated explicitly, the implication was that these individuals were trained for this purpose. Two studies explicitly stated that their pre-hospital delay time data collectors had received specific training (Luepker *et al.* 2000, Dracup *et al.* 2009). The remainder made no reference to the extent of training provided or to reliability issues. This is significant, as the issue of equivalence is important to the minimisation of

measurement errors in studies where data are collected by more than one person.

Blohm *et al.* (1994) interviewed patients within 24 hours of their admission to coronary care, while Gaspoz *et al.* (1996) did not disclose the time lapse between the event and the interview. In one study, individuals were telephoned to ascertain details of their event four to eight weeks afterwards (Ho *et al.* 1989). The prompt collection of face-to-face data and its verification against documented notes has the greatest potential to maximise information accuracy, as information can be cross-referenced and clarified simultaneously. This has been identified in other studies (Fukuoka *et al.* 2005). In addition, the collection of face-to-face data close to an event is less likely to be subject to recall bias (Pelter 2010).

## **2.12 Outcome measures**

The primary outcome measured in all interventions was pre-hospital delay time. The majority of studies defined pre-hospital delay time as the time from symptom onset until arrival at the ED or hospital (Moses *et al.* 1991, Blohm *et al.* 1994, Gaspoz *et al.* 1996, Luepker *et al.* 2000, Dracup *et al.* 2009, Naegeli *et al.* 2011). Other investigators defined it as the time from acute symptom onset until arrival at the ED (Ho *et al.* 1989, Meischke *et al.* 1997). In one study (Bett *et al.* 1993), pre-hospital delay time was measured from symptom onset until first seeking help. The definition of seeking help was not explicitly stated, although, from the study results it would appear that arrival at a hospital was the point at which help was sought.

There was also inconsistency across studies with respect to defining ACS symptoms and their interpretation. In the studies reviewed, symptoms were either poorly defined (Bett *et al.* 1993, Blohm *et al.* 1994, Gaspoz *et al.* 1996, Meischke *et al.* 1997, Luepker *et al.* 2000), restricted to pain (Ho *et al.* 1989) or not defined and taken from a broad range of potential symptoms (Moses *et al.* 1991). Precise details about symptom onset are crucial for interventions concerned with pre-hospital delay times (Mackay *et al.* 2014). It was not possible to ascertain what constituted an acute symptom from those studies whose operational definitions were poorly delineated. Consequently, an accurate estimation of study comparisons was difficult, as important information was indeterminate or differed between studies.

It was also difficult to draw comparisons between studies with respect to pre-hospital delay times. Ho *et al.* (1989) reported pre-intervention delay times by grouped-time variables, without reporting an overall median delay. This omission rendered it difficult to draw accurate comparisons between this study and the others. With the exceptions of Meischke *et al.* (1997) and Dracup *et al.* (2009), pre-intervention pre-hospital delay times were measured and reported. Reported median pre-intervention pre-hospital delay times ranged between studies from 1.0 hour (Bett *et al.* 1993) to 3.0 hours (Blohm *et al.* 1994, Gaspoz *et al.* 1996, Naegeli *et al.* 2011). Two of the nine studies reported a baseline pre-hospital delay time of less than 105 minutes (Moses *et al.* 1991, Bett *et al.* 1993). An attempt by Bett *et al.* (1993) to improve on pre-hospital delay times that were already within target treatment times seems both unnecessary and unfeasible. Likewise, the median pre-hospital delay time of 103 minutes

reported by Moses *et al.* (1991) is also very close to recommended time to treatment. Pre-intervention pre-hospital delay times of approximately one to one and a half hours obviate the need for any additional intervention, as an expectation for improvement would be unrealistic and unnecessary. Three researchers reported a statistically significant reduction ( $p < 0.001$ ) in post-intervention median pre-hospital delay times (Blohm *et al.* 1994, Gaspoz *et al.* 1996, Naegeli *et al.* 2011). Pre-intervention pre-hospital delay times were longer in these than in other studies, with median pre-hospital delay times of 3.0 hours reported.

In the case of mass media interventions, some researchers measured pre-hospital delay time during the intervention (Moses *et al.* 1991, Gaspoz *et al.* 1996, Luepker *et al.* 2000), while others measured this variable during and immediately following the intervention (Ho *et al.* 1989, Blohm *et al.* 1994, Meischke *et al.* 1997). Pre-hospital delay time was measured only after the intervention had ended in other studies (Bett *et al.* 1993, Naegeli *et al.* 2011). Variation in data collection times may account for the differences in study outcomes. A feature of one of the successful interventions was the extension of data collection for three years beyond the intervention delivery (Blohm *et al.* 1994).

Dracup *et al.* (2009) measured the impact of their intervention when patients presented to an ED with ACS symptoms. This study differed from all others, in that those who received the intervention and those who did not, were the same individuals whose data were recorded in the post-intervention period. Pre-

hospital delay time data in this study were from those who were admitted to the hospital with ACS symptoms following the intervention. The study was of two year duration, but only data on the first subsequent presentation to the ED following the intervention were included in the study.

Two of the studies that reported a reduction in pre-hospital delay time measured pre-hospital delay time during the intervention and beyond (Blohm *et al.* 1994, Gaspoz *et al.* 1996). The medium to long term impact of an intervention is more easily discerned with on-going follow up. Similarly, restricting the examination of pre-hospital delay time to the precise duration of an intervention precludes the detection of its potential longer-term effects.

### **2.13 Disseminating intervention messages**

There is evidence to suggest that mass media intervention messages increase public awareness and, in doing so can potentially influence people's thinking and learning (Ho *et al.* 1989, Goldberg *et al.* 1992, Eppler *et al.* 1994, Buckley *et al.* 2007). This is not to suggest that they are effective in altering behaviour. Mass media interventions do not take cognisance of how people learn or internalise information. Their effectiveness is therefore dependant on the characteristics of the target population. Those who are exposed to the message need to have an ability to execute the proposed behaviour in order to effect a change. This assumes a level of knowledge, understanding and willingness on the part of the target group. However, the knowledge-behaviour gap is well-documented (Valente *et al.* 2006) and knowledge and understanding cannot guarantee an alteration in behaviour. Moses *et al.* (1991) suggest that it is difficult to alter public behaviour on a broad basis, while Ho *et al.* (1989) urge



that public education programmes be of longer duration and be repeated at frequent intervals in an attempt to modify human behaviour. Yet, it is difficult to sustain awareness of a message in an intervention, as people tend to normalise unpleasant information (Alonzo & Reynolds 1997).

Irrespective of how well-designed mass media educational interventions are, they will have limitations. These interventions have the potential to expose everybody to the same message and thus preclude targeting those at greatest risk of a coronary event. As a consequence, there is no means of determining which individuals internalise the messages conveyed regarding symptom presentation and appropriate actions. Some may perceive that the messages are targeted at individuals other than themselves.

There is evidence to suggest that some GPs are unaware of, or do not appreciate the consequences of patient delay in an ACS event (Dracup *et al.* 2006). However, it is well recognised that individuals with ACS symptoms frequently attend their GP instead of going directly to the ED (Pattenden *et al.* 2002). A mass media intervention message may impact on GPs as well as patients. Consequently, an improvement in pre-hospital delay time could result from an increased acceptance of the need for reduced delay time by GPs, as opposed to patients. While this may have the desired effect of reducing pre-hospital delay during the study, the longer term outcome might be less successful if the general public fail to embrace the intervention message.

With so few mass media studies reporting successful outcomes, Blohm *et al.* (1996) propose that new media interventions be established in an effort to alter behaviour around delay in ACS. Caldwell and Miaskowski (2002), on the other hand suggest that an individualised approach to teaching symptom evaluation to those at greatest risk might be worth considering. Irrespective of the design chosen, all interventions will have inherent strengths and weaknesses. The limitations of mass media interventions may in some way account for their general failure in achieving reductions in pre-hospital delay time in ACS.

#### **2.14 The successful interventions**

The studies that reported successful outcomes following their mass media interventions (Blohm *et al.* 1994, Gaspoz *et al.* 1996, Naegeli *et al.* 2011) were similar to other studies in terms of population, study durations, variables measured and baseline pre-hospital delay time. Yet, none of the other studies reported a reduction of significance in pre-hospital delay times following their interventions. These studies (Blohm *et al.* 1994, Gaspoz *et al.* 1996, Naegeli *et al.* 2011) had some distinguishing features that may have influenced their outcomes. Conducted in Sweden and Switzerland, they were the only studies conducted in Europe. In contrast to the United States, Sweden and Switzerland are renowned for universal healthcare provision. In addition, it has been suggested that all people in Sweden over the age of eight years are literate (Blohm *et al.* 1991), and the majority of people read the daily newspapers, through which intervention messages were disseminated. Consequently, the target population in these countries may have been more exposed to the intervention message.

The pre-intervention pre-hospital delay time of 3.0 hours in these studies was longer than other reported baseline pre-hospital delay times. A pre-hospital delay time that is originally longer may be more amenable to change than one that is already short or relatively short. This finding may have been a factor in the studies' reported successes. The majority of other studies reported pre-hospital delay times of between 2.41 hours (Dracup *et al.* 2009) and 2.6 hours (Ho *et al.* 1989). The successful studies reported post-intervention pre-hospital delay time reductions of between 17 (Naegeli *et al.* 2011) and 40 minutes (Blohm *et al.* 1994). The post-intervention pre-hospital delay times in these studies are more reflective of the reported pre-intervention pre-hospital times in other studies (Ho *et al.* 1989, Luepker *et al.* 2000).

Although not unique to these studies alone, the research design may have influenced the outcomes. In these studies, comparisons were made at various points in the post-intervention phase. In the case of the two older studies (Blohm *et al.* 1994, Gaspoz *et al.* 1996), data were collected directly by designated research personnel and confirmed by cross-referencing against the case notes. With respect to the intervention by Naegeli *et al.* (2011), data were also cross-checked and clarified by the data centre. The cross-checking of data adds to the reliability of the information generated. These studies differed slightly from others in that their message emphasis was short and the main ACS symptom to which they referred in their advertisements was chest pain. Blohm *et al.* (1991) referred to their deliberate use of a single message, which they hoped would capture people of all ages.

While the successful studies did not display major distinguishing features compared with those that reported no success, there were some differences between the two. Cultural differences that may exist between Sweden and Switzerland and the non-European countries may have been a factor in their success. The ease of access to healthcare provision in these countries, coupled with the longer pre-intervention pre-hospital delay times, may have influenced the outcomes. In addition, the rigorous attention to their data collection protocols, or a combination of all these factors, may have impacted on the results. However, the lack of a control group in both studies can be viewed as a limitation.

Alonzo and Reynolds (1997) make several recommendations for educating the public. These include the provision of a clear and user-friendly algorithm to educate about signs and symptoms of ACS, the actions to take and the associated emotional sequelae. In addition, these researchers propose that those individuals, their relatives and lay others should be equipped with resources to cope with emotions such as denial, suppression or optimism in the face of ACS symptoms. Moreover, they suggest that it would be productive to provide personalised education to individuals who use maladaptive coping mechanisms. Some of these features, such as the use of motivational techniques, were reported among the intervention studies that reported successful outcomes. The literature suggests that the education of those who have been diagnosed with coronary heart disease and those who tend to deny the immediacy of signs and symptoms should be the focus of interventions (Alonzo & Reynolds 1997, Fox-Wasylyshyn *et al.* 2010). Furthermore, Van de

Werf *et al.* (2003) recommend that after an acute MI, patients at high risk of further events like re-infarction and death, be identified and intervening steps taken to prevent a recurrence. The above recommendations, in addition to the identified strengths and limitations of previous interventions, have been considered in an endeavour to develop an effective intervention for this study, which aims to reduce pre-hospital delay time in the Irish population.

### **2.15 Summary of interventions**

The development of thrombolysis and angioplasty around 1985 heralded the emphasis of the benefits of prompt presentation to EDs with ACS symptoms. Problems regarding pre-hospital delay time have since been identified and a total of nine interventions have been conducted with a view to addressing this problem. Public education through mass media interventions have been the predominant choice of intervention. Those that used media interventions attempted to expose the public to their message through advertising, written material or public education fora. Only one pre-hospital delay time intervention was delivered through individualised education. The importance of seeking assistance rapidly was the primary focus of the studies; the majority of which also referred to the recognition of heart warning symptoms, particularly chest pain. Evidence of effectiveness in reducing pre-hospital delay time came from three European studies, none of which were randomised controlled trials. Either individually or collectively, these studies: reported pre-intervention pre-hospital delay times in the region of 3.0 hours; had interventions that focused on brief succinct messages; used motivational techniques as part of the intervention and; addressed the role of denial associated with ACS symptoms. These, among other factors such as standards of healthcare provision and cultural

issues may have been factors in their successful reduction in pre-hospital delay time.

## **2.16 Conclusion**

The empirical evidence established from this review demonstrates the need for targeted reductions in patient pre-hospital delay time. Future interventions should be informed by those previously conducted to help maximise this potential. They should include the identified strengths and weaknesses of past interventions with particular reference to those that reported successful reductions in pre-hospital delay time. While randomised controlled trials provide the strongest form of evidence, there are other factors to consider in the development of an intervention aimed at reducing pre-hospital delay time. The European Society of Cardiologists emphasised the need to target individuals who were at most risk of ACS. This signals the necessity to consider an intervention aimed at individuals, as opposed to communities or groups. The individualised intervention approach has not been widely tested to date.

Evidence from the literature supports the contention that patient pre-hospital delay time is contingent on patients' behaviours in response to symptoms. Therefore, to accomplish a reduction in patient pre-hospital delay time in the presence of ACS symptoms, certain key behaviours should be addressed. The behaviours that impact on patient pre-hospital delay time are cardiac symptom recognition, the use of ambulance as the means of transport to the ED, the non-consultation with a GP in the presence of symptoms and the notification of another person that symptoms are present. Therefore, behaviours are affected not only by knowledge but also by thoughts and actions. An intervention that

encompasses all of these would be important in the reduction of patient pre-hospital delay time in the presence of ACS symptoms.

Based on prior research, it appears that interventions should incorporate the role of denial in the context of behavioural responses to symptoms, together with the use of motivational techniques, which may engender empowerment of the individual. The argument for short and succinct intervention messages is also advanced through the literature. The development of further interventions to reduce pre-hospital delay must originate from optimum scientific evidence. Accordingly, the findings from the literature review and the recommendations made by other researchers have informed this study.

### **2.17 Aim of the study**

The aim of this study was to test the effectiveness of an individualised educational intervention on patient pre-hospital delay time among patients diagnosed with ACS.

### **Study outcomes and hypotheses**

1. To determine whether there was a difference in patient pre-hospital delay time between those randomly assigned to the control group and those randomly assigned to the intervention group.

**Primary hypothesis:** Following the intervention, patients assigned to the intervention group will have reduced pre-hospital delay times if readmitted to an ED with ACS symptoms, compared to the control group.

2. To determine whether there was a difference in patient pre-hospital behaviours between those randomly assigned to the control group and those randomly assigned to the intervention group.

**Secondary hypothesis:** Following the educational intervention, and in the presence of unresolved ACS symptoms, more patients from the intervention group compared to the control group will: use prescribed nitrates; alert another person to the presence of unresolved symptoms; avoid consultation with a GP and; use an ambulance to access the ED.



## Chapter 3 Methodological considerations

### 3.1 Introduction

The need to reduce patient pre-hospital delay time among people experiencing ACS symptoms was highlighted in the literature review. Yet, there have been a limited number of interventions aimed at reducing patient pre-hospital delay time. Of those that have been conducted, the majority have been outside Europe. Switzerland and Sweden are the only European countries to have carried out successful interventions aimed at reducing pre-hospital delay time. Consequently, a decision was made to deliver an intervention aimed at reducing patient pre-hospital delay time for persons experiencing ACS symptoms in Ireland. It was envisaged that the delivery of such an intervention would result in behavioural change, which would translate into reduced patient pre-hospital delay time in the presence of ACS symptoms.

The strengths, limitations and recommendations from previously developed interventions emanated from the literature. These subsequently informed the decisions that were made with reference to the research design and type of intervention that was used in this study. Experimental designs have been credited as the most effective way to determine relationships between variables to enable understanding, prediction and control (Munhall 1982, Grove *et al.* 2013). Randomised controlled trials are the highest level of all experimental designs and their contribution to establishing cause and effect relationships with respect to intervention outcomes has been widely accepted (Feneck 2009, Bonell *et al.* 2012). They are grounded in the positivist paradigm, which is

based on the assumption that knowledge is independent and objective and can be used to predict and control phenomena. While pre-test, post-test designs have been widely used in past interventions aimed at reducing patient pre-hospital delay time, these designs generally cannot 'design-out' potential bias, unlike RCTs (Torgerson & Torgerson 2008, Feneck 2009). In light of this evidence, a randomised controlled trial was selected as the research design of choice for this study.

The type of intervention delivered was also influenced by the literature review. Mass media and individualised interventions are the two types of interventions used previously. Important limitations have been identified with respect to the use of mass media interventions. They are considered useful for changing attitudes, but their impact on behavioural change is at best, modest (Lau *et al.* 1980, Leventhal *et al.* 1980, Cavill & Bauman 2004). While individualised interventions have not been widely tested, they are thought to have the greatest impact on behaviour (Taylor 1990, Strecher *et al.* 2002, Alm-Roijer *et al.* 2006, Dracup *et al.* 2006, Jensen *et al.* 2009). Health policy advisors and researchers have advocated that individuals who are at greatest risk of an ACS event be targeted and educated about pre-hospital delay time and ACS. Given these considerations, a decision was made to deliver an individualised educational intervention, as opposed to one targeted at the general public. As with most interventions, the intervention used for this study was a complex intervention.

Further aspects that warranted consideration in this study were the potential benefits of using motivational interviewing techniques and the need to address

the role of denial in recognising, acknowledging and responding to ACS symptoms. It was decided that the intervention delivered in this study would be strengthened by incorporating these characteristics. This chapter discusses randomised controlled trials, their benefits and the criteria for their use. The chosen individualised educational intervention and the theoretical framework that underpinned it are also discussed, together with the rationale for their choice.

### **3.2 The choice of research design: a randomised controlled trial**

Randomised controlled trials are used to evaluate various types of interventions for various purposes in various settings and in various populations of participants (Jadad & Enkin 2007). For a study to be classified as an RCT, it must fulfil one main criterion, which is the random allocation of participants to the study groups. There are a number of classifications of RCTs. They can be classified according to the aspects of the intervention that they evaluate, the way in which participants are exposed to the intervention, the preferences of the investigators and participants, the units of analysis and the number of participants included in the trial.

For this current study, the classification of RCT was according to how participants were exposed to the intervention. There are three categories within this classification of design. These are the factorial design, the cross over design and the parallel design. The factorial design enables investigators to compare two or more experimental interventions together and individually. In a cross-over design all of the study participants are given all of the interventions in successive periods. The interventions are received in random order in a

cross-over design (Jadad & Enkin 2007). In parallel design studies, each group of participants is exposed to only one of the study interventions. Parallel designs are the most frequently used and were deemed to be suited to this current RCT, where one group would be exposed to the intervention, while the other group would serve as a control group.

Randomised controlled trials have been acclaimed as the gold standard for research into the effects of interventions in health care (Sackett *et al.* 1997, Richardson 2000, Hutchison & Styles 2010, Sidani & Braden 2011, Blackwood *et al.* 2010, Grove *et al.* 2013). These experiments are characterised by the randomisation of participants, the use of control groups and a clear articulation of the independent variable (Poole & Jones 1996, Singh *et al.* 2011, Bonell *et al.* 2012). They provide a framework whereby relationships between phenomena can be tested and causal relationships formalised by systematic means (Poole & Jones 1996, Bonell *et al.* 2012). The positive advantages offered by RCTs include the testing of hypotheses, the ability to ascertain whether an intervention is effective and the capacity to compare the effects of interventions (Poole & Jones 1996, Blackwood *et al.* 2010, Bonell *et al.* 2012). Their power to standardise conditions, exert control over extraneous factors and reduce bias is viewed as the epitome of good practice (Blackwood *et al.* 2010).

Randomised controlled trials are simple, yet powerful research tools that have the propensity to answer not only whether interventions work, but also how and for whom they work. They have been widely acclaimed in health-related research, as they optimise the means by which proposed changes in

healthcare, education and other areas of public policy can be influenced and evaluated (Altman *et al.* 2001, Watson *et al.* 2002, Jadad & Enkin 2007). The generation of knowledge where cause and effect relationships can be established is important for the development of a knowledge base in nursing and clinical practice. This design was viewed as appropriate in a study where an educational intervention would be delivered to individuals and its effect measured in terms of a dependent variable.

### **3.3 Criteria for a randomised controlled trial**

While RCTs that are well-designed and effectively executed can provide the best evidence on health-care intervention efficacy, they must conform to specific design and implementation criteria (Jadad & Enkin 2007, Sidani & Braden 2011). Only then, can it be inferred with confidence that the observed differences in outcomes between the control and intervention groups were due to the intervention. In addition to the necessity for quality randomisation mechanisms, RCTs must fulfil the criteria of minimisation of trial bias and fidelity to the intervention (Bellg *et al.* 2004, Borrelli 2011).

#### **3.3.1 Randomisation mechanisms**

Randomisation in an RCT refers to the assignment of participants to one of the study groups by chance alone (Altman 2006). Group allocation is normally determined randomly using a computerised random number generator or statistical calculator, which generates codes. Therefore, the allocation of participants to the study group is not influenced by the participant, the investigator or any other individual associated with the trial (Jadad & Enkin 2007).

Quality randomisation of participants is contingent on two principles. These are the provision of a clear definition for investigators about the rules that govern participant allocation and an adherence to these rules by the investigators for the duration of the study (Jadad & Enkin 2007). This is important in the conduct of an RCT, as according to statistical theory, the observed behaviour of random samples is reflective of the expected behaviour from a single population (Altman 2006).

The number and characteristics of participants allocated to study groups could differ during a study, even with the use of random allocation sequences (Altman 2006). In an RCT it is ideal for the randomised groups to be balanced and identical. If the control and intervention groups differed in size, this could potentially reduce the precision of estimates of the difference in treatment effects, and hence the efficiency of the intervention (Torgerson & Torgerson 2008). In light of this, strategies, such as block randomisation, can be used to minimise group size differences (Torgerson & Torgerson 2008).

### **Block randomisation**

Block randomisation is often used to keep the numbers of participants in each group as close as possible in size (Altman 2006, Jadad & Enkin 2007). Block randomisation can be achieved by setting up the random number generator to produce sequential numbers, which are divided into multiple blocks. In this way, equal proportions of control and intervention assignments are designated to each individual block (Jadad & Enkin 2007). For example, blocks of twenty allocations could be produced in such a way that ten of these numbers would

be allocated to the control group and ten to the intervention group. In this case, if a trial terminated ahead of schedule, the sample sizes between the randomised groups would differ by no more than ten.

### **3.3.2 Minimisation of trial bias**

The minimisation of trial bias is an important factor in the maintenance of quality RCT criteria. Trial bias can originate from the inception of a study to the interpretation of the disseminated results and can lead to an under or over estimation of the effects of an intervention (Jadad & Enkin 2007). Group characteristic imbalances can be controlled for using random allocation to study groups, and trial bias can be further minimised through the concealment of group assignment from investigators and participants until such time as it is appropriate to divulge this information (Kunz *et al.* 2007). This non-disclosure of group assignment is central to successful randomisation, as refusal to participate due to group preference could result in a sample unrepresentative of the target group (Jadad & Enkin 2007). Trial bias can threaten the validity of an RCT and measures should be taken to protect against the main forms of bias, which are selection bias and ascertainment bias (Polit & Beck 2010).

#### **Selection bias**

The term selection bias refers to the formation of groups by a process other than through randomisation, or to the intentional exclusion of potentially eligible people from a study (Torgerson & Torgerson 2008). It is more likely to occur in situations where the personal characteristics or intended group allocation are known to, but inconsistent with the views of the investigator. Selection bias

should not arise in a well conducted RCT, where randomisation is correctly adhered to. It can be prevented through the patient being formally entered into the study before group-allocation is divulged (Matthews 2000). Randomised sampling eliminates the potential problem of selection bias, as it provides for equal opportunities for all participating individuals to be assigned to either study group (Altman 2006, Torgerson & Torgerson 2008, Blackwood *et al.* 2010). The effects of new interventions have been shown to be exaggerated in studies where group-allocation concealment did not occur (Chalmers *et al.* 1983).

### **Ascertainment bias**

Ascertainment bias refers to the systematic distortion of the results or conclusions through knowledge of which intervention each participant received (Jadad & Enkin 2007). Ascertainment bias is prevented through a process called blinding, which keeps those involved in the trial unaware of group allocation for as long as possible. However, in some cases it is unethical or at times impossible to implement blinding across a trial at all levels (Jadad & Enkin 2007, Feneck 2007, Friedberg *et al.* 2010). By their nature, some trials necessitate awareness by participants or interventionists of group-allocation (Feneck 2007, Blackwood *et al.* 2010).

### **3.3.3 Intervention fidelity**

Intervention fidelity refers to the strategies used to ensure that the interventionist delivers the intervention in accordance with the specified trial protocol and design (Judge Santacroce *et al.* 2004, Sidani & Braden 2011, Grove *et al.* 2013). Definitions and interpretations of fidelity vary slightly within



the literature, but all encapsulate the concepts of theoretical and operational fidelity. Theoretical fidelity refers to the design of the intervention, while operational fidelity is concerned with the actual implementation of the intervention (Bellg *et al.* 2004, Judge Santacroce *et al.* 2004, Leventhal & Friedman 2004, Sidani & Braden 2011). The preservation of intervention fidelity represents an adherence and competence by the interventionist to the delivery of the intervention. Adherence refers to the extent to which the prescribed and proscribed elements of the intervention were delivered and avoided, respectively (Waltz *et al.* 1993). This adherence should be in accordance with the original design or research plan (Judge Santacroce *et al.* 2004, Sidani & Braden 2011).

Almost all interventions are complex interventions, of which intervention fidelity is an integral component. This is particularly the case for interventions associated with behavioural change (Campbell *et al.* 2013, Grove *et al.* 2013). Complex interventions are defined as interventions that contain more than one intervention element and may target more than one patient outcome (Aranda 2008). They comprise various interconnecting parts that can act independently and interdependently (Medical Research Council 2000, Campbell *et al.* 2007).

To increase fidelity in complex interventions, researchers should pre-determine the means by which they will assess and monitor intervention fidelity (Spillane *et al.* 2007). An adherence to fidelity increases scientific confidence that changes in the dependent variable can be attributed to the independent variable (Bellg *et al.* 2004, Borelli *et al.* 2005, Borelli 2011). The Treatment Fidelity

Workgroup of the National Institutes of Health Behaviour Change Consortium (Bellg *et al.* 2004), among others (Spillane *et al.* 2007, Sidani & Braden 2011) have provided best practice guidelines that can be applied to maximise intervention fidelity.

It is important for interventions to be implemented with minimal variation (Spillane *et al.* 2007, Waller 2009). Variations are seen as drifts or deviations from the trial protocol. This can arise if the intervention dose, components or method of intervention delivery is altered, or where there are inconsistencies in executing elements of the intervention across participants within or between research settings. A variation in, or deviation from the intervention elements can weaken the effects of the intervention on the intended outcomes, which can result in variability in the observed outcomes.

Increased variability in outcomes decreases the statistical power to detect significant effects between groups and reduces the magnitude of observed effect sizes (Bellg *et al.* 2004, Resnick *et al.* 2005). Strategies to enhance intervention fidelity include the careful selection and training of interventionists, the development and use of an intervention manual and monitoring of intervention implementation (Spillane *et al.* 2007, Sidani & Braden 2011). In addition to the above strategies, consideration should also be afforded to the receipt and enactment of treatment skills (Bellg *et al.* 2004).

## **Selection and training procedures**

The careful selection and training of interventionists is one means by which operational fidelity can be optimised. This should not be under-estimated, as the interventionist is vital to the delivery of the majority of interventions. The interaction between the interventionist and participant can determine the participant's level of appreciation of the value of the intervention and their motivation to adhere to it (DiMatteo *et al.* 1993, Van Dam *et al.* 2003, Fuentes *et al.* 2007, Sidani & Braden 2011). While currently there are no guidelines that specify the necessary attributes for interventionists, careful selection is recommended. The emphasis should be on positive characteristics including competence, formal training, licensing, experience, personality style and congruence between the interventionist and participant (Sidani & Braden 2011).

Standardised training and preparation of interventionists is essential to maximise consistent intervention delivery (Spillane *et al.* 2007). Consistency among interventionists is contingent on the delivery of intervention training, the use of a standardised training manual and consistency among training providers (Bellg *et al.* 2004). This enhances the potential for equivalence of delivery of the intervention across research sites, where more than one research site is used (Borrelli 2011). It is recommended that skill acquisition levels be monitored after training is complete, to check whether interventionist training was successful (Bellg *et al.* 2004). Interventionist training should be on-going for the duration of a trial to reinforce the required competencies and to prevent a reduction in performance by the interventionist (Johnson & Remien 2003, Borrelli *et al.* 2005). The effectiveness of the intervention training relies heavily

on the skills of the trainer and should be sufficiently comprehensive to address theoretical and practical issues (Spillane *et al.* 2007, Sidani & Braden 2011).

### **The intervention manual and trial protocol**

The development of a trial protocol and an intervention manual is strongly recommended for any intervention, as these underpin treatment fidelity (Spillane *et al.* 2007, Sidani & Braden 2011). The trial protocol refers to the step-by-step procedures to which the interventionist must adhere in carrying out all aspects of the intervention. The intervention manual provides the details of what to implement in the intervention. The manual and protocol increase the likelihood of the intervention being delivered uniformly across the research sites by different individuals (Bellg *et al.* 2004, Borrelli 2011). The use of rigorous procedures, such as standardised manuals, can minimise biases in studies where blinding of interventionists is not possible (Bellg *et al.* 2004, Friedberg *et al.* 2010).

### **Monitoring intervention implementation**

Process evaluation refers to an assessment of a procedure or process. In the case of complex interventions, it refers to a model of treatment fidelity associated with the performance of an interventionist in implementing an intervention (Spillane *et al.* 2007, Sidani & Braden 2011). This practice is important in accounting for variation in intervention delivery and intervention testing. It is an essential component of research trials that should be included to enhance internal and external validity and replication (Bellg *et al.* 2004, Resnick

*et al.* 2005). It is of particular importance in multi-site trials, where there is greater potential for variation in the way the intervention is delivered and received (Herbert & Bø 2005, Oakley *et al.* 2006).

As the implementation of behavioural interventions in a systemised manner can be difficult and is not always possible (Wells & Sturm 1996, Leventhal & Friedman 2004), a variety of methods can be used to monitor intervention implementation. This enhances the reliability and validity of the intervention. These methods include the use of intervention manuals, in vivo or recorded observation, client or interventionist self-report evaluations, case conferences for intervention discussion, monitoring and testing treatment skills acquisition and field notes (Spillane *et al.* 2007, Sidani & Braden 2011).

Leventhal and Friedman (2004) suggest that interventionists who are forced to follow strict procedures during the implementation of interventions among different individuals can fail to achieve the aims of the study. While intervention fidelity is important, an intervention may work better if adaptation to the local context is permitted, as strict fidelity to a protocol can at times be inappropriate (Craig *et al.* 2008, Blackwood *et al.* 2010). It has been suggested that rigid procedures be replaced with adaptation, where necessary and that documentation of procedures should be a requirement to achieve clearly defined outcomes (Leventhal & Friedman 2004).

### **Receipt of treatment**

Receipt of treatment refers to assisting participants to understand the intervention and monitoring their ability to do so. It necessitates engaging participants with the intervention and improving their ability to apply it at the time of its delivery (Bellg *et al.* 2004, Sidani & Braden 2011). The use of questioning before and after delivering the intervention is one means by which this can be achieved and this is a recognised strategy in the maintenance of trial fidelity (Bellg *et al.* 2004).

### **Enactment of treatment skills**

The enactment of treatment skills is the final stage of treatment fidelity. It refers to the process of monitoring and improving participants' performance of the intervention in real-life situations (Bellg *et al.* 2004). Suggested strategies for the enactment of treatment skills include in vivo interactions, such as real life observations or in the absence of these, role play sessions. Additional measures include the maintenance of contact with participants using follow-up phone calls or mail (Bellg *et al.* 2004).

### **3.4 Trial quality and reporting**

To assess a trial accurately, readers require complete, clear and transparent information on the trial's methodology and results (Schulz *et al.* 2010). Critical appraisal of trial quality is impossible when details of research methods are not made explicit. Yet, such critical information is often omitted in trial reports (Chan & Altman 2005, Glasziou *et al.* 2008). Consequently, with a view to improving

this process, the Consolidated Standards of Reporting Trials (CONSORT) statement was developed, which provides guidance for reporting RCTs (Schulz *et al.* 2010). The most recent CONSORT guidelines were issued in 2010 and comprise a 25-item checklist for RCT reporting.

### **3.5 Choosing the intervention**

After the research approach was determined for this study, a further decision was required with respect to the exact type of intervention to be used. An individualised intervention aimed at facilitating behavioural change, with a view to reducing patient pre-hospital delay time in response to ACS symptoms was considered to be most appropriate for the purpose of meeting the study aims. Furthermore, it was considered important that this intervention would address the role of denial in the presence of ACS and ideally draw on motivational techniques to enhance fostering of the intervention by the participant. Interventions designed to change behaviour are considered more effective if they are theory-based (Hafner & Kirscht 1970, Petrie *et al.* 2002). The majority of studies into the reasons why people delay in the presence of ACS symptoms refer to theoretical perspectives or contain theoretical assumptions. Furthermore, complex interventions must be theoretically grounded (Bradley *et al.* 1999, Conn *et al.* 2001, Craig *et al.* 2008, Cleary *et al.* 2012). Therefore, it was necessary for this intervention to be based on a theoretical model.

The model required for this study was one that could bridge the gap between the acquisition of health-related knowledge and the adoption of healthy behaviours. While behaviour change is central to influencing health outcomes in general, risk-reducing behaviours and health behavioural change tend to be

quite poorly understood (Gholizadeh *et al.* 2010). However, it has been suggested that self-regulatory models provide a theoretical structure that can facilitate the acquisition of healthy behaviours (Maes & Karoly 2005, de Ridder & de Wit 2006). Furthermore, adherence is most effective among interventions that increase self-regulatory capabilities (de Bruin *et al.* 2012). A model of self-regulation was therefore considered for the current intervention.

### **3.6 Self-regulation theory**

In broad terms, self-regulation refers to the on-going behaviours that individuals adopt with a view to attaining their personal goals (Boekaerts *et al.* 2000, Maes & Karoly 2005). It is a systematic process involving conscious efforts to modulate thoughts, emotions and behaviours to achieve the necessary goals in a changing environment (Carver & Scheier 1998, Cameron & Leventhal 2003). With respect to self-regulation, the term behaviour can include internal activities, such as thoughts and emotions in addition to observable actions aimed at goal-attainment. The reference to environment in self-regulation refers to internal or external conditions that require regulation. Self-regulation theory includes a feedback loop process, whereby self-monitoring, goal setting, self-evaluation and strategy implementation processes occur cyclically, which guide personal goal decisions and behaviours.

Self-regulatory models view the individual as an active problem-solver, whose behaviour reflects an attempt to ameliorate the gap between current health status and a goal or ideal state (Carver and Scheier 1998). Self-regulation differs from problem-solving in that it often involves on-going cyclical regulation of the self by the self, as opposed to the regulation of primarily external



problems (Leventhal *et al.* 2003). There are a variety of definitions of self-regulation and many theories about its nature. However, there is general consensus in the literature that as part of self-regulation, the individual must have the ability to: self-monitor the internal and external environment; self-evaluate goal states and; select and implement goal attainment strategies, all of which are functions of the feedback loop process.

Self-regulatory models of health behaviour are advanced forms of traditional health behaviour models. Self-regulatory models of health behaviour draw on traditional theories, but are more advanced in that they attempt to address many of the limits of traditional models. Leventhal's self-regulatory model of illness behaviour is one such model. This model is unique in that it is one of the few self-regulatory models that addresses coping and reasoning in response to a health threat (de Ridder & de Wit 2006). In the context of this study, the issues of coping and reasoning were viewed as important factors in responding to the presence of ACS symptoms.

In a systematic review of theory-based studies concerned with pre-hospital delay time (Baxter & Allmark 2013), Leventhal's self-regulatory model of illness behaviour was the theoretical framework most frequently cited. Previously conducted pre-hospital delay time intervention RCTs were based partly or wholly on the work of Leventhal and colleagues (Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2006). This model has been identified as the preferred model of choice for planning effective interventions, particularly those designed to reduce delay times (Leventhal *et al.* 1980, Dracup *et al.* 1995, Dracup &

Moser 1997, Alonzo & Reynolds 1998, Raczynski *et al.* 1999, Petrie *et al.* 2002, Walsh *et al.* 2004). The model can be used to explain the factors that affect behaviour in response to a health threat, such as the onset of ACS symptoms (Riegel *et al.* 2007). Leventhal's self-regulatory model of illness behaviour was selected as the framework to underpin the intervention used in this study. The rationale for its choice was based on it being a specific model of illness behaviour that included coping and reasoning, its wide use in prior delay-time interventions and its applicability to this study.

### **3.7 Leventhal's self-regulatory model of illness behaviour**

Leventhal's self-regulatory model of illness behaviour is presented in Figure 1. It provides a theoretical structure for understanding how, through the process of self-regulation, the individual interprets and responds to symptoms (Leventhal & Cameron 1987, Zerwic 1998, O' Donnell & Moser 2012, Scott *et al.* 2013). Leventhal's self-regulatory model of illness behaviour proposes that in response to a health threat, such as the onset of symptoms, behaviour adaptations occur (Figure 1). These adaptations occur in three stages that are processed cognitively (problem-solving) and emotionally and are influenced by internal and environmental factors (Leventhal *et al.* 1983, Leventhal & Cameron 1987). Internal factors include age, personality and knowledge, while environmental factors include messages from family, friends and social and cultural environments (Gholizadeh *et al.* 2010). The three stages are: the formation of an illness representation, the implementation of coping mechanisms and the appraisal of one's status (Figure 1). The model is viewed as self-regulatory because in the presence of ill-health, or when good health is threatened, the

components of the model combine to motivate the individual to restore their health equilibrium.

Illness representations are the focus of self-regulation (Leventhal *et al.* 1998). They are what individuals view as common sense definitions of a health threat. In acute illness, the representations of the health threat are structured around the five components of identity, cause, duration, consequences and control or cure (Leventhal 1970, Lau & Hartman 1983, Leventhal *et al.* 1999, Benyamini 2009). When a health threat occurs, which is usually manifested as symptoms, the person's level of perceived control over the illness and symptoms determines how he or she appraises the situation and adapts and regulates their behaviour. Each individual goes through three steps or stages to solve the perceived problem. These are dependent on cognition, coping and appraisal of the situation (Figure 1). Each stage has a cognitive and emotional component that co-exists in parallel (Leventhal *et al.* 1983, Leventhal & Cameron 1987).

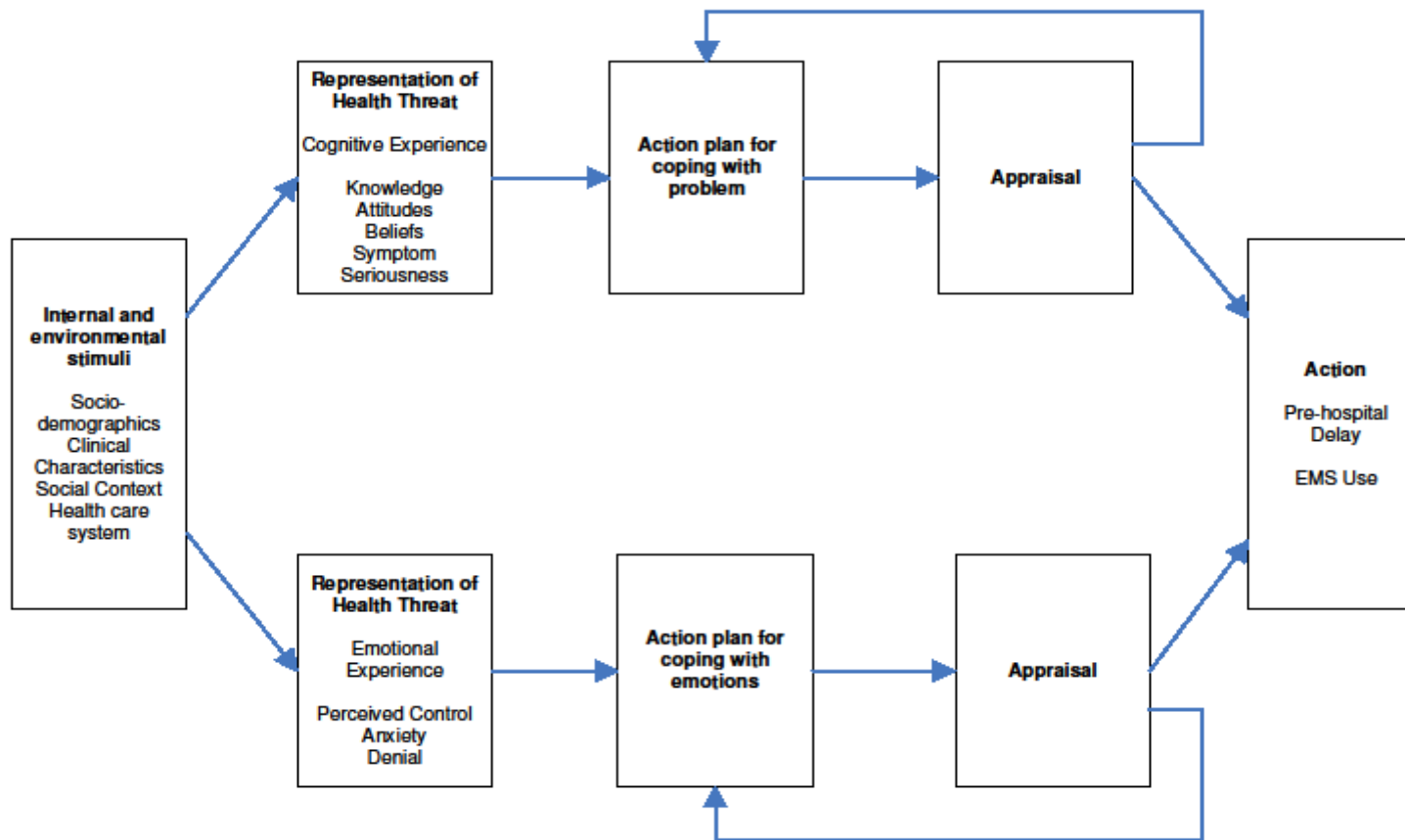


Figure 1 Leventhal's self-regulatory model of illness behaviour

### **3.7.1 The cognitive stage**

In the cognitive stage, the individual recognises that there is a threat to their health. Based on cognitive processes, the individual creates a mental representation of the illness. These cognitive processes are derived from a variety of sources including pre-existing knowledge, attitudes and beliefs and internal (symptoms) and external (influential messages from others) stimuli (Figure 1). The presence of a health threat is understood and resolved by checking the symptoms against pre-existing illness representations or “prototypes” (O' Donnell & Moser 2012, Scott *et al.* 2013). The cognitive factors influence how the health-threat is evaluated and dealt with by the individual. The model suggests that the five main components of the representations include the symptoms being experienced (identity of the health threat), the perceived causes and consequences, the duration (time-frames) and perceived degree of cure or controllability (Leventhal 1970, Leventhal *et al.* 1999, O' Donnell & Moser 2012).

From a cognitive perspective, individuals must interpret symptoms as a threat to their health before they consider the need to take action. Individuals who correctly align symptoms with their pre-existing representations of illness are potentially more likely to behave appropriately when their health is threatened. Similarly, an incorrect match of symptoms to illness conceptions may account for adversarial health actions, including prolonged delay (Baumann & Leventhal 1985, Scott *et al.* 2013). The person's emotional responses to their experience will partially determine their ability to cope with and respond to the situation. In the application of the cognitive phase of Leventhal's self-regulatory model of

illness behaviour in this study, it was anticipated that individuals would correctly recognise their symptoms as potentially cardiac in origin. From an emotional perspective, they would take control over their actions, avoid anxiety and symptom denial and act in accordance with the intervention in the presence of ACS symptoms.

### **3.7.2 The coping/action plan stage**

According to the second stage of Leventhal's self-regulatory model of illness behaviour, the individual draws on coping strategies to deal with the perceived health-threat. Coping in this context refers to specific behavioural reactions to the health threat, such as self-treatment, seeking help or monitoring the symptoms. When health is threatened, a plan of action is devised and initiated (Figure 1). The presence of symptoms triggers the person to make behaviour adaptations, which are processed cognitively (problem-solving) and emotionally and are influenced by internal and environmental factors. These factors impact on the person's ability to cope with the health threat and the action required to reduce any identified risk (Leventhal *et al.* 1992, Cherrington *et al.* 2004).

The motivation to cope with a health threat is generated in response to three factors: the illness representation, i.e. how the individual perceives the health threat, the possibilities for coping and the relationship between coping and the threat (Leventhal *et al.* 1983, Scott *et al.* 2013). Depending on the illness representation, varying coping strategies will be employed and action plans developed. These are influenced by the individual's knowledge, attitudes and beliefs. Emotions also affect the individual's ability to cope and act. Based on personal fears or cognition, individuals who are faced with similar health threats,

may respond in different ways to similar situations. For example, if a person considers that their symptoms are related to cardiac pain, they may call the ambulance, whereas if the symptoms are considered to be related to a more benign cause like indigestion, the person may instead resolve to take an antacid (Dracup *et al.* 2006). Thus, the action plan or coping stage has an impact on the illness outcomes. Consistent with the intervention delivered in this study, it was considered that individuals would devote minimum time to attempting to control or cure the symptoms and the amount of time spent coping with symptoms before disclosing their presence to another person would also be very limited.

### **3.7.3 The appraisal stage**

In the appraisal stage of the model, the person evaluates the effectiveness of their actions in reducing or eliminating the health-threat. A central feature of Leventhal's self-regulatory model of illness behaviour is the 'feedback loop', where progress is reviewed, reassessed and altered in response to this appraisal stage. It is through this feedback loop system that the self-regulatory process occurs, as the person gauges the success of their coping actions. If insufficient progress has been made, the person may resolve to re-evaluate things and alter their coping plan. Additional coping plans may be formulated to help cope with and control emotions. This means that the objectively-represented health threats are controlled through cognitively-controlled processes, while the subjectively-represented threats to health are controlled emotionally (Leventhal *et al.* 1984).

Leventhal advocates that the cognitive level of coping is primarily conscious, while coping at the emotional level tends to be automatic (Leventhal *et al.*

1984). These coping mechanisms may interact to mutually facilitate or interfere with each other (Leventhal *et al.* 1983). Based on the intervention, it was expected that in the appraisal stage, the individual would recognise the potential for a cardiac diagnosis when self-management efforts, such as the use of nitrates to relieve symptoms, failed. In doing so, it was anticipated that they would abandon attempts at further self-management, resolve to seek help and initiate the help-seeking process.

The literature review substantiated the argument that pre-hospital delay can be influenced by cognitive, emotional and social factors. The framework offered by Leventhal's self-regulatory model of illness behaviour incorporates cognitive, emotional and environmental responses to a health threat. The factors that were identified from the literature as contributors to patient pre-hospital delay, fit within these three main categories of influence. This provided further justification for the adoption of Leventhal's self-regulatory model of illness behaviour as a framework for the design of an intervention aimed at reducing patient pre-hospital delay time and altering behaviours known to affect delay-time.

### **3.8 The choice of intervention**

The intervention described (Dracup *et al.* 2006) and reported by Dracup *et al.* (2009) closely reflected the aims, objectives, research design and theoretical framework of the intervention that was intended for use in this study. Their intervention was based on the recommendations of the National Heart Lung and Blood Institute Working Group on Educational Strategies to Prevent Pre-hospital Delay in patients at High Risk for Acute Myocardial Infarction (Dracup *et al.* 1997a). The intervention was underpinned by Leventhal's self-regulatory



model of illness behaviour (Dracup *et al.* 2006, Dracup *et al.* 2009). In addition, these authors used an individualised educational intervention that incorporated motivational interviewing techniques. They also focused on the role of denial in the delivery of their intervention. It was therefore viewed as a potentially suitable intervention for use in this study. However, prior to electing to adopt the same approach as Dracup *et al.* (2006), the components of the intervention were examined and considered in the context of the Medical Research Council's framework for complex intervention development (Medical Research Council 2000, Campbell *et al.* 2007, Craig *et al.* 2008). These are the guidelines most commonly used for the development of complex interventions (Corry *et al.* 2013). The intervention design, its feasibility and its potential efficacy were considered, to ensure it was an appropriate 'fit' for this current study in the context of complex intervention criteria and the intended research setting.

### **3.8.1 Complex intervention criteria**

Consistent with complex intervention development and evaluation processes, the intervention should be underpinned by a theoretical framework that is suited to the intervention to be delivered (Bellg *et al.* 2004, Borrelli 2011). In addition, consideration must be afforded to the research problem and context. Leventhal's self-regulatory model of illness behaviour, as a theoretical framework has been well-tested and validated and has been used in prior research. It is widely accepted as a framework to depict and understand the help-seeking behaviours of persons who experience myocardial infarction (Dracup *et al.* 1995, Meischke *et al.* 1995b, MacInnes 2006) and treatment-seeking behaviour in response to new symptoms (Leventhal *et al.* 1983,

Leventhal & Cameron 1987, McKinley *et al.* 2000, Dracup *et al.* 2006, Nouredine *et al.* 2006). It has been used to study risk-perception, illness-prevention behaviour and symptom-response behaviours (Lau & Hartman 1983, Leventhal *et al.* 1983, Leventhal & Cameron 1987, French *et al.* 2002, Cherrington *et al.* 2004, Cameron *et al.* 2005, Hale *et al.* 2007). Leventhal's self-regulatory model of illness behaviour was used in previous RCTs aimed at reducing pre-hospital delay time (Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2006). There were no identified reasons not to use it as the framework for delivering the complex intervention in the current study.

### **3.8.2 The intended research setting**

The aims of this study were consistent with the central tenets of Leventhal's self-regulatory model of illness behaviour. The main criticism of this theoretical framework relates to its limited application in culturally and linguistically diverse groups (Murray *et al.* 2000, Sahin-Hodoglugil *et al.* 2003). However, in the Irish context, this was not considered to be a likely problem. Although in recent years, Ireland has become somewhat more multi-cultural, it still remains minimally culturally and linguistically diverse. Furthermore, the majority of immigrants to Ireland are young and therefore unlikely to be recipients of the intended intervention at this time. In light of this, Leventhal's self-regulatory model of illness behaviour was considered suited to the intended research setting. The intervention was originally written in the English language, which is the predominant language used in Ireland. The intervention content was easily transferred to the Irish population with respect to the graphics, terminology and

examples used to explain the content. There were no reasons identified that precluded its use in the Irish setting.

As the proposed intervention and associated framework had been developed and tested in a previous study, a decision was made to seek permission from Dracup *et al.* (2006) to replicate their intervention in the current research context and to adopt the relevant research instruments. This permission was granted. The means by which the intervention was delivered in this study will be presented in Chapter 4. In brief, the intervention comprised a 30-minute standardised, prescriptive educational script. This was followed by a 10-minute scenario and role-play session. The principles of motivational interviewing were used throughout.

### **3.9 Principles of motivational interviewing**

Motivational interviewing was used previously (Blohm *et al.* 1994) and was considered a mechanism that would contribute to a reduction in patient pre-hospital delay time. Motivational interviewing is a style of collaborative conversation that strengthens a person's individual motivation and commitment to change (Miller & Rollnick 2013). This form of therapeutic communication is often used to promote behavioural change through coaching, whereby one person acts as a helping professional for another (Brobeck *et al.* 2011, Dart 2011, Miller & Rollnick 2013). Since the development of motivational interviewing, some authors have written about its value and how it might be applied in practice (Dart 2011, Miller & Rollnick 2013). While there is variation in the terminology used among authors, the principles of motivational interviewing

are generally accepted by all. These are the expression of empathy, supporting self-efficacy, developing discrepancy and rolling with resistance.

### **3.9.1 Expression of empathy**

The expression of empathy is one of the core principles of motivational interviewing (Miller & Rollnick 2002, Hohman 2012). It encompasses acceptance, which facilitates change, reflective listening and the expectation that ambivalence is normal (Dart 2011, Thompson *et al.* 2011). The qualities of empathy, therapeutic alliance and mutual goal agreement have been shown to have the greatest impact on the counsellor-participant relationship (Hohman 2012). The expression of empathy enhances the therapeutic relationship, as the participant has a greater sense of personal comfort in sharing his/her perspective.

### **3.9.2 Supporting self-efficacy**

Self-efficacy, which is linked with self-regulation, is concerned with perceived ability and the belief in an ability to succeed. In supporting self-efficacy, the counsellor avoids imposing personal views on the participant. Insights are provided into beneficial options and the responsibility for choosing and executing change remains with the participant. In all cases, self-efficacy is enhanced through praising participants' efforts in taking an active role (Dart 2011, Thompson *et al.* 2011, Miller & Rollnick 2013).

### **3.9.3 Developing discrepancy**

The development of discrepancy is based on dissonance theory (Festinger 1962). This theory proposes that individuals have values, goals and motivators and when the "ideal self" is not synchronous with the "current self", a

discrepancy occurs. When the discrepancy is great enough, the person is ready for change (Hohman 2012). It involves assisting participants with the identification of their current status, where the participant, not the counsellor presents the argument for change (Dart 2011, Thompson *et al.* 2011).

#### **3.9.4 Rolling with resistance**

The principle of rolling with resistance has been described as potentially the most difficult of all (Dart 2011). This process involves non-opposition to resistance and the avoidance of arguing for change, both of which threaten autonomy and self-determination (Thompson *et al.* 2011, Hohman 2012, Miller & Rollnick 2013). From the perspective of the participant, challenging negative thoughts builds resistance, whereas facilitating an exploration of resistance, promotes feelings of acceptance and engagement (Dart 2011). The acronym FRAMES, which represents Feedback, Responsibility, Advice-giving, Menu of change options, Empathetic communication style and Self-efficacy, provides a guide to understanding motivational interviewing (Britt *et al.* 2004). It was decided that the intervention to be delivered in this study would incorporate the principles of motivational interviewing. The means by which this was done is outlined in Chapter 4.

#### **3.10 Summary of choice of intervention and its framework**

The necessity for an intervention aimed at reducing patient pre-hospital delay time was recognised from prior research. The decisions reached with respect to the design and form of intervention to be used for this purpose originated from the literature review. The contribution of RCTs to empirical knowledge generation was a major factor in the choice of research design, while the criteria for complex interventions determined the need for a theoretical framework

within which to situate the study. Leventhal's self-regulatory model of illness behaviour was selected as the framework to be used. After due consideration, a decision was made to conduct this study by replicating in the main, a previously developed educational intervention (Dracup *et al.* 2006). The intervention was designed to prevent delay reactions by improving cognition, challenging emotional responses and influencing social factors that prolong pre-hospital delay time. The means by which the intervention was delivered and the operationalisation of the study will be outlined in the next chapter.

## **Chapter 4 Operationalisation of the study**

### **4.1 Introduction**

The purpose of this study was to test the effectiveness of an educational intervention on patient pre-hospital delay time in the presence of ACS symptoms. Using a parallel design RCT, the educational intervention was delivered to those participants assigned to the intervention group. An individualised educational intervention, which was underpinned by Leventhal's self-regulatory model of illness behaviour, was chosen. The educational intervention was a replication of one previously designed and conducted by Dracup *et al.* (2006). This chapter describes how the study was conducted in the research sites. The content and delivery of the educational intervention will be presented initially. Detailed information will then be provided about the operational aspects of preparing for and carrying out data collection, executing the trial protocol and the other steps that were necessary to complete this RCT. The operationalisation of this study conformed to the Consolidated Standards of Reporting Trials (CONSORT) Guidelines (Schulz *et al.* 2010).

### **4.2 The intervention content**

Following the collection of baseline data, the intervention was delivered to those participants who were randomised to the intervention group. Where feasible, a family member or significant other was invited to be in attendance during the delivery of the intervention. The exact content of the educational intervention was contained in the intervention manual and is presented in Appendix 1. The intervention script was prescriptive, which ensured that each intervention session was of an approximate fixed duration and frequency and thereby

standardised across sites. In addition to the intervention script, the intervention manual contained colourful pictures and large text, which supplemented the main teaching points of the intervention. It took approximately forty minutes to deliver the intervention. This time was broken down into thirty minutes of prescriptive, standardised education and ten minutes of individualised scenario-based rehearsal of the intervention messages. Throughout the intervention, the interventionist was cognisant of the participant's literacy level. If there was any doubt about a participant's understanding of the intervention content, clarification was always provided. Table 2 provides an overview of the discrete components of the intervention.



**Table 2. Overview of intervention break-down**

<b>Time</b>	<b>Intervention component</b>	<b>Rationale for inclusion</b>
2 minutes	Introduction to the study.	To engage participants with the intervention and assist them to identify with its relevance.
10 minutes	Informational content.	To increase participants' knowledge, attitudes and beliefs about all aspects of ACS and appreciate the importance of not delaying in the presence of ACS symptoms.
10 minutes	Emotional content.	To anticipate possible emotions that can arise in the presence of ACS symptoms and how to manage these.
5 minutes	Social content. <i>Complete action plan.</i>	To nominate a designated person. Refer to external influences on behaviour.
10 minutes	Delivery of scenarios and use of role play.	To rehearse and evaluate the extent of the educational intervention absorbed. To recognise areas that posed difficulties. To clarify misconceptions or inaccuracies.
3 minutes	Summarise main intervention messages.	To enhance retention of the main educational intervention messages. Give documentation - wallet card, action plan. Closure, thank and departure.

The session was introduced and prefaced with a reminder about the purpose and aim of the study. The aim of the intervention was to alter participants' delay-related behaviours in response to ACS symptoms, thereby reducing patient pre-hospital delay time. The intended behavioural changes were that participants would (1) use prescribed nitrates for the differentiation and relief of symptoms; (2) tell somebody about the presence of symptoms; (3) not consult with their GP; (4) summon the emergency services if symptoms were unrelieved within

fifteen minutes. The intervention addressed informational, emotional and social factors associated with responses to ACS. These three factors parallel the cognitive, emotional and environmental components of Leventhal's self-regulatory model of illness behaviour.

#### **4.2.1 Information or cognitive stage**

Using the intervention manual, the education began with a simplified explanation about atherosclerosis and the mechanism by which a heart attack occurs. The concept of the golden hour was then explained to participants. The golden hour refers to one hour of golden opportunity to receive optimum care that could save life or prevent worsening disability when a heart attack occurs. The benefits of prompt hospitalisation in the presence of heart attack symptoms were outlined. This included reference to the importance of early reperfusion to restore blood flow to the myocardium and the other therapeutic options that are available for the treatment of a heart attack. Participants were also informed that many people miss out on the best possible outcomes because they delay too long before seeking care.

The next informational message was centred on symptoms. The range and variability of symptoms were discussed. Typical ACS symptoms, such as chest pain, chest tightness and chest discomfort were highlighted together with left arm discomfort, indigestion and breathlessness. Less typical symptoms were also emphasised and these include gum, neck and jaw discomfort, intrascapular discomfort and nausea. Participants were informed that symptom onset could be sudden or gradual and that symptoms could be continuous or intermittent. They were made aware that the 'Hollywood heart attack' was only one of a

range of manifestations of a heart attack or ACS symptoms. It was made clear that ACS symptoms are not individualised and that symptoms that are experienced on one occasion may differ on a subsequent occasion. They were informed about the potential for symptom variation among different groups, such as older people and diabetics. However, this aspect of the informational message was tailored to each participant and their circumstances.

Participants were then gently but firmly reminded that their current ACS diagnosis rendered them more susceptible to a future ACS event than those without a history of ACS. They were instructed that the appropriate behaviour to take in the event of symptom occurrence was to stop and rest in the presence of symptoms, and if nitrates were prescribed, to use them. They should also inform another person about the symptoms and if symptoms persisted beyond 15 minutes, they were asked to call 999 or 112 for an ambulance without first summoning the advice of a GP.

#### **4.2.2. Emotional issues**

In addressing emotional issues, advice was imparted about the role of emotional responses when ACS symptoms are present. It was acknowledged that emotional responses could interfere with symptom identification, acknowledgement and coping.

The reasons for delay were discussed in the context of emotional responses. This was the first introduction to the role of denial in delayed treatment-seeking behaviour. The potential for emotions such as fear, denial, anxiety and

embarrassment to interfere with treatment-seeking behaviour was discussed. Participants were advised that people often fear the consequences of acknowledging their symptoms. Consequently, they may deny the seriousness of symptoms or engage in symptom misattribution, which can delay the time to seeking treatment.

The reasons for delay were discussed objectively. The objective discussion avoided blame-focused messages or implications of wrong-doing by the participant. Much of this discussion took place in the first person plural. One example of this was with respect to the role of anxiety in patient pre-hospital delay. The words used to explain this were as follows: “anxiety can cause us to think less clearly and make excuses about what is happening...” and “fear causes many people to delay seeking care”. These words indicated that delay-related responses were not isolated to the participant, but could be applied generally to individuals with ACS symptoms.

Scenarios and role play were used to re-enact a recurrence of an ACS event. This was to increase the likelihood of appropriate future reactions, to challenge emotional responses to symptoms and to reinforce the intervention messages. Participants were encouraged to treat unresolved ACS symptoms as an emergency. This was important, as behaviour in threatened-health is dependent on how the individual views that threat (Leventhal & Cameron 1987).

Previous ED admission experiences were discussed, as negative experiences could impact on the person’s willingness to return to the ED in the future.

Unpleasant past experiences were acknowledged, but these were reconciled with the intervention message that the beneficial rewards of seeking treatment promptly would outweigh everything else. Positive messages were disseminated, such as early attendance at the ED would enhance preservation of heart muscle and increase the chance of survival. This was considered important, as positive messages are considered potentially more effective (Dracup *et al.* 1997b).

While addressing the emotional stimuli, the participant was asked to consider what they would do if they thought they were having a heart attack. A range of reactions were suggested including adopting the stance that the symptoms were not heart related or not serious. Further suggestions included emotional issues, such as concern about troubling others and embarrassment about seeking help for something that may transpire to be clinically insignificant. It was anticipated that normal reactions would be identified so that these could be acknowledged, addressed and set aside with a view to addressing self-care needs.

In the final ten minutes of the intervention, and to further address the role of emotional responses to a health threat, participants were given pre-prepared scenarios to consider. The scenarios that were most reflective of the participant's cardiac event experience were chosen from the range of scenarios available. Based on these scenarios, and using role play, participants were asked to anticipate some or preferably all of the emotions they might experience in the presence of ACS symptoms. It was considered that the rehearsal of

responses using role play would improve participants' level of perceived control on a subsequent occasion. It has been suggested that anxiety levels reduce if a person is confident in their ability to act appropriately (Moser *et al.* 2007). Furthermore, even when experiencing emotional reactions to symptoms, the use of guidance on the appropriate actions to take increases the likelihood of appropriate responses to a future health threat (Leventhal *et al.* 2010).

#### **4.2.3 Social and environmental stimuli**

The role of denial was further emphasised in addressing social stimuli. As part of the intervention, participants were informed that family and friends can delay them seeking care, as they may wish to deny the possibility of symptoms. The importance of avoiding consultation with a GP was discussed in the context of social stimuli. The misunderstanding by individuals that it is correct to summon the advice of a GP in the presence of ACS was clarified.

Participants then completed an action plan, which they were given to take home as a reminder of what to do if symptoms arose. This action plan included the name and phone number of the person they would call if symptoms occurred and the emergency numbers to call in the face of unresolved symptoms. It was intended that the named person would act as the external stimulus to encourage the participant to implement the recommended responses to ACS symptoms, if they were reticent to do so. Participants were asked to place the action plan in a prominent position in their home, such as on their refrigerator. The action plan was printed on pink paper, so that it could be quite easily identified. A pre-printed wallet card with a summary of what to do in the presence of ACS symptoms was also given to each participant. It was important

for participants to have an action plan that was realistic and achievable, which is why it was devised in conjunction with each participant.

Motivational interviewing techniques were used to promote the uptake of the intervention and to help participants reconcile elements of the intervention that they found challenging. As the role-play component of the intervention was not prescriptive, it was guided by the participant and their reactions and responses. Their event was recounted and reflective statements were used to indicate active listening. Participants' receptiveness and enthusiasm for change was generally dependant on the extent of ambivalence they were experiencing at that time. When participants demonstrated interest in moving forward and changing their behaviour, the individualised scenarios were presented for their consideration. Role play was used to discretely evaluate the extent of information the participant gleaned from the intervention. In the case of incorrect or incomplete responses, the motivation to change was re-evaluated and misinformation or misunderstandings were clarified.

At the end of the education session, the information was summarised together with the correct course of action to be taken in the event of symptom recurrence. This included the following message: In the event of symptoms you should:

- Stop and rest.
- If nitrates are prescribed, take these as directed.
- Inform somebody about what is happening.

- If symptoms persist for more than 15 minutes then call directly for an ambulance.

In accordance with the trial protocol, permission was sought from each participant to contact him/her one month later to reinforce the intervention. They were also informed that after six months, an action plan with a summary of the intervention messages would be sent to them by post. The intervention content was pre-documented, standardised and prescriptive, yet individualised.

#### **4.3 The intervention delivery**

The intervention was delivered in a room on the ward or, where circumstances prevented this, it was implemented at the bedside. As the intervention was delivered to one group only, the risk of contamination between the randomised groups was identified and controlled for, as much as possible. In the event of the intervention being delivered at the bedside, every effort was made to confine the delivery of the information to the relevant participant only. The strategies used to achieve this included closing the curtains, sitting close to the participant at the head of the bed and using a low tone of voice. This was done with a view to ensuring that only those in receipt of the intervention were exposed to its content. No participant's group assignment was divulged to clinical staff in an effort to limit any temptation by them to give additional information to those assigned to the control group.

#### **4.4 Usual care**

The intervention and control group received usual care. Prior to undertaking this study, each research site was requested to specify what constituted usual care for their patients diagnosed with ACS, with respect to pre-discharge education.



According to the information received, pre-discharge education is always delivered by a nurse in the first instance, although this is sometimes complemented by ancillary staff including physicians, pharmacists, dieticians and physiotherapists. For patients who are reviewed by dedicated specialist nurses, such as the PCI nurse, these patients receive more detailed information about all aspects of post-discharge self-management.

The cardiac rehabilitation (CR) nurse also plays a role in pre-discharge education in usual care. Not all patients who are admitted with ACS are seen by the CR nurse. The CR nurse generally sees all patients whose return to CR is intended and information about the CR programme is given to all eligible patients. The amount of education provided seemed to vary within and between research sites. This variability depended on whether the patient was discharged home from the coronary care unit or a hospital ward. Pre-discharge education generally involved the provision of information to patients about the condition with which they presented (heart-attack or angina), the procedures they had undergone, or those that were planned for the future (such as PCI, CABG or medical management). Patients also received information about the risk factors for heart disease, secondary prevention advice and the effects and side effects of prescribed medications. Detailed information was provided about the use of prescribed nitrates. In addition to the effects and side effects of nitrate-use, education was also given about how, when and where to use them. All health service providers delivered education about resumption of activities of daily living including exercise, work and sexual activity.

The information received, indicated that usual care comprised less focused education on the range and variability of ACS symptoms than what was delivered in the intervention. The implications of pre-hospital delay were not included as part of usual care and there was no reference to the concept of the golden hour or to any time targets from symptom onset until arrival at the ED. The intervention content placed far greater emphasis on symptom variability, onset and unpredictability than that described in usual care. The emotional, cognitive or social factors that underlie delay were not substantially addressed in usual care and there was less emphasis placed on the importance of ambulance use, the necessity to disclose symptoms to another individual and the need to avoid consultation with a GP. In some sites, patients were informed about the importance of coming into the hospital if nitrates failed to provide symptom relief.

#### **4.5 The research sites**

Data were collected from five tertiary hospitals in Dublin. Following informal discussions, an information letter and a copy of the proposed research study were sent to a link consultant cardiologist and the relevant directors of nursing in each hospital. Research access was granted following ethical approval. A decision was made to focus recruitment on the coronary care units and cardiology wards in each hospital. Before the study commenced, the staff in each research site were briefed about the study. Particulars such as patient recruitment and the identification of gatekeepers were negotiated. In addition, local ward restrictions and requirements were discussed and noted. The clinical nurse managers and their delegates acted as gatekeepers for the study.

#### **4.6 The study sample**

The target population for this study was all patients admitted through an ED with a diagnosis of ACS. Patients were admitted to the study under specified inclusion and exclusion criteria. They were eligible for study inclusion if they met the following criteria: had a provisional diagnosis of ACS; were stable and planning for discharge; had access to a telephone; had an ability to read, understand and communicate in English and; were willing to participate voluntarily in the study. Potential participants were excluded from the study if they had any condition that inhibited their understanding of the intervention or decision-making process. This included a major or uncorrected hearing loss, a profound learning disability or any neurological disorder that impaired cognition. Those who lived in an institutional setting and those with serious complicating co-morbidities or untreated malignancies were excluded from the trial. Purposive sampling was used in the recruitment of participants, whose study numbers were assigned in sequential order. The assignment of each participant to the control or intervention group was determined by the random allocation that was linked to their study number.

While most of the inclusion and exclusion criteria are self-explanatory, a note to explain the rationale for some decisions in the sampling process is warranted. It was necessary for participants to have a telephone and no hearing impairment, as those from the intervention group were telephoned at home one month following recruitment. Those who lived in an institutional setting were excluded because responses to ACS symptoms, particularly decision time, would be influenced by the care or supervision of healthcare professionals.

#### **4.6.1 Sample size**

Consistent with the CONSORT statement (Schulz *et al.* 2010), the means by which the sample size was determined for a randomised controlled trial must be explicit. In a two-group comparative study, the sample size depends on the level of significance ( $p$ -value or alpha level), the minimum difference to be expected (effect size) and the chance of detecting the anticipated difference (power of the test) (Daly & Bourke 2000, Devane *et al.* 2004).

To achieve a sample with a power of 0.80, an alpha of  $<0.05$  and an effect size of 0.20, it was calculated that 393 participants who returned after the intervention with ACS symptoms would be needed to detect a significant difference in pre-hospital delay time between the two groups (Cohen 1992). Based on estimates retrieved from two of the research sites in this study, a readmission rate of between 10% and 14% among patients with ACS was expected. Therefore, in order to achieve a readmission sample of at least 393, it was estimated that at least 2,807 participants needed to be recruited. In order to maintain the statistical assumption of independence, data on participants' first subsequent readmission were recorded for the study duration. There are approximately 3,000 patients admitted and diagnosed with ACS across the research sites annually. It was anticipated that of these, a small proportion would not meet the inclusion criteria. Of those remaining, it was considered that some patients would not be willing to participate. It was estimated therefore, that approximately 50% of those who were admitted annually would be recruited to the study. This meant that there would be approximately 1,500 participants

available per year and that data collection needed to take place over a two-year period. The CONSORT checklist for this study is included in Appendix 2.

#### **4.7 The research instruments**

A suite of questionnaires (Appendix 3) was used in the collection of baseline and readmission data and to measure variables related to the primary outcome, namely pre-hospital delay time. The primary research instrument was the ACS Response Index, which has been widely used in the investigation and measurement of pre-hospital delay time and has been formally tested for reliability and validity (Riegel *et al.* 2007). The questionnaire was designed to obtain information about events that occurred before hospital admission, including symptom appraisal and the cognitive and social factors that influence treatment-seeking behaviour (Burnett *et al.* 1995, Dracup *et al.* 2003). It has been tested in multiple studies (Burnett *et al.* 1995, Dracup *et al.* 1997b, Dracup & Moser 1997, McKinley *et al.* 2000, Dracup *et al.* 2003, McKinley *et al.* 2004, Nouredine *et al.* 2008), and has been shown to obtain accurate delay times in more than 97% of cases (Dracup *et al.* 2006). The ACS Response Index is consistent with Leventhal's self-regulatory model of illness behaviour, as it measures cognitive, emotional and social factors (Riegel *et al.* 2007).

##### **4.7.1 Socio-demographic and clinical history questionnaire**

The ACS Response Index was preceded by a set of 27 questions, which were concerned with baseline information. This helped to describe the sample. Demographic details including gender, age, ethnicity, educational background, number of dependants and household income category were established together with marital, employment and health insurance status. Information

about past cardiac history, co-morbidities, risk factors, weight, height and exercise was also documented in this section.

#### **4.7.2 The ACS Response Index**

The ACS Response Index is presented in three sections (Appendix 3). The first section measures knowledge, attitudes and beliefs about ACS. The second section measures perceived level of control, and is entitled the Control Attitudes Scale. The third section is the Response Time Questionnaire, which is sometimes also referred to as the Response to Symptoms Questionnaire. Data collected on this latter part of the questionnaire were used to measure the primary and secondary outcomes of this trial. As the questionnaire was adopted from Dracup *et al.* (2006), some minor amendments were necessary to adapt it to the Irish context. The adaptation included, for example, the names of the relevant hospitals to which the participants in this study were admitted and the means by which those who were readmitted were identified.

The Response Time Questionnaire included 25 items (Appendix 3). The first question was completed by the interventionist and pertained to information about the participant's study number and date of data collection. Questions 2 to 20 were concerned with the nature and onset of symptoms and the individual's responses to them. All questions were closed and had to be answered by the participant. Some required yes or no responses, while others provided a range of potential answers, from which the participant could choose. For example, one question asked "what was the nature of your symptoms?" The only available answers were continuous or intermittent. With respect to the question on symptom attribution, the question asked "To what did you initially attribute

your symptoms?” Only one answer was permitted to this question, but a range of seven possible answers was provided, including an option to include an alternative to those listed. The remaining questions were based on data taken from the participant’s medical chart and included the date and time of arrival in the ED, the ACS diagnosis and the treatment that the participant received.

When a participant was first readmitted to an ED with ACS symptoms following the educational intervention, the Response Time Questionnaire was again administered. This questionnaire included the same questions as the original Response Time Questionnaire, but contained some additional items. These pertained to the means by which the interventionist learned that the person had been readmitted, the date that the phone call was made to complete the questionnaire and, where applicable, the time of death (Appendix 3). Throughout the study, the primary outcome measure, pre-hospital delay time, was defined as the time from acute symptom onset until the documented time of arrival at the hospital ED. A comparison between the baseline and readmission pre-hospital delay times was necessary for the outcomes of this trial.

## **4.8 Validity and reliability**

### **4.8.1 Validity**

The Response Time Questionnaire was developed in 1995 (Burnett *et al.* 1995) and adapted in 1997 (Dracup & Moser 1997). The adapted version was used for the current study. The content and face validity of the instrument was established by cardiologists and cardiology nurses (McKinley *et al.* 2000, Moser *et al.* 2005). The questionnaire, which measures a range of factors associated with pre-hospital delay time in ACS, has been used extensively in a variety of

settings and populations (Dracup *et al.* 1997b, Dracup & Moser 1997, McKinley *et al.* 2000, Banks & Dracup 2006, Moser *et al.* 2005, Nouredine *et al.* 2008). The questionnaire is well-validated and, as a component of the ACS Response Index, has well-recognised psychometric properties (Riegel *et al.* 2007). Nonetheless, the issues of face and content validity were considered and these are outlined below.

#### **4.8.2 Face validity**

In this study, face validity was sought through the administration of the questionnaire to two colleagues who were independent of this research study and four independent individuals over the age of 65 years. All reviewers stated that they could identify with the content and understood what was being asked and why.

#### **4.8.3 Content validity**

Three individuals who work in the field of cardiology and one academic were selected to judge the content validity of the questionnaire. These comprised an advanced nurse practitioner in cardiology, two coronary care nurses and an academic with a background in cardiology. Each person had at least ten years of experience in the field of cardiology. The review panel members were asked to evaluate the scope of the research instrument, whether it had sufficient items to adequately measure the phenomenon of interest and the relevance and clarity of each question on the questionnaire. Although the adapted questionnaire was already written in the English language, the panel were also asked to consider the appropriateness of the wording for the Irish context.



Based on feedback from the panel, the question pertaining to the time of symptom onset was sub-divided into prodromal and acute symptom onset. The panel suggested that this would further delineate the specific times of general and acute symptom onset, which would add to the accuracy of the information retrieved. While the content validity index is often used for the purpose of establishing content validity, judgment by a panel of experts can also be used (Polit & Beck 2008). In this study, the content validity of the questionnaire was established, based on the professional judgement of the selected panel.

#### **4.8.4 Reliability**

Reliability of the ACS Response Index has been well established. To assess its stability, this instrument has undergone test re-test reliability on several occasions in various populations and has been shown to be reliable (Dracup *et al.* 1997b, Dracup & Moser 1997, McKinley *et al.* 2000, Dracup *et al.* 2003, McKinley *et al.* 2004). Test re-test reliability was not performed. Inter-rater reliability was established during interventionist training and rehearsals.

#### **4.9 Pilot study**

The study procedures and instruments were piloted in advance of the main study with the aim of obtaining an opportunity to refine and improve the intervention, where warranted (Gerrish & Lacey 2006, Polit & Beck 2008). Data from the pilot study can highlight the extent to which intervention fidelity can be maintained, the acceptability of the intervention to recipients and the adequacy and comprehensiveness of the intervention. The pilot study was conducted over a two-week period. During this time, the research instruments were tested alongside the educational intervention and the ease at which it could be

delivered. The operational procedures were also evaluated during the pilot study. A total of 34 participants were recruited during the pilot study period.

Each instrument was piloted to assess the amount of time and level of difficulty associated with its administration. In addition, this time was used to assess how easily understood the instruments were for both participants and interventionists. Data collection took approximately 30 minutes. However, this was dependent on the participant and their willingness to converse. The intervention took an additional forty minutes to administer.

At the end of the pilot study, a change was made to the trial protocol, but no changes were made to the questionnaires or the means by which the intervention was delivered. In light of this, all data collected during the pilot study were included in the final analyses. The change to the trial protocol related to the timing of patient informed consent. Patients were initially given 24 hours to consider their willingness and interest in participating in the study before informed consent was obtained. However, by the end of the pilot study, this protocol was revised. Opportunities for recruitment were lost due to the 24-hour consideration period. Patients who were available and willing to participate in the study were often discharged, transferred or unavailable for consultation 24 hours after the interventionist had first seen and spoken to them. The suggestion to recruit and enrol in the study on the same day came from patients. Consequently, a decision was made to reapply to each ethics committee for an amendment to the 24-hour consideration period. The rationale for the change was noted and the change in consent protocol was approved by

each ethics committee. From January 2008, informed consent was obtained at the time of study enrolment.

#### **4.10 Maintaining the criteria for the RCT**

Throughout the study, an adherence to the trial protocol was viewed as elementary. To help ensure this, time was dedicated to the selection and training of the interventionists. The interventionists were made aware of the procedures for recruitment, randomisation and the means by which trial bias could be avoided. As there were five research sites, with one interventionist in each site, it was important that the research process was standardised. The process by which the criteria for the RCT were maintained are outlined in the next section.

##### **4.10.1 Selection and training of the interventionists**

There were five interventionists selected to deliver the intervention. Of these, two were PhD students and three other nurses were recruited for the purpose of the study. All five interventionists were registered general nurses. Personality style, communication skills and the demonstration of interest in the study were considered when selecting the three interventionists for this study.

The first two weeks of the study were dedicated to interventionist training. The ACS team received the intervention training in the first instance and they subsequently trained the remaining interventionists to deliver the intervention. The initial training was delivered to the ACS team by a nurse, who was an expert in the field of cardiovascular nursing and in the intervention. As an interventionist, she had previously delivered this intervention and had a background in training others to deliver it also. The trainer produced a compact

disc (CD) recording and a digital videodisc (DVD) of the intervention, which demonstrated an expert interventionist delivering the intervention.

An interventionist training manual was devised (Appendix 4), the content of which was based on the Trial Protocol (Appendix 5) and the educational intervention. Each of the five interventionists received a copy of the trial protocol, the educational interventional manual and the CD. The DVD was viewed collectively.

The interventionists rehearsed the delivery of the intervention and feedback on their performance was provided by the trainers. To further evaluate post-training skills, informal questioning and role play were used to evaluate the interventionists' understanding of the intervention. Monthly meetings were held, which were attended by the principal investigator (PI) of the study and members of the ACS team. Discussions at these meetings centred on minimising the potential for drift in skills through the provision of coaching and reinforcement of the intervention and trial protocol. The meetings also helped to maintain motivation and consistency among the interventionists, while simultaneously offering an opportunity to debrief, as necessary (Borrelli 2011). The interventionists self-reported on their delivery of the intervention at the monthly meetings and written monthly reports were produced by each interventionist. These, among other issues relating to the educational intervention and its delivery were discussed at the monthly meetings.

#### **4.10.2 Recruitment to the study**

In each research site, the clinical nurse manager of the ward or unit served as the study gatekeeper. Study eligibility was determined by the gatekeeper, based on the study's inclusion and exclusion criteria. The gatekeeper provided eligible patients with an overview of the study. The names of those who expressed an interest in participating and those who requested further information were given to the interventionist on arrival to the unit or ward. Recruitment to the study took place between November 2007 and October 2009. Data were collected and recorded until the end of November 2010. Study recruitment and enrolment generally took place within 2 to 4 days of hospital admission.

#### **4.10.3 Randomisation**

Using a random number generator, randomisations were devised, with 50% of participants allocated to the intervention group and 50% to the control group for each research site. Using block randomisation, the allocations of control and intervention numbers were further sub-divided into batches of twenty, each of which comprised 10 intervention and 10 control allocations. This meant that equal proportions of participants were allocated to each of the control and intervention groups within each block of twenty allocations. Numbers ranging from 1 to 500 were printed sequentially for each site, but group allocation was random. Each number, known as the study number, was exclusive to a research site and the associated participant's data.

#### **4.10.4 Concealment of group allocation**

Successful randomisation is contingent on the concealment of group allocation. To preserve this integrity, the interventionists were fully briefed about how randomisation was to be executed in this study. The study numbers and group

allocations were contained in sealed envelopes with opaque windows. The study numbers were clearly visible through the opaque windows, but the group allocation was concealed. The sealed envelopes were prepared and numbered sequentially before recruitment began. As participants were recruited to the study, they were automatically given the next number in the sequence. Group assignment was only established when baseline data were collected.

#### **4.10.5 Blinding**

One interventionist was assigned to each research site. The interventionist received the names of eligible and interested patients, collected data, randomised participants and, where appropriate, delivered the intervention. This same interventionist communicated with the participants after they were discharged from hospital. For this study, there were at least two further communications with those from the intervention group. These comprised a one month phone call and a copy of the action plan, which was posted six months after the intervention was delivered. In some cases, further telephone communication was necessary to discuss and collect readmission data. Therefore, it was not feasible to blind the interventionists to participants' randomised groups. It was also impossible to blind participants to their group allocation, as those who received the intervention were aware of their allocation to the intervention group.

When participants provided the information about their readmission, group assignment was never referred to in these conversations. Where participants were readmitted to a hospital other than the one from which they were originally recruited, their readmission data were collected by the interventionist at the site

of readmission. This interventionist had no knowledge of the readmitted participant's original group assignment. At the end of the study, all participants who were not known to be readmitted were contacted to check for unrecorded or missed readmissions. During this time, the interventionists were blinded to the participants' original group-allocation.

#### **4.10.6 Selection bias**

The explicit inclusion and exclusion criteria for this trial helped protect against selection bias. These criteria were clearly documented and circulated to the interventionists and the gatekeepers before the study began. This eliminated ambiguity about who was or was not to be invited to participate in the study. The gatekeepers screened the patients for eligibility and invited them to consider participation. These names were given to the interventionist. Therefore, the interventionist had no control over which patients would be informed about the study. If the interventionist deliberately by-passed a patient who had expressed an interest in participating, this would have been identified and highlighted by the patient and gatekeeper.

#### **4.10.7 Baseline data collection**

Baseline data were collected immediately after recruitment, which was normally within 2-4 days of hospital admission, and always prior to discharge. When interest in participation was ascertained, informed consent was obtained and baseline data were then collected. This took place in one of two ways. In most circumstances, the interventionist read each of the questions aloud to the participant, while he or she followed the content on a duplicate copy of the questionnaire. They were instructed to choose the answers that most accurately reflected their experience. The interventionist manually entered their responses

onto the original hard copy of the questionnaire. Very occasionally, participants requested to complete the questionnaire independently and returned it to the interventionist on completion. It was standard procedure that all questionnaires were checked for missing data and information was cross-checked against the medical chart.

Questions that ask participants to recall events, behaviours or emotions can potentially be subject to recall bias, as poor recall is associated with inaccurate reporting (Gerrish & Lacey 2006). To achieve maximum precision in this regard, a validated method of assisting recall was used (McKinley *et al.* 2004), in which pre-hospital delay times were elicited by asking participants to recount the events surrounding their symptom onset. Broad questions about when symptoms began were asked initially. These questions were then narrowed down and contextualised by placing them in the chain of daily events. Questions such as “Was it bright or dark outside”? “Had you eaten lunch”? or “Had you left for work”?, helped to determine precise information from participants and relatives. The time of arrival in hospital and other clinical data were always checked against the medical notes for further verification. In the case of transfers from other hospitals, confirmation data of admission times were provided by the ED of the hospital to which the participant was originally admitted. Any noted discrepancies were reconciled with the participant.

On completion of baseline data collection, the sealed envelope that corresponded with the participant’s study number was opened to reveal the participant’s group allocation. In the case of both groups, participants were



asked to notify the interventionist if they attended an ED with ACS symptoms in the future. To assist with this request, a refrigerator magnet was given with contact details for the interventionist. Those assigned to the control group were invited to contact the interventionist at the end of the study should they wish to avail of the intervention and their participation in the study was gratefully acknowledged before the interventionist left them. Those who were assigned to the intervention group were given a short break before the intervention was delivered.

#### **4.10.8 Fidelity in delivering the intervention**

Each interventionist delivered the same dose and intensity of intervention to each participant and there were clear procedures in the trial protocol for implementing this. This was important in the maintenance of trial fidelity. Each interventionist was provided with the intervention manual and advised to adhere strictly to it. It has been suggested that the use of rigorous procedures, such as standardised manuals, can minimise biases in studies (Bellg *et al.* 2004, Friedberg *et al.* 2010). In addition to adhering to the manual, each interventionist formulated personal field notes while in the research sites. These notes mostly pertained to issues around aspects of intervention delivery. The monthly meetings were used as a forum to discuss and reconcile issues that arose in relation to the conduct of the study.

#### **4.10.9 Receipt and enactment of treatment skills**

It was not automatically assumed that participants would understand the intervention content. Consequently, in the final ten minutes of the intervention, measures were taken to determine participants' potential to enact those treatment skills that were given during the intervention. Role play and scenario

sessions were used to assess their comprehension and ability to apply the intervention. The intervention was aimed at implementing appropriate actions if symptoms reoccurred. Receipt and enactment of skills were further evaluated during the telephone call that was made to participants one month after recruitment. During this call, their understanding of the components of the intervention was evaluated and the information was reinforced with a view to maximising the enactment of treatment skills.

#### **4.10.10 Follow-up protocol**

All participants from the intervention group were telephoned one month after receipt of the intervention. During this call, participants were asked about the presence of cardiac symptoms since discharge from hospital and about their recollection of the components of the educational intervention. The recommended call duration was ten minutes. The interventionists were provided with the script to guide the conversation for the follow-up call (Appendix 6). While the intervention component of the telephone call never extended beyond the recommended time, the calls usually lasted much longer than originally anticipated. Participants seemed to welcome the opportunity to discuss their day to day lives. Most were very receptive to the follow-up call and appreciated the time taken to phone them.

Five months later, participants in the intervention group were sent a letter, together with a summary action plan (Appendix 7). A flow chart outlining the recruitment and follow-up procedures is shown in Figure 2.

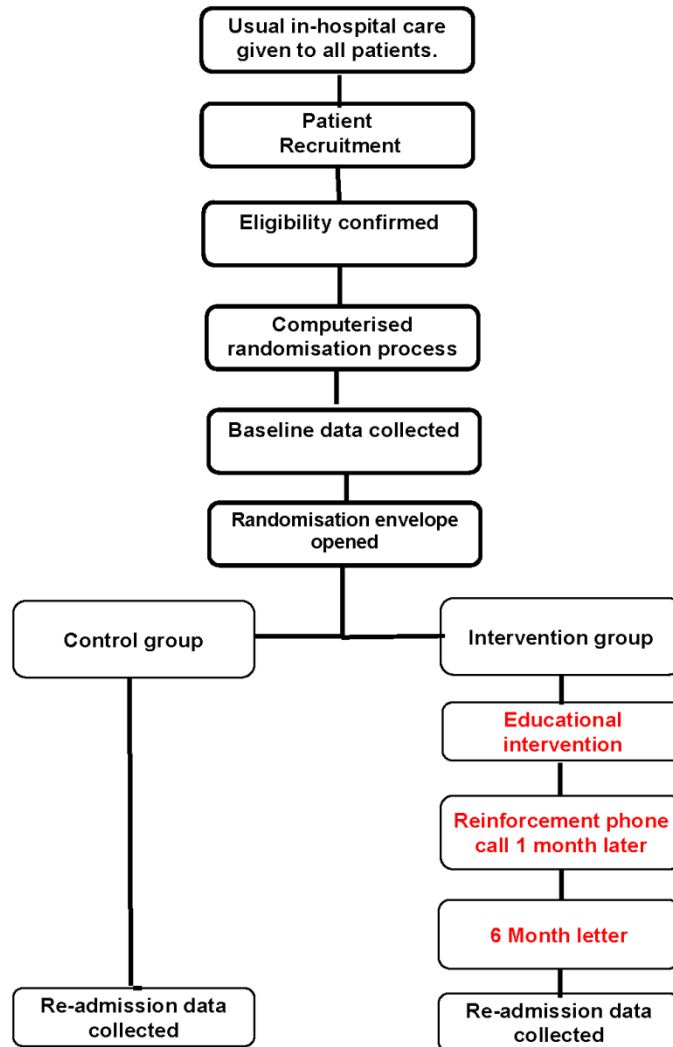


Figure 2 Flow chart for recruitment and follow-up

#### **4.11 Identification of participants who were readmitted**

The identification of participants from the control and intervention groups who were re-admitted to an ED was critical to the outcome of this study. This was important in order to test whether those who were randomly assigned to the intervention group had reduced pre-hospital delay times on readmission to an ED with ACS symptoms, compared to the control group. Therefore, there were planned means by which readmissions were identified.

In the first instance, participants from the control and intervention groups were requested to contact the interventionist by telephone, if they attended an ED with a further suspected ACS event. It was envisaged that the distribution of the refrigerator magnets displaying the interventionists' contact details would augment this chance.

With respect to participants in the intervention group, they were asked if they had been back to the ED with symptoms in the previous month when they were contacted by telephone one month following discharge.

Pre-printed yellow stickers were applied to the covers of all participants' medical charts. This easily identifiable sticker contained a message to medical and nursing staff requesting that they telephone the interventionist if the participant was readmitted to an ED with ACS symptoms. However, this was only beneficial if the participant was readmitted to the original research site.

All participants were sent postal questionnaires at three and twelve months following recruitment. These questionnaires pertained to a separate study using the same sample. As part of these questionnaires, participants were asked to declare whether or not they had attended an ED with ACS symptoms in the previous three or twelve months, as relevant. The returned questionnaires were inspected for readmission declarations. Participants who returned their questionnaires were phoned to acknowledge their receipt. This phone call opportunity was also used to ascertain whether or not participants from either group had been readmitted.

Despite these planned measures, the main means by which those who were readmitted was through the direct identification of individual participants or their medical notes, which displayed the conspicuous yellow stickers, on the wards. When approached by the gatekeepers, participants sometimes informed them that they were already involved in the study. In these circumstances, participants' names were given to the interventionist, as readmissions. The follow-up phone calls and questionnaires were a very successful means of identifying those who were readmitted, while the response to the yellow stickers and fridge magnets was minimal. At the end of the study, all participants not known to be readmitted, were contacted by telephone and asked whether they had been readmitted to an ED with symptoms since they had joined the study. Through this, a small number of additional cases were identified.

#### **4.12 Ethical considerations**

Randomised controlled trials are regarded as the cornerstone of the advancement of knowledge through research (Kerr *et al.* 2004). However, an

ethical issue is raised when participants are randomised to an arm of a trial that is potentially inferior. The research intention should always be to promote respect and avoid exploitation of participants and so the utilitarian component must be controlled by the non-utilitarian standards (Miller & Brody 2007). It has been suggested that randomisation in clinical trials may be ethically supported in situations where there is a genuine uncertainty on the part of the researcher regarding the comparative therapeutic merits of each arm of the trial (Freedman 1987, Lilford 2003). This is referred to as clinical equipoise.

The protection of human rights was considered very important in this trial and the ethical principles on which it was founded were based on the ten articles of the Nuremberg Code, the basic ethical principles derived from the Belmont Report and The Code of Professional Conduct for Each Nurse and Midwife (An Bord Altranais 2000). Ethical approval to conduct the study was sought and granted through the ethics committees of each individual research site (Appendix 8). The over-arching principles of respect, justice and beneficence are paramount to the ethical conduct of all research studies.

#### **4.12.1 The principle of respect**

The principle of respect includes the right to self-determination and incorporates autonomy, informed consent and confidentiality (Lobiondo-Wood & Haber 2006). In this study, patients were informed about the trial by the gatekeeper, who had no trial involvement. This gave participants absolute freedom to choose whether or not to participate in the study. For those who chose not to participate, an assurance was given that this would not impact on the care they would receive. Furthermore, informed consent was taken by the interventionists,

who were not involved in caring for these patients. Those who were unsure about participation were encouraged to think further before deciding, while those who preferred not to be involved were excluded without question and were not approached again. Participants were also given autonomy to enter and leave the study at any stage without implication. For those that withdrew from the study retrospectively, permission was sought to include their data in the final analyses and these wishes were respected.

Every effort was made to ensure that participants understood what they were consenting to when they joined the study. Each participant received written and verbal information about the study and the interventionist went through the written information with the participant before they chose or declined to participate (Appendix 9). The information provided was accurate and the language was simplified to make it easily understood. Furthermore, the participant information sheets were tested for readability against current Irish adult literacy guidelines, and amendments were made, as necessary. Time was given to answering questions about the study before a decision about participating in the trial was sought and the consent form signed (Appendix 10). Participants were encouraged to make contact with the interventionist if they had any queries or questions about the study.

The identities of the research sites and participants have been held in confidence throughout this trial. To do this, the research sites were allocated site numbers and participants' names were not included on the questionnaires. Data entries were by study number only. Participants' contact details were

stored separately from their questionnaires. During the study, all hardcopy data were locked in filing cabinets. Participants' medical and nursing notes were never removed from the research site. Computerised data were password protected and individual passwords were known only to the relevant interventionist. At the end of 2015 all non-anonymised hardcopy data will be shredded.

#### **4.12.2 The principle of justice**

The ethical principle of justice is of particular significance when participants are assigned to an intervention and control group, as was the case in this study. However, in accordance with ethical research guidelines (Kerr *et al.* 2004), group randomisation was selected by a computer, which had no information about the participants or research sites. Therefore, all participants had an equal chance of being assigned to either the control or the intervention group.

While it was considered that the intervention group would benefit from receipt of the intervention, participants from the control group were given the opportunity to avail of the intervention on completion of the study, if they so wished. Participants were informed that they could withdraw from the study at any time without prejudice to their care. This was especially important in this study, where patients did not have the 24-hour consideration period to reflect on their involvement.

#### **4.12.3 The principle of beneficence**

The principle of beneficence imposes an obligation on behalf of the researcher to maximise benefits for research participants, while simultaneously ensuring that non-maleficence is minimised (Polit & Beck 2008). It was considered that



individuals from the intervention group could potentially benefit from the intervention by reducing their pre-hospital delay time in the future. However, this was not guaranteed, as the intervention may not be successful. In the event of the intervention being unsuccessful, these patients could not be harmed by the information that they received.

There was no likelihood of causing emotional or physical distress to anyone who took part in this study. However, participants may be regarded as a 'vulnerable group', as they had just had a cardiac event, which can be stressful and cause tiredness and anxiety. Their vulnerability was considered and their needs superseded those of the trial at all times. To ensure this, only patients who were deemed sufficiently well by the appointed gatekeeper were seen and recruited by the interventionist. If participants became tired, stressed or upset, data collection or intervention delivery was stopped immediately and participants were given the opportunity to postpone the process until another time. They were also given time to reconsider their involvement in the study, if that was a better option for them.

#### **4.13 Database development and maintenance**

All study data were initially handled using Version 16 of the Statistical Package for Social Sciences (SPSS Inc. Chicago IL) and this programme was updated annually as new versions were made available. Data from the five research sites were merged onto one central database. At the outset of the study, a code book was developed and maintained. The meaning of labels assigned to variables and the units of response measurements were documented in this book, which was maintained for reference purposes (Pallant 2010). Following

data collection, the data were entered point by point onto the central database from the hard copy of the questionnaire. These original hard copies were secured and stored in numerical order in designated filing cabinets in the School of Nursing and Midwifery.

#### **4.14 Quality control measures**

Data cleansing was on-going throughout the study. Where inconsistencies or discrepancies appeared in the data, for example, a negative delay time, these were resolved on detection. Missing data were labelled as code 999. Before the database could be finalised, further work in the form of data cleansing and data proofing was required. Baseline and readmission pre-hospital delay times were cross-checked for 100% of the sample who were readmitted. In addition, over 10% of the hard copy questionnaires from each site were randomly checked against the inputted data to monitor for data entry errors. Amendments to missing or incorrect data were made as appropriate, but the error rate was low, at less than 1%. Frequencies and scatter plots were used to identify any additional outliers or errors. Where discrepancies arose, these were cross-checked against the hard copy of the questionnaires and amendments were made where appropriate. There were three participants on whom pre-hospital delay time was unavailable. These participants' data were removed from the final analyses. The database was formally locked on completion of the final cleansing and proofing. No additional amendments were permitted after this time.

#### **4.15 Data analysis**

Data were analysed using PASW version 18 (SPSS Inc. Chicago IL). A decision was made that no interim inferential analyses would be conducted until the end

of the two-year data collection period in order to avoid bias and preserve the 5% false positive error rate. Initial comparisons of patient socio-demographic variables and clinical characteristics for the total sample and the randomised groups were undertaken using descriptive statistics. Chi-square tests were used to analyse and compare categorical variables between the groups. These include sociodemographic and clinical characteristics, the results of which were presented as proportions and percentages. An independent samples *t*-tests was used to compare the continuous variable of age. The results of these are presented as means and standard deviations.

Data on pre-hospital delay time are generally markedly skewed. Consequently, log transformation was applied for the purpose of statistical analysis. The log-transformed data were labelled as such and were easily distinguished from the data that pertained to real numbers. Because delay-time data were skewed, the median times were reported, as these are a more representative measure of central tendency. Pre-hospital delay time calculations were managed in one of two ways. For statistical analyses, the log-transformed delay times were used and applied. Median pre-hospital delay times were calculated for actual real-time delay hours using descriptive statistics, frequencies and quartiles. Data remained abnormally distributed despite log-transformation; therefore a Mann Whitney *U*-test was used to compare median pre-hospital delay times.

To test the primary research hypothesis, a repeated measures analysis of variance (RM-ANOVA) was used. Analysis of variance can be used to measure the same subjects under different conditions or at different time points (Pallant

2007). The initial step involved testing that the general assumptions of ANOVA were not violated. The assumptions of independence of observations and homogeneity of variance were met and, following log transformation, data were approximately normally distributed. This rendered it suited to analysis using ANOVA.

Analysis of variance permitted the exploration of between-subject effect (group) and within-subject effect (changes over time). Using analysis of variance, the relationship between the dependent variable (delay time) and group (control and intervention) could be adjusted, for differences associated with any covariates. This test was chosen not only because it met the necessary assumptions but also to reduce the likelihood of a type I error.

To determine the impact of the intervention on pre-hospital behaviours and to make statistical comparisons between the groups, a chi-squared test for independence was used. Group was selected as the independent variable, while individual behaviours were entered as dependent variables.

#### **4.16 Summary**

This chapter provided details about how data were collected using the ACS Response Index and how the educational intervention was delivered. The content of the intervention, which can be located in the intervention manual, was also discussed. The intervention key message was to stop and rest in the presence of ACS symptoms and to inform somebody about symptoms. Further advice included the use of prescribed nitrates to help differentiate and relieve

symptoms and to phone an ambulance, not a GP, if symptoms persisted beyond 15 minutes. When participants were readmitted to an ED with ACS symptoms, their pre-hospital delay times were measured and compared with their baseline readings. To minimise the potential disadvantage imposed on the control group in this study, they were advised that they could avail of this intervention by contacting the interventionist on completion of the study. The aim of the study was to reduce pre-hospital delay time on readmission to an ED with ACS symptoms and to counteract behaviours that increase pre-hospital delay. The study results will be presented in the next chapter.

## Chapter 5 Study results

### 5.1 Introduction

The aim of this study was to test the effectiveness of an individualised educational intervention on patient pre-hospital delay time among patients diagnosed with ACS. The primary hypothesis tested whether following the intervention, patients assigned to the intervention group had reduced pre-hospital delay times when readmitted to an ED with ACS symptoms, compared to the control group. The secondary hypothesis tested whether following the intervention, and in the presence of unresolved ACS symptoms, more patients in the intervention group compared to the control group: used prescribed nitrates; alerted another person to the presence of unresolved symptoms; avoided consultation with a GP and; used an ambulance to access the ED.

The recommended behavioural responses to ACS symptoms were discussed at length during the educational intervention. These recommendations were incorporated into the personalised action plan that was developed in conjunction with each participant in the intervention group. The intervention was reinforced during a follow-up telephone call, which was made one month after the intervention was delivered. Six months after recruitment, an action plan and accompanying letter was posted to each participant in the intervention group.

This chapter is divided into four sections. The first section describes study eligibility and recruitment. The second section provides an overview of the characteristics of the total sample recruited (N=1,944) and includes information

about study attrition. A comparison of the randomised control and intervention groups at baseline is also presented in this section. The third section focuses on the sub-sample of the total sample that was readmitted to an ED with ACS symptoms (314/1,944). For ease of differentiation between the total sample (N=1,944) and the sub-sample who were readmitted (N=314), the term study cohort will be used when referring to the sub-sample (N=314), for the remainder of the thesis. A comparison of the sociodemographic and clinical characteristics of the control and intervention groups who were readmitted can also be found in this section. The impact of the educational intervention on pre-hospital delay time, which is the primary study hypothesis, will also be presented here. The third section also presents a comparison of those from the total sample who were not readmitted with ACS symptoms (N=1,630) and those who were readmitted (N=314). The fourth and final section is centred on the secondary hypothesis; behaviours associated with pre-hospital delay time.

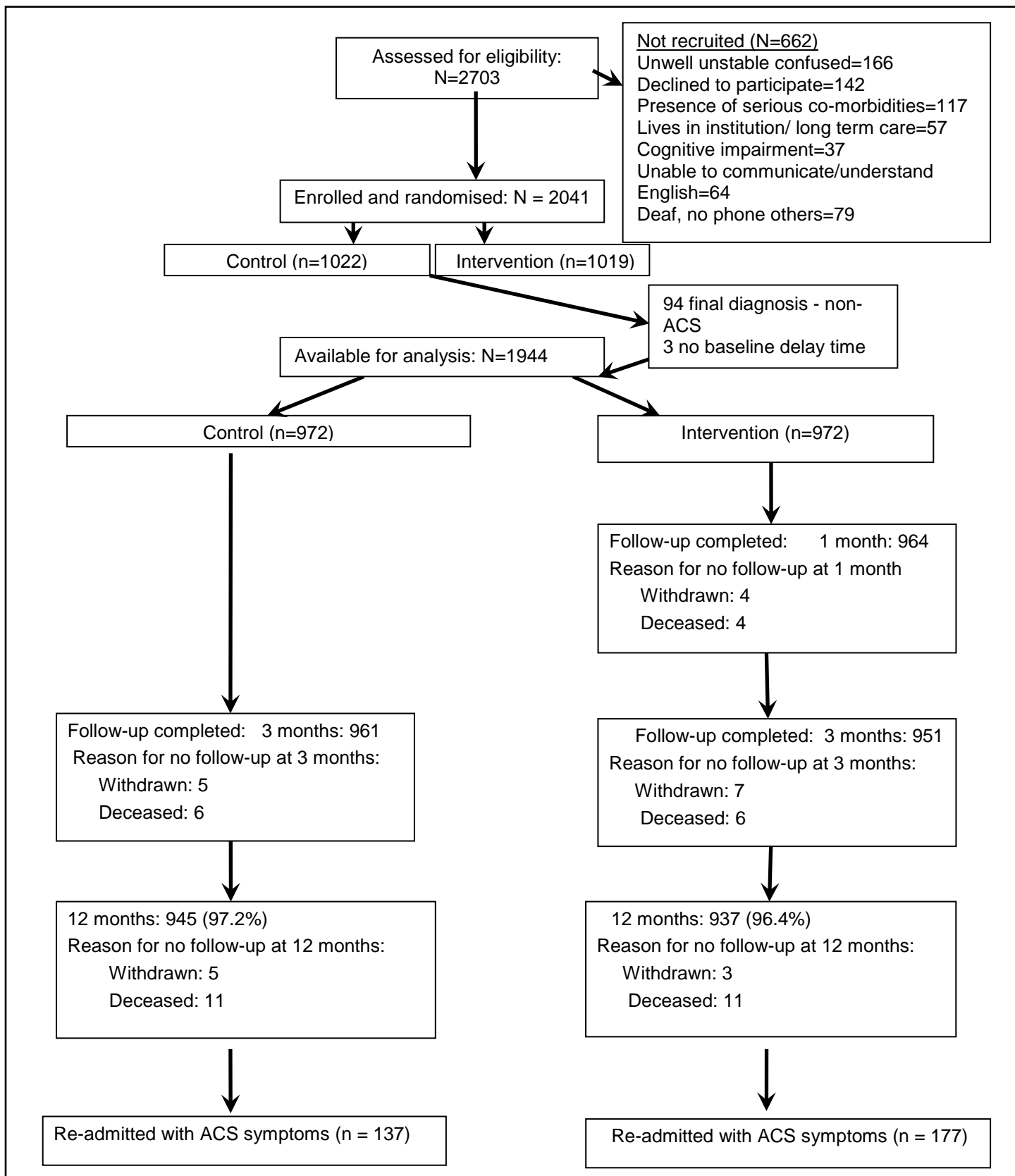
## **Section 1**

### **5.2 Study eligibility and recruitment**

Data collection took place over a three-year period. Recruitment to the study took place for the first two years, from November 1<sup>st</sup> 2007 to October 31<sup>st</sup> 2009. Follow-up data were collected and recorded until the end of the third year. There were 2,703 patients assessed for study eligibility (Figure 3). This figure represents approximately 77% of the total population (N=3,507) who presented to the hospitals' EDs that served as the research sites for this study. Of those who were assessed for eligibility, 662 (24.4%) were rendered ineligible for study inclusion. While in some cases there may have been more than one reason for exclusion from the study, it was the primary reason for exclusion that was

recorded. Reasons for ineligibility included: being unstable, unwell or confused (n=166; 6.1%), refusing to participate in the study (n=142;5.2%), the presence of a serious co-morbidity (n=117;4.3%), a cognitive impairment (n=37;1.3%), living in an institution (n=57;2.1%), an inability to communicate in or understand the English language (n=64;2.3%) and the presence of deafness, absence of a phone or some other occasional reason (n=79;2.9%). An additional 97 (3.5%) participants were lost to the study. Of these, 94 were lost because they were admitted to the study with a provisional diagnosis of ACS that was later unsubstantiated. The remaining 3 were lost because there was no documented pre-hospital delay time available for them (Figure 3). Data on 1,944 participants with an actual diagnosis of ACS and a documented pre-hospital delay time was therefore available for analysis. These 1,944 participants were randomly assigned between the control and the intervention groups.





**Figure 3 Consort flow diagram**

### 5.2.1 Recruitment distribution

The number of participants enrolled and randomised from each of the five research sites differed. The number ranged from 222 to 518. Because block randomisation was used, the allocation of participants to the control and intervention groups did not differ significantly between the sites (Chi-square,  $p=0.66$ ). Table 3 summarises the site-specific numbers recruited.

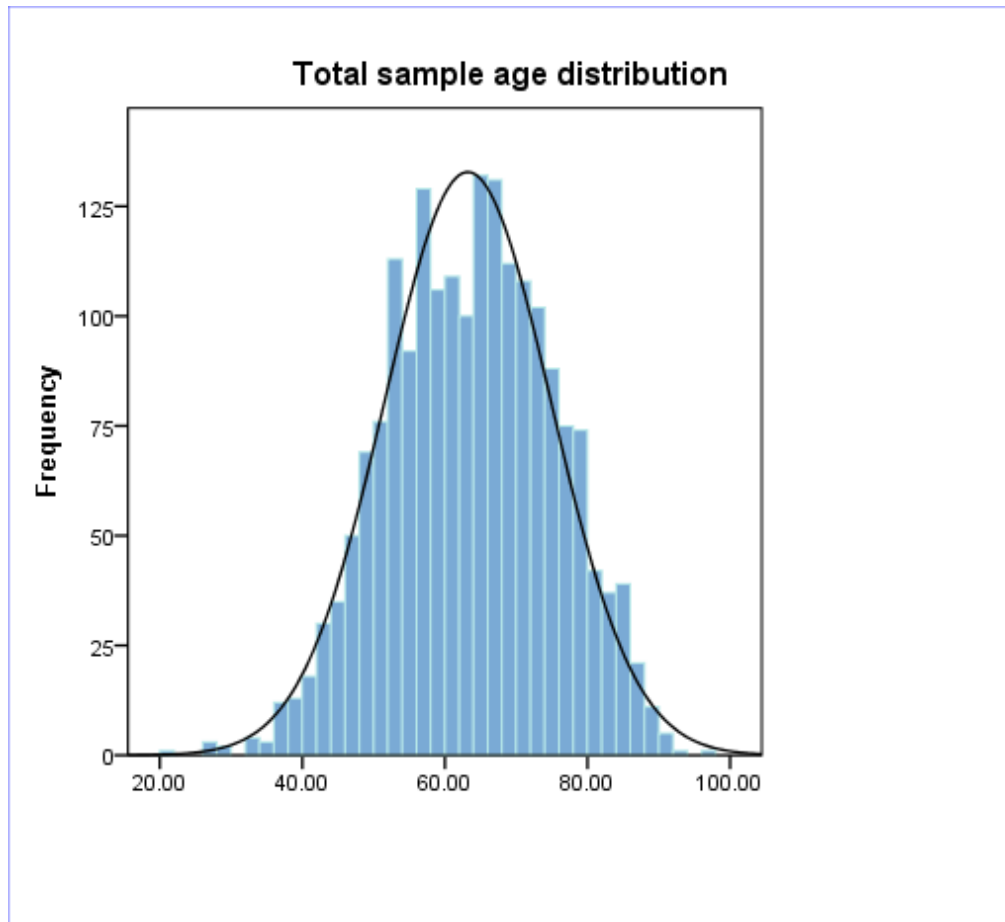
**Table 3. Site-specific numbers recruited**

Research site	Number recruited	Valid percent %	Control group N (%)	Intervention group N (%)
Hospital A	518	26.7	254 (49)	264 (51)
Hospital B	331	17.0	158 (47.7)	173 (52.3)
Hospital C	453	23.3	228(50.3)	225(49.7)
Hospital D	420	21.6	212(50.5)	208(49.5)
Hospital E	222	11.4	120(54.1)	102(45.9)
Total	1,944	100	972 (50)	972 (50)

## Section 2

### 5.3 Total sample profile

Details of the total sample are presented in Table 4. It was from the total sample (N=1,944) that the study cohort (N=314) emerged. During the two-year follow-up period, 24 (1.2%) participants withdrew from the study. Of these, 10 participants were from the control group and 14 were from the intervention group. Of the 38 (2%) participants who died, 17 (0.9%) were from the control group and 21 (1.1%) were from the intervention group (Figure 3). With respect to the total sample of 1,944 participants, the majority was male (72%), Irish (96%) and married or in a partnership (66%). The mean age was 63.2 (SD+/- 11.7) years. Age was normally distributed (Figure 4).



**Figure 4 Histogram for age of the total sample (N=1,944)**

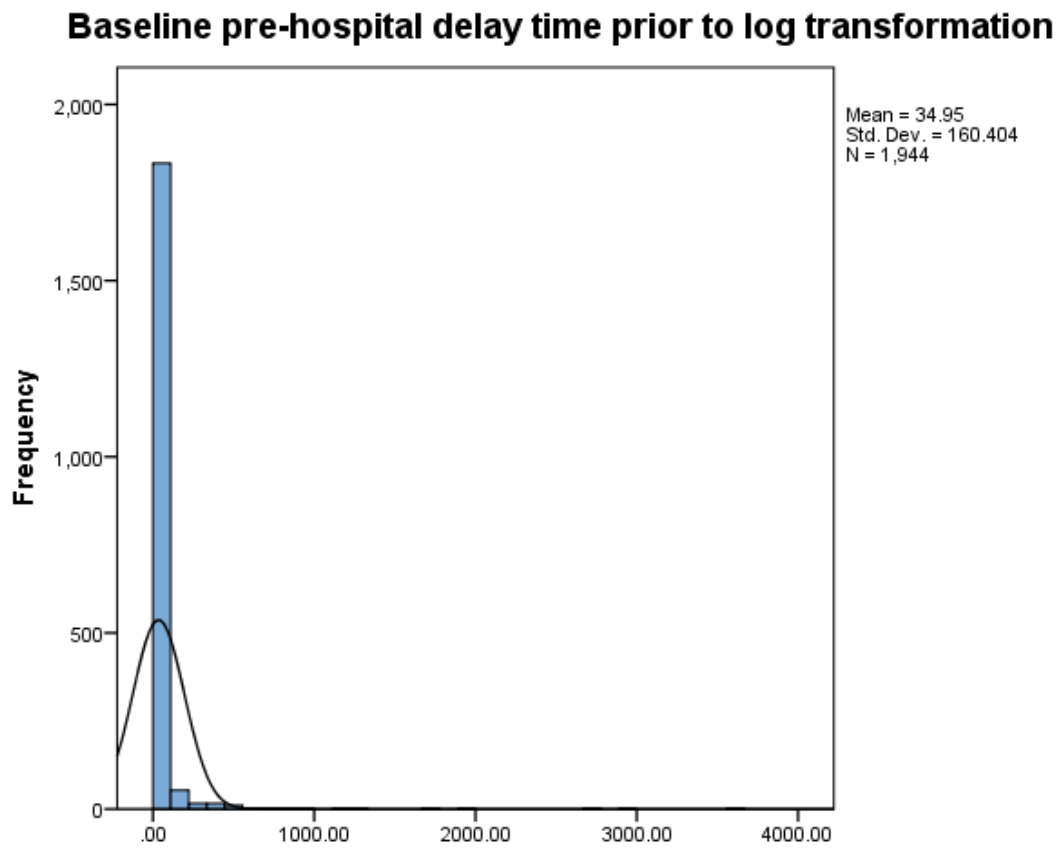
Despite the strict randomisation protocol employed, some baseline differences were noted between the control and intervention groups with respect to socio-demographic and clinical characteristics. These differences related to a greater proportion of participants with diabetes being randomised to the control group ( $p=0.005$ ). In addition, more of those randomised to the intervention group were younger ( $p=0.02$ ), had private health insurance ( $p=0.001$ ), had attained third level education ( $p=0.001$ ) and were in employment ( $p=0.01$ ). All characteristics can be seen in Table 4.

**Table 4. Total sample profile: intervention and control group comparison**

Demographic variable	Overall (N=1944) N (%)	Control (n=972) n (%)	Intervention (n=972) n (%)	p*
<b>Median baseline pre-hospital delay time hours</b>	4.04 hours (25 <sup>th</sup> percentile=1.63, 75 <sup>th</sup> percentile=18.16).	4.28 hours (25 <sup>th</sup> percentile=1.71, 75 <sup>th</sup> percentile=17.37).	3.96 hours (25 <sup>th</sup> percentile=1.53, 75 <sup>th</sup> percentile=18.51).	0.34
<b>Age, years-mean ± SD</b>	63.19±11.68	63.83±11.62	62.55±11.71	0.02*
Male	1401(72.1)	692 (49.4)	709 (50.6)	0.39
Female	543 (27.9)	280 (51.6)	263 (48.4)	
<b>Education</b>				0.001*
Some or little formal	714 (36.7)	380 (53.2)	334 (46.8)	
Second level	869 (44.7)	443 (51.0)	426 (49.0)	
Third level	361 (18.6)	149 (41.3)	212 (58.7)	
Married or partnership.	1278(65.7)	642(50.2)	636 (49.8)	0.77
Single/separated/ widowed.	666 (34.3)	330 (49.5)	336 (50.5)	
<b>Financial status</b>				0.36
Comfortable	423(24.8)	199 (47.0)	224 (53.0)	
Enough to make ends meet	1089(63.9)	554 (50.9)	535 (49.1)	
Not enough for ends to meet	193(11.3)	100 (51.8)	93 (48.2)	
<b>Employment</b>				0.01*
Employed/looking after home/student.	832 (42.8)	388(46.6)	444 (53.4)	
Unemployed/retired/disability	1110 (57.2)	583 (52.5)	527 (47.5)	
No private health insurance	1251(65.6)	655(52.4)	596(47.6)	0.001*
Private health insurance	657 (34.4)	293(44.6)	364 (55.4)	
<b>Prior cardiac history</b>				
Angina	660 (34.0)	341 (51.7)	319 (48.3)	0.29
Myocardial infarction	583 (30.0)	301 (51.6)	282 (48.4)	0.35
PCI	513 (26.4)	264 (51.5)	249 (48.5)	0.44
CABG	259 (13.3)	140 (54.1)	119 (45.9)	0.16
<b>Presence of risk factors</b>				
Diabetes	318 (16.4)	182 (57.2)	136 (42.8)	0.005*
CVA	114 (5.9)	59 (51.8)	55 (48.2)	0.70
Family history	1274(65.5)	622 (48.8)	652 (51.2)	0.15
Hypertension	1157(59.5)	581 (50.2)	576 (49.8)	0.82
Hypercholesterolaemia	1388 (71.4)	710 (51.2)	678 (48.8)	0.10
Current or recent smoker	628(32.3)	323 (51.4)	305 (48.6)	0.38
<b>Admission diagnosis</b>				
STEMI	548(28.2)	268 (48.9)	280 (51.1)	0.03*
NSTEMI	705(36.3)	331 (47.0)	374 (53.0)	
Unstable Angina	691(35.5)	373 (54.0)	318 (46.0)	
<b>Immediate treatment</b>				
Thrombolysis	229 (11.8)	105(45.9)	124 (54.1)	0.18
Primary PCI	324 (16.7)	150 (46.3)	174 (53.7)	0.14
Primary CABG	4 (0.2)	2(50.0)	2 (50.0)	1.0
Resuscitation	43(2.2)	22(51.2)	21(48.8)	0.88

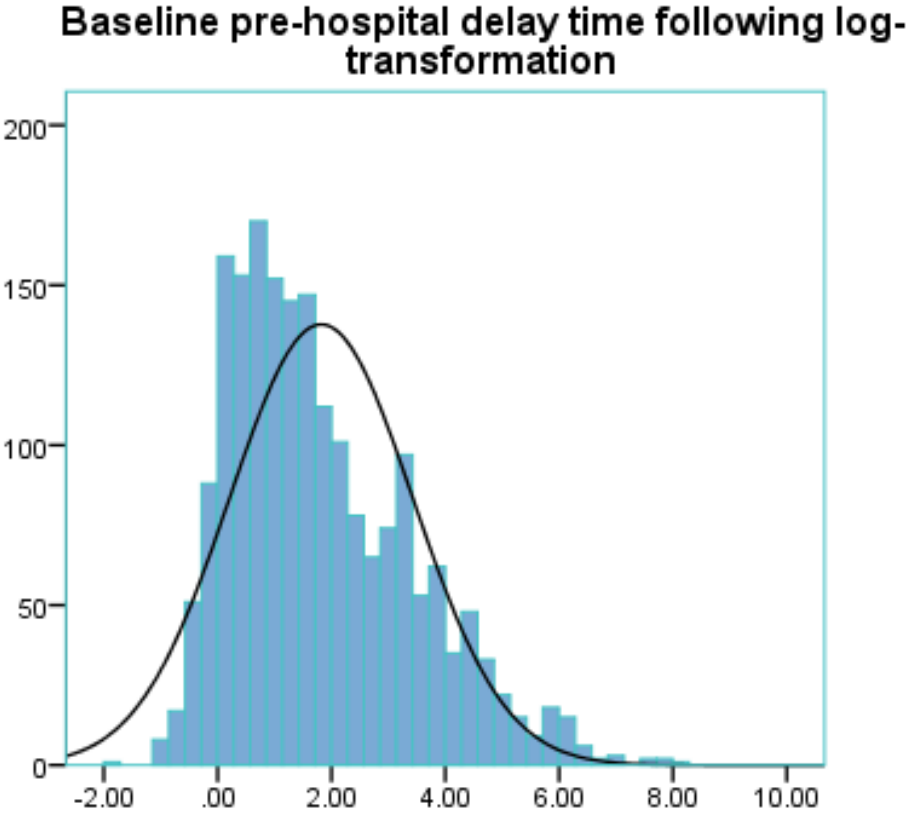
**Legend:** Values represent frequencies (percentages) or mean ± SD (Standard Deviation). \* indicates p value significant at <0.05. CABG = coronary artery bypass graft; STEMI= ST segment elevation myocardial infarction; NSTEMI= non-ST segment elevation myocardial infarction; CVA= cerebral vascular accident; PCI= percutaneous coronary intervention.

For the total sample, the delay-time data were abnormally distributed before log-transformation (Figure 5).



**Figure 5 Histogram for pre-hospital delay time before log-transformation**

The data were also abnormally distributed following log-transformation, albeit to a lesser extent (Figure 6).



**Figure 6 Histogram for pre-hospital delay time after log-transformation**

The baseline median pre-hospital delay time for the total sample (N=1,944) was 4.04 hours (25<sup>th</sup> percentile=1.63, 75<sup>th</sup> percentile=18.16). As delay-time data were not normally distributed despite log-transformation, a non-parametric Mann Whitney *U* test was applied to compare median pre-hospital delay times between the intervention and control groups. Median baseline pre-hospital delay times did not differ significantly between the control and intervention groups at baseline (Mann-Whitney *U*,  $p=0.34$ : Control: 4.28 hours, 25<sup>th</sup>

percentile=1.71, 75<sup>th</sup> percentile=17.37; Intervention 3.96 hours, 25<sup>th</sup> percentile=1.53, 75<sup>th</sup> percentile=18.51).

### **Section 3**

#### **5.4 The study cohort**

The study cohort emerged from the total study sample and was comprised of those participants who were readmitted to an ED with ACS symptoms. Within the two years of study follow-up, 314 (16.2%) participants from the total sample were readmitted to an ED with ACS symptoms. Of these, 137 (14%) were from the control group and 177 (18.2%) were from the intervention group.

##### **5.4.1 Socio-demographic characteristics of the study cohort**

The socio-demographic characteristics of the study cohort are presented in Table 5. The mean age of those who were readmitted was 62.6 (SD+/-12.2) years. The majority was male (65.9%) and married or in a partnership (62.7%). Less than one-third of those who were readmitted had private health insurance (30%). Most reported having sufficient finances to make ends meet (64.9%). Almost two thirds were unemployed, retired or in receipt of a disability allowance (61.5%). No significant differences were noted between the groups with respect to any socio-demographic variables, except the level of education attained. The groups differed significantly in this regard, with a greater proportion of participants from the intervention group having attained third level education (Chi-square,  $p=0.02$ ) (Table 5).

##### **5.4.2 Clinical characteristics of the study cohort**

Of those who were readmitted, almost two-thirds had a prior history of hypertension (63.7%). Three-quarters had hypercholesterolaemia (75.8%), while 67.2% had a family history of heart disease. The prevalence of other

clinical risk factors including diabetes (17.8%), history of cerebrovascular accident (6.4%) and a current smoking habit (29.3%) were less pronounced (Table 5). With respect to baseline diagnosis, the majority of participants who were readmitted had originally been diagnosed with unstable angina (44.6%), while smaller proportions had been diagnosed originally with NSTEMI (30.9%) and STEMI (24.5%). No significant differences between the groups with respect to these variables were observed (Chi-square,  $p=0.16$ ) (Table 5).

On readmission, the majority of participants were diagnosed with unstable angina (54.8%). Just over 10% were diagnosed with a myocardial infarction. In total, 7.6% and 3.2% were diagnosed with NSTEMI and STEMI, respectively. The majority of those who were readmitted and diagnosed with ACS were medically managed. From the study cohort, there were no significant differences between the control and intervention groups with respect to their clinical characteristics (Table 5).

While 100% of those who were readmitted presented with ACS symptoms, just over one-third (34.4%; 108/314) of these were not diagnosed with ACS on readmission. Although there were more readmissions among the intervention group ( $n=177/972$ ) compared to the control group ( $n=137/972$ ) (Chi-square,  $p=0.02$ ), there were no significant differences between the groups with respect to readmission diagnoses (Chi-square,  $p=0.17$ ). The term 'other' is used in Table 5 to collectively describe the range of diagnoses of those readmitted with conditions other than ACS.



**Table 5. Study cohort profile: intervention and control group comparison**

Demographic variable	Overall (N=314) N (%)	Control (n=137) n (%)	Intervention (n=177) n (%)	p*
<b>Median baseline pre-hospital delay time hours.</b>	5.0 hours (25 <sup>th</sup> percentile= 2.0, 75 <sup>th</sup> percentile=23.5).	5.5 hours (25 <sup>th</sup> percentile= 2.67; 75 <sup>th</sup> percentile=23.13).	4.5 hours (25 <sup>th</sup> percentile=1.55, 75 <sup>th</sup> percentile=23.70)	0.39
<b>Age, years ± SD</b>	62.6 ± 12.2	62.6 ± 11.6	62.6 ± 12.8	0.97
<b>Gender</b>				
Male	207 (65.9 )	87 (42.0)	120 (58.0)	0.47
Female	107 (34.1)	50 (46.7)	57 (53.3)	
<b>Education</b>				
Some or little formal	140 (44.6)	72 (51.4)	68 (48.6)	0.02*
Second level	131 (41.7)	52 (39.7)	79 (60.3)	
Third level	43 (13.7)	13 (30.2)	30 (69.8)	
<b>Marital status</b>				
Married or living in partnership	197 (62.7)	88 (44.7)	109 (55.3)	0.63
Single/separated/divorced/ widowed	117 (37.3 )	49 (41.9)	68 (58.1)	
<b>Financial status</b>				
Comfortable	53 (20.0)	21 (39.6)	32 (60.4)	0.50
Enough to make ends meet	172 (64.9)	69 (40.1)	103 (59.9)	
Not enough to make ends meet	40 (15.1)	20 (50.0)	20 (50.0)	
<b>Employment</b>				
Employed or looking after home or a student status	121 (38.5)	47 (38.8)	74 (61.2)	0.18
Unemployed/retired/disability	193 (61.5)	90 (46.6)	103 (53.4)	
<b>Health insurance</b>				
No private health insurance	215 (70.0)	93 (43.3)	122 (56.7)	0.75
Private health insurance	92 (30.0)	38 (41.3)	54 (58.7)	
<b>Presence of risk factors</b>				
Diabetes	56 (17.8)	29 (51.8)	27 (48.2)	0.18
CVA	20 (6.4)	9 (45.0)	11 (55.0)	0.90
Family history	211 (67.2 )	87 (41.2)	124 (58.8)	0.22
Hypertension	200 (63.7)	90 (45.0)	110 (55.0)	0.51
Hypercholesterolaemia	238 (75.8)	101 (42.4)	137 (57.6)	0.45
Current or recent smoker	92 (29.3)	46 (50.0)	46 (50.0)	0.14
<b>Cardiac history prior to baseline</b>				
Angina	142 (45.2)	60 (43.3)	82 (57.7)	0.66
Myocardial infarction	126 (40.1)	60 (47.6)	66 (52.4)	0.24
PCI	43 (37.3)	49 (41.9)	68 (58.1)	0.63
CABG	62 (19.7)	28 (45.2)	34 (54.8)	0.79
<b>Baseline diagnosis</b>				
STEMI	77 (24.5)	34 (44.2)	43(55.8)	0.16
NSTEMI	97 (30.9)	35 (36.1)	62 (63.9)	
Unstable Angina	140 (44.6)	68 (48.6)	72 (51.4)	
<b>Baseline treatment</b>				
Thrombolysis	34 (10.8)	10 (29.4)	24 (70.6)	0.07
Primary PCI	46 (14.6)	23(50.0)	23 (50.0)	0.35
Primary CABG	1 (0.3)	1(100)	0 (0)	NA
Resuscitation	5 (1.6)	4 (80.0)	1 (20.0)	NA
<b>Readmission diagnosis</b>				
STEMI	10 (3.2)	4 (40.0)	6 (60.0)	0.17
NSTEMI	24 (7.6)	14 (58.3)	10 (41.7)	
Unstable Angina	172 (54.8)	68 (39.5)	104 (60.5)	
Other	108 (34.4)	51 (47.2)	57 (52.8)	
<b>Readmission treatment (n=309)</b>				
Thrombolysis	1(0.3)	1(100)	0 (0)	NA
Primary PCI	11(3.6)	2(18.2)	9 (81.8)	NA
Primary CABG	0	0	0	NA
Resuscitation	4 (1.3)	2 (50.0)	2 (50.0)	NA

**Legend:** Values represent frequencies (percentages) or mean ± SD (Standard Deviation). \* indicates p value significant at <0.05.  
HRS=hours; CABG = coronary artery bypass graft; STEMI= ST segment elevation myocardial infarction; NSTEMI= non-ST segment elevation myocardial infarction; CVA= cerebral vascular accident; PCI= percutaneous coronary intervention. NA= results not available as subgroup sample too small to perform analysis.

### **5.5 Baseline pre-hospital delay times among the study cohort**

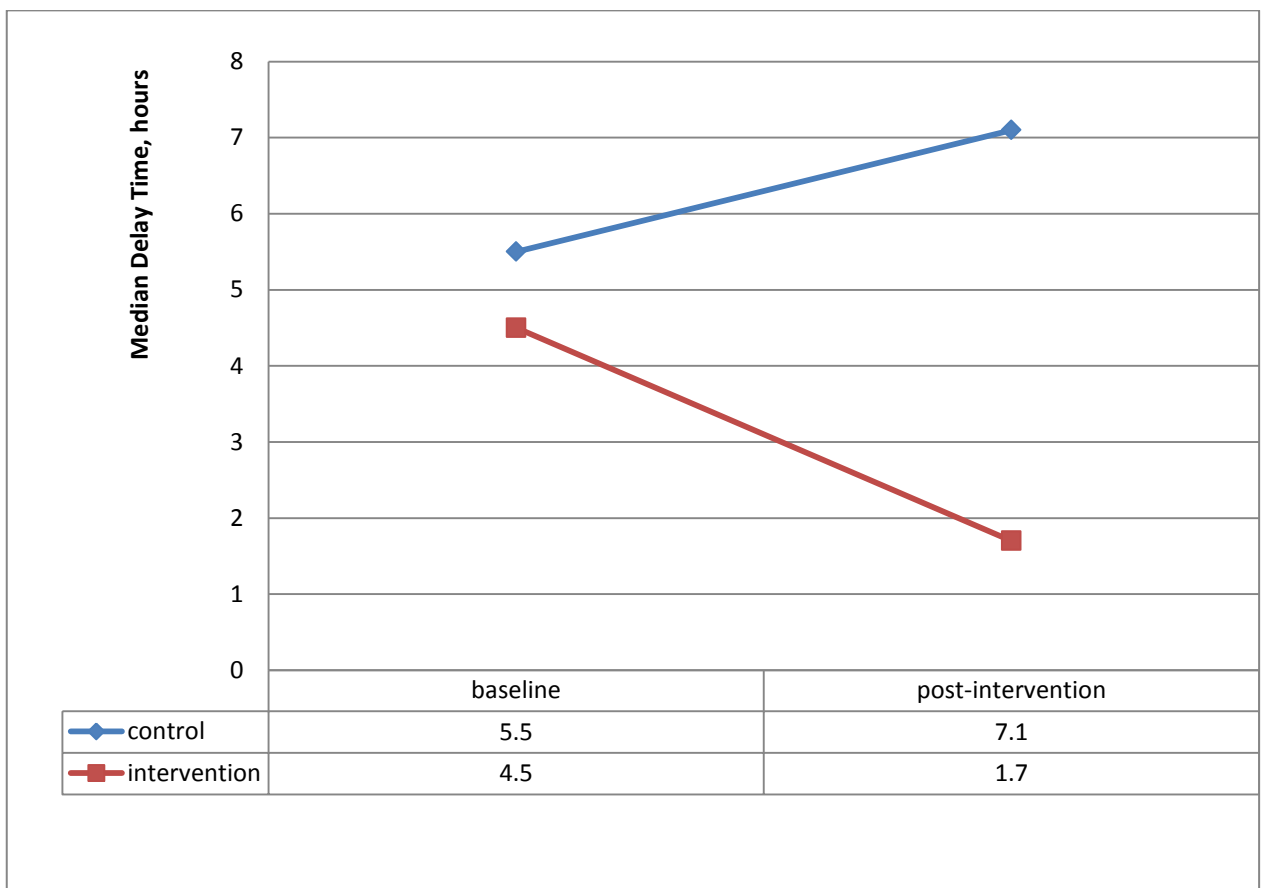
Baseline pre-hospital delay time for the study cohort (N=314) was measured and compared between the control and intervention groups. As was the case with the total sample, baseline pre-hospital delay-time data were abnormally distributed. A Mann Whitney *U* test was applied to compare median pre-hospital delay times. There was no significant difference between the two groups in their original (baseline) pre-hospital delay times (control median 5.5 [25<sup>th</sup> percentile, 2.67 and 75<sup>th</sup> percentile, 23.13] and intervention median 4.51 [25<sup>th</sup> percentile, 1.55 and 75<sup>th</sup> percentile, 23.70]) (Mann-Whitney *U*,  $p=0.39$ ) (Table 5).

### **5.6 The impact of the intervention on pre-hospital delay time**

Following the educational intervention and on readmission to an ED, pre-hospital delay times were again measured for the study cohort. The post-intervention median pre-hospital delay time for the study cohort (N=314) was 2.54 hours [25<sup>th</sup> percentile 1.31 hours and 75<sup>th</sup> percentile 7.75 hours]. Highest level of attained education was the only noted difference between the two groups who were readmitted and so this variable was adjusted for in the analysis.

To examine the impact of the intervention on pre-hospital delay time, repeated measures ANOVA was used. The examination of post-intervention pre-hospital delay time revealed that there was a significant difference in pre-hospital delay times between the groups, after controlling for level of education. Among the intervention group, the median pre-hospital delay time was reduced to 1.7 hours [25<sup>th</sup> percentile 1.1, 75<sup>th</sup> percentile 2.9], which represented a 62%

improvement on pre-intervention pre-hospital delay times. The post-intervention median pre-hospital delay time for the control group who were readmitted increased to 7.1 hours [25th percentile 2.7, 75th percentile 16.7] (Figure 7), which was an increase of 29% compared to the pre-intervention values. These post-intervention readmission pre-hospital delay times represent an increase of 1.6 hours in the control group and a reduction of 2.8 hours in the intervention group (Figure 7). The change over time remained significantly different between the groups  $F(1, 310) = 37.599, p < 0.001$ . The primary study hypothesis was therefore accepted.



**Figure 7 The effect of the intervention on pre-hospital delay time (N=314)**

A comparison between the study cohort (N=314) and those who were not readmitted with ACS symptoms (N=1,630) was explored to determine whether or not those who were readmitted were representative of the total sample. These results are presented in Table 6. There was no significant baseline pre-hospital delay time difference between the study cohort and those not readmitted ( $p=0.36$ ). From a sociodemographic perspective, there were differences between the two groups with respect to gender, education and financial status. More of those from the study cohort had little or no formal education ( $p=0.003$ ), while more of those from the group who were not readmitted were comfortable financially ( $p=0.03$ ). With respect to gender, significantly more women were readmitted ( $p=0.008$ ) than not.

From a clinical history perspective, the study cohort differed from the non-readmitted group in that they had a cardiac history of angina ( $p=0.001$ ), myocardial infarction ( $p=0.001$ ), PCI ( $p=0.001$ ) and CABG ( $p=0.001$ ) prior to their baseline admission. In addition, significantly more of the study cohort had a baseline diagnosis of unstable angina (Table 6).

**Table 6. Comparison of study cohort and sample not readmitted**

Demographic variable	Sample not readmitted (N=1630) N (%)	The Study cohort (N=314) N (%)	p*
<b>Median baseline pre-hospital delay time hours.</b>	4.0 hours (25 <sup>th</sup> percentile= 1.58, 75 <sup>th</sup> percentile=16.43).	5.0 hours (25 <sup>th</sup> percentile=2.0, 75 <sup>th</sup> percentile=23.5).	0.36
<b>Age, years ± SD</b>	62.4±11.6	62.6± 12.2	0.94
<b>Gender</b>			0.008*
Male	1194 (73.3)	207 (65.9)	
Female	436 (26.7)	107 (34.1)	
<b>Education</b>			0.003*
Some or little formal	574 (35.2)	140 (44.6)	
Second level	738 (45.3)	131 (41.7)	
Third level	318 (19.5)	43 (13.7)	
<b>Marital status</b>			0.22
Married or living in partnership	1081 (66.3)	197 (62.7)	
Single/separated/divorced/ widowed	549 (33.7)	117 (37.3)	
<b>Financial status</b>			0.03*
Comfortable	370 (25.7)	53 (20)	
Enough to make ends meet	917 (63.7)	172 (64.9)	
Not enough to make ends meet	153 (10.6)	40 (15.1)	
<b>Employment</b>			0.09
Employed or looking after home or a student status	711 (43.7)	121 (38.5)	
Unemployed/retired/disability	917 (56.3)	193 (61.5)	
<b>Health insurance</b>			0.72
No private health insurance	1036 (64.7)	215 (70)	
Private health insurance	565 (35.3)	92 (30)	
<b>Presence of risk factors</b>			
Diabetes	262 (16.1)	56 (17.8)	0.44
CVA	94 (5.8)	20 (6.4)	0.67
Family history	1063 (65.2)	211 (67.2)	0.49
Hypertension	957 (58.7)	200 (63.7)	0.10
Hypercholesterolaemia	1150 (70.6)	238 (75.8)	0.06
Current or recent smoker	536 (32.9)	92 (29.3)	0.21
<b>Cardiac history prior to baseline</b>			
Angina	518 (31.8)	142 (45.2)	<0.01*
Myocardial infarction	457 (28)	126 (40.1)	<0.01*
PCI	396 (24.3)	43 (37.3)	<0.01*
CABG	197 (12.1)	62 (19.7)	<0.01*
<b>Baseline diagnosis</b>			<0.01*
STEMI	471 (28.9)	77 (24.5)	
NSTEMI	608 (37.3)	97 (30.9)	
Unstable Angina	551 (33.8)	140 (44.6)	
<b>Baseline treatment</b>			
Thrombolysis	195 (12)	34 (10.8)	0.57
Primary PCI	278 (17)	46 (14.6)	0.26
Primary CABG	3 (0.1)	1 (0.3)	0.63
Resuscitation	38 (2.3)	5 (1.6)	0.41
<b>Legend:</b> Values represent frequencies (percentages) or mean ± SD (Standard Deviation). * indicates p value significant at <0.05. CABG = coronary artery bypass graft; STEMI= ST segment elevation myocardial infarction; NSTEMI= non-ST segment elevation myocardial infarction; CVA= cerebral vascular accident; PCI= percutaneous coronary intervention.			

## **Section 4**

### **5.7 Pre-hospital behaviours**

As a secondary study outcome, the study tested whether there was a difference between the control group and intervention group with respect to pre-hospital behaviours in the presence of ACS symptoms. The behaviours included the use of prescribed nitrates for the differentiation and relief of symptoms, the use of an ambulance to access the ED, non-consultation with a GP in advance of attending the ED and the notification of another person about the presence of symptoms. A comparison of baseline pre-hospital behaviours for the total sample (N=1,944) was conducted initially. At baseline, the percentage of participants who used the ambulance as a means of transport to the hospital did not differ between the intervention group (40.7%) and control group (39.5%) (Chi-square,  $p=0.61$ ). Furthermore, there was no difference between the intervention group (19.6%) and control group (21%) with respect to the use of prescribed nitrates (Chi-square,  $p = 0.46$ ). There was also no difference in those who avoided consultation with a GP prior to attending the ED between the intervention (57%) and control (53.5%) groups (Chi-square,  $p = 0.13$ ), or among those who disclosed the presence of symptoms to another person (intervention 47.3%) (control 42.9%) (Chi-square,  $p = 0.05$ ). The groups were therefore comparable at baseline with reference to their pre-hospital behaviours.

### **5.8 Baseline pre-hospital behaviours among the study cohort**

A comparison of the study cohort was conducted to analyse the baseline pre-hospital behaviours of those who were readmitted with ACS symptoms (N=314) (Table 7). This revealed that at baseline, more of those assigned to the intervention group (63.1%) than the control group (36.9%) disclosed the

presence of symptoms to another person (Chi-square,  $p=0.03$ ). With respect to the use of prescribed nitrates at baseline, one third of the study cohort used nitrates for the relief of symptoms, and of those who did, there were significantly more users from the control group, compared to the intervention group (Chi-square,  $p=0.04$ ). While a greater percentage of those assigned to the intervention group (57%) than the control group (43%) used an ambulance as the mode of transport to the ED at baseline, this was not significantly different between the groups (Chi-square,  $p=0.90$ ). Additionally, there was no difference between the groups with respect to consultation with a GP (Chi-square,  $p=0.82$ ) prior to attending the ED (Table 7).

**Table 7. Baseline pre-hospital behaviours among the study cohort**

<b>Pre-hospital behaviour.</b>	<b>N=314 N (%)</b>	<b>Intervention group n= 177 n (%)</b>	<b>Control group n=137 n (%)</b>	<b><i>p</i>*</b>
Used ambulance as mode of transport to get to ED.	142 (45.2)	81 (57.0)	61 (43.0)	0.90
Disclosed symptoms to another person.	141 (44.9)	89 (63.1)	52 (36.9)	0.03*
Consulted with a general practitioner before attending ED.	139 (44.3)	77 (55.4)	62 (44.6)	0.82
Self-administered nitrates when symptoms occurred.	104 (33.1)	50 (48.1)	54 (51.9)	0.04*
Values represent frequencies (percentages). * indicates <i>p</i> value significant at <0.05. ED=Emergency department.				

### **5.9 Post-intervention behaviours among the study cohort**

Using a chi-square test, the impact of the intervention on behavioural responses to ACS symptoms was tested as follows: 1) use of ambulance; 2) consultation with a GP; 3) notification of another person about symptoms; and 4) use of prescribed nitrates. There was no significant difference in the use of ambulance

(Chi-square,  $p=0.51$ ) or nitrates (Chi-square,  $p=0.06$ ) between the control and intervention groups following the intervention (Table 8).

There was a significantly lower rate of consultation with a GP before attending the ED among those assigned to the intervention group, compared to the control group (Chi-square,  $p=0.02$ ). Furthermore, a significantly greater proportion of participants assigned to the intervention group reported their symptoms to another individual (Chi-square,  $p=0.01$ ). Table 8 illustrates the study cohort's post-intervention behavioural responses to symptoms. The secondary study hypothesis was not accepted, as the observed differences could not be attributed to the intervention.

**Table 8. Impact of the intervention on pre-hospital behaviours**

<b>Pre-hospital behaviour.</b>	<b>N=314 N (%)</b>	<b>Intervention group (n= 177) n (%)</b>	<b>Control group (n=137) n (%)</b>	<b><i>p</i>*</b>
Used ambulance as mode of transport to get to ED.	123 (39.1)	69 (56.1)	54 (43.9)	0.51
Disclosed symptoms to another person.	178 (56.7)	111 (62.4)	67 (37.6)	0.01*
Consulted with a general practitioner before attending ED.	89 (28.3)	42 (47.2)	47 (52.8)	0.02*
Self-administered nitrates when symptoms occurred.	154 (49.0)	91 (59.1)	63 (40.9)	0.06
Values represent frequencies (percentages). * indicates <i>p</i> value significant at <0.05. ED=Emergency department.				

### 5.10 Summary

The total sample in this study was comprised of the 1,944 participants who had a diagnosis of ACS and a documented pre-hospital delay time. Of these, 972 were randomised to each of the control and intervention groups. The median baseline pre-hospital delay time for the total sample was 4.04 hours (25th



percentile, 1.63; 75th percentile, 18.16 hours). At baseline, there was no significant pre-hospital delay time difference between the control and intervention groups (Mann-Whitney  $U$ ,  $p=0.34$ ) for the total sample.

The term study cohort was used to identify those participants who were readmitted via an ED with ACS symptoms ( $N=314$ ). Of these, there were 137 from the control group and 177 from the intervention group. The level of education attained was the only variable on which the two groups differed significantly. While there was no significant difference between the groups with respect to their baseline pre-hospital delay times (Mann-Whitney  $U$ ,  $p=0.39$ ), there was a significant change in post-intervention pre-hospital delay times between the groups (ANOVA,  $p=0.001$ ). The primary study hypothesis was therefore accepted.

The pre-hospital behaviours of interest were: ambulance use to access the ED, the use of prescribed nitrates, non-consultation with a GP in advance of attending the ED and the notification of another individual about the presence of ACS symptoms. With respect to these behaviours, there were no baseline differences between the control and intervention groups in the total sample. Among the study cohort ( $N=314$ ), there was no pre-intervention difference between the groups in terms of ambulance use or pre-hospital consultation with a GP. However, the intervention group had disclosed the presence of symptoms more promptly than the control group, while the control group had a higher rate of nitrate use.

Following the intervention, in comparison to the control group, the intervention group was less likely to consult with a GP in the presence of symptoms before attending the ED and they reported the presence of ACS symptoms more promptly to another person. There was no significant difference between the groups with respect to the use of nitrates or the uptake of ambulance for transport to the ED. The study results will be contextualised in the discussion, which is presented in Chapter 6.

## **Chapter 6 Discussion**

### **6.1 Introduction**

The purpose of this parallel design RCT was to test the effectiveness of an individualised educational intervention on patient pre-hospital delay time among patients diagnosed with ACS. As its primary hypothesis, the trial tested whether there was a post-intervention difference in patient pre-hospital delay time between those randomly assigned to the control group and those assigned to the intervention group. The secondary hypothesis tested whether following the intervention, the intervention group conformed more readily to the recommended behaviours outlined in the intervention, compared to the control group. The recommended behaviours were: the use of prescribed nitrates for symptom relief; the prompt notification of another person that symptoms were present; the avoidance of consultation with a GP in the presence of ACS symptoms and; the use of an ambulance to access the ED. The primary hypothesis was accepted. The secondary hypothesis was not accepted, but there were some observed changes between the two groups with respect to the recommended behaviours. This chapter discusses the study's results and presents the strengths and weaknesses of this trial. The final section of this chapter will address the potential impact and contribution of this study, together with a conclusion and recommendations for the future.

### **6.2 The primary hypothesis: patient pre-hospital delay time**

The primary hypothesis was accepted in this study, as following the intervention, patient pre-hospital delay time was significantly reduced among the intervention group, compared to the control group. Previous interventions

aimed at reducing patient pre-hospital delay time have been attempted (Ho *et al.* 1989, Moses *et al.* 1991, Bett *et al.* 1993, Blohm *et al.* 1994, Gaspoz *et al.* 1996, Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009, Naegeli *et al.* 2011). Three of these were RCTs and none were effective in reducing pre-hospital delay time. A number of factors may have contributed to the acceptance of the primary hypothesis in this study. These include the sample and sampling approaches, the intervention design, the content of the intervention and the theoretical framework on which the intervention was based.

### **6.2.1 Sample and sampling approaches**

While this RCT was modelled on a previously conducted study (Dracup *et al.* 2006), this study's methodology was original in many respects. To be included in this study, an ACS diagnosis was a pre-requisite. This criterion differed from other delay-time intervention studies in which the samples were known to have ischaemic heart disease (Dracup *et al.* 2006), had a potential ACS diagnosis (Moses *et al.* 1991) or the sample's risk profile status was unknown (Ho *et al.* 1989, Bett *et al.* 1993, Blohm *et al.* 1994, Gaspoz *et al.* 1996, Meischke *et al.* 1997, Luepker *et al.* 2000). The requirement for a definitive ACS diagnosis in this study may have rendered the sample more vulnerable to the recurrence of an ACS event than the samples included in the above studies. Furthermore, in this study, the sample's baseline pre-hospital delay times were measured in addition to post-intervention pre-hospital delay times. This is the first RCT of this kind, where pre-hospital delay data were measured for both groups on both occasions. Dracup *et al.* (2006) measured post-intervention pre-hospital delay times only.

This study was the first RCT in Europe to target patient pre-hospital delay time using an educational intervention. It was also the first RCT to report a successful reduction in patient pre-hospital delay time. Reductions in median pre-hospital delay times were also reported by the other European studies that used an intervention to reduce pre-hospital delay time (Blohm *et al.* 1994, Gaspoz *et al.* 1996). Most prior interventions were conducted outside Europe (Ho *et al.* 1989, Moses *et al.* 1991, Bett *et al.* 1993, Meischke *et al.* 1997, Luepker *et al.* 2000, Dracup *et al.* 2009) and none reported success in reducing pre-hospital delay times. The possibility of cultural influence on the outcomes cannot therefore be overlooked, although the precise cultural mechanism is not readily evident from the sample characteristics.

Consistent with the majority of studies (Dracup *et al.* 2003, Johansson *et al.* 2004a, Ottesen *et al.* 2004, Walsh *et al.* 2004, Fukuoka *et al.* 2005, O' Donnell *et al.* 2006, Thuresson *et al.* 2007, Perkins-Porras *et al.* 2009, DeVon *et al.* 2010, O' Donnell & Moser 2012), participants were recruited to this study and received the intervention within 2-4 days of admission to the hospital. Although nurses often believe that patient education is best given immediately prior to discharge, patients prefer to be educated as close to the event as possible (Tilley *et al.* 1987). Patients are often more amenable to interventions aimed at behavioural change if they are targeted immediately following an illness or health threat, such as a heart attack (Weinman *et al.* 2001, Petrie *et al.* 2002). Furthermore, improved functioning can be expected if negative thinking about myocardial infarction is identified early and resolved using an intervention (Petrie *et al.* 2002). The intervention in this study, which was delivered soon

after the cardiac event, focused on positive reinforcement and the reconciliation of negative responses. Therefore, the timing of intervention delivery may have been a factor in the observed reduction in pre-hospital delay time following the intervention.

### **6.2.2 The intervention design**

This study and one other (Dracup *et al.* 2006) used an individualised approach to intervention delivery. Other previous interventions aimed at reducing pre-hospital delay time were mass media interventions, the majority of which were unsuccessful in reducing pre-hospital delay time. It has been suggested that the use of television for mass media interventions may be ineffective because the majority of people view television for entertainment, not education. Therefore, educational information is likely to attract only a minority of interested viewers (Lau *et al.* 1980). Furthermore, media-driven intervention messages may not be salient for all recipients, while others, for whom the messages are intended, may not assimilate or internalise the information, despite their exposure to it.

In assessing whether mass media interventions play a role in changing how individuals think about health-related activity, Cavill and Bauman (2004) suggested that mass media interventions were likely to increase levels of awareness, although any effect beyond an increased awareness of the intervention message remained unclear. Furthermore, media interventions were not shown to change knowledge, beliefs and understanding (Cavill & Bauman 2004). Baseline data are often not measured in mass media interventions and, where these data are available, the information is often not reported (Cavill & Bauman 2004). In studies where baseline data for the control

and intervention groups is not reported, readers assume that there is equivalence between the groups at baseline (Kahn *et al.* 2002). Such an assumption can be both limiting and erroneous. However, by their nature and design, mass media interventions are often not amenable to the measurement of the baseline and post-intervention data, particularly in the same individuals (Lau *et al.* 1980).

In contrast to mass media targeted interventions, this study used an individualised approach to intervention delivery. In accordance with RCT fidelity and the trial protocol, the intervention content in the study was standardised, but tailored to each individual, their personal context and their literacy level. It has been suggested that although educational interventions are standardised, they should still accommodate each individual's learning literacy level (Dewalt *et al.* 2004, Commodore-Mensah & Dennison-Himmelfarb 2012, Gallagher *et al.* 2013). This approach was adopted in the current intervention. Health behaviour interventions that are tailored to the individual are considered more efficacious than their non-tailored counterparts (Commodore-Mensah & Dennison-Himmelfarb 2012), and have been known to increase the chance of behaviour modification (Lauver *et al.* 2002, Ryan & Lauver 2002, Strecher *et al.* 2002, Alm-Roijer *et al.* 2006, Jensen *et al.* 2009). In comparison to standardised health-related informational interventions, those that were tailored to the individual were read more often, remembered better and discussed more frequently with others (De Vries & Brug 1999, Skinner *et al.* 1999, Ryan & Lauver 2002). It was intended that the intervention in this study would be meaningful and remembered by the participants. The individualisation of the

intervention and the tailoring of the intervention message to each individual may have been a factor in the study's success.

The intervention duration may also have contributed to the success of this study. This is an important aspect of intervention delivery, as participants' intervention uptake can decrease if an intervention is too demanding of time or effort (Conn *et al.* 2001, Aranda 2008). The need for researchers to be cognisant of the burden of interventions on participants has been highlighted previously (Cleary *et al.* 2012). An intervention dose of one hour is considered compatible with a busy healthcare environment and could be replicated clinically (Cleary *et al.* 2012). The intervention in this study was less than one hour duration. This indicates that it was possibly not over-burdensome on participants, which may have enhanced their uptake of the content.

### **6.2.3 The intervention content**

The study cohort differed significantly from those who were not readmitted with respect to their cardiac history. Significantly more (Chi-square,  $p=0.01$ ) of the study cohort had previous histories of angina, MI, PCI and CABG. It was likely that their previous history of cardiac events increased their predisposition to further events and readmission, as was observed in this study. Individuals tend to be generally unaware of their risk for cardiovascular disease (Mosca *et al.* 2005, Jensen *et al.* 2009). Consequently, as a component of this intervention, participants were gently but clearly informed that they were at risk for a further cardiac event. This message was important, given that high risk individuals often under-estimate or reject their risk status for a cardiac event and are therefore less likely to alter their health behaviours (Chapman *et al.* 1993,



Weinstein & Klein 1995, Ayanian & Cleary 1999, Weinstein 1999). In this study, the descriptions of usual care did not routinely include discussions with patients about future health risks for ACS. This might be explained by the relatively short hospitalisation period following a cardiac event, which limits the time available to health professionals to support and educate patients (Timmins 2005, Fernandez *et al.* 2006 Commodore-Mensah & Dennison-Himmelfarb 2012). However, an accurate risk-perception is important in shaping responses in the face of health threats (Furze *et al.* 2003, Smith *et al.* 2006).

From a patient's perspective, the brevity of hospital stay following an ACS event could be interpreted by them as a sign of a less serious illness than some other conditions. In addition, revascularisation using PCI must seem like a relatively simple procedure when compared to the more invasive and traumatic conventional CABG procedure (Holmboe *et al.* 2000, Shirai *et al.* 2004). Furthermore, the perception of 'being cured' following an intervention is not uncommon (Eastwood 2001). These indicators provide plausible explanations for any low-risk perceptions held by individuals, and the consequent belief that an ACS event does not necessarily pose a future threat. In this study, misperceptions were rectified and reconciled with the message that the participant was at risk of another event. The emphasis on the potential for event recurrence may have resulted in a greater uptake and internalisation of the intervention by the intervention group in the short term and possibly beyond.

While an acknowledgement of the risk for future events was a component of the intervention, it was intended not to cause participants unnecessary anxiety.

This was important, as individuals who over-estimate their health-risk can become anxious and tend to over-use medical facilities (Kreuter & Strecher 1995). Furthermore, patients can hesitate in seeking help and subsequently delay longer if they experience excess fear (Burgess *et al.* 2001, Sullivan *et al.* 2009). To date, four studies have addressed the role of the intensity of fear on patients' delay in relation to acute MI (Dracup & Moser 1997, McKinley *et al.* 2000, Kentsch *et al.* 2002, Moser *et al.* 2005). From these, it has been established that fear prolongs patient-delay, although the reverse occurs in the presence of panic and anxiety (Khraim *et al.* 2009, Dubayova *et al.* 2010). This finding that people who are more anxious delay less has also been reported in other contexts (O' Mahony & Hegarty 2009). In this study, there was no significant difference in the rate of readmission between the control and intervention groups who were diagnosed with ACS (Chi-square,  $p=0.17$ ). This infers that the intervention group did not over-estimate their risk. While the intervention content highlighted future risk possibilities, it also equipped participants to deal with future symptoms through the use of the individualised scenario rehearsal and the development of the action plan. This may have reduced the likelihood of the intervention group over-reacting to symptoms following the intervention.

In addition to the emphasis on risk perception, the potential for symptom variability on a subsequent occasion was also emphasised in this study during the intervention. Researchers have reported that delay-time is increased among individuals whose symptoms are incongruent with their expectations (Zerwic 1998, Horne *et al.* 2000, Nymark *et al.* 2009, Fox-Wasylyshyn *et al.* 2010, O'

Donnell & Moser 2012). Likewise, the interpretation of symptoms as serious or of cardiac origin is consistently associated with reduced pre-hospital delay times (Johansson *et al.* 2004a, Herlitz *et al.* 2010a, Vavouranakis *et al.* 2010, McKee *et al.* 2013). The necessity to provide the public with accurate information about the constellation and significance of symptoms that can arise with ACS has been highlighted previously (Sjostrom-Strand & Fridlund 2008, Herlitz *et al.* 2010a, Farquharson *et al.* 2012, O' Donnell & Moser 2012). In this study, the range and potential variation of symptoms, their significance and their management was addressed. When people make appropriate matches of symptoms to their representations of illness they may seek treatment more promptly and demonstrate effective follow-through, whereas improper match of symptoms to illness conceptions can account for delay behaviour (Turk *et al.* 1984, Baumann & Leventhal 1985, Taylor 1990). These factors may have influenced the acceptance of the primary hypothesis, as the intervention group sought help more rapidly for their symptoms, which were outlined in the intervention.

Patients who display greater levels of cardiac denial have longer pre-hospital delays (Buckley *et al.* 2007, Perkins-Porras *et al.* 2008). Information on the role of cardiac denial and its association with extended pre-hospital delay times may have been a factor in reducing patient pre-hospital delay time in this study. It has been suggested that greater cardiac-denial may be linked with an underlying sense of invulnerability (Fowers 1992). Participants in this study were deprived of the opportunity to deny their vulnerability, as their ACS diagnosis was clearly established and incorporated into their intervention. This

too may have been a factor in the effectiveness of the intervention in reducing patient pre-hospital delay time among the intervention group.

Dracup *et al.* (2009), who reported no reduction in pre-hospital delay time among their intervention group, also used these same key intervention messages about cardiac denial (Dracup *et al.* 2006). However, its application may have differed between their study and this one. In this present study, symptom denial could be placed in context for all participants, as each of them had recently experienced a cardiac event. Their recent experience of the event enabled them to relate to symptom denial, as was discussed in the intervention. While all participants in the study by Dracup *et al.* (2006) had a diagnosis of ischaemic heart disease, some had never experienced a cardiac event. In the absence of personal experience, symptom denial may have been less realistic for these participants.

In the current study, participants randomised to the control group had extended pre-hospital delay times when they were readmitted with ACS symptoms. Although this finding may seem paradoxical, it is not unique. It has been well-established that a prior myocardial infarction does not necessarily increase the capacity to seek treatment, but may in fact prolong this process on a subsequent occasion (Dracup & Moser 1997, Goldberg *et al.* 2002, Finn *et al.* 2007, Dracup *et al.* 2009). While the rationale for this is unclear, it has been suggested that a dissonance between symptom expectation and experience, taking and awaiting the effects of analgesia and cardiac denial prolong patients'

pre-hospital delay times (Johnson & King 1995, Thuresson *et al.* 2007, Gartner *et al.* 2008, Perkins-Porras *et al.* 2008, O' Donnell & Moser 2012).

An understanding of attachment theory (Ciechanowski *et al.* 2002) could provide an explanation for the extended pre-hospital delay time among the control group in this study. Attachment theory is a model that outlines attachment styles. These styles determine whether or not individuals deem themselves worthy of care and whether they view others sufficiently trust-worthy to provide that care, particularly in times of crisis. They are referred to as models of self and models of others, respectively. According to the theory, a negative model of self is associated with anxiety and feelings of low self-worth, while a negative model of others is associated with limited trust in others and poor collaboration (Ciechanowski *et al.* 2002). In testing this theory, patients with low trust in others reported a greater intention to delay seeking care for possible ACS symptoms (Sullivan *et al.* 2009). During the intervention in the present study, time was devoted to reconciling past negative experiences or issues that may have caused distrust of personnel or services, in the face of ACS. This included ambulance and hospital services. This may have helped to shorten the intervention group's pre-hospital delay time on readmission. The prolonged pre-hospital delay time by the control group may have been related to unresolved issues related to their original event.

The use of motivational interviewing principles may also have influenced the success of the intervention in reducing patient pre-hospital delay time. Although motivational interviewing techniques were also used during the counselling

session by Dracup *et al.* (2006), participants may have been more readily able to recognise the need for change in the present study, where the risks for future cardiac events were openly discussed and recognised. Accordingly, the beneficial effects of motivational interviewing may be reaped to a greater extent where the need to initiate and maintain a behavioural change is identified.

During this study, the principles of motivational interviewing were contextualised. Participants' experiences were drawn on in the expression of empathy. Reflective listening was used to identify participants' objections to aspects of the intervention. In this study, objections were normally related to the participants' personal experiences of their ACS event. In the absence of such experience, the principles of motivational interviewing may have been less salient for participants. Motivational interviewing has also been used in other studies (Eppler *et al.* 1994, Blohm *et al.* 1996), one of which also reported a reduction in pre-hospital delay time (Blohm *et al.* 1994).

#### **6.2.4 The theoretical framework**

The use of the theoretical framework on which the intervention was based in this study may have been influential in the acceptance of the primary hypothesis. The intervention was based on Leventhal's self-regulatory model of illness behaviour (Leventhal *et al.* 1980, Leventhal *et al.* 1983, Leventhal & Cameron 1987). Standard patient education following myocardial infarction tends not to be theoretically based and can be ambiguous and inconsistent (Petrie *et al.* 2002, Timmins 2005). In the descriptions of usual care in this study, there was a relative absence of assessment of individual goal-setting,

absence of assessment of illness representations and an absence of assessment of responses to health threats. These were included as part of the intervention, which the intervention group received, in addition to usual care. This receipt of theoretically-based education differentiated the control and intervention groups. Theoretically based education is considered superior to a non-theory based equivalent (Hafner & Kirscht 1970, Petrie *et al.* 2002), as education based on theoretical models is considered to be both important and effective (Coates 1999, Cleary & Hegarty 2011).

It has been suggested that with respect to patient education, the use of appropriate teaching skills may be more useful than simply imparting knowledge (Dickson & Riegel 2009). In addition to helping patients learn, theoretical models of health behaviour can also help clinicians, as they can assist with understanding patient behaviour (Taylor 1990, Petrie *et al.* 2002). If ACS-related patient education was based on a self-regulatory model, this would enable nurses to assist patients to adopt positive self-regulatory health behaviours in the presence of symptoms (Petrie *et al.* 2002). Their contribution is important to patient education, as the literature suggests that there is a need for nurses to move beyond formally planned teaching and information-giving to assisting patients with coping with their illness (Benner 1984, Timmins 2005). Leventhal's self-regulatory model of illness behaviour is one means by which all patients could be assisted with coping in the face of a health threat.

Leventhal's self-regulatory model of illness behaviour addressed conceptual issues, particularly with respect to symptoms and reactions to symptoms. The

intervention addressed risk perception, illness representations, goal-setting, devising action plans and the assessment of coping. These strategies are important to the self-regulatory process in illness (Maes & Karoly 2005, Scott *et al.* 2013). The theoretical base and the inclusion of these important principles may have contributed to the observed outcomes of the intervention.

Leventhal's self-regulatory model of illness behaviour is similar to other problem-solving theories, wherein illness is conceptualised as a stressful event (Lazarus & Folkman 1984, Hale *et al.* 2007). However, the model differs from most, in so far as it provides an explicit link between illness cognitions and coping behaviours and strategies (Leventhal *et al.* 1980, Hagger & Orbell 2003). The use of conceptualisation during patient education sessions can help the individual to visualise similarities between past and current experiences and provides a benchmark for current symptoms as signals for other symptoms (Dracup *et al.* 1995, Bunde & Martin 2006). The inclusion of familiar and unfamiliar concepts during an intervention could enable participants to envisage the regulation of their behaviour in line with the expectations that are associated with the abstract notion of a heart attack (Leventhal *et al.* 2008). This was the case in the current study, where the range of possible symptoms and responses to them were explored and discussed.

Leventhal's self-regulatory model of illness behaviour delineates the active parallel cognitive processing of how individuals regulate illness responses to the regulation of emotional control (Hale *et al.* 2007). Consequently, when this model was applied to the current study, the participants were asked to



objectively consider the nature of the posed health threat and, what could be done about it. They were also asked to consider, from an emotional perspective, how they felt about the threat and what could be done to make themselves feel better about it. To address the cognitive and emotional processes in this way was important for the current study, where in the presence of ACS symptoms, emotions could be integrated with existing schema to enable the individual to make sense of the symptoms and guide future coping mechanisms.

With respect to goals and intentions, Leventhal's self-regulatory model of illness behaviour advocates that each individual's personal goals should be set by the individual and not for them. Furthermore, each individual's goals should be accounted for (Maes & Karoly 2005). Consistent with this, as part of the intervention, participants from the intervention group in this study were involved in setting their own goals. This meant that their goals were meaningful and congruent with their personalised action plan. This may have contributed to their acceptance of the main intervention message, which was not to delay in the presence of ACS symptoms. Unlike most health behaviour models, Leventhal's self-regulatory model of illness behaviour casts goal achievement as a process, rather than an event (Maes & Karoly 2005). The on-going pursuit of goals was addressed in the follow-up aspect of the intervention. This was important, as participants could potentially develop symptoms at any time following the delivery of the intervention.

### **6.3 The secondary hypothesis: patient pre-hospital behaviours**

The educational intervention was designed to reduce patient pre-hospital delay time, in part by effecting behaviour in the presence of unresolved ACS symptoms. Participants were advised to use prescribed nitrates if they were available, to alert another person that symptoms were present, to avoid consultation with a GP in the presence of symptoms and to use an ambulance to access the ED. In this study, the intervention group informed another person more promptly about their symptoms and consulted less frequently with a GP before attending the ED. However, there was no significant post-intervention change in ambulance use and prescribed nitrate use among the intervention group and no significant change between the groups. These issues are further discussed here.

#### **6.3.1 Nitrate use**

Participants in this study were advised that prescribed nitrates were the medication of choice to treat and differentiate ACS symptoms. Despite this advice, the post-intervention use of prescribed nitrates to relieve ACS symptoms was not significantly different between the groups (Chi-square,  $p=0.06$ ). Although little research has been conducted into the association between self-administered nitrates and pre-hospital delay time, it has been recognised that an initial response to a health emergency is to self-medicate (Archer *et al.* 2008). The use of nitrates or no medications in the presence of ACS symptoms has been independently associated with shorter pre-hospital delay time (McKee *et al.* 2013). Conversely, the use of general medications in the self-treatment of symptoms has been identified as a factor that prolongs seeking treatment for symptoms (Thuresson *et al.* 2007, McKee *et al.* 2013).

There are three possible explanations for the unchanged post-intervention use of nitrates among the intervention group. Firstly, the majority of participants from both groups had prescribed nitrates available to them, as these are generally prescribed for all patients with ACS before discharge. Secondly, as a component of usual care, information about medications in general, and about nitrates in particular, was imparted to both groups. Therefore, participants from both groups received instruction about where, when and how to use nitrates. Consequently, nitrate use increased in both groups following the intervention.

The third possible explanation for the lack of observed difference between the groups with respect to nitrate use relates to group assignment. In the study, participants in the intervention group were instructed not to delay in attending the ED if they had unresolved symptoms. Perhaps in the face of symptoms, these individuals viewed ED attendance to be of greater importance than any interim measure, such as using prescribed nitrates. Meanwhile, those assigned to the control group may have considered that ED attendance was an option only after they had exhausted all other measures to control symptoms. Furthermore, the use of nitrates can lessen the symptoms and contribute to the belief that symptoms are resolving, thereby extending the time to seeking treatment (Pattenden *et al.* 2002). This may have been a factor for the control group in this study. The published literature on pre-hospital delay suggests that the use of nitrates can predispose patients to increased delay, as they often use nitrates in an attempt to distinguish between ACS and non-ACS symptoms, before making a decision to seek treatment (Sheifer *et al.* 2000, Johansson *et al.* 2004a, McGinn *et al.* 2005, Xanthos *et al.* 2010). While there was no

statistically significant difference between the intervention and control groups with respect to nitrate use following the intervention, the use of nitrates almost doubled among the intervention group. This increase was not so remarkable among the control group. However, it is not possible to establish whether this change was attributable to the intervention or to usual care. With respect to nitrate use, the secondary hypothesis was not accepted.

### **6.3.2 Disclosure of symptoms**

The disclosure of symptoms to another person has been shown to impact positively on help seeking behaviour in ACS and other contexts (Johansson *et al.* 2004a, Herlitz *et al.* 2010a, O'Mahony *et al.* 2011). In this study, participants in the intervention group were asked to identify and nominate an individual to whom they would disclose the presence of symptoms if they had another ACS event. It was recommended that the presence of unresolving ACS symptoms be disclosed promptly to another individual. Consistent with these recommendations, significantly more participants from the intervention group disclosed their symptoms to another individual within half an hour of onset (Chi-square,  $p=0.01$ ). However, prior to the intervention, significantly more participants from the intervention group had disclosed their symptoms to another individual within this time frame (Chi-square,  $p=0.03$ ). Therefore, the intervention may not have been the factor in the observed behavioural change. Nevertheless, there are possible reasons for the post-intervention finding that significantly more participants from the intervention group disclosed the presence of symptoms within thirty minutes of symptom onset.

Consultation with a lay individual is common in the presence of ACS symptoms and frequently it is the lay individual that contacts the emergency services (Banks & Dracup 2006, Løvlien *et al.* 2007, Thuresson *et al.* 2007, Løvlien *et al.* 2008, Goldberg *et al.* 2009, Khraim & Carey 2009). Notifying somebody about symptoms has been shown to shorten pre-hospital delay time (Kentsch *et al.* 2002, Thuresson *et al.* 2007). Likewise, non-disclosure of symptoms to another person has been found to prolong seeking medical care (Meischke *et al.* 1995a, Lockyer 2005, MacInnes 2006). Some authors suggest that the presence of another individual has no impact on pre-hospital delay time (McKinley *et al.* 2004, Moser *et al.* 2005, Noureddine *et al.* 2006). However, being physically present during symptoms is not the same thing as being notified about symptoms. The disclosure of the presence of symptoms was the issue of importance in this study and it was envisaged that the deputised individual would promote prompt care-seeking decisions. Participants adhered well to this component of the intervention. The inclusion of the deputised individual on the action plan may have prompted the intervention group to notify their chosen individual.

### **6.3.3 General practitioner consultation**

As a component of the intervention, participants in this study were asked to avoid consultation with a GP in the presence of unresolved symptoms. The study findings suggest that those in the intervention group acted on this advice. Significantly more participants from the intervention group accessed the ED directly and consequently, they also had shorter pre-hospital delay times. As this message was not reported to be a component of 'usual care' by the health

service providers, it is reasonable to suggest that the difference was due to the intervention.

In the study, significantly more participants from the control group ( $p=0.02$ ) consulted with a GP prior to attending the ED. The literature suggests that reasons for GP consultation include not feeling sufficiently unwell to attend the ED (Lozzi *et al.* 2005) and the need for sanction by a GP that ED attendance is genuinely warranted (Pattenden *et al.* 2002). Furthermore, many individuals assume that a review by a GP is the correct course of action (Pattenden *et al.* 2002) in the presence of ACS symptoms and that GP services are faster and more accessible than ED services (Leslie *et al.* 2000, Ruston 2001, Dracup *et al.* 2006, Alonzo 2007). Misconceptions such as these were clarified for the intervention group in this study, and this aspect of the intervention may explain the overall observed reduction in GP consultation.

Over the past decade in Ireland, much media attention has been directed at coverage concerning the pressures that are exerted on ED services and such concerns are reflected throughout Western society (Philips *et al.* 2010). In light of this, it is possible that those participants in the control group in this study may have been deterred from using ED services without the sanction to do so from their GP. In the study, participants from the intervention group were provided with clear information about when and by which mode of transport they should attend the ED. This may have eliminated any ambiguity about what exactly constitutes an emergency and the need to attend an ED.

The literature suggests that there is a disparity between patients and clinical staff with respect to their perceptions of what would be interpreted as an emergency (Lowe & Bindman 1997, Callen *et al.* 2008). While clarification on this matter was provided for those in the intervention group, the control group did not receive precise information in this regard. Consequently more of the control group participants may have felt compelled to seek sanction from their GP in the first instance. However, people who opt for GP consultation are subjected to increased pre-hospital delays (Johansson *et al.* 2004a, O' Donnell *et al.* 2006, Alonzo 2007, Løvlien *et al.* 2007, McKee *et al.* 2013). This may be another factor in the extended pre-hospital delay time observed in the control group in this study.

#### **6.3.4 Ambulance Use**

In this study less than 40% of participants in both groups used an ambulance to access the ED on readmission. This post-intervention lack of observed behavioural change with respect to ambulance use is not easily explained. The importance of ambulance use as a significant component of reduction in pre-hospital delay time was emphasised during the intervention and has been highlighted previously (Luepker *et al.* 2000, Johansson *et al.* 2004a, Kerr *et al.* 2006, O' Donnell *et al.* 2006, Dracup *et al.* 2009, Perkins-Porras *et al.* 2009, Steg *et al.* 2012). Yet, there was no significant difference between the control and intervention groups with respect to this variable ( $p=0.51$ ) This is noteworthy, given that patients with myocardial infarction who use the EMS ambulance to access the ED have shorter pre-hospital delay times (Johansson *et al.* 2004a, Kerr *et al.* 2006, Perkins-Porras *et al.* 2009, McKee *et al.* 2013).

The reticence by individuals with ACS to use the emergency services as a means of transport has been reported in other studies (Eppler *et al.* 1994, Pattenden *et al.* 2002, McGinn *et al.* 2005, Thuresson *et al.* 2007, Dracup *et al.* 2009, Coventry *et al.* 2013). Ambulance use rates vary, with some researchers reporting this rate at 50% or less (Meischke *et al.* 1993, Meischke *et al.* 1995a, Hedges *et al.* 2000, Srivastava & Canto 2003, Kerr *et al.* 2006, Widimsky *et al.* 2010). Yet, others have reported higher rates of ambulance use (Johansson *et al.* 2004b, Widimsky *et al.* 2010, Mathews *et al.* 2011, Coventry *et al.* 2013). With specific reference to patients in Europe, only about half of those with STE-ACS use the ambulance to access the hospital. However, there is a wide variation between countries with figures for ambulance use for this group ranging from 17% in Greece to 85% in the United Kingdom (Dracup *et al.* 2003, Widimsky *et al.* 2010).

There is inconsistency between studies with respect to the factors that influence ambulance use. Consequently, consensus has not been reached regarding which variables are truly influential. Although there are variations between studies with respect to their methodological approaches to ascertain this information, there are also wide variations within and between countries that regulate ambulance use. For example, some regions restrict direct summoning of an ambulance without prior medical assessment (Vavouranakis *et al.* 2010), while in other areas there are costs associated with ambulance use (Siepmann *et al.* 2000, Lozzi *et al.* 2005, Mathews *et al.* 2011). Such regional variations can make it more difficult to make comparisons between countries and to draw subsequent conclusions. Cost and regulation are unlikely explanations for the



rate of ambulance use found in this study, as ambulance use is unrestricted and cost-free in Ireland.

Symptom severity is thought to be a considerable factor in the decision to use an ambulance. This may have been a factor in this study. It has been shown that patients will call an ambulance if they feel sufficiently unwell and feel that their symptoms warrant this recourse (Lozzi *et al.* 2005, Thuresson *et al.* 2008, Herlitz *et al.* 2010a). Consequently, those whose symptoms are sudden, severe and continuous are reportedly more likely to use an ambulance than those whose symptoms are gradual and insidious (Meischke *et al.* 1995b, Johansson *et al.* 2004a, Thuresson *et al.* 2007, O' Donnell & Moser 2012). In this study, only 10.8% of those re-admitted were diagnosed with a myocardial infarction, while almost 90% were readmitted with another diagnosis, including unstable angina. Angina symptoms tend to be more gradual, intermittent and less intense than those of an MI, while symptoms that are non-ACS related could be even less pronounced. This fact could explain the failure by participants in both groups to use an ambulance to access the ED.

The failure by both groups, particularly the intervention group, to use the ambulance gives rise to concern for health systems that aim to obtain optimal patient outcomes from treatment. Researchers have reported that patients fail to call an ambulance because of a lack of awareness of the benefits of EMS use (Johansson *et al.* 2004b, Johansson *et al.* 2008, Sullivan *et al.* 2009, Mathews *et al.* 2011). The benefits of EMS ambulance use in many European countries include improvements in triage, with a subsequent reduction of in-

hospital delay, recording, interpretation and transmitting of ECGs by ambulance personnel, the potential to start reperfusion on the scene and immediate transfer to a PCI centre (Curtis *et al.* 2006, Herlitz *et al.* 2010b). The benefits of ambulance use were discussed during the intervention in this study.

Countries vary considerably in the role and services that they offer through their EMS ambulance services (Widimsky *et al.* 2010). Some countries have doctors assigned to their ambulances and to the ambulance control room. In other countries, ambulance personnel are trained paramedics or emergency technicians who work within defined protocols (Quinn *et al.* 2002, Tubaro *et al.* 2011). The importance of ambulance use was included in the intervention, but many of the aforementioned services, which are available in other European countries, were not established in Ireland at the time of the study. Participants in both groups may perceive that in Ireland, the level of pre-hospital services offered by ambulance personnel are relatively limited, compared to other countries.

#### **6.4 Summary**

This study was the first European RCT to target and successfully reduce patient pre-hospital delay time. The study's primary hypothesis was accepted, while the secondary hypothesis was not fully accepted. The intervention replicated a previously developed intervention, but the study was original in many respects. The acceptance of the primary hypothesis may be attributable to a number of factors, including the sample and sampling criteria, the theoretical framework the intervention design and the intervention content. The high risk sample may have been a particularly important factor in this study. This, together with the

emphasis on future risk and coping with ACS symptoms, may have enhanced the internalisation of the intervention messages. Conversely, the control group's extended delay may have been attributed to a low risk perception, cardiac denial or a dissonance between symptom experience and expectation.

The use of Leventhal's theoretically-based self-regulatory model of illness behaviour may have made a substantial contribution to the successful outcomes of the study. Theoretically-based education is considered more effective than non-theory based education. Health psychology literature supports the need to translate self-regulation theory into action in clinical areas to support patients with self-regulation in health behaviour. The outcomes from this study support the suggestion that patients could benefit from information on self-regulation in the face of a health threat. Theoretical and conceptual frameworks from health psychology have made substantial contributions to the understanding and explanation of human behaviour in health and illness. In their absence, human behaviour in health and illness might not be easily understood. On the other hand, their adoption in the clinical arena could enhance the nurse-patient relationship with respect to mutual understanding in areas such as assessment of illness representation, goal setting and facilitating patient teaching.

There were observed changes with respect to pre-hospital behaviours following the intervention. However, these could not be attributed to the intervention alone. The only intervention-related behaviour that might be attributed to the intervention was non-consultation with a GP. Significantly more participants

from the intervention group followed the advice given in the intervention and went directly to an ED without accessing the GP. The finding that nitrate use was no different between the groups after the intervention points to uniformity of care received by the control and intervention groups in the research sites. Information on nitrate-use in symptom management was a component of usual care, which both groups received. The limited use of ambulance before and following the intervention is a cause for concern. The lack of appreciation of the necessity for emergency services use was evidenced in the study's results and supported by the literature. Perceptions such as these may somewhat explain the post-intervention behaviours with respect to ambulance use in Ireland.

## **6.5 Study limitations and strengths**

While there were many strengths associated with this study, some limitations were also identified. The study limitations are initially presented below, followed by an overview of the strengths of the study and the contribution it makes to nursing and society.

### **6.5.1 Study limitations**

The primary aim of this study was to reduce patient pre-hospital delay time in the presence of ACS symptoms. Therefore, the accurate measurement of pre-hospital delay time was central to the study's results. There was no pre-hospital delay time documented on three participants and this data was not available retrospectively. Consequently, three otherwise eligible participants were removed from the analyses.

With respect to all those participants on whom a pre-hospital delay time was available, efforts were made to deduce the exact time of their symptom onset.

However, there was no definitive way of being absolutely certain that symptom onset was at the exact time reported by participants.

Participants who were clinically unstable were excluded from this trial; hence it was not possible to study the potential impact of the intervention on this cohort of individuals.

There is limited information on the 2% of patients who died during the study. Of these, a small percentage died outside the research sites and in these cases, the cause of death was unknown. If these participants died from an ACS related event, their pre-hospital delay times were missed.

As 96% of the study sample was Irish, and if culture played a major role in acceptance and uptake of the intervention, then it is not possible to generalise the study findings to other cultures. While this study included participants who lived anywhere in Ireland and beyond, the study was conducted in five urban hospitals. The effectiveness of the intervention may vary if it was carried out in rural hospitals. Therefore, the findings may not be generalisable to rural settings.

Regarding fidelity of the interventionist to the intervention, it has been recommended that the delivery of the intervention be observed or recorded. This procedure was not executed in this study. However, this may have been worth considering to assess the consistency of intervention delivery across research sites and to help identify drift in skills.

The intervention was generally delivered in a day room or a designated room. When this was not possible, the intervention was delivered at the participant's bedside. This meant that there was a possibility that some participants assigned to the control group may have over-heard parts of the intervention. Furthermore, participants from the intervention group may have shared components of the educational intervention with their control-group counterparts.

As an educational intervention, the study necessitates on-going provision, emphasis and follow-up, to be deemed wholly successful as an intervention in the long term.

### **6.5.2 Study strengths**

This was a large, methodologically sound, robust study that was well-conducted using an RCT. The study, which was nursing-based, was conducted over a three year period, comprised a large sample size and spanned five separate research sites. The RCT was original in that baseline and post-intervention pre-hospital delay time data were collected and measured for the control and intervention groups. Post-intervention data were collected for a minimum of one year and a maximum of two years. From a European perspective, this was the first RCT to target a reduction in patient pre-hospital delay time. Furthermore, it was the first RCT in the world to be effective in this regard. Therefore, this study makes a major contribution of the body of existing knowledge about pre-hospital delay time. It can also pave the way for changes to nursing practice with respect to the content and delivery of usual care.

## **6.6 Contribution of this study to health, social and economic gain**

This study has the potential to offer considerable benefits in terms of health, social and economic gain. Although health and social gain per se are not directly measurable, quality-adjusted life years and reductions in morbidity are two possible means by which the impact of research can be measured in the short and long term. Health gain is concerned with health status, in terms of both increasing life expectancy and improving the quality of life, while social gain is concerned with broader issues surrounding quality of life (Department of Health and Children 1994, Health Service Executive 2012b).

This study demonstrated that the intervention significantly reduced pre-hospital delay time in the presence of ACS, thereby optimising the timely receipt of treatment. The advantages of timely treatment in patients with ACS include reduced ischaemia, improved prognosis and reductions in mortality and morbidity. At the time of writing, the beneficiaries of this intervention were those participants who received it. However, receipt of this intervention could potentially alter the quality of life for all who receive it. The study outcomes signal the need for this intervention to be incorporated into a component of usual care in the future. The need to implement effective interventions in nursing has been highlighted, as has the need to provide patients with appropriate information (Strömberg 2007, Cleary *et al.* 2012). While outside the remit of the present study, these aspects of health and social gain could be further explored.

In addition to health and social gain, there may be broader economic and social benefits to this study. From a fiscal perspective, the implementation of this intervention could offer direct savings to the Irish health sector. Timely treatment in the presence of ACS would culminate in a relatively healthier society, with reduced expenditure across a range of areas in the health system. Disability and morbidity associated with myocardial damage places unnecessary burden on the individual and on the healthcare system on which they become reliant for care. A reduced burden of ill-health would impact from micro to macro level. At micro level, patients would, for example have increased longevity with a better quality of life. At macro level, cost savings would be made through, among other things, reduced hospital stays, reduced incidence of hospital acquired infection and increased potential for hospital turnover. In addition to an intrinsically improved lifestyle, this intervention could culminate in a healthier, more able-bodied workforce with a greater propensity to contribute more, for longer, towards the economy. From the perspective of clinicians and healthcare stakeholders, the rewards of timely and effective treatments would be reflected in positive patient outcomes.

While there is some ambiguity about whose role it is to implement research into practice, a joint responsibility for this process has been suggested (Strömberg 2007). With respect to this study, it is anticipated that implementation of the intervention may be met with limited resistance, as the nurses were aware of the study and witnessed the intervention being clinically tested. It is anticipated that this may engender interest and positive attitudes among nurses towards clinical research. One of the primary aims of the Health Research Board in



Ireland is to increase the number of clinicians and health professionals involved in conducting research (Health Research Board 2009). The generation of nurses' interest in interventional research may translate into major contributions to health gain in the future. Meanwhile, in the short term and beyond, it is anticipated that the translation of this intervention into practice will contribute to clinical effectiveness and improved patient care.

### **6.7 Study conclusion and recommendations**

Individuals who survive myocardial infarction or an acute angina attack are likely to sustain a further event in the future. Further events include myocardial infarction, re-infarction or a complication of infarction (Department of Health and Children 1999). However, ACS diagnosis typology cannot be differentiated by symptoms alone, and medical contact is necessary to verify a diagnosis. Until a diagnosis is attained, pre-hospital delay time is an important factor for all patients with ACS symptoms. Most previous interventions have been unsuccessful in reducing pre-hospital delay time. However, this RCT demonstrated that using an individualised educational intervention, patient pre-hospital delay time can be reduced.

This intervention has the potential to bring about change initiatives in areas of nursing research, nursing practice and health policy. It will pave the way for amendments to what constitutes usual care, with particular respect to the provision of focused patient education. Furthermore, this intervention can protect health, through reducing mortality and morbidity. Consequently, health resources and fiscal savings can ensue, with a net contribution to increased quality of life and a reduction in the burden of ill-health. This study, and the

literature that informed it, indicate that individuals at risk of ACS are likely to be the greatest beneficiaries of delay-reducing interventions. Based on this study, and its possible implications, the following recommendations are made for future research and practice.

The principal recommendation of this RCT, relates to its effectiveness. As the intervention was shown to be effective, it should ideally be offered to all patients who are diagnosed with ACS and admitted via an ED with symptoms. This could be achieved through the incorporation of the intervention into usual care. Participants in this study were made aware of the extent of their risk and vulnerability for a future cardiac event. This information does not appear to have been highlighted in most previous interventions. While hearing and accepting this information may be objectionable, it is important that all patients are assisted in understanding their potential to develop future symptoms.

If, due to limited resources, or other restrictions this exact educational intervention could not be offered to all patients diagnosed with ACS, then the cognitive, social and emotional factors that influence patient pre-hospital delay should be included as part of usual pre-discharge patient education.

In this study, participants were often reluctant to phone for an ambulance. However, since September 2012, primary PCI centres have been established. This has changed the course of management of all patients with ACS in Irish EDs. The main change relates to the automatic transfer of patients diagnosed with MI to a PCI centre. It is therefore recommended that the general public be made aware of the establishment of these centres and the likelihood of transfer to a PCI centre, by ambulance, irrespective of their original mode of transport to

the ED. This may help to promote ambulance use. There is a need for additional, relevant research, which focuses on the promotion of ambulance use and how to promote its use in the presence of ACS.

The incongruence between symptom expectation and reality arose in the literature as an important factor with respect to ambulance use. In light of this, it is recommended that educational messages about the range of potential symptoms be disseminated beyond those who have been diagnosed with ACS. This would contribute towards informing those who are presenting for the first time with this condition.

In keeping with the theme of symptom significance, the general public should receive clarity about the role of the ED and its service availability. The inability of EDs to cope with ever increasing numbers of admissions is regularly highlighted in the media in Ireland. Individuals may therefore feel reluctant to attend the ED in an effort not to impose further burden on these services. This may arise particularly where symptom origin is uncertain. It is recommended therefore, that the public be made aware of the need to attend an ED in the presence of ACS symptoms. This would provide clarity and help prevent the dissemination of mixed messages, particularly if this intervention is offered to all ACS patients in the future.

As the vast majority of the sample in this study was Irish, it is recommended that this study be replicated in other countries, to test its effectiveness in other cultures. Furthermore, this study was confined to urban hospitals in Dublin. It is also recommended that the study be replicated in Irish rural hospitals to determine its effectiveness.

The use of motivational interviewing principles during the intervention may have been a factor in this study's success. As a means of coaching and information dissemination, motivational interviewing is gaining credence. Furthermore, it is recommended that nurses be taught about the role of self-regulation in illness behaviour and the use of frameworks to assist patients to deal with health threats. Given the success of this intervention and the growing level of appreciation of theory-based patient education and motivational interviewing, it is recommended that these elements be used more frequently by nurses. These could be used in health promotion as well as patient education. At present, these are not essential components of undergraduate or post-graduate nursing education, but their incorporation into nursing curricula should be considered.

### **6.8 Study Dissemination**

In the first instance, the results of this intervention were disseminated to stakeholders in the research sites in which the study was conducted. Consultant cardiologists and members of the cardiology team, clinical nurse managers, cardiac rehabilitation nurses and nursing staff were invited to attend the presentation. Individual pre-hospital delay times for the relevant hospitals were presented. Discussions took place about the importance of implementing the intervention at clinical level. The feasibility of its incorporation into usual pre-discharge education was discussed, together with the potential barriers to its implementation. To date, the study results have been disseminated through peer reviewed publications and conference presentations (Appendix 11).

## References

Al-Hassan M.A. & Omran S.M. (2005) The effects of health beliefs on health care-seeking decisions of Jordanian patients with myocardial infarction symptoms. *International Journal of Nursing Practice* **11**(1), 13-20.

Albarran J., Clarke B. & Crawford J. (2007) "It was not chest pain really, I can't explain it!". *Journal of Clinical Nursing* **16**, 1292-1301.

Alm-Roijer C., Fridlund B., Stagmo M. & Erhardt L. (2006) Knowing your risk factors for coronary heart disease improves adherence to advice on lifestyle changes and medication. *Journal of Cardiovascular Nursing* **21**(5), E24-E31.

Alonzo A. (1986) The impact of the family and lay others on care-seeking during life-threatening episodes of suspected coronary artery disease. *Social Science and Medicine* **22**(12), 1297-1311.

Alonzo A. & Reynolds N. (1997) Responding to symptoms and signs of acute myocardial infarction- how do you educate the public? A social- psychological approach to intervention. *Heart and Lung* **26**, 263-272.

Alonzo A. & Reynolds N. (1998) The structure of emotions during acute myocardial infarction: a model of coping. *Science and Medicine* **46**(9), 1099-1110.

Alonzo A. (2007) The effect of health care provider consultation on acute coronary syndrome care-seeking delay. *Heart & Lung-The Journal of Acute and Critical Care* **36**(5), 307-318.

Altman D.G. (2006) *Practical Statistics for Medical Research*. 2nd edn. Chapman & Hall, London.

Altman D.G., Schulz K.F., Moher D., Egger M., Davidoff F., Elbourne D., Gotzsche P.C. & Lang T. (2001) The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Annals of Internal Medicine* **134**(8), 663-694.

An Bord Altranais (2000) *The Code of Professional Conduct for Each Nurse and Midwife*. An Bord Altranais, Dublin.

Anderson J.L., Adams C.D., Antman E.M., Bridges C.R., Califf R.M., Casey Jr D.E., Chavey 2nd W.E., Fesmire F.M., Hochman J.S., Levin T.N., Lincoff A.M., Peterson E.D., Theroux P., Wenger N.K., Wright R.S., Smith Jr S.C., Jacobs A.K., Halperin J.L., Hunt S.A., Krumholz H.M., Kushner F.G., Lytle B.W., Nishimura R., Ornato J.P., Page R.L. & Riegel B. (2007) ACC/AHA 2007 guidelines for the management of patients with unstable angina/non ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of

Patients With Unstable Angina/Non ST-Elevation Myocardial Infarction). *Circulation* **116**(7), e148-304.

Ängerud K., Brulin C., Näslund U. & Eliasson M. (2012) Patients with diabetes are not more likely to have atypical symptoms when seeking care of a first myocardial infarction. An analysis of 4028 patients in the Northern Sweden MONICA Study. *Diabetic Medicine* **29**(7), e82-e87.

Ängerud K.H., Brulin C., Näslund U. & Eliasson M. (2013) Longer pre-hospital delay in first myocardial infarction among patients with diabetes: an analysis of 4266 patients in the Northern Sweden MONICA Study. *BMC Cardiovascular Disorders* **13**(1), 1-7.

Antman E.M., Cohen M., Bernink P., McCabe C., Horacek T., Papuchis G., Mautner B., Corbalan R., Radley D. & Braunwald E. (2000) The TIMI risk score for unstable angina/non-ST elevation MI: a method for prognostication and therapeutic decision making. *Journal of the American Medical Association* **284**, 835-842.

Aranda S. (2008) Designing nursing interventions. *Collegian* **15**, 19-25.

Archer F., Morgans A. & Allen F. (2008) Patient decision making in pre-hospital health emergencies: determinants and predictors of patient delay. *Journal of Emergency Primary Healthcare* **6**(3), 13-24.

Arslanian-Engoren C., Patel A., Fang J., Armstrong D., Kline-Rogers E., Duvernoy C.S. & Eagle K.A. (2006) Symptoms of men and women presenting with acute coronary syndromes. *American Journal of Cardiology* **98**(9), 1177-1181.

Asseburg C., Vergel Y.B., Palmer S., Fenwick E., de Belder M., Abrams K.R. & Sculpher M. (2007) Assessing the effectiveness of primary angioplasty compared with thrombolysis and its relationship to time delay: a Bayesian evidence synthesis. *Heart* **93**(10), 1244-1250.

Atzema C., Austin C., Huynh T., Hassan A., Chiu M., Wang J. & Tu J. (2011) Effect of marriage on duration of chest pain associated with myocardial infarction before seeking care. *Canadian Medical Association Journal* **183**(13), 1482-1491.

Ayanian J.Z. & Cleary P.D. (1999) Perceived risks of heart disease and cancer among cigarette smokers. *JAMA* **281**(11), 1019-1021.

Banks A.D. & Dracup K. (2006) Factors associated with prolonged prehospital delay of African Americans with acute myocardial infarction. *American Journal of Critical Care* **15**(2), 149-157.

Bassand J.P., Hamm C.W., Ardissino D., Boersma E., Budaj A., Fernandez-Aviles F., Fox K.A.A., Hasdai D., Ohman E.M., Wallentin L. & Wijns W. (2007) Guidelines for the diagnosis and treatment of non-ST-segment elevation acute

coronary syndromes: The Task Force for the Diagnosis and Treatment of Non-ST-Segment Elevation Acute Coronary Syndromes of the European Society of Cardiology. *European Heart Journal* **28**(13), 1598-1660.

Baumann L.J. & Leventhal H. (1985) I can tell when my blood pressure is up, can't I? *Health Psychology* **4**(3), 203-218.

Baxter S. & Allmark P. (2013) Reducing the time-lag between onset of chest pain and seeking professional medical help: a theory-based review. *BMC Medical Research Methodology* **13**(15), 11-22.

Bellg A.J., Borrelli B., Resnick B., Hecht J., Minicucci D.S., Ory M., Ogedegbe G., Orwig D., Ernst D. & Czajkowski S. (2004) Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology* **23**(5), 443-451.

Benyamini Y. (2009) Stress and coping with women's health issues: a review from a self-regulation perspective. *European Psychologist* **14**(1), 63-71.

Benner P. (1984) From novice to expert excellence and power in clinical nursing practice. *AJN The American Journal of Nursing* **84**(12), 1479-1484.

Bett N., Aroney G. & Thompson P. (1993) Impact of a national educational campaign to reduce patient delay in possible heart attack. *Australia and New Zealand Journal of Medicine* **23**(2), 157-161.

Birkhead J.S., Walker L., Pearson M., Weston C., Cunningham A.D. & Rickards A.F. (2004) Improving care for patients with acute coronary syndromes: initial results from the National Audit of Myocardial Infarction Project (MINAP). *Heart* **90**(9), 1004 -1009.

Blackwood B., O'Halloran P. & Porter S. (2010) On the problems of mixing RCTs with qualitative research: the case of the MRC framework for the evaluation of complex healthcare interventions. *Journal of Research in Nursing* **15**(6), 511-521.

Bleeker J.K., Lamers L.M., Leenders I.M., Kruyssen D.C., Simoons M.L., Trijsburg R.W. & Erdman R.A. (1995) Psychological and knowledge factors related to delay of help-seeking by patients with acute myocardial infarction. *Psychotherapy and Psychosomatics* **63**,151-158.

Blohm M., Hartford M., Karlson B.W., Karlsson T. & Herlitz J. (1994) A media campaign aiming at reducing delay times and increasing the use of ambulance in AMI. *The American Journal of Emergency Medicine* **12**(3), 315-318.

Blohm M., Herlitz J., Schröder U., Hartford M., Karlson B.W., Risenfors M., Larsson E., Luepker R., Wennerblom B. & Holmberg S. (1991) Reaction to a media campaign focusing on delay in acute myocardial infarction. *Heart & Lung: the Journal of Critical Care* **20**(6), 661-666.

Blohm M.B., Hartford M., Karlson B.W., Luepker R.V. & Herlitz J. (1996) An evaluation of the results of media and educational campaigns designed to shorten the time taken by patients with acute myocardial infarction to decide to go to hospital. *British Medical Journal* **76**(5), 430-434.

Boekaerts M., Pintrich P. & Zeidner M. (2000) *Self-regulation: theory, research, and applications*. Academic Press, Orlando.

Bonell C., Fletcher A., Morton M., Lorenc T. & Moore L. (2012) Realist randomised controlled trials: a new approach to evaluating complex public health interventions. *Social Science and Medicine* **75**(12), 2299-2306.

Borrelli B., Sepinwall D., Ernst D., Bellg A.J., Czajkowski S., Breger R., DeFrancesco C., Levesque C., Sharp D.L. & Ogedegbe G. (2005) A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *Journal of Consulting and Clinical Psychology* **73**(5), 852-860.

Borrelli B. (2011) The assessment, monitoring and enhancement of treatment fidelity in public health clinical trials. *Journal of Public Health Dentistry* **71**(s1), s52-s63.

Bradley F., Wiles R., Kinmonth D. & Gantley M. (1999) Development and evaluation of complex interventions in health services research: case study of the Southampton integrated care project (SHIP). *British Medical Journal* **318**, 711-715.

Brieger D., Eagle K.A., Goodman S.G., Steg P.G., Budaj A., White K. & Montalescot G. (2004) Acute coronary syndromes without chest pain, an underdiagnosed and undertreated high-risk group: Insights from the global registry of acute coronary events. *Chest* **126**(2), 461-469.

Britt E., Hudson S.M. & Blampied N.M. (2004) Motivational interviewing in health settings: a review. *Patient Education and Counseling* **53**(2), 147-155.

Brobeck E., Bergh H., Odencrants S. & Hildingh C. (2011) Primary healthcare nurses' experiences with motivational interviewing in health promotion practice. *Journal of Clinical Nursing* **20**, 3322-3330.

Brown J.D., Bauman K.E. & Padgett C.A. (1990) A validity problem in measuring exposure to mass media campaigns. *Health Education and Behavior* **17**(3), 299-306.

Buckley T., McKinley S., Gallagher R., Dracup K., Moser D.K. & Aitken L.M. (2007) The effect of education and counselling on knowledge, attitudes and beliefs about responses to acute myocardial infarction symptoms. *European Journal of Cardiovascular Nursing* **6**(2), 105-111.



- Bunde J. & Martin R. (2006) Depression and prehospital delay in the context of myocardial infarction. *Psychosomatic Medicine* **68**(1), 51-57.
- Burgess C., Hunter M. & Ramirez A. (2001) A qualitative study of delay among women reporting symptoms of breast cancer. *British Journal of General Practice* **51**, 967-971.
- Burnett R.E., Blumenthal J.A., Mark D.B., Leimberger J.D. & Califf R.M. (1995) Distinguishing between early and late responders to symptoms of acute myocardial infarction. *American Journal of Cardiology* **75**(15), 1019-1022.
- Caldwell M.A. & Miaskowski C. (2002) Mass media interventions to reduce help-seeking delay in people with symptoms of acute myocardial infarction: time for a new approach? *Patient Education and Counseling* **46**(1), 1-9.
- Callen J.L., Blundell L. & Prgomet M. (2008) Emergency department use in a rural Australian setting: are the factors prompting attendance appropriate? *Australian Health Review* **32**(4), 710-720.
- Cameron L.D. & Leventhal H. (2003) *The Self-Regulation of Health and Illness Behaviour*. Routledge, New York.
- Cameron L.D., Petrie K., Ellis C., Buick D. & Weinman J. (2005) Trait negative affectivity and responses to a health education intervention for myocardial infarction patients. *Psychology and Health* **20**(1), 1-18.
- Campbell B., Manuel J., Manser S., Peavy K., Stelmokas J., McCarthy D. & Guydish J. (2013) Assessing fidelity of treatment delivery in group and individual 12-step facilitation. *Journal of Substance Abuse Treatment* **44**, 169-176.
- Campbell-Yeo M., Ragner M. & Johnston C. (2009) Controlling bias in complex nursing intervention studies: a checklist. *Canadian Journal of Nursing Research* **41**, 32-50.
- Campbell N., Murray E., Darbyshire J., Emery J., Farmer A., Griffiths F., Guthrie B., Lester H., Wilson P. & Kinmonth A.L. (2007) Designing and evaluating complex interventions to improve healthcare. *British Medical Journal* **334**, 455-459.
- Canto J.G., Goldberg R.J., Hand M.M., Bonow R.O., Sopko G., Pepine C.J. & Long T. (2007) Symptom presentation of women with acute coronary syndromes: myth vs reality. *Archives of Internal Medicine* **167**(22), 2405-2413.
- Canto J.G., Shlipak M.G., Rogers W.J., Malmgren J.A., Frederick P.D., Lambrew C.T., Ornato J.P., Barron H.V. & Kiefe C.I. (2000) Prevalence, clinical characteristics, and mortality among patients with myocardial infarction presenting without chest pain. *JAMA* **283**(24), 3223-3229.

Carney R., Fitzsimons D. & Dempster M. (2002) Why people experiencing acute myocardial infarction delay seeking medical assistance. *European Journal of Cardiovascular Nursing* **1**(4), 237-242.

Carver C. & Scheier M. (1998) *On the Self-Regulation of Behavior*. Cambridge University Press. New York.

Cavill N. & Bauman A. (2004) Changing the way people think about health-enhancing physical activity: do mass media campaigns have a role? *Journal of Sports Sciences* **22**(8), 771-790.

Chalmers T.C., Celano P., Sacks H.S. & Smith Jr H. (1983) Bias in treatment assignment in controlled clinical trials. *The New England Journal of Medicine* **309**(22), 1358-1361.

Chan A.-W. & Altman D.G. (2005) Epidemiology and reporting of randomised trials published in PubMed journals. *The Lancet* **365**(9465), 1159-1162.

Chapman S., Wong W.L. & Smith W. (1993) Self-exempting beliefs about smoking and health: differences between smokers and ex-smokers. *American Journal of Public Health* **83**(2), 215-219.

Cherrington C., Moser D., Lennie T. & Kennedy C. (2004) Illness representation after acute myocardial infarction: impact on in-hospital recovery. *American Journal of Critical Care* **13**, 136-145.

Ciechanowski P.S., Walker E.A., Katon W.J. & Russo J.E. (2002) Attachment theory: a model for health care utilization and somatization. *Psychosomatic Medicine* **64**(4), 660-667.

Cleary V. & Hegarty J. (2011) Understanding sexuality in women with gynaecological cancer. *European Journal of Oncology Nursing* **15** (1), 38-45.

Cleary V., McCarthy G. & Hegarty J. (2012) Development of an educational intervention focused on sexuality for women with gynaecological cancer. *Journal of Psychosocial Oncology* **30**, 535-555.

Cohen J. (1992) A power primer. *Psychological Bulletin* **112**(1), 155-159.

Coates V. (1999) *Education for Patients and Clients*. Routledge, London.

Commodore-Mensah Y. & Dennison-Himmelfarb C. (2012) Patient education strategies for hospitalised cardiovascular patients: a systematic review. *Journal of Cardiovascular Nursing* **27**(2), 154-174.

Commonwealth Fund (2010) *International Profiles of Healthcare Systems*. The Commonwealth Fund, New-York.

- Conn V., Rantz M., Wipke-Tevis D. & Maas M. (2001) Focus on research methods: designing effective nursing interventions. *Research in Nursing and Health* **24**, 433-442.
- Corry M., Clarke M., While A. & Lalor J. (2013) Developing complex interventions for nursing: a critical review of key guidelines. *Journal of Clinical Nursing* **22** (17/18), 2366-2386.
- Coventry L.L., Bremner A.P., Jacobs I.G. & Finn J. (2013) Myocardial infarction: sex differences in symptoms reported to emergency dispatch. *Prehospital Emergency Care* **17**(2), 193-202.
- Craig P., Dieppe P., Macintyre S., Mitchie S., Nazareth I. & Petticrew M. (2008) Developing and evaluating complex interventions: the new Medical Research Council guidance. *British Medical Journal (International Edition)* **337**, 979-983.
- Curtis J.P., Portnay E.L., Wang Y., McNamara R.L., Herrin J., Bradley E.H., Magid D.J., Blaney M.E., Canto J.G. & Krumholz H.M. (2006) The Pre-Hospital Electrocardiogram and Time to Reperfusion in Patients With Acute Myocardial Infarction, 2000–2002. Findings From the National Registry of Myocardial Infarction-4. *Journal of the American College of Cardiology* **47**(8), 1544-1552.
- Daly L. & Bourke G. (2000) *Interpretation and Uses of Medical Statistics*. Blackwell Science, Oxford.
- Dart M. (2011) *Motivational Interviewing in Nursing Practice*. Jones and Bartlett, Sudbury, Massachusetts.
- De Luca G., Suryapranata H., Ottervanger J.P. & Antman E.M. (2004) Time Delay to Treatment and Mortality in Primary Angioplasty for Acute Myocardial Infarction: Every Minute of Delay Counts. *Circulation* **109**(10), 1223-1225.
- de Boer S.P., Lenzen M.J., Oemrawsingh R.M., Simsek C., Duckers H.J., van der Giessen W.J., Serruys P.W. & Boersma E. (2011) Evaluating the 'all-comers' design: a comparison of participants in two 'all-comers' PCI trials with non-participants. *European Heart Journal* **32**(17), 2161-2167.
- de Bruin M., Sheeran P., Kok G., Hiemstra A., Prins J., Hospers H. & van Breukelen G. (2012) Self-regulatory processes mediate the intention-behavior relation for adherence and exercise behaviors. *Health Psychology* **31**(6), 695-703.
- de Ridder D. & de Wit J. (2006) *Self-regulation in Health Behavior*. John Wiley & Sons, New York.
- De Von H.A. & Zerwic J.J. (2003) The symptoms of unstable angina: Do women and men differ? *Nursing Research* **52**(2), 108-118.
- De Von H., Ryan C. & Zerwic J.J. (2004) Is the medical record an accurate reflection of patients' symptoms during acute myocardial infarction? *Western Journal of Nursing Research* **26**, 547-560.

De Von H., Ryan C., Ochs A.L. & Shapiro M. (2008) Symptoms across the continuum of acute coronary syndromes: differences between women and men. *American Journal of Critical Care* **17**(1), 14-25.

DeVon H.A., Hogan N., Ochs A.L. & Shapiro M. (2010) Time to Treatment for Acute Coronary Syndromes. *Journal of Cardiovascular Nursing* **25**(2), 106-114.

De Vries H. & Brug J. (1999) Computer-tailored interventions motivating people to adopt health promoting behaviours: introduction to a new approach. *Patient Education and Counseling* **36**(2), 99-105.

Department of Health and Children (1994) *Shaping a Healthier Future. A Strategy for Effective Healthcare in the 1990s*. The Stationary Office, Dublin [http://www.dohc.ie/publications/fulltext/quality\\_and\\_fairness/part1.html](http://www.dohc.ie/publications/fulltext/quality_and_fairness/part1.html).

Department of Health and Children (1999) *Building Healthier Hearts. The Report of the Cardiovascular Health Strategy Group*. The Stationary Office, Dublin.

Devane D., Begley C. & Clarke M. (2004) How many do I need? Basic principles of sample size estimation. *Journal of Advanced Nursing* **47**(3), 297-302.

Dewalt D., Berkman N., Sheridan S., Lohr K. & Pignone M. (2004) Literacy and health outcomes: a systematic review of the literature. *Journal of General Internal Medicine* **19**(12), 1228-1239.

Dickson V.V. & Riegel B. (2009) Are we teaching what patients need to know? Building skills in heart failure self-care. *Heart & Lung: The Journal of Acute and Critical Care* **38**(3), 253-261.

DiMatteoa M., Sherbourne C. & Hays R. (1993) Physicians' characteristics influence patient adherence to medical treatment: results from the medical outcomes study. *Health Psychology* **12**, 93-102.

Doyle F., De la Harpe D., McGee H., Shelley E. & Conroy R. (2005) Nine-year comparison of presentation and management of acute coronary syndromes in Ireland: a national cross-sectional survey. *Biomed Central* **13** (3), 2010.

Dracup K., Moser D.K., Eisenberg M., Meischke H., Alonzo A. & Braslow A. (1995) Causes of delay in seeking treatment for heart attack symptoms. *Social Science and Medicine* **40**, 379-392.

Dracup K., Alonzo A.A., Atkins J.M., Bennett N.M., Braslow A., Clark L.T., Eisenberg M., Ferdinand K.C., Frye R., Green L., Hill M.N., Kennedy J.W., Kline-Rogers E., Moser D.K., Ornato J.P., Pitt B., Scott J.D., Selker H.P., Silva S.J., Thies W., Weaver W.D., Wenger N.K., White S.K., Jung A., Lynn J., Hand M.M., Horan M., Bradley J.C., Christian P.A. & Shero S. (1997a) The physician's role in minimizing prehospital delay in patients at high risk for acute

myocardial infarction: Recommendations from the National Heart Attack Alert Program. *Annals of Internal Medicine* **126**(8), 645-651.

Dracup K., McKinley S.M. & Moser D.K. (1997b) Australian patients' delay in response to heart attack symptoms. *Medical Journal of Australia* **166**(5), 233-236.

Dracup K. & Moser D.K. (1997) Beyond sociodemographics: Factors influencing the decision to seek treatment for symptoms of acute myocardial infarction. *Heart and Lung: Journal of Acute and Critical Care* **26**(4), 253-262.

Dracup K., Moser D.K., McKinley S., Ball C., Yamasaki K., Kim C.J., Doering L.V. & Caldwell M.A. (2003) An international perspective on the time to treatment for acute myocardial infarction. *Journal of Nursing Scholarship* **35**(4), 317-323.

Dracup K., McKinley S., Riegel B., Mieschke H., Doering L.V. & Moser D.K. (2006) A nursing intervention to reduce prehospital delay in acute coronary syndrome: a randomized clinical trial. *The Journal of Cardiovascular Nursing*. **21**(3), 186-193.

Dracup K., McKinley S., Riegel B., Moser D.K., Meischke H., Doering L., Davidson P.M., Paul S.M., Baker H. & Pelter M. (2009) A randomized clinical trial to reduce patient prehospital delay to treatment in acute coronary syndrome. *Circulation: Cardiovascular Quality And Outcomes* **2**, 524-532.

Dubayova T., van Dijk J.P., Nagyova I., Rosenberger J., Havlikova E., Gdovinova Z., Middel B. & Groothoff J.W. (2010) The impact of the intensity of fear on patient's delay regarding health care seeking behavior: a systematic review. *International Journal of Public Health* **55**(5), 459-468.

Eastwood G. (2001) Lifestyle pattern change in males following percutaneous transluminal coronary angioplasty/intracoronary stenting. *International Journal of Nursing Practice* **7**(2), 131-137.

Eppler E., Eisenberg M.S., Schaeffer S., Meischke H. & Larson M.P. (1994) 911 and emergency department use for chest pain: results of a media campaign. *Annals of Emergency Medicine* **24**(2), 202-208.

Farquharson B., Johnston M. & Brugge C. (2012) Appraisal and illness delay with symptoms of ACS: A questionnaire study of illness representations. *British Journal of Cardiac Nursing* **7**(10), 493-499.

Farshidi H., Rahimi S., Abdi A., Salehi S. & Madani A. (2013) Factors Associated With Pre-hospital Delay in Patients With Acute Myocardial Infarction. *Iranian Red Crescent Medical Journal* **15**(4), 312-316.

Feneck R. (2007) Clinical research in anaesthesia; randomized controlled trials or observational studies? *European Journal of Anaesthesiology* **24**(1), 1-5.

Fernandez R., Griffiths R., Juergens C., Davidson P. & Salamonson Y. (2006) Persistence of coronary risk factor status in participants 12 to 18 months after percutaneous coronary intervention. *Journal of Cardiovascular Nursing* **21**(5), 379-387.

Festinger L. (1962) *A Theory of Cognitive Dissonance*. Stanford University Press, California.

Finn J.C., Bett J.H.N., Shilton T.R., Cunningham C. & Thompson P.L. (2007) Patient delay in responding to symptoms of possible heart attack: can we reduce time to care? *Medical Journal of Australia* **187**(5), 293-298.

Finn J.C., Jacobs I.G., Holman C. & Oxeer H.F. (2001) Outcomes of out-of-hospital cardiac arrest patients in Perth, Western Australia, 1996–1999. *Resuscitation* **51**(3), 247-255.

Finnegan J.R., Meischke H., Zapka J.G., Leviton L., Meshack A., Benjamin-Garner R., Estabrook B., Hall N.J., Schaeffer S. & Smith C. (2000) Patient delay in seeking care for heart attack symptoms: findings from focus groups conducted in five US regions. *Preventive Medicine* **31**(3), 205-213.

Foraker R.E., Rose K.M., McGinn A.P., Suchindran C.M., Goff Jr D.C., Whitsel E.A., Wood J.L. & Rosamond W.D. (2008) Neighborhood income, health insurance, and prehospital delay for myocardial infarction: the atherosclerosis risk in communities study. *Archives of Internal Medicine* **168**(17), 1874-1879.

Fowers B. (1992) The Cardiac Denial of Impact Scale: A brief self report research measure. *Journal of Psychosomatic Research* **36**, 469-475.

Fox-Wasylyshyn S.M., El-Masri M. & Artinian N.T. (2010) Testing a Model of Delayed Care-Seeking for Acute Myocardial Infarction. *Clinical Nursing Research* **19**(1), 38-54.

Fox K., Dabbous O., Goldberg R.J., Pieper N., Eagle K., Van De Werf F., Avezum A., Goodman S., Flather M., Anderson F.J. & Granger C. (2006) Prediction of risk of death and myocardial infarction in the six months after presentation with acute coronary syndrome: prospective multinational observational study (GRACE). *British Medical Journal* **333**, 1091-1106.

Freedman B. (1987) Equipoise and the ethics of clinical research. *The New England Journal of Medicine* **317**(3), 141-145.

French D., Marteau T., Senior V. & Weinman J. (2002) The structure of beliefs about the causes of heart attacks: a network analysis. *British Journal of Health Psychology* **7**, 463-479.

Friedberg J., Lipsitz S. & Natarajan S. (2010) Challenges and recommendations for blinding in behavioural interventions illustrated using a case study of a behavioural intervention to lower blood pressure. *Patient Education and Counseling* **78**, 5-11.

- Fuertes J., Mislouack A. & Bennett J. (2007) The physician-patient working alliance. *Patient Education and Counseling* **66**, 29-36.
- Fukuoka Y., Dracup K., Ohno M., Kobayashi F. & Hirayama H. (2005) Symptom severity as a predictor of reported differences of prehospital delay between medical records and structured interviews among patients with AMI. *European Journal of Cardiovascular Nursing* **4**(2), 171-176.
- Furze G., Bull P., Lewin R.J. & Thompson D.R. (2003) Development of the York angina beliefs questionnaire. *Journal of Health Psychology* **8**(3), 307-315.
- Gallagher R., Roach K., Belshaw J., Kirkness A., Sadler L. & Warrington D. (2013) A pre-test post-test study of a brief educational intervention demonstrates improved knowledge of potential acute myocardial infarction symptoms and appropriate responses in cardiac rehabilitation patients. *Australian Critical Care* **26** (2), 49-54.
- Garofalo D., Grey C., Lee M., Exeter D. & Kerr A.J. (2012) Pre-hospital delay in acute coronary syndromes: PREDICT CVD-18. *New Zealand Medical Journal* **125**, 12-22.
- Gartner C., Walz L., Bauernschmitt E. & Ladwig K. (2008) The causes of prehospital delay in myocardial infarction. *Deutsches Arzteblatt International* **105**(15), 286-291.
- Gaspoz J.M., Unger P.F., Urban P., Chevrolet J.C., Rutishauser W., Lovis C., Goldman L., Heliot C., Sechaud L. & Mischler S. (1996) Impact of a public campaign on pre-hospital delay in patients reporting chest pain. *British Medical Journal* **76**(2), 150-155.
- Gerrish K. & Lacey A. (2006) *The Research Process in Nursing*. 5th edn. Blackwell Publishing, Oxford.
- Gholizadeh L., Davidson P., Salamonson Y. & Worrall-Carter L. (2010) Theoretical considerations in reducing risk for cardiovascular disease: implications for nursing practice. *Journal of Clinical Nursing* **19**, 2137-2145.
- Gibler W.B., Armstrong P.W., Ohman E.M., Weaver W.D., Stebbins A.L., Gore J.M., Newby L.K., Califf R.M. & Topol E.J. (2002) Persistence of delays in presentation and treatment for patients with acute myocardial infarction: the GUSTO-I and GUSTO-III experience. *Annals of Emergency Medicine* **39**(2), 123-130.
- Glasziou P., Meats E., Heneghan C. & Shepperd S. (2008) What is missing from descriptions of treatment in trials and reviews? *BMJ: British Medical Journal* **336**(7659), 1472-1474.
- Goldberg R.J., Goff D., Cooper L., Luepker R., Zapka J., Bittner V., Osganian S., Lessard D., Cornell C. & Meshack A. (2000) Age and sex differences in

presentation of symptoms among patients with acute coronary disease: the REACT trial. *Coronary Artery Disease* **11**(5), 399-407.

Goldberg R.J., Gurwitz J., Yarzebski J., Landon J., Gore J.M., Alpert J.S., Dalen P.M. & Dalen J.E. (1992) Patient delay and receipt of thrombolytic therapy among patients with acute myocardial infarction from a community-wide perspective. *American Journal of Cardiology* **70**(4), 421-425.

Goldberg R.J., Steg P.G., Sadiq I., Granger C.B., Jackson E.A., Budaj A., Brieger D., Avezum A. & Goodman S. (2002) Extent of, and factors associated with, delay to hospital presentation in patients with acute coronary disease (The GRACE registry). *American Journal of Cardiology* **89**(7), 791-796.

Goldberg R.J., Spencer F.A., Fox K.A.A., Brieger D., Steg P.G., Gurfinkel E., Dedrick R. & Gore J.M. (2009) Prehospital Delay in Patients With Acute Coronary Syndromes (from the Global Registry of Acute Coronary Events [GRACE]). *American Journal of Cardiology* **103**(5), 598-603.

Goldstein P. & Wiel E. (2005) Management of prehospital thrombolytic therapy in ST-segment elevation in acute coronary syndrome (<12 hours). *Minerva Anestesiologica* **71**, 297-302.

Graham I., Atar D., Borch-Johnsen K., Boysen G., Burell G., Cifkova R., Dallongeville J., De Backer G., Ebrahim S., Gjelsvik B., Herrmann-Lingen C., Hoes A., Humphries S., Knapton M., Perk J., Priori S.G., Pyorala K., Reiner Z., Ruilope L., Sans-Menendez S., Op Reimer W.S., Weissberg P., Wood D., Yarnell J. & Zamorano J.L. (2007) European guidelines on cardiovascular disease prevention in clinical practice: Executive summary: Fourth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice (Constituted by representatives of nine societies and by invited experts). *European Journal of Cardiovascular Prevention and Rehabilitation* **14**(SUPPL. 2), E1-E40.

Granger C., Goldberg R.J., Dabbous O., Pieper N., Eagle K., Cannon C., Van De Werf F., Avezum A., Goodman S., Flather M. & Fox K. (2003) Predictors of hospital mortality in the global registry of acute coronary events. *Archives of Internal Medicine* **163**, 2345-2353.

Grove S., Burns N. & Gray J. (2013) *The Practice of Nursing Research: Appraisal, Synthesis and Generation of Evidence*. 7th edn. Elsevier, St. Louis, Missouri.

Gurwitz J.H., McLaughlin T.J., Willison D.J., Guadagnoli E., Hauptman P.J., Gao X. & Soumerai S.B. (1997) Delayed hospital presentation in patients who have had acute myocardial infarction. *Annals of Internal Medicine* **126**(8), 593-599.

Hafner D. & Kirscht J. (1970) Motivational and behavioural effects of modifying health beliefs. *Public Health Reports* **85**, 478-484.



- Hagger M.S. & Orbell S. (2003) A meta-analytic review of the common-sense model of illness representations. *Psychology and Health* **18**(2), 141-184.
- Hale E., Treharne G. & Kitas G. (2007) The Common-Sense Model of self-regulation of health and illness: how can we use it to understand and respond to our patients' needs? *Rheumatology* **46**(6), 904.
- Hamm C.W., Bassand J.P., Agewall S., Bax J., Boersma E., Bueno H., Caso P., Dudek D., Gielen S. & Huber K. (2011) ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. *European Heart Journal* **32**(23), 2999-3054.
- Hartford M., Karlson B.W., Sjölin M., Holmberg S. & Herlitz J. (1993) Symptoms, thoughts, and environmental factors in suspected acute myocardial infarction. *Heart & lung : the Journal of Critical Care* **22**(1), 64-70.
- Health Research Board (2009). *Health Research Board Strategic Business Plan 2010-2014*. Health Research Board, Dublin.
- Health Service Executive (2012a) *National Acute Coronary Syndromes Programme*. The Stationary Office, Dublin.
- Health Service Executive (2012b) *How to Conduct Research for Service Improvement: A Guidebook for Health & Social Care Professionals*. Health Service Executive, Dublin.
- Hedges J.R., Feldman H.A., Bittner V., Goldberg R.J., Zapka J., Osganian S.K., Murray D.M., Simons-Morton D.G., Linares A. & Williams J. (2000) Impact of Community Intervention to Reduce Patient Delay Time on Use of Reperfusion Therapy for Acute Myocardial Infarction Rapid Early Action for Coronary Treatment (REACT) Trial. *Academic Emergency Medicine* **7**(8), 862-872.
- Herbert R.D. & Bø K. (2005) Analysis of quality of interventions in systematic reviews. *BMJ: British Medical Journal* **331**(7515), 507-509.
- Herlitz J., Thuresson M., Svensson L., Lindqvist J., Lindahl B., Zedigh C. & Jarlöv M. (2010a) Factors of importance for patients' decision time in acute coronary syndrome. *International Journal of Cardiology* **141** (3), 236-242.
- Herlitz J., Wireklint Sundström B., Bång A., Berglund A., Svensson L. & Blomstrand C. (2010b) Early identification and delay to treatment in myocardial infarction and stroke: differences and similarities. *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine* **6**, 18-48.
- Higginson R. (2008) Women's help-seeking behaviour at the onset of myocardial infarction. *British Journal of Nursing* **17**(1), 10-14.
- Hitchcock T., Rossouw F., McCoubrie D. & Meek S. (2003) Observational study of prehospital delays in patients with chest pain. *Emergency Medicine Journal* **20**, 270-273.

Ho M.T., Eisenberg M.S., Litwin P.E., Schaeffer S.M. & Damon S.K. (1989) Delay between onset of chest pain and seeking medical care: the effect of public education. *Annals of Emergency Medicine* **18**(7), 727-731.

Hohman M. (2012) *Motivational Interviewing in Social Work Practice*. The Guilford Press, New York.

Holmboe E.S., Fiellin D.A., Cusanelli E., Remetz M. & Krumholz H.M. (2000) Perceptions of Benefit and Risk of Patients Undergoing First-time Elective Percutaneous Coronary Revascularization. *Journal of General Internal Medicine* **15**(9), 632-637.

Horne R., James D., Petrie K., Weinman J. & Vincent R. (2000) Patients' interpretation of symptoms as a cause of delay in reaching hospital during acute myocardial infarction. *British Medical Journal* **83**(4), 388-393.

Hutchings C.B., Mann N.C., Daya M., Jui J., Goldberg R., Cooper L., Goff Jr D.C. & Cornell C. (2004) Patients with chest pain calling 9-1-1 or self-transporting to reach definitive care: which mode is quicker? *American Heart Journal* **147**(1), 35-41.

Hutchison D. & Styles B. (2010) *A Guide to Running Randomised Controlled Trials for Educational Researchers*. National Foundation for Educational Research, Berkshire.

Hwang S.Y., Park E.H., Shin E.S. & Jeong M.H. (2009) Comparison of Factors Associated with Atypical Symptoms in Younger and Older Patients with Acute Coronary Syndromes. *Journal of Korean Medical Science*. **24**(5), 789–794.

Hwang S.Y., Ryan C. & Zerwic J.J. (2006) The influence of age on acute myocardial infarction symptoms and patient delay in seeking treatment. *Progress in Cardiovascular Nursing* **21**(1), 20-27.

Isaksson R.M., Holmgren L., Lundblad D., Brulin C. & Eliasson M. (2008) Time trends in symptoms and pre hospital delay time in women vs. men with myocardial infarction over a 15 year period. The Northern Sweden MONICA study. *European Journal of Cardiovascular Nursing* **7**, 152-158.

Jadad A. & Enkin M. (2007) *Randomized Controlled Trials: Questions, Answers and Musings*. Second edn. Blackwell Publishing, Massachusetts.

Jankowski P., Bednarek A., Surowiec S., Loster M., Pajak A. & Kawecka-Jaszcz K. (2011) Half of coronary patients are not instructed how to respond to symptoms of a heart attack. *Cardiology Journal* **18**, 668-674.

Jensen L., Leeman-Castillo B., Coronel S.M., Perry D., Belz C., Kapral C. & Krantz M.J. (2009) Impact of a nurse telephone intervention among high-cardiovascular-risk, health fair participants. *Journal of Cardiovascular Nursing* **24**(6), 447-453.

- Johansson I., Strömberg A. & Swahn E. (2004a) Factors related to delay times in patients with suspected acute myocardial infarction. *Heart and Lung: Journal of Acute and Critical Care* **33**(5), 291-300.
- Johansson I., Strömberg A. & Swahn E. (2004b) Ambulance use in patients with acute myocardial infarction. *Journal of Cardiovascular Nursing* **19**(1), 5-12.
- Johansson I., Swahn E. & Strömberg A. (2008) Spouses' conceptions of the pre-hospital phase when their partners suffered an acute myocardial infarction—a qualitative analysis. *European Journal of Cardiovascular Nursing* **7**(3), 182-188.
- Johnson J.A. & King K.B. (1995) Influence of expectations about symptoms on delay in seeking treatment during myocardial infarction. *American Journal of Critical Care* **4**(1), 29-35.
- Johnson M. & Remien R. (2003) Adherence to research protocols in a clinical context: challenges and recommendations from behavioural intervention trials. *American Journal of Psychotherapy* **57**, 348-360.
- Judge Santacroce S., Maccarelli L. & Grey M. (2004) Intervention fidelity. *Nursing Research* **53**(1), 63-66.
- Kahn E.B., Ramsey L.T., Brownson R.C., Heath G.W., Howze E.H., Powell K.E., Stone E.J., Rajab M.W. & Corso P. (2002) The effectiveness of interventions to increase physical activity: A systematic review. *American Journal of Preventive Medicine* **22**(4), 73-107.
- Kainth A., Hewitt A., Pattenden J., Sowden A., Duffy S., Watt I., Thompson D. & Lewin R. (2004) Systematic review of interventions to reduce delay in patients with suspected heart attack. *Emergency Medicine Journal* **21**(4), 506-508.
- Karras C., Donlan S., Aitchison R., Aitchison P., Wang E. & Kharasch M. (2013) Acute coronary syndromes. *Disease a Month* **59**, 202-209.
- Kaur R., Lopez V. & Thompson D.R. (2006) Factors influencing Hong Kong Chinese patients' decision-making in seeking early treatment for acute myocardial infarction. *Research in Nursing and Health* **29**(6), 636-646.
- Kentsch M., Rodemerk U., Müller-Esch G., Schnoor U., Münzel T., Ittel T.-H. & Mitusch R. (2002a) Emotional attitudes toward symptoms and inadequate coping strategies are major determinants of patient delay in acute myocardial infarction. *Zeitschrift für Kardiologie* **91**(2), 147-155.
- Kenyon L.W., Ketterer M.W., Gheorghide M. & Goldstein S. (1991) Psychological factors related to prehospital delay during acute myocardial infarction. *Circulation* **84**(5), 1969-1976.

Kerr C., Robinson E., Stevens A., Braunholtz D., Edwards S. & Lilford R. (2004) Randomisation in trials: do potential trial participants understand it and find it acceptable? *Journal of Medical Ethics* **30**(1), 80-84.

Kerr D., Holden D., Smith J., Kelly A. & Bunker S. (2006) Predictors of ambulance use in patients with acute myocardial infarction in Australia. *Emergency Medicine Journal* **23**(12), 948-952.

Khraim F. & Carey M. (2009) Predictors of pre-hospital delay among patients with acute myocardial infarction. *Patient Education and Counseling* **75**, 155-161.

Khraim F., Scherer Y., Dorn J. & Carey M. (2009) Predictors of decision delay to seeking health care among Jordanians with acute myocardial infarction. *Journal of Nursing Scholarship* **41**(3), 260-267.

Kreuter M. & Strecher V. (1995) Changing inaccurate perceptions of health risk: results from a randomized trial. *Health Psychology* **14**(1), 56-63.

Kumar A. & Cannon C. (2009) Acute Coronary Syndromes: Diagnosis and Management, Part 1. *Mayo Clinic proceedings* **84**(10), 917-938.

Kunz R., Vist G. & Oxman A. (2007) Randomisation to protect against selection bias in healthcare trials. *Cochrane Database of Systematic Reviews*.

Lau R., Kane R., Berry S., Ware J. & Roy D. (1980) Channeling health: a review of the evaluation of televised health campaigns. *Health Education and Behavior* **7**(1), 56-89.

Lau R.R. & Hartman K.A. (1983) Common sense representations of common illnesses. *Health Psychology* **2**(2), 167-185.

Lauver D.R., Ward S.E., Heidrich S.M., Keller M.L., Bowers B.J., Brennan P.F., Kirchhoff K.T. & Wells T.J. (2002) Patient-centered interventions. *Research in Nursing and Health* **25**(4), 246-255.

Lazarus R.S. & Folkman S. (1984) *Stress, Appraisal and Coping*. Springer Publishing Company, New York.

Lefler L.L. & Bondy K.N. (2004) Women's delay in seeking treatment with myocardial infarction: a meta-synthesis. *Journal of Cardiovascular Nursing* **19**(4), 251-268.

Leslie W., Urie A., Hooper J. & Morrison C. (2000) Delay in calling for help during myocardial infarction: reasons for the delay and subsequent pattern of accessing care. *Heart* **84**, 137-141.

Leventhal H. (1970) Findings and theory in the study of fear communications. *Advances in Experimental Social Psychology* **5**, 119-186.

- Leventhal H., Meyer D. & Nerenz D. (1980) The common sense representation of illness danger. *Contributions to Medical Psychology* **2**, 7-30.
- Leventhal H., Safer M. & Panagis D. (1983) The impact of communications on the self-regulation of health beliefs, decisions and behavior. *Health Education Quarterly* **10**(1), 3-29.
- Leventhal H., Nerenz D. & Steele D. (1984) Illness representations and coping with health threats. In *Handbook of Psychology and Health*, Vol. 4 (Baum E., Taylor S. & Singer J. eds), Lawrence Erlbaum, Hillsdale, pp. 219-252.
- Leventhal H. & Cameron L. (1987) Behavioral theories and the problem of compliance. *Patient Education and Counseling* **10**, 117-138.
- Leventhal H., Diefenbach M. & Leventhal E.A. (1992) Illness cognition: using common sense to understand treatment adherence and affect cognition interactions. *Cognitive Therapy and Research* **16**(2), 143-163.
- Leventhal H., Leventhal E. & Contrada R. (1998) Self-regulation, health and behaviour: a perceptual-cognitive approach. *Psychology and Health* **13**, 717-733.
- Leventhal H., Kelly K. & Leventhal E.A. (1999) Population risk, actual risk, perceived risk and cancer control. *Journal of the National Cancer Institute* **91**, 81-85.
- Leventhal H., Brissette I. & Leventhal E.A. (2003) *The Self-Regulation of Health and Illness Behaviour*. Routledge, New York.
- Leventhal H. & Friedman M. (2004) Does establishing fidelity of treatment help in understanding treatment efficacy? comment on Bellg. et al (2004). *Health Psychology* **23**, 452-456.
- Leventhal H., Weinman J., Leventhal E.A. & Phillips L.A. (2008) Health psychology: the search for pathways between behavior and health. *Annual Review of Psychology* **59**, 477-505.
- Leventhal H., Breland J.Y., Mora P.A. & Leventhal E.A. (2010) Lay representations of illness and treatment: a framework for action. In *Handbook of Behavioral Medicine*, Springer, New York, pp. 137-154.
- Lilford R.J. (2003) Ethics of clinical trials from a bayesian and decision analytic perspective: whose equipoise is it anyway? *British Medical Journal* **326**(7396), 980-981.
- Lobiondo-Wood G. & Haber J. (2006) *Nursing Research: Methods and Critical Appraisal for Evidence-Based Practice*. Sixth edn. Mosby Elsevier, Missouri.
- Lockyer L. (2005) Women's interpretation of their coronary heart disease symptoms. *European Journal of Cardiovascular Nursing* **4**(1), 29-35.

Løvlien M., Schei B. & Hole T. (2007) Prehospital delay, contributing aspects and responses to symptoms among Norwegian women and men with first time acute myocardial infarction. *European Journal of Cardiovascular Nursing* **6**(4), 308-313.

Løvlien M., Schei B. & Hole T. (2008) Myocardial infarction: psychosocial aspects, gender differences and impact on pre-hospital delay. *Journal of Advanced Nursing* **63**(2), 148-154.

Lowe R. & Bindman A. (1997) Judging who needs emergency department care: a prerequisite for policy making. *American Journal of Emergency Medicine* **15**(2), 133-136.

Lozzi L., Carstensen S., Rasmussen H. & Nelson G. (2005) Why do acute myocardial infarction patients not call an ambulance? An interview with patients presenting to hospital with acute myocardial infarction symptoms. *Internal Medicine Journal* **35**(11), 668-671.

Luepker R.V., Raczynski J.M., Osganian S., Goldberg R.J., Finnegan Jr J.R., Hedges J.R., Goff Jr D.C., Eisenberg M.S., Zapka J.G. & Feldman H.A. (2000) Effect of a community intervention on patient delay and emergency medical service use in acute coronary heart disease: the Rapid Early Action for Coronary Treatment (REACT) trial. *JAMA* **284**(1), 60-67.

MacInnes J.D. (2006) The illness perceptions of women following symptoms of acute myocardial infarction: a self-regulatory approach. *European Journal of Cardiovascular Nursing* **5**(4), 280-288.

Mackay M., Ratner P., Nguyen M., Percy M., Galdas P. & Grunau G. (2014) Inconsistent measurement of acute coronary syndrome patients' pre-hospital delay in research: a review of the literature. *European Journal of Cardiovascular Nursing*. **In press**.<http://dx.doi.10.1177/1474515114524866>.

Maes S. & Karoly P. (2005) Self-Regulation Assessment and Intervention in Physical Health and Illness: A Review. *Applied Psychology* **54**(2), 267-299.

Mandelzweig L., Battler A., Boyko V., Bueno H., Danchin N., Filippatos G., Gitt A., Hasdai D., Hasin Y. & Marrugat J. (2006) The second Euro Heart Survey on acute coronary syndromes: characteristics, treatment, and outcome of patients with ACS in Europe and the Mediterranean Basin in 2004. *European Heart Journal* **27**(19), 2285-2293.

Mathews R., Peterson E.D., Li S., Roe M.T., Glickman S.W., Wiviott S.D., Saucedo J.F., Antman E.M., Jacobs A.K. & Wang T.Y. (2011) Use of Emergency Medical Service Transport Among Patients With ST-Segment-Elevation Myocardial Infarction Clinical Perspective Findings From the National Cardiovascular Data Registry Acute Coronary Treatment Intervention Outcomes Network Registry—Get With the Guidelines. *Circulation* **124**(2), 154-163.

Matthews J. (2000) *An Introduction to Randomized Controlled Clinical Trials*. Oxford University Press, New York.

McGinn A.P., Rosamond W.D., Goff Jr D.C., Taylor H.A., Miles J.S. & Chambless L. (2005) Trends in prehospital delay time and use of emergency medical services for acute myocardial infarction: Experience in 4 US communities from 1987-2000. *American Heart Journal* **150**(3), 392-400.

McKee G., Mooney M., O' Donnell S., O' Brien F., Biddle M. & Moser D. (2013) Multivariate analysis of predictors of pre-hospital delay in acute coronary syndrome. *International Journal of Cardiology* **168** (3), 2706-2713.

McKinley S., Moser D.K. & Dracup K. (2000) Treatment seeking behaviour for acute myocardial infarction symptoms in North America and Australia. *Heart and Lung* **29**, 237-247.

McKinley S., Dracup K., Moser D.K., Ball C., Yamasaki K., Kim C.J. & Barnett M. (2004) International comparison of factors associated with delay in presentation for AMI treatment. *European Journal of Cardiovascular Nursing* **3**(3), 225-230.

McKinley S., Dracup K., Moser D.K., Riegel B., Doering L.V., Meischke H., Aitken L.M., Buckley T., Marshall A. & Pelter M. (2009) The effect of a short one-on-one nursing intervention on knowledge, attitudes and beliefs related to response to acute coronary syndrome in people with coronary heart disease: A randomized controlled trial. *International Journal of Nursing Studies* **46**(8), 1037-1046.

McSweeney J.C., Cody M., O'Sullivan P., Elberson K., Moser D.K. & Garvin B.J. (2003) Women's early warning symptoms of acute myocardial infarction. *Circulation* **108**(21), 2619-2623.

McSweeney J.C., Lefler L.L., Fischer E.P., Naylor Jr A.J. & Evans L.K. (2007) Women's Prehospital Delay Associated With Myocardial Infarction: Does Race Really Matter? *Journal of Cardiovascular Nursing* **22**(4), 279-285.

Medical Research Council (2000) *A Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health*. Medical Research Council, London.

Meischke H., Eisenberg M.S. & Larsen M.P. (1993) Prehospital delay interval for patients who use emergency medical services: the effect of heart-related medical conditions and demographic variables. *Annals of Emergency Medicine* **22**(10), 1597-1601.

Meischke H., Eisenberg M.S., Schaeffer S.M., Damon S.K., Larsen M.P. & Henwood D.K. (1995a) Utilization of emergency medical services for symptoms of acute myocardial infarction. *Heart & Lung: The Journal of Acute and Critical Care* **24**(1), 11-18.

Meischke H., Ho M.T., Eisenberg M.S., Schaeffer S.M. & Larsen M.P. (1995b) Reasons patients with chest pain delay or do not call 911. *Annals of Emergency Medicine* **25**(2), 193-197.

Meischke H., Dulberg E.M., Schaeffer S.S., Henwood D.K., Larsen M.P. & Eisenberg M.S. (1997) 'Call fast, Call 911': a direct mail campaign to reduce patient delay in acute myocardial infarction. *American Journal of Public Health* **87**(10), 1705-1709.

Meischke H., Larsen M.P. & Eisenberg M.S. (1998) Gender differences in reported symptoms for acute myocardial infarction: impact on prehospital delay time interval. *The American Journal of Emergency Medicine* **16**(4), 363-366.

Miller F. & Brody H. (2007) Clinical equipoise and the incoherence of research ethics. *Journal of Medicine and Philosophy* **32**, 151-165.

Miller W. & Rollnick S. (2002) *Motivational Interviewing: Preparing People for Change*. The Guilford Press, New York.

Miller W. & Rollnick S. (2013) *Motivational Interviewing*. Third edn. The Guilford Press, New York.

Milner K., Funk M., Arnold A. & Vaccarino V. (2002) Typical symptoms are predictive of acute coronary syndromes in women. *American Heart Journal* **143**(2), 283-288.

Milner K.A., Vaccarino V., Arnold A.L., Funk M. & Goldberg R.J. (2004) Gender and age differences in chief complaints of acute myocardial infarction (Worcester Heart Attack Study). *The American Journal of Cardiology* **93**(5), 606-608.

Mooney M., McKee G., Fealy G., Brien F.O., Donnell S.O. & Moser D. (2012) A review of interventions aimed at reducing pre-hospital delay time in acute coronary syndrome: What has worked and why? *European Journal of Cardiovascular Nursing* **11**(4), 445-453.

Morgan D.M. (2005) Effect of incongruence of acute myocardial infarction symptoms on the decision to seek treatment in a rural population. *Journal of Cardiovascular Nursing* **20**(5), 365-371.

Mosca L., Linfante A.H., Benjamin E.J., Berra K., Hayes S.N., Walsh B.W., Fabunmi R.P., Kwan J., Mills T. & Simpson S.L. (2005) National study of physician awareness and adherence to cardiovascular disease prevention guidelines. *Circulation* **111**(4), 499-510.

Moser D.K., McKinley S., Dracup K. & Chung M.L. (2005) Gender differences in reasons patients delay in seeking treatment for acute myocardial infarction symptoms. *Patient Education and Counseling* **56**(1), 45-54.



Moser D.K., Kimble L.P., Alberts M.J., Alonzo A., Croft J.B., Dracup K., Evenson K.R., Go A.S., Hand M.M., Kothari R.U., Mensah G.A., Morris D.L., Pancioli A.M., Riegel B. & Zerwic J.J. (2006) Reducing delay in seeking treatment by patients with acute coronary syndrome and stroke: a scientific statement from the American Heart Association Council on cardiovascular nursing and stroke council. *Circulation* **114**(2), 168-182.

Moser D.K., Riegel B., McKinley S., Doering L.V., An K. & Sheahan S. (2007) Impact of anxiety and perceived control on in-hospital complications after acute myocardial infarction. *Psychosomatic Medicine* **69**(1), 10-16.

Moses H.W., Engelking N., Taylor G.J., Prabhakar C., Vallala M., Colliver J.A., Silberman H. & Schneider J.A. (1991) Effect of a two-year public education campaign on reducing response time of patients with symptoms of acute myocardial infarction. *The American Journal of Cardiology* **68**(2), 249-251.

Mosley I., Nicol M., Donnan G. & Dewey H. (2011) Family physician decisions following stroke symptom onset and delay times to ambulance call. *BMC family practice* doi:10.1186/1471-2296-12-82.

Munhall P.L. (1982) Nursing philosophy and nursing research: in apposition or opposition? *Nursing Research* **31**(3), 176-177.

Murray S., Manktelow K. & Clifford C. (2000) The interplay between social and cultural context and perceptions of cardiovascular disease. *Journal of Advanced Nursing* **32**, 1224-1233.

Naegeli B., Radovanovic D., Rickli H., Erne P., Seifert B., Duvoisin N., Pedrazzini G., Urban P. & Bertel O. (2011) Impact of a nationwide public campaign on delays and outcome in Swiss patients with acute coronary syndrome. *European Journal of Cardiovascular Prevention and Rehabilitation* **18**(2), 297-304.

Newby L.K., Rutsch W.R., Califf R.M., Simoons M.L., Aylward P.E., Armstrong P.W., Woodlief L.H., Lee K.L., Topol E.J. & Van De Werf F. (1996) Time from symptom onset to treatment and outcomes after thrombolytic therapy. GUSTO - 1 Investigators. *Journal of the American College of Cardiology* **27**(7), 1646-1655.

Nguyen H., Saczynski J., Gore J. & Goldberg R.J. (2010) Age and sex differences in duration of prehospital delay in patients with acute myocardial infarction: a systematic review. *Circulation: Cardiovascular Quality and Outcomes* **3**, 82-92.

Noureddine S., Adra M., Arevian M., Dumit N.Y., Puzantian H., Shehab D. & Abchee A. (2006) Delay in seeking health care for acute coronary syndromes in a Lebanese sample. *Journal of Transcultural Nursing* **17**(4), 341-348.

Noureddine S., Arevian M., Adra M. & Puzantian H. (2008) Response to signs and symptoms of acute coronary syndrome: differences between lebanese men and women. *American Journal of Critical Care* **17**(1), 26-35.

Nymark C., Mattiasson A.C., Henriksson P. & Kiessling A. (2009) The turning point: from self-regulative illness behaviour to care-seeking in patients with an acute myocardial infarction. *Journal of Clinical Nursing* **18**(23), 3358-3365.

O'Donnell S., Condell S. & Begley C.M. (2004a) 'Add women & stir'—the biomedical approach to cardiac research! *European Journal of Cardiovascular Nursing* **3**(2), 119-127.

O' Donnell S., Condell S., Begley C. & Fitzgerald T. (2004b) In-hospital care pathway delays: gender and myocardial infarction. *Journal of Advanced Nursing* **52**(1), 14-21.

O' Donnell S., Condell S., Begley C. & Fitzgerald T. (2006) Pre-hospital care pathway delays: gender and myocardial infarction. *Journal of Advanced Nursing* **53**(3), 268-276.

O' Donnell S. & Moser D. (2012) Slow-onset myocardial infarction and its influence on help-seeking behaviors. *Journal of Cardiovascular Nursing* **27**(4), 334-344.

O' Donnell S., McKee G., Mooney M., O' Brien F. & Moser D. (2013) Slow-onset and fast-onset symptom presentations in acute coronary syndrome (ACS): new perspectives on prehospital delay in patients with ACS. *Journal of Emergency Medicine*. **In press**.<http://dx.doi.org/10.1016/j.jemermed.2013.08.038>.

O'Mahony M. & Hegarty J. (2009) Factors influencing women in seeking help from a health care professional on self discovery of a breast symptom, in an Irish context. *Journal of Clinical Nursing* **18**, 2020-2029.

O'Mahony M., Hegarty J. & McCarthy G. (2011) Women's help seeking behaviour for self discovered breast cancer symptoms. *European Journal of Oncology Nursing* **15**, 410-418.

Oakley A., Strange V., Bonell C., Allen E. & Stephenson J. (2006) Health services research: process evaluation in randomised controlled trials of complex interventions. *British Medical Journal* **332**(7538), 413-416.

Ottesen M., Dixen U., Torp-Pedersen C. & Kober L. (2003) Pre-hospital behaviour of patients admitted with acute coronary syndrome or witnessed cardiac arrest. *Scandinavian Cardiovascular Journal* **37**, 141-148.

Ottesen M.M., Dixen U., Torp-Pedersen C. & Køber L. (2004) Prehospital delay in acute coronary syndrome—an analysis of the components of delay. *International Journal of Cardiology* **96**(1), 97-103.

- Ottesen M.M., Kober L., Jorgensen S. & Torp-Pedersen C. (1996) Determinants of delay between symptoms and hospital admission in 5978 patients with acute myocardial infarction. *European Heart Journal* **17**(3), 429-437.
- Pallant J. (2007) *SPSS Survival Manual*. Third edn. Open University Press, New York.
- Pallant J. (2010) *SPSS survival manual: A Step by Step Guide to Data Analysis using SPSS*. Open University Press, New York.
- Park Y.H., Kang G.H., Song B.G., Chun W.J., Lee J.H., Hwang S.Y., Oh J.H., Park K. & Kim Y.D. (2012) Factors Related to Prehospital Time Delay in Acute ST-Segment Elevation Myocardial Infarction. *Journal of Korean Medical Science* **27**(8), 864-869.
- Patel H., Rosengren A. & Ekman I. (2004) Symptoms in acute coronary syndromes: does sex make a difference? *American Heart Journal* **148**(1), 27-33.
- Pattenden J., Watt I., Lewin R.J.P. & Stanford N. (2002) Decision making processes in people with symptoms of acute myocardial infarction: qualitative study. *British Medical Journal* **324**(7344), 1006-1009.
- Pelter M. (2010) Time to treatment for acute coronary syndromes: the cost of indecision. *Journal of Cardiovascular Nursing* **25**(2), 115-116.
- Perkins-Porras L., Whitehead D.L., Strike P.C. & Steptoe A. (2008) Causal beliefs, cardiac denial and pre-hospital delays following the onset of acute coronary syndromes. *Journal of Behavioural Medicine* **31**, 498-505.
- Perkins-Porras L., Whitehead D.L., Strike P.C. & Steptoe A. (2009) Pre-hospital delay in patients with acute coronary syndrome: Factors associated with patient decision time and home-to-hospital delay. *European Journal of Cardiovascular Nursing* **8**(1), 26-33.
- Perry K., Petrie K.J., Ellis C.J., Horne R. & Moss-Morris R. (2001) Symptom expectations and delay in acute myocardial infarction patients. *Heart* **86**(1), 91-93.
- Petrie K.J., Cameron L.D., Ellis C.J., Buick D. & Weinman J. (2002) Changing illness perceptions after myocardial infarction: an early intervention randomized controlled trial. *Psychosomatic Medicine* **64**(4), 580-586.
- Philips H., Remmen R., De Paepe P., Buylaert W. & Van Royen P. (2010) Out of hours care: a profile analysis of patients attending the emergency department and the general practitioner on call. *BMC family practice* **11**(1), 88-96.
- Polit D. & Beck C. (2008) *Nursing Research: Generating and Assessing Evidence of Nursing Practice*. Eighth edn. Wolters Kluger Health/Lippincott Williams & Wilkins, Philadelphia.

Polit D. & Beck C. (2010) *Essentials of Nursing Research : Appraising Evidence for Nursing Practice*. Wolters Kluwer Health/Lippincott Williams & Wilkins, Philadelphia.

Poole K. & Jones A. (1996) A re-examination of the experimental design for nursing research. *Journal of Advanced Nursing* **24**(1), 108-114.

Qian L., Ji K.-t., Nan J.-l., Lu Q., Zhu Y.-j., Wang L.-p., Liao L.-m. & Tang J.-f. (2013) Factors associated with decision time for patients with ST-segment elevation acute myocardial infarction. *Journal of Zhejiang University Science* **14**(8), 754-758.

Quinn T., Butters A. & Todd I. (2002) Implementing paramedic thrombolysis—an overview. *Accident and Emergency Nursing* **10**(4), 189-196.

Quinn J.R. (2005) Delay in seeking care for symptoms of acute myocardial infarction: applying a theoretical model. *Research in Nursing and Health* **28**, 283-294.

Randolph W. & Viswanath K. (2004) Lessons learned from public health mass media campaigns: marketing health in a crowded media world. *Annual Review of Public Health* **25**, 419-437.

Rasmussen C., H, Munck A., M., Kragstrup J K. & Haghfelt T H. (2003) Patient delay from onset of chest pain suggesting acute coronary syndrome to hospital admission. *Scandinavian Cardiovascular Journal* **37**(4), 183-186.

Raczynski J.M., Finnegan J.R., Zapka J.G., Meischke H., Meshack A., Stone E.J., Bracht N., Sellers D.E., Daya M. & Robbins M. (1999) REACT theory-based intervention to reduce treatment-seeking delay for acute myocardial infarction. *American Journal of Preventive Medicine* **16**(4), 325-334.

Resnick B., Bellg A.J., Borrelli B., De Francesco C., Breger R., Hecht J., Sharp D.L., Levesque C., Orwig D. & Ernst D. (2005) Examples of implementation and evaluation of treatment fidelity in the BCC studies: Where we are and where we need to go. *Annals of Behavioral Medicine* **29**(2), 46-54.

Richardson J. (2000) The use of randomized controlled trials in complementary therapies: exploring the issues. *Journal of Advanced Nursing* **32**, 398-406.

Riegel B., McKinley S., Moser D.K., Meischke H., Doering L. & Dracup K. (2007) Psychometric evaluation of the Acute Coronary Syndrome (ACS) response index. *Research in Nursing and Health* **30**(6), 584-594.

Rogers W.J., Frederick P.D., Stoehr E., Canto J.G., Ornato J.P., Gibson M.C., Pollack Jr C.V., Gore J.M., Chandra-Strobos N. & Peterson E.D. (2008) Trends in presenting characteristics and hospital mortality among patients with ST elevation and non-ST elevation myocardial infarction in the National Registry of

Myocardial Infarction from 1990 to 2006. *American Heart Journal* **156**(6), 1026-1034.

Rosenfeld A.G. (2004) Treatment-seeking delay among women with acute myocardial infarction: decision trajectories and their predictors. *Nursing Research* **53**(4), 225-236.

Rucker D.W., Brennan T.A. & Burstin H.R. (2008) Delay in seeking emergency care. *Academic Emergency Medicine* **8**(2), 163-169.

Ruston A., Clayton R. & Calnan M. (1998) Patients' action during their cardiac event: Qualitative study exploring differences and modifiable factors. *British Medical Journal* **316**(7137), 1060-1065.

Ruston A. (2001) Accessing emergency care at the time of a heart attack: why people do not dial 999 for an ambulance. *The Journal of the Royal Society for the Promotion of Health* **121**(4), 243-247.

Ruston A. (2007) Womens interpretation of cardiac symptoms at the time of their cardiac event:the effect of co-occurring illness. *European Journal of Cardiovascular Nursing* **6**(4), 321-328.

Ryan C.J. & Zerwic J.J. (2004) Knowledge of symptom clusters among adults at risk for acute myocardial infarction. *Nursing Research* **53**(6), 363-369.

Ryan P. & Lauver D.R. (2002) The efficacy of tailored interventions. *Journal of Nursing Scholarship* **34**(4), 331-337.

Ryden L., Standl E., Bartnik M., Van den Berghe G., Betteridge J., De Boer M.J., Cosentino F., Jonsson B., Laakso M. & Malmberg K. (2007) Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC); European Association for the Study of Diabetes (EASD). Guidelines on diabetes, pre-diabetes, and cardiovascular diseases: executive summary: The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). *European Heart Journal* **28**(1), 88-136.

Sackett D., Richardson W., Rosenberg W. & Haynes R. (1997) *Evidence-Based Medicine: How to Practice and Teach EBM*. Churchill-Livingstone, London.

Saczynski J.S., Yarzbeski J., Lessard D., Spencer F.A., Gurwitz J.H., Gore J.M. & Goldberg R.J. (2008) Trends in prehospital delay in patients with acute myocardial infarction (from the Worcester Heart Attack Study). *The American Journal of Cardiology* **102**, 1589-1594.

Sahin-Hodoglugil N., Sommerfeld J. & Gursoy A. (2003) Perceptions of cardiovascular disease risk factors in a semi-urban community in Turkey and implications for behaviour-change interventions. *13th Annual Meeting of American Public Health Association*, Washington.

Schoenberg N.E., Peters J.C. & Drew E.M. (2003) Unraveling the mysteries of timing: Women's perceptions about time to treatment for cardiac symptoms. *Social Science and Medicine* **56**(2), 271-284.

Schulz K.F., Altman D.G. & Moher D. (2010) CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BiomMed Central* **8**(18), 1-9.

Scott S., Walter F., Webster A., Sutton S. & Emery J. (2013) The model of pathways to treatment: conceptualization and integration with existing theory. *British Journal of Health Psychology* **18**(1), 45-65.

Sheifer S.E., Rathore S.S., Gersh B.J., Weinfurt K.P., Oetgen W.J., Breall J.A. & Schulman K.A. (2000) Time to presentation with acute myocardial infarction in the elderly: associations with race, sex, and socioeconomic characteristics. *Circulation* **102**(14), 1651-1656.

Shirai K., Lansky A.J., Mehran R., Dangas G.D., Costantini C.O., Fahy M., Slack S., Mintz G.S., Stone G.W. & Leon M.B. (2004) Minimally invasive coronary artery bypass grafting versus stenting for patients with proximal left anterior descending coronary artery disease. *American Journal of Cardiology* **93**(8), 959-962.

Sidani S. & Braden C.J. (2011) *Design, Evaluation and Translation of Nursing Interventions*. Wiley-Blackwell, New Delhi.

Siepmann D.B., Mann N.C., Hedges J.R. & Daya M.R. (2000) Association between prepayment systems and emergency medical services use among patients with acute chest discomfort syndrome. *Annals of Emergency Medicine* **35**(6), 573-578.

Singh N.P., Kumar A. & Sarkar T. (2011) Randomised controlled trials. *Indian Journal of Medical Specialities* **2**(2), 194-199.

Sjostrom-Strand A. & Fridlund B. (2008) Women's descriptions of symptoms and delay reasons in seeking medical care at the time of a first myocardial infarction: a qualitative study. *International Journal of Nursing Studies* **45**, 1003-1010.

Skinner C.S., Campbell M.K., Rimer B.K., Curry S. & Prochaska J.O. (1999) How effective is tailored print communication? *Annals of Behavioral Medicine* **21**(4), 290-298.

Smith S.C., Feldman T.E., Hirshfeld J.W., Jacobs A.K., Kern M.J., King S.B., Morrison D.A., O'Neill W.W., Schaff H.V. & Whitlow P.L. (2006) ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). *Journal of the American College of Cardiology* **47**(1), e1-e121.

Smolderen K.G., Spertus J.A., Nallamothu B.K., Krumholz H.M., Tang F., Ross J.S., Ting H.H., Alexander K.P., Rathore S.S. & Chan P.S. (2010) Health care insurance, financial concerns in accessing care, and delays to hospital presentation in acute myocardial infarction. *JAMA* **303**(14), 1392-1400.

Spillane V., Byrne M.C., Byrne M., Leathem C.S., O'Malley M. & Cupples M.E. (2007) Monitoring treatment fidelity in a randomized controlled trial of a complex intervention. *Journal of Advanced Nursing* **60**(3), 343-352.

Srivastava R. & Canto J.G. (2003) Use of emergency medical services in acute myocardial infarction and subsequent quality of care. *Cardiovascular Reviews & Reports* **24**(10), 527-531.

Steg P.G., James S.K., Atar D., Badano L.P., Lundqvist C.B., Borger M.A., Di Mario C., Dickstein K., Ducrocq G. & Fernandez-Aviles F. (2012) ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation The Task Force on the management of ST-segment elevation acute myocardial infarction of the European Society of Cardiology (ESC). *European Heart Journal* **33**(20), 2569-2619.

Strömberg A. (2007) The challenge of improving practice and improving care. *European Journal of Cardiovascular Nursing* **6**, 87-88.

Strecher V., Wang C., Derry H., Wildenhaus K. & Johnson C. (2002) Tailored interventions for multiple risk behaviors. *Health Education Research* **17**(5), 619-626.

Sullivan M.D., Ciechanowski P.S., Russo J.E., Soine L.A., Jordan-Keith K., Ting H.H. & Caldwell J.H. (2009) Understanding why patients delay seeking care for acute coronary syndromes. *Circulation: Cardiovascular Quality and Outcomes* **2**(3), 148-154.

Taha R., Oraby M., Nasr G. & El-Hawary A. (2013) Prevalence and causes of failure of receiving thrombolytic therapy in patients with acute ST-segment elevation myocardial infarction. *The Egyptian Heart Journal* **65**(2), 51-55.

Taylor D.M.D., Garewal D., Carter M., Bailey M. & Aggarwal A. (2005) Factors that impact upon the time to hospital presentation following the onset of chest pain. *Emergency Medicine Australasia* **17**(3), 204-211.

Taylor S. (1990) Health Psychology: the science and the field. *American Psychologist* **45**(1), 40-50.

Terkelsen C.J., Lassen J.F., Nørgaard B.L., Gerdes J.C., Poulsen S.H., Bendix K., Ankersen J.P., Gøtzsche L.B.-H., Rømer F.K. & Nielsen T.T. (2005) Reduction of treatment delay in patients with ST-elevation myocardial infarction: impact of pre-hospital diagnosis and direct referral to primary percutaneous coronary intervention. *European Heart Journal* **26**(8), 770-777.

Theisen M.E., MacNeill S.E., Lumley M.A., Ketterer M.W., Goldberg A.D. & Borzak S. (1995) Psychosocial factors related to unrecognized acute myocardial infarction. *The American Journal of Cardiology* **75**(17), 1214-1219.

Thompson D.R., Chan S.W., Astin F., Davidson P.M. & Ski C.F. (2011) Motivational interviewing: a useful approach to improving cardiovascular health? *Journal of Clinical Nursing* **20**, 1236-1244.

Thuresson M., Berglin-Jarlov M., Lindahl B., Svensson L., Zedigh C. & Herlitz J. (2007) Thoughts, actions and factors associated with pre-hospital delay in patients with acute coronary syndrome. *Heart and Lung* **36**(6), 398-409.

Thuresson M., Jarlöv M.B., Lindahl B., Svensson L., Zedigh C. & Herlitz J. (2008) Factors that influence the use of ambulance in acute coronary syndrome. *American Heart Journal* **156**(1), 170-176.

Thygesen K., Alpert J.S. & White H.D. (2007) Universal definition of myocardial infarction. *European Heart Journal* **28**(20), 2525-2538.

Tilley J.D., Gregor F.M. & Thiessen V. (1987) The nurse's role in patient education: incongruent perceptions among nurses and patients. *Journal of Advanced Nursing* **12**(3), 291-301.

Timmins F. (2005) A review of the information needs of patients with acute coronary syndromes. *Nursing in Critical Care* **10**(4), 174-183.

Ting H.H., Bradley E.H., Wang Y., Lichtman J.H., Nallamothu B.K., Sullivan M.D., Gersh B.J., Roger V.L., Curtis J.P. & Krumholz H.M. (2008) Factors associated with longer time from symptom onset to hospital presentation for patients with ST-elevation myocardial infarction. *Archives of Internal Medicine* **168**(9), 959-968.

Ting H.H. & Bradley E.H. (2009) Patient education to reduce prehospital delay time in acute coronary syndrome- necessary but not sufficient. *Circulation: Cardiovascular Quality and Outcomes* **2**, 522-533.

Ting H.H., Chen A., Roe M.T., Chan P., Spertus J., Nallamothu B., Sullivan M.D., De Long E., Bradley E.H., Krumholz H.M. & Peterson E.D. (2010) Delay from symptom onset to hospital presentation for patients with non-ST segment elevation myocardial infarction. *Archives of Internal Medicine* **170**(20), 1834 - 1841.

Torgerson D. & Torgerson C. (2008) *Designing Randomised Trials in Health, Education and Social Sciences*. Palgrave Macmillan, Hampshire.

Tubaro M., Danchin N., Goldstein P., Filippatos G., Hasin Y., Heras M., Jansky P., Norekval T.M., Swahn E. & Thygesen K. (2011) Pre-hospital treatment of STEMI patients. A scientific statement of the Working Group Acute Cardiac Care of the European Society of Cardiology: Acute Coronary Syndromes. *Acute Cardiac Care* **13**(2), 56-67.



- Turk D.C., Rudy T.E. & Salovey P. (1984) Health protection: attitudes and behaviors and LPNs, teachers, and college students. *Health Psychology* **3**(3), 189-210.
- Turris S.A. & Finamore S. (2008) Reducing delay for women seeking treatment in emergency department for symptoms of potential cardiac illness. *Journal of Emergency Nursing* **34**, 509-515.
- Valente T.W., Paredes P. & Poppe P.R. (2006) Matching the message to the process: the relative ordering of knowledge, attitudes, and practices in behavior change research. *Human Communication Research* **24**(3), 366-385.
- Van Dam H., Horst V.D. & Borne V.D. (2003) Provider-patient interaction in diabetes care: effects on patient self-care and outcomes. A systematic review. *Patient Education and Counseling* **51**, 17-28.
- Van de Werf F., Ardissino D., Betriu A., Cokkinos D.V., Falk E., Fox K.A.A., Julian D., Lengyel M., Neumann F.J. & Ruzyllo W. (2003) Management of acute myocardial infarction in patients presenting with ST-segment elevation. *European Heart Journal* **24**(1), 28-66.
- Van de Werf F., Bax J., Betriu A., Blomstrom-Lundqvist C., Crea F., Falk V., Filippatos G., Fox K., Huber K. & Kastrati A. (2008) Management of acute myocardial infarction in patients presenting with persistent ST-segment elevation. *European Heart Journal* **29**(23), 2909-2945.
- Van Meijel B., Gamel C. & Van Swieten-Duijfjes B. (2004) The development of evidence-based nursing interventions: methodological considerations. *Journal of Advanced Nursing* **48**, 84-92.
- Vavouranakis I., Fanioudaki A., Lamprogiannakis E., Baltzakis I., Sidiropoulou K., Porfiri E. & Ganotakis E. (2010) Delays incurred during acute myocardial infarction: a comparative study of rural and urban populations in Greece. *Rural and Remote Health* **10**, 1271-1281.
- Walkiewicz M., Krówczyńska D., Kuchta U., Kmiećicka M., Kurjata P. & Stepińska J. (2008) Acute coronary syndrome--how to reduce the time from the onset of chest pain to treatment? *Kardiologia Polska* **66**(11), 1163-1170.
- Waller G. (2009) Evidence-based treatment and therapist drift. *Behaviour Research and Therapy* **47**(2), 119-127.
- Walsh J.C., Lynch M., Murphy A.W. & Daly K. (2004) Factors influencing the decision to seek treatment for symptoms of acute myocardial infarction: an evaluation of the self regulatory model of illness behaviour. *Journal of Psychosomatic Research* **56**(1), 67-73.
- Waltz J., Addis M.E., Koerner K. & Jacobson N.S. (1993) Testing the integrity of a psychotherapy protocol: assessment of adherence and competence. *Journal of Consulting and Clinical Psychology* **61**(4), 620-630.

Watson M., Woods A. & Kendrick D. (2002) Randomised controlled trials in primary care. *Community Practitioner* **75**, 131-134.

Weinman J., Petrie K., Sharpe N. & Walker S. (2001) Causal attributions in patients and spouses after a heart attack and subsequent lifestyle changes. *British Journal of Health Psychology* **5**, 263-273.

Weinstein N.D. & Klein W.M. (1995) Resistance of personal risk perceptions to debiasing interventions. *Health Psychology* **14**(2), 132.

Weinstein N. (1999) What does it mean to understand a risk? Evaluating risk comprehension. *Journal of the National Cancer Institute Monographs* **25**, 15-20.

Wells K.B. & Sturm R. (1996) Informing the policy process: From efficacy to effectiveness data on pharmacotherapy. *Journal of Consulting and Clinical Psychology* **64**(4), 638-645.

Widimsky P., Wijns W., Fajadet J., de Belder M., Knot J., Aaberge L., Andrikopoulos G., Baz J.A., Betriu A. & Claeys M. (2010) Reperfusion therapy for ST elevation acute myocardial infarction in Europe: description of the current situation in 30 countries. *European Heart Journal* **31**(8), 943-957.

Wodarski J. & Hopson L. (2012) *Research methods for evidence-based practice*. Sage Publications, London.

Xanthos T., Pantazopoulos I., Vlachos I., Stroumpoulis K., Barouxis D., Kitsou V., Marathias K., Karabinis A. & Papadimitriou L. (2010) Factors influencing arrival of patients with acute myocardial infarction at emergency departments: implications for community nursing interventions. *Journal of Advanced Nursing* **66**(7), 1469-1477.

Yan H.-b., Song L., Chen H., Zhang J., Li S.-y., Li Q.-x., CHENG S.-j., WANG J., ZHAO H.-j. & HU D.-y. (2009) Factors influencing ambulance use in patients with ST-elevation myocardial infarction in Beijing, China. *Chinese Medical Journal (English Edition)* **122**(3), 272-278.

Yarzebski J., Goldberg R.J., Gore J.M. & Alpert J.S. (1994) Temporal trends and factors associated with extent of delay to hospital arrival in patients with acute myocardial infarction: The Worcester Heart Attack Study. *American Heart Journal* **128**(2), 255-263.

Zbierajewski-Eischeid S.J. & Loeb S.J. (2009) Myocardial infarction in women: promoting symptom recognition, early diagnosis, and risk assessment. *Dimensions of Critical Care Nursing* **28**(1), 1-6.

Zegrean M., Fox-Wasylyshyn S.M. & El-Masri M.M. (2009) Alternative Coping Strategies and Decision Delay in Seeking Care for Acute Myocardial Infarction. *Journal of Cardiovascular Nursing* **24**(2), 151-155.

Zerwic J.J. (1998) Symptoms of acute myocardial infarction: expectations of a community sample. *Heart & Lung: The Journal of Acute and Critical Care* **27**(2), 75-81.

Zerwic J.J., Ryan C.J., DeVon H.A. & Drell M.J. (2003) Treatment seeking for acute myocardial infarction symptoms: differences in delay across sex and race. *Nursing Research* **52**(3), 159-167.

## Appendices

## Appendix 1: The Intervention Manual

### The Intervention Manual



### ACS Response-Time Intervention Trial

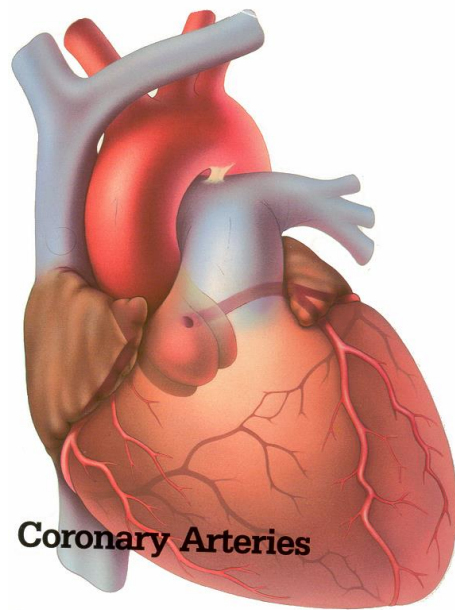
## **Intervention PowerPoint slides and associated script.**

- Welcome family member if present. Identify importance of them being there.
- Throughout the intervention, **use reflective statements** to recount aspects of the participant's event, to demonstrate reflective listening.
- Throughout the intervention, be cognisant of the participant's literacy level and, where necessary provide clarification for the participant if there is any doubt about their understanding of the content.

The reason for this study is that we know some people delay in going to hospital when they have heart symptoms. I want to talk to you about that and go over some information with you.

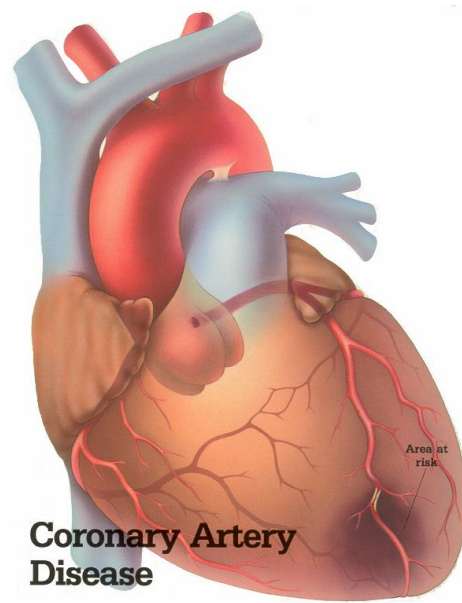
The aim of this study is to teach patients how to recognise common heart symptoms and the benefits of seeking care early (to promote early response to heart symptoms).

We want to see if we can shorten the length of time that people wait from the onset of the first signs of heart symptoms until they are treated. We can do this by getting patients to recognise the symptoms of a heart attack and by explaining to them the importance of getting to the hospital quickly. Right now the average length of time that patients delay is 2 to 6 ½ hours and that's worldwide. We would like patients to go to hospital within the hour and we will go over that again later.



This is a picture of a normal heart. The heart is a pump but it also has its own blood supply. There are two main coronary arteries (the right and left coronary arteries).

The coronary arteries supply the heart muscle with oxygen. Most heart attacks are caused by something called coronary artery disease. Coronary artery disease occurs when fat and scar tissue create blockages in the vessels that feed the heart. Over time, fatty deposits build up and lead to atherosclerosis. If these blood vessels get blocked then that's how a heart attack occurs. Because you have had a heart attack, or angina event, you are at risk of having another event.



This diagram shows the darkening of muscle tissue that is not receiving enough oxygen because of the narrowing of the coronary artery. Eventually, if the blood supply is restricted long enough, this muscle tissue will die and cause a heart attack. We want to prevent this from happening as much as possible.



## Benefits of going to the hospital quickly

- Hospitals have treatments which can restore the blood and oxygen supply to the heart.
  - thrombolytic drugs (clotbusters)
  - coronary angioplasty
  - coronary artery stents
  - coronary bypass surgery
- These unblock the blockage
  - Greater survival
  - Better quality of life
  - Fewer complications

There are many benefits to arriving at the hospital early after symptoms start. Hospitals have treatments to restore blood and oxygen supply to the heart, but the treatments have to be started early so that's why we want patients to get there within the hour of symptoms starting.

- **Thrombolytic drugs** – dissolve clots. They can actually stop a heart attack that has already begun and save heart muscle from damage, if given soon enough. They can turn a potentially large heart attack into a smaller one by getting oxygen to the starving muscle. However, in order to work, they must be given quickly. There is a narrow window of opportunity with these drugs. Remember time is muscle so act quickly.
- **Coronary angioplasty** – is a procedure in which a small catheter is threaded from an artery in the groin to the blocked portion of the artery in the heart, the balloon is blown up and the vessel wall made larger by the pressure exerted by the balloon. Angioplasty is very effective but frequently these arteries reclose in a short period of time.
- **Coronary artery stents** are used as a kind of scaffolding to keep the arteries open after angioplasty. Once the stent is securely in place, holding the vessel wall open, the catheter and balloon are removed, leaving a wider opening in the vessel.

- **Coronary artery bypass surgery** works by putting new “pipes” in place using other vessels to bypass the clogged area (Surgery won’t happen within the hour, but it will start the preparation).

**By getting to the hospital in time to use these therapies and restore blood flow to oxygen-starved muscle, patients have:**

- Greater chance of survival,
- Better quality of life after recovery,
- Less complications

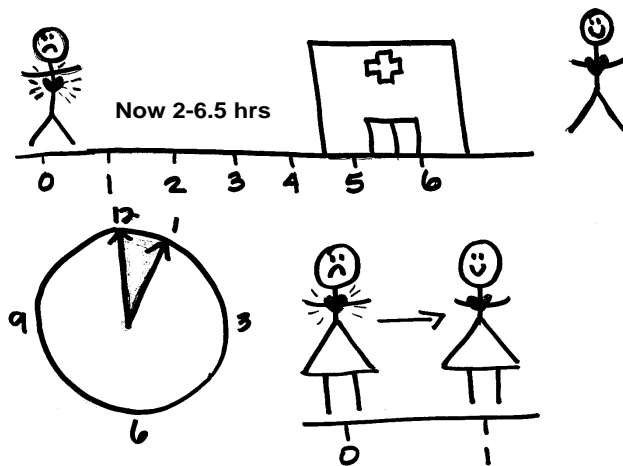
**By getting to the hospital quickly, patients spend the first hour near trained personnel with emergency equipment to treat the life threatening complications, which often lead to sudden death within the first hour of a heart attack. Remember, you are at increased risk of another event and so timely treatment is really important for you.**

## Don't Delay

- Treatments are less effective the more patients delay

Incorporate the patient's story into the educational intervention - using reflective statements.

## The Golden Hour



We refer to the first hour following the onset of your symptoms as the “golden hour”, wherein you may receive care in order to save your life or prevent further disability. Right now, patients wait anywhere from hours to days before receiving the care they need to restore blood flow to the heart muscle. The average length of time is between 2 and 6 ½ hours, depending on where the patient lives. Our goal is to shorten that to 1 hour for every patient. This means one hour from the onset of the first symptom to the time that treatment is given in the hospital. This would save many lives and improve the lives of patients that survive heart attacks. **Every minute counts!**

Seeking treatment within an hour of symptom onset can

- Reduce the size of the infarct,
- Lessen disability,
- Reduce mortality.

## Reasons for Delaying

- “Hollywood Heart attack”
- Unsure of symptoms
- Gradual onset
- No pain
- Different pain
- Embarrassment
- Family/friends
- Calling GP for advice
- Ethnicity
- Female
- Age (young or old)
- Diabetes
- Fear
- Anxiety
- A&E Crisis
- Traffic congestion

There are many reasons for “delay” in seeking and receiving care.

A lot of people recognise a heart attack as a Hollywood heart attack. They expect a dramatic event with crushing chest pain and falling to the floor.

Many patients are not sure of the symptoms of a heart attack and do not believe that the symptoms they are experiencing are serious.

When symptoms come on gradually, patients are much less likely to seek care than when they come on suddenly or severely.

Some heart attacks are associated with no pain or pain that is not severe. This is especially true in the elderly and in diabetics. Sometimes women report less pain than men.

Sometimes patients who have had a previous heart attack expect the symptoms to be the same, but a second or third heart attack may be in a new location and have completely different symptoms or pain in a new location.

Sometimes patients delay because they are embarrassed and don’t want to draw attention to themselves or bother others.

Sometimes care is delayed by family or friends. Studies have shown that patients receive care faster if they discuss their symptoms with a stranger, instead of someone they know. We often don’t want to believe that a loved one is having a heart attack, so we talk them out of seeing the seriousness of the

situation, and delay their care. However, it is really important to notify someone when symptoms occur and do not resolve.

A big reason for delay is calling your doctor for advice. Precious minutes are wasted by taking the time to make the phone call and waiting to receive advice. Sometimes doctors believe the symptoms are not that serious, simply because the patient took the time to call and ask for advice. Some doctors will make suggestions like attending the surgery. This also delays care.

A patient's ethnicity sometimes leads to a delay in care. African Americans have more heart attacks at a younger age than whites due to a higher incidence of high B/P. Hispanics have heart attacks at younger ages because of higher incidence of diabetes.

Women often delay more than men. Some of this is because women think that they are less likely to have a heart attack than men. Health care professionals often overlook heart attack symptoms in women, and treat men more aggressively than women, with similar symptoms. Heart attacks are the leading cause of death in women. Heart attacks in women are more often fatal than heart attacks in men.

Age is a cause of delay in treatment. The very young often don't believe that they could have a heart attack. The very old have many complaints and often make excuses for their discomfort. This leads to further delays in seeking care. It is often difficult for the elderly to tell the difference between heart attack pain and other discomforts. Sometimes the elderly do not have pain with a heart attack. Instead, they feel weak, tired, dizzy or short of breath.

Diabetics often suffer delays in treatment because they do not feel pain with heart attacks. Just like a diabetic can have less feeling in their feet and legs, they can have nerve damage to their heart muscle as well. This lack of sensation leads to more severe heart attacks going undetected.

Fear causes many people to delay seeking care. They don't want to be having a heart attack, so they wait to see if it will "go away." While they wait, muscle is dying due to lack of oxygen.

Anxiety can cause us to think less clearly, and make excuses about what is happening to our bodies. The anxiety related to a possible heart attack, or the care that will be necessary, causes many people to delay seeking the care they need. **Relate delay slide to patient's current reasons for delay.**

## Typical symptoms of heart attack

- Chest discomfort or pain
  - may radiate to the arm, neck or jaw
- Pain or heaviness in the left arm
- Shortness of breath
- A sense of dread

Find out what the patient's symptoms were for this admission (incorporate the patient's answer for the rest of the intervention). Clarify misconceptions that were identified during baseline data collection

We want you to know the common symptoms of a heart attack. Remember, if you have another episode of angina or heart attack, the symptoms may not be the same.

- Chest discomfort or pain may radiate to left arm, neck, jaw, teeth, shoulder.
- Pain or heaviness in the left arm, or both arms.
- Shortness of breath.
- A sense of dread (something is wrong, but don't know what it is).

## Other symptoms which may occur

- **Feeling cold and clammy**
- **Nausea and or indigestion**
- **Feeling faint or lightheaded**
- **Fatigue**
- **Discomfort in any area from your nose to the navel**

### Other symptoms, which may occur

- Feeling cold and clammy, or sweaty.
- Feeling nauseated or vomiting, or a feeling of heart burn.
- Feeling faint or lightheaded.
- Extremely fatigued – often a symptom that women feel.
- Nose to naval – good locator.



## Variations in symptoms

- Symptoms may come on gradually rather than suddenly
- Symptoms may come and go
- Some people have no pain, especially older people and people with diabetes
- The symptoms of a second heart attack /angina etc could be different from the first one.

Everyone is different and each heart attack differs, even in the same person.

- Symptoms may come on gradually or suddenly. This can happen over days or hours or within minutes. Symptoms may come and go. Some people have no pain, especially older people and diabetics.
- The symptoms of a second heart attack or event could be very different from the first one. Many people are convinced that the second heart attack is not a “real” heart attack because the symptoms are not the same as before and they delay seeking care. Remember you are at risk of a future heart event.

### Common sites for chest pain

Different parts of the heart are supplied by different blood vessels and different nerves. Sometimes the heart will share the same nerve as the left arm, so a person will feel left arm pain or discomfort when having a heart attack. The bottom of the heart often shares a nerve with the diaphragm or the stomach, so they will feel heart burn or nausea with a heart attack.

## What to do if you think you are having a heart attack

- Recognise how you might feel about a possible heart attack. You may:
  - believe the symptoms are not serious
  - believe the symptoms are not related to your heart
  - feel embarrassed about seeking help for the symptoms
  - be concerned about troubling others
  - be afraid of the consequences of seeking help

### What to do when you think you are having a heart attack.

There are things that may make you delay in seeking medical aid. We want you to think about these things. To begin, you need to recognise how you might feel about a possible heart attack. You may:

- Believe the symptoms are not serious,
- Believe the symptoms are not related to your heart,
- Feel embarrassed about seeking help for the symptoms,
- Be concerned about troubling others,
- Be afraid of the consequences of seeking help.

Once you recognise these normal reactions, set them aside and do what is needed to take care of yourself.

## What to do if you think you are having a heart attack

- Stop and Rest
- Take your GTN (Angina spray) as instructed.
- Let someone know what is happening
- If symptoms continue for more than 15 minutes, act immediately.
- Phone 999 or 112 for an ambulance wherever you are.



The important thing here is that you **know the signs and symptoms of a heart attack** and what to do when you get heart symptoms. I will give you a form to take home with the signs and symptoms of a heart attack on it. I will also give you a fridge magnet and a wallet card with reminders of what to do if you get symptoms.

If you do have symptoms the first thing you must do is stop and rest...regardless of what you are doing....

Take prescribed nitrate medication as instructed (as per hospital policy).

Take the prescribed nitrates as soon as you feel discomfort.

If the discomfort is still there after 5 minutes, take another two puffs

If the discomfort persists for another 5 minutes, take another two puffs

If the symptoms persist for more than 15 minutes, act immediately.

Let someone know what is happening.

Call the ambulance wherever you are (call 999 or 112). Stress the importance of this to the patient and how they will be seen quicker when they arrive (they will not be left in the waiting room).

Ambulances have life-saving equipment and trained personnel who can deal with emergencies outside the hospital.

You should view the ambulance as an extension of the hospital. So, it is like the hospital coming to you when you call for an ambulance.

If you do not have access to 999 or 112, have someone take you to the nearest full-service ED.

Do not drive yourself

Do not stop to call your doctor.

Do not stop to call other friends or family (just the person you originally called).

Remember: take your nitroglycerine, dial 999 and rest until help arrives. Patients with heart symptoms are given highest priority in the ED. You will not be left waiting. Those arriving by ambulance are seen quickest.

**Does this sound like something you could do?**

- The participant's response will indicate their level of discrepancy, whether the motivation for change is present, their uptake of the intervention and receptiveness to change.
- If the participant's goals or values do not match the intervention, remember to roll with resistance.

**DON'T HESITATE**

**DONT DELAY**

***IF IN DOUBT LET A&E CHECK IT OUT***



- You are at risk of this happening again
- The main reason why patients don't receive these treatments is because they delay too long before coming to A&E.
- Treatments can stop a heart attack in its tracks. They work best if given within 1 hour of the start of symptoms.

## Scenarios

- Patient
- Family member

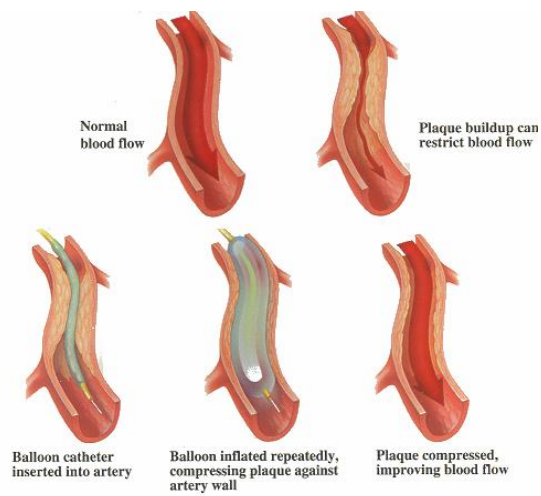
Use scenarios that most resemble the participant's age, gender and lifestyle. Ask the participant to anticipate emotions they might experience. Acknowledge that a range of emotions are normal and can affect coping and actions. Determine what actions the participant might take in the presence of symptoms.

In the presence of resistance, roll with it:

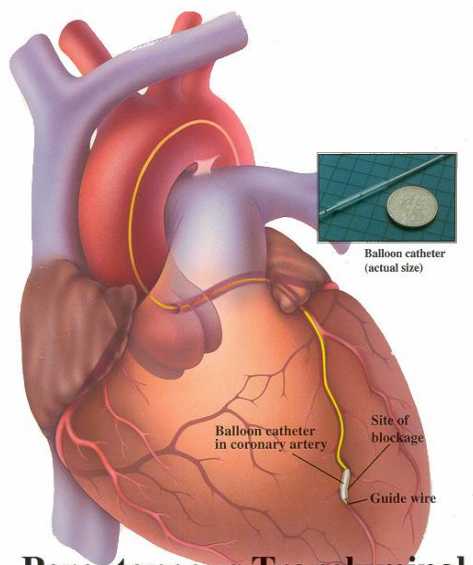
- Arguments for change should be avoided.
- Encourage discussion and collaboration to develop new perspectives and personal goals.
- Empathise and acknowledge the clients' perspective.
- Aim to find solutions based on the participant's current level of knowledge, attitudes and beliefs.

Do you have any questions about this education?

## Percutaneous Transluminal Coronary Angioplasty (PTCA)



This diagram shows a normal coronary artery with smooth walls. Next to it is an artery that is narrowed because of plaque build-up. The angioplasty catheter is threaded into the narrow artery, the balloon is blown up and the vessel wall made larger by the pressure exerted by the balloon. Angioplasty is very effective but frequently these arteries reclose in a short period of time.

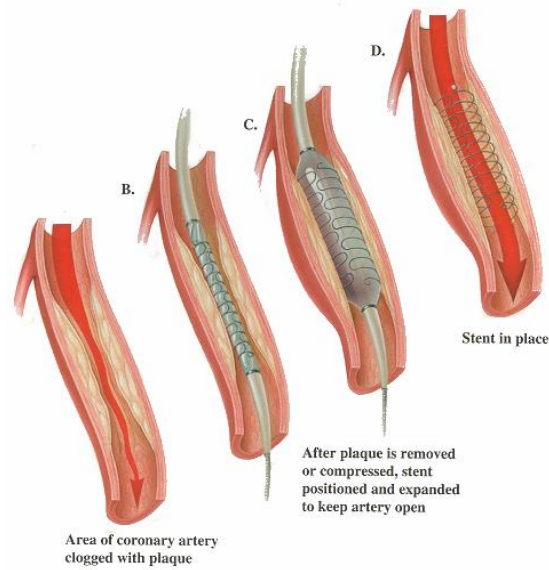


## **Percutaneous Transluminal Angioplasty**

Percutaneous Transluminal Angioplasty is a procedure in which a small catheter is threaded from an artery in the groin to the blocked portion of the artery in the heart.

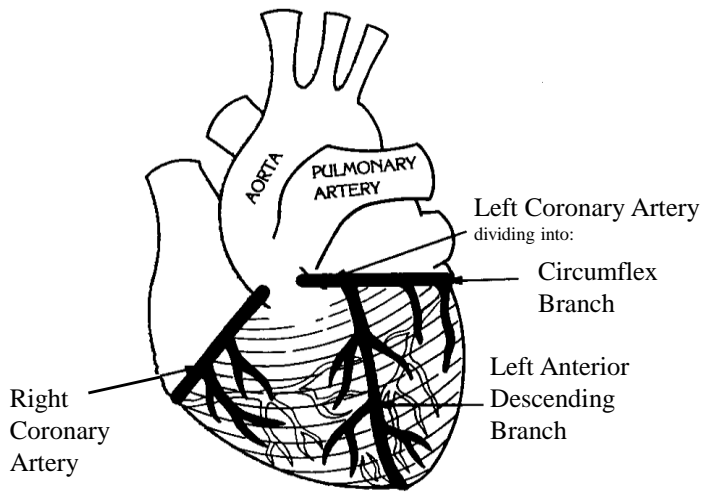


## PTCA and Intracoronary Stenting

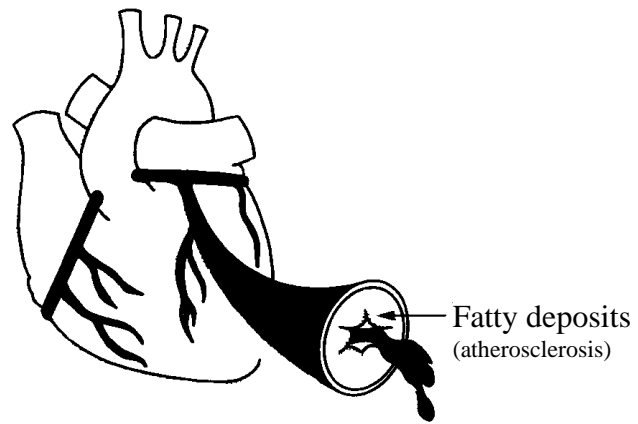


Over the past few years coronary artery stents have been perfected and are used as a kind of scaffolding to keep the arteries open after angioplasty. This diagram shows you how an angioplasty catheter is used to introduce the narrowed stent into the artery. When the angioplasty balloon is inflated, the stent is opened up and “deployed” into the vessel wall. Once the stent is securely in place, holding the vessel wall open, the catheter and balloon are removed leaving a wider opening in the vessel.

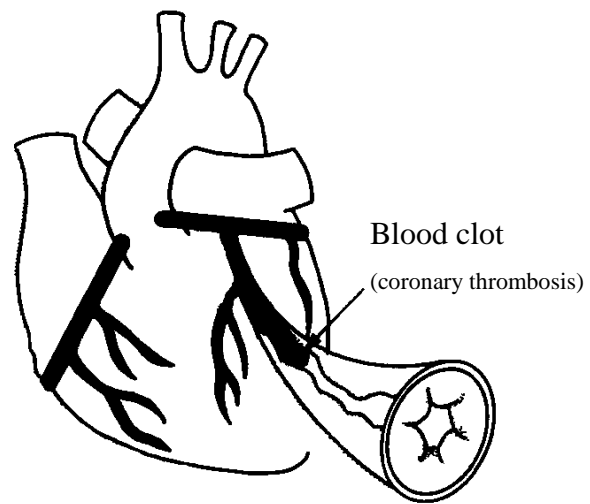
# Blood supply to the heart



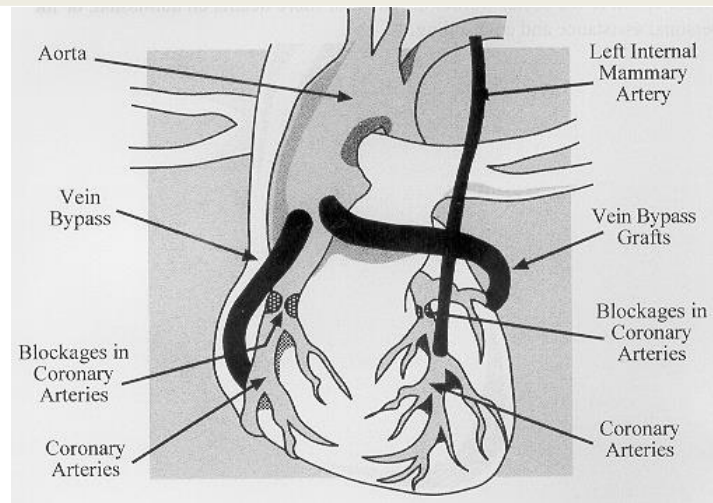
## Atherosclerosis



## Blockage of the coronary arteries

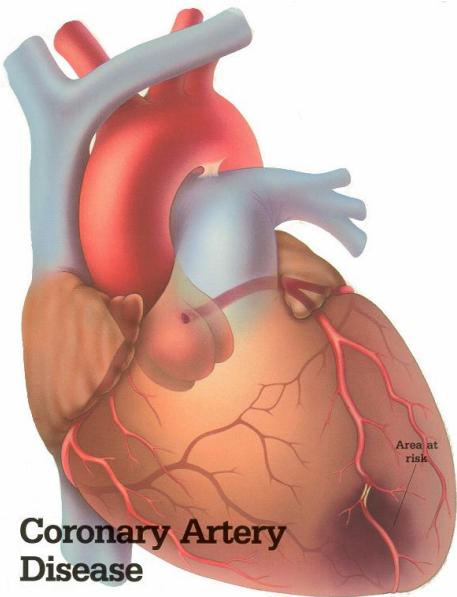


## Coronary bypass surgery



In this surgery, vessels are taken from the chest wall, the leg or the wrist to create a new channel for blood flow to the muscle that is lacking blood supply. Surgery is done for patients who have many clogged or narrowed arteries, or if the part of the artery that is narrowed is not possible to reach safely with an angioplasty catheter. If done quickly during a heart attack, it is possible for patients to suffer very little muscle damage to their heart.

**ANGINA**



## Action plan leaflet

### WHAT TO DO IF YOU HAVE ONE OR MORE HEART WARNING SYMPTOMS?

**1. You may experience some or all of these symptoms:**

- Chest discomfort, heaviness or pain
- Arm pain or ache
- Pain radiating to your neck, jaw, arms or shoulder blades
- Shortness of breath
- Sweating
- Nausea and/or indigestion
- A sense of dread
- Discomfort in any area from your nose to your navel



**2. If symptoms are present:**

- Stop and Rest
- Take your GTN spray as directed: \_\_\_\_\_
  
- Let someone know what is happening



**3. If the symptoms continue longer than 15 minutes, phone 999 or 112 for an ambulance.**

- Don't wait
- Don't hesitate
- ***IF IN DOUBT LET A&E CHECK IT OUT***

**If you experience any heart symptoms and go to A&E please record below**

Date:	Time:
I had some or all of the above symptoms: Yes                      No	
I took GTN spray at:	
Pain persisted beyond 15 minutes:    Yes:                      No:	
I phoned ambulance at :	
Ambulance arrived at:	
I got to A&E at:	
If you attend hospital with heart symptoms please leave a message to inform the researcher - 085 51381267	

## Appendix 2: Consort 2010 Checklist

CONSORT 2010 checklist for this randomised controlled trial

Section/Topic	Aspects included	Chapter & Section
<b>Title</b>	Identification as a randomised trial in the title.	Thesis summary, page v.
<b>Abstract</b>	Structure summary of trial design, methods, results and conclusions.	
<b>Introduction</b> Background & objectives.	Background and explanation of rationale. Specific objectives & hypotheses.	1.1,1.2 2.17
<b>Methods</b> Trial design. Sample size.  Participants. Intervention outcomes.  Randomisation sequence generation  Allocation concealment Blinding Statistical methods	Description of trial design. How sample was determined. Setting and location where data were collected. Eligibility criteria. Sufficient detail of the intervention to allow replication. Completed pre-defined outcome measures including method of analysis. Method used to generate random sequence allocation and type of randomisation. Who generated the randomisation sequence and enrolled and assigned participants to their group? Steps taken to conceal allocation sequence until assignment. Who was blinded after assignment to intervention? Statistical methods used to compare groups for outcomes and all analyses.	3.2-3.10 4.6.1 4.5 4.6 4.2-4.11 4.7.2, 4.15 4.10.3 4.10.3 4.10.4 4.10.5 4.15
<b>Results</b> Participant flow diagram  Recruitment Baseline data  Numbers analysed and outcomes.	Flow chart of participants by group, through each stage, including losses and exclusions after randomisation, together with reasons. Dates defining the periods of recruitment and follow-up. A table showing baseline demographic and clinical characteristics for each group. Number of participants included in each analysis with results for each primary & secondary outcome.	Figure 3  4.10.2 Table 4.  Tables 4,5, 6, 7, 8 Figure 7.
<b>Discussion</b> Interpretation Limitations Generalisability	Interpretation, consistent with the trial results. Trial limitations including source of potential bias. Generalisability of the trial findings.	6.2.1-6.3.4 6.5 6.6
<b>Other information</b> Protocol Funding	The inclusion of the full trial protocol. Source of funding acknowledged.	Appendix 5 Page iv



## Appendix 3: ACS Response Index



## ACS Response-Time Intervention Trial

**ACS RESPONSE-TIME INTERVENTION TRIAL**

**Clinical History and Socio-Demographic Information**

Study number  Group: Intervention  Control

Date entered in study   Consent confirmed

Was family member present?  Yes  No

**Clinical History**

The following questions will come mostly from the patient and checked with the medical records. Tick all the relevant boxes.

	Yes	No	Don't know	
<b>Cardiac history</b>				
Angina	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
MI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
PICA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Stent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CABG	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Valve surgery	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Co-morbidities</b>				
Diabetes mellitus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Peripheral vascular disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Stroke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Current known cardiac risk factors</b>				
Positive family history of CHD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Current smoker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
History of smoking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hypercholesterolaemia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hypertension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Do you intend to attend cardiac rehabilitation programme?</b>	<input type="checkbox"/>	<input type="checkbox"/>	If no why not <input type="text"/>	
<b>Physical activity questionnaire</b>	Days/week	Hrs./day	Mins./day	None
Vigorous activity	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Moderate activity	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Walking	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Sitting	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>
Weight <input type="text"/> stones <input type="text"/> pounds <input type="text"/> KG				
Height <input type="text"/> feet <input type="text"/> inches or metres <input type="text"/>	<b>BMI</b>	<input type="text"/>		

ACS RESPONSE-TIME INTERVENTION TRIAL

Socio-Demographic Information

Gender: Male  Female

Age:

Ethnicity: White   
Irish   
Other - please specify   
Black   
African   
Other - please specify   
Asian   
Chinese   
Other - please specify

Other including mixed background please specify

Education:  Little or no formal education  
 Primary level education completed  
 Some second level education  
 Second level education completed  
 Third level education, college or equivalent  
 Other - please specify

Marital status:  Single  Married  Divorced  
 Separated  Widowed  Living with significant other

Current employment status  Employed  Student  
 Unemployed  Looking after home or family  
 Retired  Permanent sickness or disability  
 Other

---

Considering how well your household lives on its income. Financially, would you say you are:  Comfortable; have more than enough to make ends meet  
 Have enough to make ends meet  
 Do not have enough to make ends meet

Number of dependents

Method of health payment:  Medical card  Social health insurance (PRSI)  
 Private Health Insurance  Uninsured  
 Don't know  Other:

**ACS RESPONSE TIME INTERVENTION TRIAL**  
**Baseline Questionnaire**

Study Number

This questionnaire has questions about your health and your perceptions about heart attack symptoms. It also has questions asking for information about you. The study investigators would be grateful if you would answer all of the questions in each section. Please guess the answers to the questions you do not know.

1. Please tick whichever box you feel is correct.

		True	False
a.	Heart disease is the most common cause of death in women in Ireland.	<input type="checkbox"/>	<input type="checkbox"/>
b.	Most heart attacks occur in people over age 65.	<input type="checkbox"/>	<input type="checkbox"/>
c.	Hospitals have treatments that can reduce the damage of a heart attack.	<input type="checkbox"/>	<input type="checkbox"/>
d.	The location and size of a heart attack can vary depending on which blood vessel in the heart is blocked.	<input type="checkbox"/>	<input type="checkbox"/>
e.	Most patients benefit from taking two puffs of GTN spray immediately if they experience heart attack symptoms.	<input type="checkbox"/>	<input type="checkbox"/>

2. Do you think the following are symptoms of a heart attack? Please tick yes or no. Please answer all questions.

		Yes	No
1.	Lower abdominal pain ( stomach pain)	<input type="checkbox"/>	<input type="checkbox"/>
2.	Arm pain or shoulder pain	<input type="checkbox"/>	<input type="checkbox"/>
3.	Arm paralysis ( unable to move arm)	<input type="checkbox"/>	<input type="checkbox"/>
4.	Back pain	<input type="checkbox"/>	<input type="checkbox"/>
5.	Chest pain/pressure/tightness	<input type="checkbox"/>	<input type="checkbox"/>
6.	Chest discomfort (heaviness, burning, tenderness)	<input type="checkbox"/>	<input type="checkbox"/>
7.	Cough	<input type="checkbox"/>	<input type="checkbox"/>
8.	Dizziness, light-headedness	<input type="checkbox"/>	<input type="checkbox"/>
9.	Headache	<input type="checkbox"/>	<input type="checkbox"/>
10.	Heartburn/indigestion/stomach problem	<input type="checkbox"/>	<input type="checkbox"/>
11.	Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>
12.	Loss of consciousness/fainting	<input type="checkbox"/>	<input type="checkbox"/>
13.	Nausea/vomiting	<input type="checkbox"/>	<input type="checkbox"/>
14.	Neck pain	<input type="checkbox"/>	<input type="checkbox"/>
15.	Numbness/tingling in arm or hand	<input type="checkbox"/>	<input type="checkbox"/>
16.	Pale, ashen, loss/change of colour	<input type="checkbox"/>	<input type="checkbox"/>
17.	Palpitations/rapid heart rate	<input type="checkbox"/>	<input type="checkbox"/>
18.	Shortness of breath/difficulty breathing	<input type="checkbox"/>	<input type="checkbox"/>
19.	Slurred speech	<input type="checkbox"/>	<input type="checkbox"/>
20.	Sweating	<input type="checkbox"/>	<input type="checkbox"/>
21.	Weakness/fatigue	<input type="checkbox"/>	<input type="checkbox"/>

Next are some questions about some statements of attitude. In response to each statement, please tick only one box.

	Not at all	Little sure	Pretty sure	Very sure
3.1 How sure are you that you could recognise the signs and symptoms of a heart attack in someone else?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
3.2 How sure are you that you could recognise the signs and symptoms of a heart attack in yourself?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
3.3 How sure are you that you could tell the difference between the signs or symptoms of a heart attack and other medical problems?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
3.4 How sure are you that you could get help for someone if you thought they were having a heart attack?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input checked="" type="checkbox"/> 3	<input type="checkbox"/> 4
3.5 How sure are you that you could get help for yourself if you thought you were having a heart attack?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

Next are some questions about some statements of opinions. In response to each statement, please tick only one box.

	Strongly agree	Agree	Disagree	Strongly disagree
4.1 Most people who think they're having a heart attack should drive themselves to the hospital.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
4.2 Most people who have heart attacks have crushing, severe chest pain.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
4.3 Women rarely have heart attacks	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
4.4 If I have chest pain that doesn't stop after 15 minutes, I should get to the hospital as soon as possible.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

	<b>Strongly Agree</b>	<b>Agree</b>	<b>Disagree</b>	<b>Strongly disagree</b>
4.5 I would be embarrassed to go to the hospital if I thought I was having a heart attack but I wasn't.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
4.6 If I thought I was having a heart attack, I would wait until I was very sure before going to the hospital.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
4.7 If I thought I was having a heart attack, I would rather have someone drive me to the hospital than have an ambulance come to my home.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
4.8 If I'm having chest pain and I'm not very sure if it's a heart attack, I should go to the hospital.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
4.9 If I thought I was having a heart attack, I would go to the hospital right away.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

	<b>Much less likely</b>	<b>Somewhat less likely</b>	<b>About the same</b>	<b>Somewhat more likely</b>	<b>Much more likely</b>
5.1 Compared to other people your age, how likely do you think it is that you could have a heart attack in the next five years?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

	<b>Excellent</b>	<b>Very good</b>	<b>Good</b>	<b>Fair</b>	<b>Poor</b>
5.2 In general would you say your health is	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

### Control Attitudes Scale

Please read each statement, taking your time to think about what each statement says. Then circle the number that most closely measures how you feel about your heart condition.

	Strongly Disagree	Disagree	Do Not Agree or Disagree	Agree	Strongly Agree
6.1 If I do all the right things, I can successfully manage my heart condition.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6.2 I can do a lot of things myself to cope with my heart condition.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6.3 When I manage my personal life well, my heart condition does not bother me as much.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6.4 I have considerable ability to control my symptoms.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6.5 No matter what I do, or how hard I try, I just can't seem to get relief from my symptoms.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6.6 I am coping effectively with my heart condition.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6.7 Regarding my heart problems, I feel lots of control.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6.8 Regarding my heart problems, I feel helpless.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

Expression of feelings Scale

On this sheet you will find words which describe different kinds of moods & feelings. Tick the box beside the words that describe how you generally have felt within the last week. Some of the words may sound alike, but we want you to tick all the words that describe your feelings.

- |   |   |   |
|---|---|---|
| 1. <input type="checkbox"/> Active        | 45. <input type="checkbox"/> Forlorn      | 89. <input type="checkbox"/> Pleased        |
| 2. <input type="checkbox"/> Adventurous   | 46. <input type="checkbox"/> Frank        | 90. <input type="checkbox"/> Pleasant       |
| 3. <input type="checkbox"/> Affectionate  | 47. <input type="checkbox"/> Free         | 91. <input type="checkbox"/> Polite         |
| 4. <input type="checkbox"/> Afraid        | 48. <input type="checkbox"/> Friendly     | 92. <input type="checkbox"/> Powerful       |
| 5. <input type="checkbox"/> Agitated      | 49. <input type="checkbox"/> Frightened   | 93. <input type="checkbox"/> Quiet          |
| 6. <input type="checkbox"/> Agreeable     | 50. <input type="checkbox"/> Furious      | 94. <input type="checkbox"/> Reckless       |
| 7. <input type="checkbox"/> Aggressive    | 51. <input type="checkbox"/> Gay          | 95. <input type="checkbox"/> Rejected       |
| 8. <input type="checkbox"/> Alive         | 52. <input type="checkbox"/> Gentle       | 96. <input type="checkbox"/> Rough          |
| 9. <input type="checkbox"/> Alone         | 53. <input type="checkbox"/> Glad         | 97. <input type="checkbox"/> Sad            |
| 10. <input type="checkbox"/> Amiable      | 54. <input type="checkbox"/> Gloomy       | 98. <input type="checkbox"/> Safe           |
| 11. <input type="checkbox"/> Amused       | 55. <input type="checkbox"/> Good         | 99. <input type="checkbox"/> Satisfied      |
| 12. <input type="checkbox"/> Angry        | 56. <input type="checkbox"/> Good-natured | 100. <input type="checkbox"/> Secure        |
| 13. <input type="checkbox"/> Annoyed      | 57. <input type="checkbox"/> Grim         | 101. <input type="checkbox"/> Shaky         |
| 14. <input type="checkbox"/> Awful        | 58. <input type="checkbox"/> Happy        | 102. <input type="checkbox"/> Shy           |
| 15. <input type="checkbox"/> Bashful      | 59. <input type="checkbox"/> Healthy      | 103. <input type="checkbox"/> Soothed       |
| 16. <input type="checkbox"/> Bitter       | 60. <input type="checkbox"/> Hopeless     | 104. <input type="checkbox"/> Steady        |
| 17. <input type="checkbox"/> Blue         | 61. <input type="checkbox"/> Hostile      | 105. <input type="checkbox"/> Stubborn      |
| 18. <input type="checkbox"/> Bored        | 62. <input type="checkbox"/> Impatient    | 106. <input type="checkbox"/> Stormy        |
| 19. <input type="checkbox"/> Calm         | 63. <input type="checkbox"/> Incensed     | 107. <input type="checkbox"/> Strong        |
| 20. <input type="checkbox"/> Cautious     | 64. <input type="checkbox"/> Indignant    | 108. <input type="checkbox"/> Suffering     |
| 21. <input type="checkbox"/> Cheerful     | 65. <input type="checkbox"/> Inspired     | 109. <input type="checkbox"/> Sullen        |
| 22. <input type="checkbox"/> Clean        | 66. <input type="checkbox"/> Interested   | 110. <input type="checkbox"/> Sunk          |
| 23. <input type="checkbox"/> Complaining  | 67. <input type="checkbox"/> Irritated    | 111. <input type="checkbox"/> Sympathetic   |
| 24. <input type="checkbox"/> Contented    | 68. <input type="checkbox"/> Jealous      | 112. <input type="checkbox"/> Tame          |
| 25. <input type="checkbox"/> Contrary     | 69. <input type="checkbox"/> Joyful       | 113. <input type="checkbox"/> Tender        |
| 26. <input type="checkbox"/> Cool         | 70. <input type="checkbox"/> Kindly       | 114. <input type="checkbox"/> Tense         |
| 27. <input type="checkbox"/> Cooperative  | 71. <input type="checkbox"/> Lonely       | 115. <input type="checkbox"/> Terrible      |
| 28. <input type="checkbox"/> Critical     | 72. <input type="checkbox"/> Lost         | 116. <input type="checkbox"/> Terrified     |
| 29. <input type="checkbox"/> Cross        | 73. <input type="checkbox"/> Loving       | 117. <input type="checkbox"/> Thoughtful    |
| 30. <input type="checkbox"/> Cruel        | 74. <input type="checkbox"/> Low          | 118. <input type="checkbox"/> Timid         |
| 31. <input type="checkbox"/> Daring       | 75. <input type="checkbox"/> Lucky        | 119. <input type="checkbox"/> Tormented     |
| 32. <input type="checkbox"/> Desperate    | 76. <input type="checkbox"/> Mad          | 120. <input type="checkbox"/> Understanding |
| 33. <input type="checkbox"/> Destroyed    | 77. <input type="checkbox"/> Mean         | 121. <input type="checkbox"/> Unhappy       |
| 34. <input type="checkbox"/> Devoted      | 78. <input type="checkbox"/> Meek         | 122. <input type="checkbox"/> Unsociable    |
| 35. <input type="checkbox"/> Disagreeable | 79. <input type="checkbox"/> Merry        | 123. <input type="checkbox"/> Upset         |
| 36. <input type="checkbox"/> Discontented | 80. <input type="checkbox"/> Mild         | 124. <input type="checkbox"/> Vexed         |
| 37. <input type="checkbox"/> Discouraged  | 81. <input type="checkbox"/> Miserable    | 125. <input type="checkbox"/> Warm          |
| 38. <input type="checkbox"/> Disgusted    | 82. <input type="checkbox"/> Nervous      | 126. <input type="checkbox"/> Whole         |
| 39. <input type="checkbox"/> Displeased   | 83. <input type="checkbox"/> Obliging     | 127. <input type="checkbox"/> Wild          |
| 40. <input type="checkbox"/> Energetic    | 84. <input type="checkbox"/> Offended     | 128. <input type="checkbox"/> Willful       |
| 41. <input type="checkbox"/> Enraged      | 85. <input type="checkbox"/> Outraged     | 129. <input type="checkbox"/> Wilted        |
| 42. <input type="checkbox"/> Enthusiastic | 86. <input type="checkbox"/> Panicky      | 130. <input type="checkbox"/> Worrying      |
| 43. <input type="checkbox"/> Fearful      | 87. <input type="checkbox"/> Patient      | 131. <input type="checkbox"/> Young         |
| 44. <input type="checkbox"/> Fit          | 88. <input type="checkbox"/> Peaceful     |   |



**ACS Response-Time Intervention Trial**  
**RESPONSE TIME QUESTIONNAIRE- RTQ form**

1. Study number  Date

**2 A. When did your heart symptoms start generally? (Prodromal)**

Date/Time Field

**2 B. When did the symptoms start that made you make a decision to seek care? (Acute)**

Date/Time Field

**3. What heart symptoms did you experience?**

- Chest pain     Chest Discomfort     Chest pressure or heaviness
- Left arm pain or discomfort
- Neck or jaw pain     Shortness of breath     Sweating
- Upset stomach or nausea     Indigestion
- A sense of dread
- Fatigue
- Other:

**4. What was the nature of your heart symptoms?**

- Continuous     Intermittent

**5. Was the onset of heart symptoms?**

- Sudden
- Gradual

**6. To what did you initially attribute your symptoms? (one answer)**

- Heart     Indigestion     Muscle Pain     Arthritis
- Fatigue     Menopause     Other

**7. What was your initial response to your symptoms? (one answer)**

- Did nothing, hoped it would go away
- Ignored it and continued what I was doing
- Lay down and tried to relax
- Self-medicated
- Told someone
- Called/visited the GP
- Called an ambulance
- Took myself to A&E
- Other

8. On a scale of 0-10, what was the severity of your symptoms at its worst?

0-10

9. Where were you when your heart symptoms started? (*one answer*)

At home

At work

Driving

Out walking

Shopping

Visiting

Other

10. Who were you with when your heart symptoms started?

Alone

With spouse

With close family member (other than spouse)

With friend

With neighbour

With co-worker

With stranger

Other

11. Did you take any medication before you went to hospital?

Yes

No

12. If yes, what medication did you take?

GTN spray/puff

Aspirin

Antacid

Other Analgesic (pain-killer)

Other medication

13. Who did you first tell about your symptoms before you arrived in A&E?

Phoned 999

Co-worker

Spouse

Stranger

Other Family Relative

GP:

Friend

Other:

14. How long did you wait before telling this person about your symptoms?

<15 minutes

31-60 minutes

15-30 minutes

1-2 hours

> 2 hours

15a. Did you phone your GP Yes  No

15b. Did you visit your GP Yes  No

**16. What kind of transportation did you use for travelling to the hospital?**

- Ambulance
- Private car passenger
- Private car driver
- Taxi
- Rail
- Bus
- Walk
- Other:

**17. If you did not take an ambulance what was the main reason why you did not?**

- Too embarrassed
- Didn't feel it was needed
- Followed the advice of others
- Thought it would be quicker by other mode of transport
- Other:

**18. Which hospital did you go to?**

- AMNCH  Beaumont
- St. James's  The Mater
- St. Vincent's
- Other:

**19. If you used an ambulance, at approximately what time was the ambulance called?**

Date/Time Field   Unknown

**20. At approximately what time did the ambulance arrive?**

Date/Time Field   Unknown

|

**MEDICAL CHART REVIEW**

**21. Arrival Time to A&E**

Date/Time Field

**22. If cardiac then provide details of diagnosis:**

- STEMI
- NSTEMI
- Unstable angina
- Stable Angina
- Other

**23. Which of the following treatment(s) (if any) did the patient receive?**

- Thrombolysis
- Primary PTCA  $\pm$  Stent (within 12 hours from arrival in A&E)
- Coronary Artery Bypass Graft (within 24 hours from arrival in A&E)
- Resuscitation
- None of the above/medical management
- PTCA > 12 hrs
- CABG > 12 hrs
- PTCA + Stent > 12 hours

ACS Response-Time Intervention Trial

Response Time Questionnaire (Readmission)

Study Number

Research Assistant Questions:

1. Date of call:
2. Date of representation:
3. Please tick the methods of contact:
  - Patient contacted reply line
  - Family member contacted reply line
  - Hospital/gatekeeper contacted reply line
  - Research assistant received information from hospital when doing follow-up questions or when screening charts for re-presentations
  - Research assistant found out when phoned patient

Questions to Patient:

4A. When did your heart symptoms start generally? (Prodromal)

Date/Time Field

4B. When did the symptoms start that made you make a decision to seek care? (Acute)

Date/Time Field

5. What heart symptoms did you experience?

- Chest pain     Chest discomfort     Chest heaviness or pressure
- Left arm pain or discomfort
- Neck or jaw pain     Shortness of breath     Sweating
- Upset stomach, or nausea     Indigestion
- A sense of dread
- Fatigue
- Other:

6. What was the nature of your heart symptoms?

- Continuous     Intermittent

7. Was the onset of heart symptoms

- Sudden     Gradual

**8. To what did you initially attribute your symptoms? (One answer)**

- Heart       Indigestion       Muscle Pain  
 Arthritis       Fatigue       Menopause  
 Other

**9. What was your initial response to your symptoms?**

- Did nothing, hoped it would go away  
 Ignored it and continued what I was doing  
 Lay down and tried to relax  
 Self-medicated  
 Told someone  
 Called/visited the GP  
 Called an ambulance  
 Took myself to A&E  
 Other

**10. On a scale of 0-10, what was the severity of your symptoms at its worst?**

0-10

**11. Where were you when your heart symptoms started?**

- At home  
 At work  
 Driving  
 Out walking  
 Shopping  
 Visiting  
 Other

**12. Who were you with when your heart symptoms started?**

- Alone
- With spouse
- With close family member (other than spouse)
- With friend
- With neighbour
- With co-worker
- With stranger
- Other

**13. Did you take any medication before you went to hospital?**

- Yes
- No

**14. If yes, what medication did you take?**

- GTN spray/puff
- Aspirin
- Antacid
- Other Analgesic (pain-killer)
- Other medication

**15. Who did you first tell about your symptoms before you arrived in A&E?**

- Phoned 999
- Spouse
- Other Family Relative
- Friend
- Co-worker
- Stranger
- GP
- Other: (including nobody)

**16. How long did you wait before telling this person about your symptoms?**

- <15 minutes
- 15-30 minutes
- 31-60 minutes
- 1-2 hours
- > 2 hours

17a. Did you phone your GP  Yes  No

17b. Did you visit your GP  Yes  No

**18. What kind of transportation did you use for travelling to the hospital?**

- Ambulance
- Private car passenger
- Private car driver
- Taxi
- Rail
- Bus
- Walk
- Other:

**19. If you did not take an ambulance what was the main reason why you did not?**

- Too embarrassed
- Didn't feel it was needed
- Followed the advice of others
- Thought it would be quicker by other mode of transport
- Other:

**20. Which hospital did you go to?**

- AMNCH
- Beaumont
- St. James's
- Mater
- St. Vincent's
- Other:

**21. If you used an ambulance, at approximately what time was the ambulance called?**

Date/Time   Unknown

**22. At approximately what time did the ambulance arrive?**

Date/Time   Unknown



## MEDICAL CHART REVIEW

**23. Arrival Time to A&E:**

Date/ Time

**24. Cardiac event or cardiac related pain:**

Yes  No

**25. If cardiac, then provide details of diagnosis:**

STEMI

NSTEMI

Unstable angina

Stable Angina

Other

**26. If a non-cardiac related event, then provide brief diagnosis details:**

**27. Which of the following treatment(s) (if any) did the patient receive?**

Thrombolysis

Primary PTCA (within 12 hours from arrival in A&E)

Coronary Artery Bypass Graft (within 24 hours from arrival in A&E)

Resuscitation

None of the above

**28. Time of Death, if applicable**

Date/Time

## Appendix 4: Interventionist Training Manual



### **Interventionist Training Manual for the ACS Response-Time Intervention Trial**

### ACS Response-Time Intervention Trial.

- Welcome and Introductions.
- Project overview.
- Outline of interventionist training programme.

### Overview of Training

- Introduction to the project,
- ACS and pre-hospital delay time research.
- The intervention and how to deliver it.
- Ethics
- Completing Questionnaires
- Data Management & Storage
- Access Training
- Review of the Intervention
  - Role play to ascertain interventionists' skills acquisition

### Organisation of the project.



#### ACS Team

- Principle Investigator
  - Dr Gabrielle McKee
- ACS Research Team, School of Nursing and Midwifery, Trinity College Dublin.
  - Dr Sharon O'Donnell, Prof Debra Moser, Mary Mooney and Frances O'Brien.

### ACS Collaborators

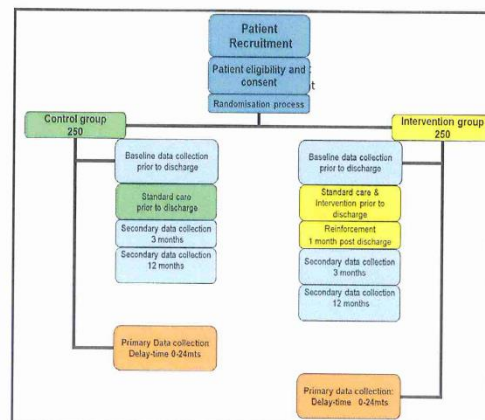


- **AMNCH**
  - Clinical collaborator : Prof Ian Graham,
  - Project team member: Dr Sharon O'Donnell
  - Gatekeeper:
  - Research assistant
- **Beaumont**
  - Clinical collaborator : Dr Thomas Gumbrielle
  - Project team member: Dr Gabrielle McKee
  - Gatekeeper:
  - Research assistant
- **Mater**
  - Clinical collaborator : Dr Declan Sugrue
  - Project team member: Dr. Gabrielle McKee
  - Gatekeeper:
  - Research assistant
- **St. James's**
  - Clinical collaborator : Dr Peter Crean
  - Project team member : Ms Frances O'Brien
  - Gatekeeper:
- **St. Vincent's**
  - Clinical collaborator: Dr Martin Quinn
  - Project team member: Ms Mary Mooney
  - Gatekeeper:

### Project



- What causes delay?
  - Gender, age, ethnicity, education levels, family members present, location of event and others.
- Develop intervention
  - 40 minute educational intervention pre-discharge.
    - Information, emotional issues, social factors
    - Action plan, individualisation
  - 1 Month support phone call
- This study is a randomised controlled trial that aims to test the effectiveness of the intervention.



## Recruitment of patients



1. Gatekeeper.
  1. Brief screening for eligible patients and see if patient interested.
  2. Provide research assistant with list of interested patients.
2. Research assistant.
  1. Inform patient about the study and confirm eligibility.
  2. Complete informed consent.
  3. Arrange to meet patient at least 24hrs later for baseline data collection.

## Implementation



- Collect baseline data.
  - Reveal randomised group.
  - Intervention group only
    - 40 minute educational intervention pre hospital discharge.
- Information, emotional issues, social factors, action plan, individualisation.

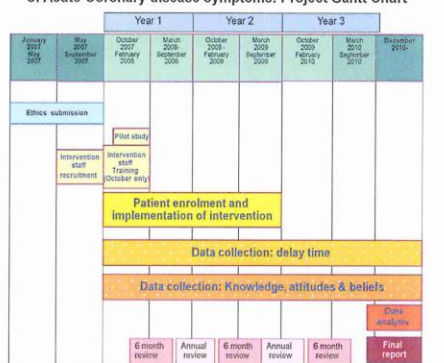
Refer to trial protocol.

## Questionnaires



- Baseline (in hospital )
  - Socio-Demographic and Clinical history questionnaires.
    - Completed by research assistant with access to case notes and through discussion with patient.
  - Complete ACS Response Index
- Questionnaires completed on readmission and at 3 & 12 months.

## Effectiveness of Intervention to decrease delay time in the presentation of Acute Coronary disease symptoms: Project Gantt Chart



## Acute Coronary Syndrome

## Explanation

- Death or necrosis of a portion of myocardium.
- Due to interruption, reduction or cessation of blood flow.
- The most common cause is occlusion of the coronary arteries.

### Pathophysiology

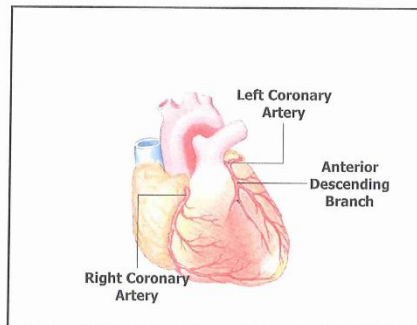
- Cells require constant O<sub>2</sub> & Nutrients.
- If perfusion is reduced, cells become irreversibly injured.
- Cell death takes a finite period.
- Complete necrosis takes 4-6 hours.
- Collateral perfusion helpful

(Alpert et al. 2000)

### Causes

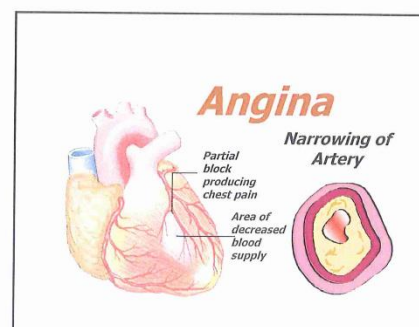
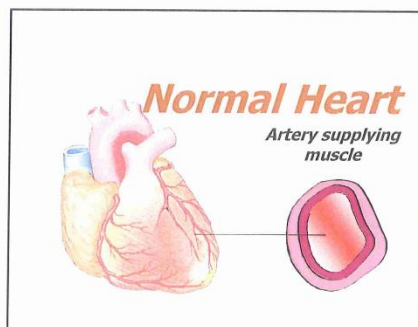
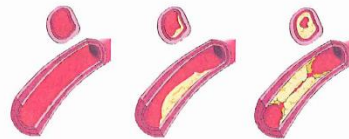
Reduced blood flow due to

- Atherosclerosis
- Embolus
- Thrombus
- Arterial spasm
- Shock or Haemorrhage



### Causes of Heart Disease

- Narrowing of Coronary Arteries  
Blockage of Coronary Arteries  
*Caused by Fatty Material*



### Risk factors

- Smoking
- Hypertension
- Positive Family History
- Diabetes
- Race
- Hypercholesterolaemia
- Obesity
- Increasing age - younger males > females
- Inactivity
- Angina

### Risk factors

Further suggested factors include:

- Impaired glucose tolerance levels
- Raised levels of CRP
- Raised levels of fibrinogen
- Raised levels of Homocysteine
- Raised levels of apolipoprotein B or LP(a)
- Raised levels of triglycerides with low HDL
- (Ref. ESC 2003)

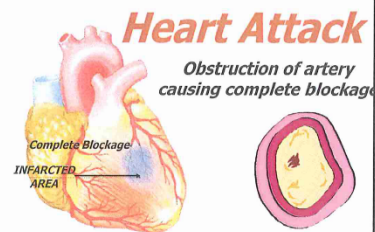
### Types of Infarcts

#### ST elevation MI

- Mainly associated with thrombus.
- Acute coronary occlusion

#### Non-ST elevation MI

- Associated with global reduction in perfusion
- Sub-endocardium is most susceptible to ischaemia when B/P drops.



### Heart Attack Clinical manifestations

- Chest Pain-  
*Dull, Central, may Radiate*
- Sweating
- Sick Feeling
- Shortness of Breath
- Feeling of Impending Doom
- Denial
- Generally Unwell
- 80% experience pain within 60 sec.



### Clinical Manifestations

- **Pain**
- Occurs at rest
- Unrelieved by Nitrates/Rest
- Crushing, vice-like, tight, painful, constricting
- May radiate
- May awaken person from sleep

#### Other Possible Manifestations

- Dyspnoea / Cyanosis / Hyperventilation
- Pallor / Diaphoresis
- Anxiety / Restlessness
- Nausea / Vomiting
- Altered B/P - usually low
- Altered Cardiac rhythm
- Altered level of consciousness

#### Silent Ischaemia

##### • Those at Risk

- Diabetics
- Elderly
- Women
- PHx CVA/Heart failure
- Non-white racial or ethnic groups
- Those with increased degrees of pulmonary congestion on admission
- ?Those who have taken alcohol prior to infarction

#### Initial Assessment

- Triage.
- Emergency equipment Resuscitate - ABC
- Vital signs
- Comprehensive History-taking
- Monitor, CXR, ECG, IV lines, Bloods,
- **Pain evaluation:** Sensation, location, duration, radiation, exacerbation.
- Transfer to CCU - monitored, fast-track
- **Medications:** O<sub>2</sub>, Analgesia, Heparin, nitrates, Aspirin, B-Blockers.
- Thrombolysis within 30 mins. – if indicated

#### Diagnosis of Myocardial Infarction

- History
- ECG
- Cardiac Enzymes (WHO 1997)

#### ECG changes

- ST elevation > 2mm in two chest leads
  - or
- ST elevation > 1 mm in two limb leads
  - or
- New onset Bundle Branch Block

#### Biochemical markers

- Specific for Myocardial injury
- Troponin I & T
- Creatine Kinase
- Myoglobin levels
- Serial enzymes & ECG taken
- Refer to lecture on cardiac investigations

#### Other Blood tests

- Fasting Lipid profile
- Fasting Glucose
- Thyroid function tests
- Full Blood Count
- Coagulation screen
- Renal profile
- ABG - occasionally
- Homocystine/ CRP/Fibrinogen/Lipo-protein a

#### Thrombolytic Therapy

- Pharmacological therapy
- IV bolus
- Ideally within 6 hours – mins=myocardium
- Catalyses the conversion of plasminogen to plasmin – dissolves fibrin which binds clot together.
- Restoration of normal myocardial perfusion within 60-90 mins.
- Fibrinolytic therapy: Retaplast—one example
- Protocol to be followed
- Prepare heparin infusion

#### Complications of Thrombolysis

- **Allergic reaction** - itch, nausea, rigours, dyspnoea, flushing
- **Bleeding** - cerebral, puncture sites, gums
- **Hypotension.**
- **Reperfusional dysrhythmias**- Due to irritability of myocardium - Ventricular Tachycardia/ fibrillation/ Bradycardia.

#### Primary PCI

- Superior to fibrinolysis
- Optimum patency achieved
- Specialised –Cath. Lab. & surgical cover
- Ideally suited if fibrinolysis unsuitable or failed
- See preparation of patient pre, during and post angiogram.
- Clopidogrel – after stent

#### Complications of Myocardial Infarction

- Sudden Death within 1 hour
- Pain
- Extension / Re-Infarction
- Congestive cardiac failure
- Cardiogenic shock
- Pericarditis
- Hypoxia
- Myocardial wall rupture
- Ventricular-Septal Defect
- Pulmonary Embolus
- Anxiety / Depression

#### Angina

- Discomfort occurring during episodes of myocardial ischaemia
- A symptom – not a disease
- Imbalance between myocardial O<sub>2</sub> demand & supply
- **Unstable Angina is part of Acute Coronary Syndrome(s)**



### Causes of Angina-type pain

- Myocardial infarction
- Atherosclerosis
- Arterial thrombi
- Coronary artery spasm
- Aortic stenosis
- Hypertension
- Conditions that increase MVO<sub>2</sub> - eg. Hypertrophy
- Pericarditis
- Pulmonary embolus
- Oesophageal disorders

### High Risk Patients

- ST segment changes on ECG
- Recurring pain
- Diabetics
- Those with elevated cardiac enzymes
- Haemodynamic instability
- Patients post infarction
- Major dysrhythmias

### Characteristics of angina

- Begins gradually- max. intensity in mins.,
- Typically described as:**
- Heavy/ Crushing/Squeezing/Constricting/Vice-like
- May present as:**
- Vague discomfort/suffocating feeling /Pressure/Heaviness/ numbness/ indigestion
  - Symptoms- none sometimes

### Precipitating Factors

- Exertion/exercise.
- Cold weather or Walking against the wind.
- Emotional upset / stress
- Anger/ fright.
- Eating a heavy meal.
- Any condition that increases MV O<sub>2</sub> demand
- Anaemia
- Thyrotoxicosis

### Typical Location

- Retrosternal & Often radiates
- Intra-scapular/Infrascapular region
- Arms (L>R)
- Gums / Teeth
- Back of neck
- Abdomen / Upper chest
- Sub-sternal pain
- Epigastric
- Neck and jaw
- May radiate from any point of origin



### Classification of angina

- Stable angina – increased O<sub>2</sub> demand
- Unstable angina –unprovoked
- Prinzmetal angina - spasm
- Angina decubitus – nocturnal angina

### Unstable Angina

- Acceleration of previously controlled symptoms.
- Atherosclerotic plaque rupture.
- Intermittent or prolonged obstruction.
- Pain onset unpredictable - can occur at rest.
- Pain intense - may radiate.
- Episodes of angina become more frequent.
- Nitrates may not relieve.
- ECG changes may include ~
  - ST segment depression
  - T-Wave inversion or flattening

### Stable Angina

- Transient reversible episode of inadequate blood supply to the myocardium.
- Associated with increased O<sub>2</sub> demand & vasoconstriction
- Pain occurs in a predictable fashion, i.e. usually precipitated by exertion above a certain level.
- Pain onset usually predictable
- Pain usually ceases within 5-10 mins. with rest / GTN spray.

### Prinzmetal (variant angina)

- Least common type
- Can be severe or prolonged
- The pain is similar to stable angina, but typically occurs at rest ( frequently in the morning.
- Associated with spasm of arteries (Newton, 1998)

### Treatment Options

- Determined by risk.
- Observation - Angiogram / Stress test.
- Percutaneous Transluminal Coronary Angioplasty (PTCA)
  - Coronary artery stents
- Minimally invasive surgery
- Coronary artery by-pass grafts (CABG)
- Medically managed- if neither above option suitable
  - Target Risk factors, Rehab., Medication.

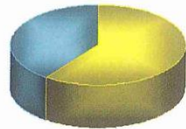
### Acute Coronary Syndrome:

#### An Intervention to Reduce Delay

### Ireland's No.1 Killer

- Approximately 10,000 people die each year from cardiovascular disease (CVD)
- CVD is the most common cause of death in Ireland, accounting for 36% of all deaths.
- The largest number of these deaths (n= 5,000) relate to Acute Coronary Syndrome, mainly heart attack.

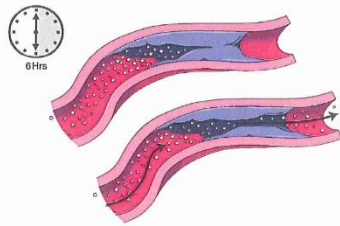
Most deaths occur within 1 hour of symptoms onset



### The Golden Hour

- Survival from a heart attack is greatly increased with early admission to hospital
- Seeking treatment with the an hour of symptom onset can:
  - Reduce infarct size
  - Lessen disability
  - Reduce mortality
  - Abort MI process in 40% of patients
  - prevent irreversible damage and dysfunction

### Time is Muscle



### A Global Epidemic of Delay

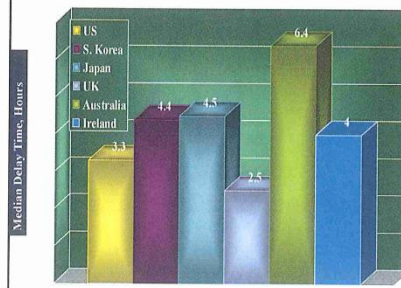
- The greatest obstacle to survival following a heart attack is 'patient delay'.
- Patients, on a global scale, delay in seeking help following symptoms of heart attack.
- As many survival interventions/treatments are time dependent, patients frequently miss the 'window' of optimum therapeutic benefit.

### Delay in Seeking Treatment

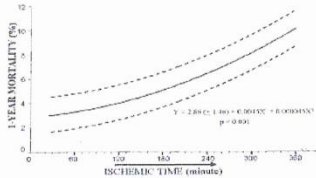


- Median delay times 2 - 6.4 hours
  - NRM1 = 2.2
  - REACT = 2.4
  - African-Americans 2006 = 4.4
  - Irish MI Census =4,0 hours
- Delay times have not changed substantially over past 30 years

### Pre-Hospital Delay Times in Six Countries



**Every 30 Minutes of Delay with Ischemia Increases 1-year Mortality by 7.5%**



Relationship between time to treatment and 1-year mortality, as continuous function, was assessed with quadratic regression model. Dotted lines represent 95% CIs of predicted mortality.

*DeLuca, Circulation 109, 2004*

**Consequences of Delay**

- Higher mortality
  - *Maynard et al., 1989; Newby et al. 1996, Gibler et al., 2002;*
- Reduced benefit of PCI
  - *Kent et al., 2001*
- Larger infarct size
  - *Liem et al., 1998*
- Higher incidence of shock
  - *Newby et al., 1996*
- Worse left ventricular function or heart failure with associated increased disability
  - *Newby et al., 1996; Liem et al., 1998;*

**Fibrinolytic Therapy**

- < 5% of eligible patients receive thrombolytics within 1 hour
- < 25% overall receive any fibrinolytic
  - < 15% in Medicare eligible population
    - NRMI and CCP (cooperative cardiovascular project)
    - *Every et al., 1999, JACC*

**Two Studies**

- American Study: REACT 1994-1998 – intervention study.
- Irish Study: MATHS MI Census 2001/2002 examination of delay and predisposing factors – specific interest in gender aspects of delay.

**Rapid Early Action for Coronary Treatment**



**REACT Study Design**

- Community trial
- 10 pairs medium-sized cities
  - 100,000+ population; 10 states
- Randomised each pair
  - Intervention or comparison
- 1994-1998, NHLBI-funded

### Study Hypothesis/ Main Outcome

- Community-based intervention of 18 months' duration will reduce patient delay in seeking treatment for suspect acute myocardial infarction.
- Measured as time from symptom onset to arrival at hospital emergency department.

### REACT Results

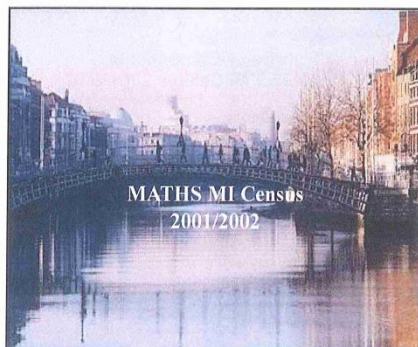
- Data were collected on 29,398 (reference) and 31,645 (intervention) patients presenting to A&E's with suspected acute CHD.
- Hospitalized during the intervention period with a CHD-related discharge diagnosis
  - 9801 reference patients
  - 10563 intervention patients

### REACT Main Results: *Delay Time*

- Estimated median delay time at baseline was 140 minutes (2 hrs, 20 minutes)
- Mean delay time trend in intervention communities declined significantly (-4.7% per yr) but did not differ significantly from the trend in reference communities (-6.8% per yr)

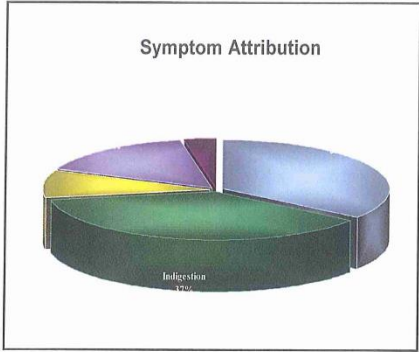
### REACT Results

- Baseline ambulance use in all 20 communities: 33%
- Ambulance use increased steadily and significantly in the intervention communities (16%/yr)
- Mean trend in ambulance use in reference communities did not change
- Net effect: 20% increase in ambulance use in intervention vs. reference communities

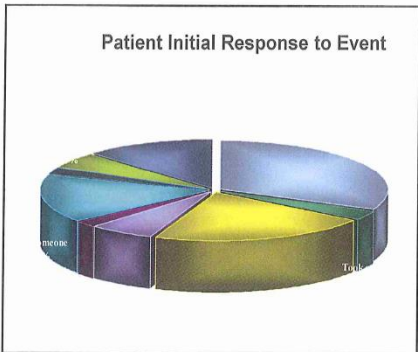


### The MATHS MI Census 2001-2002

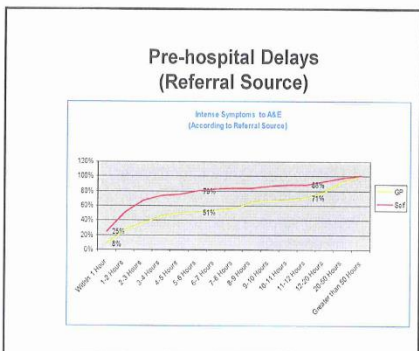
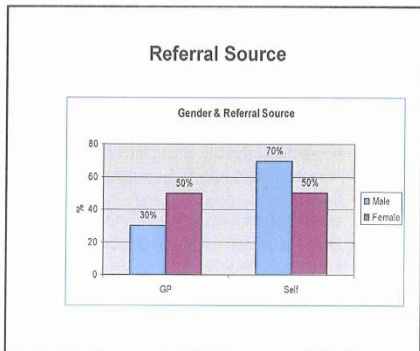
- 1-year Prospective Myocardial Infarction Census
- Duration: December 1<sup>st</sup> 2001 - November 30<sup>th</sup> 2002
  - Site: 6 Major Academic Teaching Hospitals in Dublin



- ### Patient Coping Actions
- Covert Coping – initially didn't disclose symptoms or concerns to others – many didn't want to make a fuss
  - Attempts to normalise symptoms by self-treating
  - Overt Coping- only told others when symptoms became really severe



- ### Seeking Expert Help
- Approximately 40% of patients didn't call an ambulance – this was mostly due to embarrassment
  - Many visited their GP's before attending the A&E department
  - Many delayed going to the A&E department because of fears of long delays





**REACT and MATHS Lessons Learned:  
Reasons Patients Delay**

- Key reason— the "*Hollywood Heart Attack*".  
Expectation – dramatic event with crushing chest pain.
- Uncertainty about symptoms/thought would go away; "wait and see approach".
- Tendency to attribute to other conditions.
- Less knowledge of non-chest pain symptoms
- Fear of embarrassment if outcome is a "false alarm".



**REACT & MATHS Lessons Learned:  
Reasons Patients Delay (cont.)**

- Reluctance to trouble others unless "really sick"
- Stereotype of who is at risk—e.g., women do not perceive themselves at risk
- Little awareness of rationale for rapid action, knowledge of reperfusion treatment, and/or benefits of calling an ambulance
- Little talk or planning occurred before or after an event with family, spouse, health care providers.

**Recommendations for Public  
Education**

- Avoid a large, expensive public education campaign – they rarely work
- Target those with longer delay times e.g. women and the elderly
- Utilize multiple strategies and new approaches such as informatics, focused teaching sessions
- Focus on key messages—e.g., dispel myth of Hollywood Heart Attack; call an ambulance

**Seven Steps to Survival**

1. Learn heart attack warning signs.
2. Think through your steps if warning signs occur.
3. Talk with family and friends about warning signs and calling an ambulance.
4. Talk to your doctor about heart attack risk.



**Seven Steps to Survival**

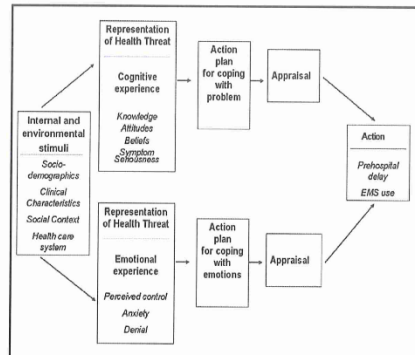
5. Talk to doctor about what to do if warning signs occur.
6. Gather important information to take to hospital.
7. Call insurance plan to check on coverage.



**New Approaches Needed to Interventions  
to Decrease Patient Delay**

- Changing patient and provider perspectives about the chronicity of cardiac disease.
  - Increase saliency of message.
- Include social, cognitive, and emotional context of decision-making in messages.
- Deputise witnesses to take action.
- Make every provider an "interventionist" and every encounter an intervention.

### Symptom Onset Experience



### Factors Associated with Delay

#### No Impact on Delay

- Education level
  - Except possibly at extreme low end
- Knowledge of myocardial infarction symptoms
- History of previous MI, CAD, CHF
- Severity of chest pain

#### Predictors of Pre-Hospital Delay *Socio-demographics*

- Older age (> 60 years)
- Female gender
- Economically disadvantaged
- Minorities

#### Predictors of Pre-hospital Delay *Emotional and Cognitive*

- Low somatic/emotional awareness
- Perception of 'low risk victim'
- Attribution to benign cause
- Disconnect between expectations and experience
  - "Hollywood heart attack"
- Cognitive processes
  - feared what would happen if sought help
  - waited, hoping pain would disappear
  - not wanting to trouble others
  - embarrassed



### Reducing Pre-Hospital Delay for Treatment of AMI

- Prospective, randomized 5 year multi-national trial
- Sample: high risk patients (3,500 +)
- Same patients followed
- Intervention:
  - standardized, individualized education program
  - delivered by an RN
  - provides information, but *emphasises* emotional reactions, social influences and cognitive errors

- 2-year follow-up
- Primary Outcomes
  - Delay time, ASA use, 911 use, resource utilization
- Secondary Outcomes
  - Cognitive
    - knowledge, attitudes, beliefs
  - Emotional
    - perceived control, anxiety, depression, hostility

### Key Intervention Components

- Individualise
  - Let them tell their story
- Interactive
  - Ask them questions throughout to find out what they are hearing
  - Correct misperceptions
- Positive not negative messages
  - Acting quickly will save heart muscle *not* delaying will kill more heart muscle

### Key Intervention Components

- Point out unique aspects of their group (e.g., women, diabetics).
- Tell them most people delay and why
  - Natural reaction that needs to be overcome
- Deputise family members to act.
- Rehearse what they would do.

### The Randomised Controlled Trial.

- What is an RCT.
- Criteria for an RCT.
- Randomisation
  - Concealment of randomised group
  - Blinding.
- Trial bias.
- Intervention fidelity.

### Delivering the Intervention.

- Overview of the intervention.
- How to deliver the intervention using the intervention manual and script, CD, DVD, scenarios.
- Familiarisation with delivering the intervention.
- Practising the intervention using role play.
- Maintaining field notes and self-reporting of intervention delivery.

### How Can We Motivate Patients to Change Behaviors?

- Patient education is an integral component of pre-discharge care.
- Although patients recall being taught
  - 50% knew "some"
  - 38% knew "a little or nothing" about how to care for themselves.



### Educating vs. Motivating

- Educating is effective for people who perceive a need to know or want to change.
- Motivating is needed for those who do not see a problem or do not wish to change.

### What is Known about Health Behaviors?

Health behaviors are:

- Largely independent of each other.
- Controlled by different factors.
- Unstable over time.

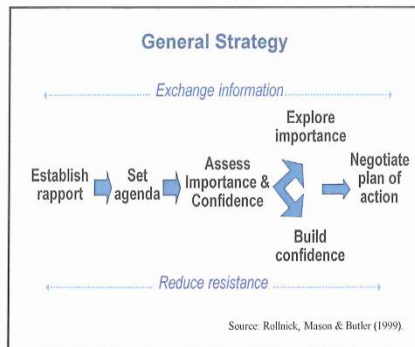
*"Helping people change depends on doing the right things (processes) at the right time (stages)" (Prochaska, et al, 1992)*

### Brief Motivational Counseling "Dancing, not wrestling"



### Theory of Motivational Counselling.

- People are naturally motivated for growth
- Ambivalence about change is normal
- Dissonance between values and behavior is motivational
- Arguing one side causes defensiveness
- Patient leads, provider follows



- ### Principles of Motivation
- Express empathy
  - Develop discrepancy
  - Roll with resistance
  - Support self-efficacy

- ### Express Empathy with Reflections
- Reflections are simple, short statements that capture the essence of the message
    - “It sounds like you are feeling...”
    - “So, you are saying that you believe...”
  - Reflections are more than questions
  - Reflections do *not* need to be perfect

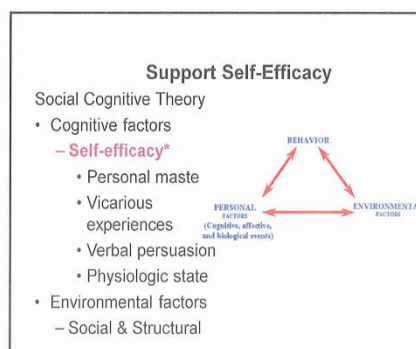
### Develop Discrepancy: Evoke Self-Motivational Statements

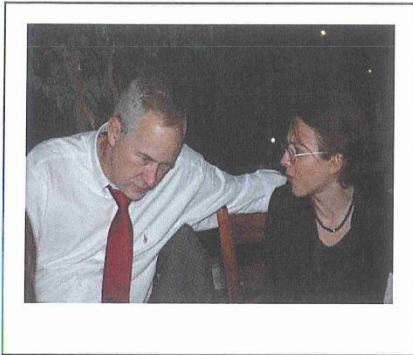
*“makes you think this is a problem?”*

*“Sounds like things can’t stay the way they are. What would you like to do about ...?”*

*In relation to what we have just talked about do you think you could do this time to make the response even better*

- ### Roll with Resistance
- Avoid “yes, but...”
  - Avoid “premature focus” on change
    - pushing ahead too soon
  - Avoid simple solutions
  - **Avoid advice giving**





#### How to apply these principles in this intervention

- Patient-led - reflection
- Communication - establish rapport & empathy
- Active listening - agreement, self disclosure
- Motivate patients
  - Explore the importance of topic to them
  - Develop positive health attitudes
  - Increase understanding and knowledge
- Enlist / develop natural support system
  - Involve family
- Overcoming barriers

#### Phases of intervention

- Phase I
  - Patient led elaboration of “their story”
- Phase II
  - Individualised education intervention
- Phase III
  - Application of intervention
    - Using scenarios
    - Devising action plan to take home.

#### Phase I

- Set agenda
  - Explain purpose of talk to patient, timing
- “Building on what we talked about earlier”
  - Let the patient tell the story
- Principles to be used
- Goals to be achieved

#### Phase II

- Individualise.
- Identify
  - Apply their specific diagnosis
  - Delay factors
  - Symptoms experienced
    - Other symptoms
  - Previous responses & experiences
  - Clarify misconceptions.

#### Phase III

- Individualised scenario
  - Patient
  - Family member
- Action plan
  - Allow patient to say what they would do
  - Deputise family member to take responsibility in event of patient not following recommendations
- Inappropriate responses
  - another scenario (if required)

### Ethics in Research

- All research has ethical implications
- Different research approaches and methods require different ethical considerations
- Various codes of ethics have been developed
  - Nuremberg Code
  - Declaration of Helsinki (adopted in 1964 by World Medical Assembly)

### Protection of Human Rights

- Researchers and reviewers of research have an ethical responsibility to recognise and protect the rights of human **research** subjects (Burns & Grove 1993).
  - Self-determination
  - Privacy
  - Anonymity and Confidentiality
  - Fair treatment
  - Protection from Discomfort and Harm

### Self-determination

- Humans are capable of controlling their own destiny
- Should be treated as autonomous agents
- Participants should be informed about the study and be allowed voluntarily choose to participate or not
- Right to withdraw at any time without penalty
- Can be violated through the use of coercion, deception, unaware that they are part of research, diminished autonomy.

### Privacy

- Freedom to determine the time, extent, circumstances under which private information will be shared or withheld
- Invasion of privacy occurs when private information is shared without an individual's knowledge or consent
- Occurs most frequently during data collection ie.
  - recording interviews without participants knowing

### Anonymity and Confidentiality

- Anonymity exists if the participant's identity cannot be linked even by the researcher with data
- Confidentiality relates to the researchers management of private information shared
- Can be breached if unauthorised person has access to the raw data or real names of participants or institutions are named
- Use of codes/pseudonyms can be used to ensure anonymity and confidentiality.

### Right to Fair Treatment

- Subjects considered as especially suitable include: the poor, prisoners, children.
- Should be prior agreement on the role of the researcher and participant in the study.
- All participants should be treated equally.

### Protection from Discomfort and Harm

- Can be physiological, emotional, social and economical
- No Anticipated Effects
- Temporary Discomfort
- Unusual levels of temporary discomfort
- Risk of permanent damage
- Certainty of Permanent Damage.

### Informed Consent

- Disclosure of essential information
  - Comprehension
  - Competency
  - Voluntarism
- (Nuremberg Code, 1986)

### Ethical Principles

(Parahoo 1997, Fry and Veatch 2000)

- Beneficence – study should benefit the participant and/or society
- Non-maleficence – Should not harm the participants (physical/psychological)
- Fidelity – Trust and respect
- Justice – Fair and equal treatment, participants needs come first
- Veracity – Researcher must tell the truth – being economical can be deception

### Ethical Principles

- Autonomy – individuals permitted personal liberty to determine their own actions according to plans they themselves have chosen
- Confidentiality – respect participants – take care not to reveal identifying details.

### Introduction to Questionnaires

- Questionnaires
  - Clinical history and socio-demographic questionnaires.
  - ACS Response Index.
- Familiarisation with questionnaires.
- How to complete questionnaires.

### Completion of ACS Response Index.

- Baseline with patient.
- 3 months by post
  - Phone if questionnaire not returned
  - Phone also used to assist completion of incomplete questionnaires and to thank patient for posting
- 12 month by post
  - Phone if questionnaire not returned
  - Phone also used to assist completion of incomplete questionnaires and to thank patient for posting.

**Completion of ACS Response Index.**

- Response time questionnaire.

**Role play of data collection**

**Data Management & Storage.**

- Storage of sequentially number-ordered sealed envelopes with randomised group.
- Storage of patient contact details, eligibility and consent forms.
- Storage of questionnaires.
- Data entry.
- Storage and back up of electronic files.
- General administration tips.

**How to use the access database.**

**Review of interventionists' skills acquisition**

- Role play
- Questioning
- Prevention of "*drift*"

## Appendix 5: Trial Protocol

### ACS Response-Time Intervention Trial





**The effectiveness of a structured educational intervention on the length of pre-hospital delay in patients at risk of acute coronary syndrome: a randomised controlled trial.**

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### **Trial Steering Committee**

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### **Research collaborators**

One consultant cardiologist from each of the 5 research sites.

## **Background**

Cardiovascular disease (CVD) accounts for approximately 40% of all deaths in most European countries (Sans *et al.* 1997). The problem of CVD is no less serious in Ireland, where coronary heart diseases accounts for 38% of all deaths, with 20% of these from ischaemic heart disease (Department of Health and Children 2006). In Ireland and other Western countries, the mortality rate from CVD, particularly in younger age groups, has declined in recent years (Department of Health and Children 1999, Bennett *et al.* 2006). Therefore, there is a growing concern that the number of ageing, chronically ill people with CVD, who are at risk of ACS events, will continue to increase (Sans *et al.* 1997). Furthermore, those who survive can sustain complications of infarction, including re-infarction and heart failure (Department of Health and Children 1999). Many of those who survive will have a reduced quality of life and chronic ill health (Department of Health and Children 2006).

A significant number of deaths and substantial disability from cardiovascular disease could be prevented. Seeking early treatment optimises the chances of survival and optimal recovery (Department of Health and Children 1999). The outcome for patients who suffer ischemic symptoms from a potentially life-threatening cardiac condition is partly dependant on decisions and associated actions taken by patients (Erhardt *et al.* 2002). The greatest contributors to the prevention or postponement of cardiac deaths from ACS are considered to be reperfusion therapies (i.e. thrombolysis and percutaneous coronary interventions) and advanced cardiac life support, including cardiopulmonary resuscitation (Bennett *et al.* 2006). Treatment benefits of reperfusion therapies are optimised when they are initiated early following the event (United Kingdom Heart Attack Study Collaborative Group 1998). The GUSTO trial (Simoons *et al.* 1993) demonstrated that mortality is halved when thrombolysis is administered within 1 to 2 hours of symptom onset. Death and life-threatening dysrhythmias can be prevented, while infarction size can be reduced substantially if early intervention is initiated (Dempsey *et al.* 1995). The chances of successful defibrillation are also optimised when professional assistance is sought in the early stages of symptom onset (Norris 1998). Mortality and morbidity rates

associated with cardiovascular disease can be reduced through the prompt recognition and acquisition of these necessary treatments when a coronary event arises. Yet, the major factor limiting early use of definitive therapies is patient delay in seeking treatment for symptoms (Erhardt *et al.* 2002, O'Donnell *et al.* 2006).

An examination of treatment delays was recommended in the Irish Cardiovascular Health Strategy (Department of Health & Children 1999). The longest phase of delay is the time it takes for patients to recognise symptoms until they seek treatment (O'Donnell *et al.* 2006). The length of pre-hospital delay varies considerably, but median times range from 2-6 hours (Moser *et al.* 2006). The Department of Health and Children (1999) recommended auditing pre-hospital transport time, with the aim of achieving a standard 90 minute "call to needle" time (Department of Health & Children 2001); however this timing assumes that patients promptly seek treatment for their symptoms, when most do not. This proposed study intends to target the initial phase of delay, patient pre-hospital delay, by "*increasing awareness of symptoms of impending heart attack*" (Department of Health & Children 2003, p.75) and taking appropriate action. Public awareness campaigns designed to decrease patient delay have been disappointing to date (Erhardt *et al.* 2002, Caldwell & Miaskowski 2002). Individualisation of interventions is advocated as being more effective in secondary prevention in cardiac patients (Clark *et al.* 2002). In addition, targeting those to whom the message is most salient, is likely to increase its effectiveness.

Studies have demonstrated reluctance by patients with ACS to seek prompt medical help, which presents as a major mitigating factor against the timely receipt of reperfusion and other therapies (Bury *et al.* 1992, Erhardt *et al.* 2002, Johansson *et al.* 2004, O'Donnell *et al.* 2006). Major reasons for patient delay in seeking treatment include: failure to attribute symptoms to the heart and a lack of appreciation of the significance of symptoms and their severity (Fukuoka *et al.* 2005, Johansson *et al.* 2004, McKinley *et al.* 2004). Certain identified groups consistently delay longer in seeking treatment in the face of suspected ACS. These include older people, women (Erhardt *et al.* 2002, O'Donnell *et al.* 2006),

ethnic minority groups, those with markedly lower education levels and those with diabetes (Erhardt *et al.* 2002, Moser *et al.* 2006). It is worth noting that those with a prior history of ACS also commonly delay seeking treatment in the face of recurring symptoms (Gurwitz *et al.* 1997; Moser *et al.* 2006).

The extent of mortality and morbidity from cardiovascular disease could be significantly reduced for patients who suffer from ACS if prompt decisions were made and appropriate actions taken to seek medical assistance in the face of cardiac symptoms (Erhardt *et al.* 2002). One means by which improvements could be implemented is through focused education. The Department of Health & Children (1999) has recommended that special attention be paid to providing guidance to patients with pre-existing cardiac disease. To date, no Irish interventional study aimed at reducing patient pre-hospital delay time has been conducted. This is what the proposed study sets out to achieve. The focus will be on reducing patient pre-hospital delay time and increasing knowledge, attitudes and beliefs about ACS among patients who have had an ACS event.

ACS is defined as ST elevation myocardial infarction, non-ST elevation myocardial infarction and unstable angina.

### **Study aim**

To test the effectiveness of an educational intervention in: reducing patient pre-hospital delay time and; improving knowledge, attitudes and beliefs about ACS among patients who present to an ED with ACS symptoms.

### **Hypotheses**

Following the intervention:

- The intervention group will have a shorter pre-hospital delay time than the control group.
- The intervention group will demonstrate more appropriate behaviours in the presence of ACS symptoms than the control group.

- Patients assigned to the intervention group will demonstrate greater knowledge, better attitudes and more accurate beliefs about ACS at 3 and 12 months than those assigned to the control group.

### **Outcome measures**

- Pre-hospital delay time (time from acute symptom onset until arrival at the ED)
- Behaviours: use of prescribed nitrates, use of ambulance, notification of nominated individual about symptoms, non-consultation with a general practitioner.
- Knowledge, attitude and belief scores.

### **Study Design**

The ACS Response Time Intervention Trial is a two-group, parallel design randomised controlled trial (RCT). Patients assigned to the control group will receive usual care. In addition to usual care, patients assigned to the intervention group will receive a one-to-one, 40-minute educational intervention following baseline data collection. Knowledge, attitudes and beliefs about ACS will be addressed through the medium of the intervention. The intervention will focus on the importance of preventing pre-hospital delay time in the presence of ACS symptoms.

### **The intervention**

Patients allocated to the intervention group will receive a one-to-one, 40-minute nurse-administered educational intervention, which will focus on the importance of preventing pre-hospital delay time in the event of the onset of subsequent ACS symptoms. The intervention is based on Leventhal's self-regulatory model of illness behaviour (Leventhal *et al.* 1980, Leventhal *et al.* 1981, Leventhal & Cameron 1987), which effectively guides interventions designed to change and improve treatment-seeking behaviour. The intervention has been tested in previous studies (Dracup *et al.* 2006).

The intervention will address three areas recommended as strategies to prevent pre-hospital delay in patients at high risk for ACS i) Information, ii) Emotional

issues and iii) Social factors (Dracup *et al.* 2006). These parallel the three components of Leventhal's self-regulatory model of illness behaviour: cognitive, emotional, and environmental stimuli.

Information (Approximately 10 minutes): Patients will be given information about typical symptoms, possible variability in symptom presentation and the fact that onset may be gradual and intermittent, rather than stereotypical sudden crushing chest pain. They will be advised to take appropriate actions such as, taking prescribed nitrates and calling an ambulance if symptoms do not resolve within 15 minutes.

Emotional issues (Approximately 10 minutes): Patients will be assisted in anticipating and recognising emotional responses to ACS symptoms and acknowledging that these could delay their pre-hospital time and their receipt of treatment. To accompany this aversive message, the rewards of seeking treatment quickly will be emphasised (i.e. preservation of heart muscle and increased chance of survival). They will be told that denial or suppression of the seriousness of symptoms is common and contributes to treatment delay. They will be informed that attribution of symptoms to a non-cardiac cause is common. As patients are likely to have experienced previous ED admissions, they will be questioned about their experiences and any negative issues will be acknowledged and reconciled with the current informational message. Emotional issues will be addressed partially through the use of scenarios that most closely resemble that of the patient. Through role playing, patients will be asked to anticipate emotions they might experience when they have ACS symptoms. They will be guided through these and the appropriate actions to take. Patients will rehearse their responses to a possible ACS with the interventionist. This will increase the likelihood of responding appropriately, even when experiencing emotional reactions to the symptoms.

Social factors (Approximately 5 minutes): Family members/significant others play an important role in preventing patient denial and in facilitating the call to access the emergency services. Patients will be asked to nominate the person they are most likely to call upon for help, if they need to go to the hospital. This individual may attend the intervention, so that they will have an understanding of the nature of ACS symptoms and the importance of calling an ambulance quickly. If symptoms arise and do not respond to nitrates, patients will be

advised to consult with their nominated person, who will act as the decision-maker, if the patient hesitates to call an ambulance. An individualised action plan will be developed in conjunction with the participant. This will include the emergency phone numbers 999 or 112, the action to take in the presence of symptoms and the name and phone number of the nominated individual that they would contact in the event of unresolving symptoms.

Scenarios (Approximately 10 minutes): These will be presented to the participant and where appropriate, the nominated individual to help them experience emotions involved in witnessing a possible ACS event. They will be asked to role-play an interaction with the patient. One month and six months later, the intervention will be reinforced by telephone and post, respectively.

Summarise the main intervention messages (Approximately 3 minutes) before departing.

### **Usual care**

Both groups will receive usual care from the hospital. With respect to pre-discharge education, usual care generally focuses on the most commonly experienced ACS symptoms and how to respond to them. In usual care, there is limited emphasis on the cognitive, emotional and social factors that underlie delay. These are addressed in the intervention planned for this study.

### **Research sites**

- 5 tertiary hospitals with emergency departments in Dublin.

### **Patient recruitment**

Recruitment will take place between November 2007 and October 2009 in the coronary care units and cardiology wards in the research sites. Randomisation and intervention delivery will occur within days of recruitment. The gatekeepers for this study will be consultant cardiologists or clinical nurse managers. The gatekeepers will determine patients' eligibility, brief the patients about the study and furnish the interventionist with the names of those interested in participating (Table A). Refer to table A for detailed information on the trial protocol process.



Participants are eligible to be entered into the study if they:

- have a provisional diagnosis of ACS,
- are stable and planning for discharge,
- have access to a telephone,
- have an ability to read, understand and communicate in English,
- are willing to participate voluntarily in the study.

Exclusion criteria include:

- a major or uncorrected hearing loss,
- a profound learning disability or any neurological disorder that impairs cognition,
- those who live in an institutional setting,
- those with serious complicating co-morbidities or untreated malignancies.

### **Sample**

To achieve a sample with a power of 0.80, an alpha of  $<0.05$  and an effect size of 0.20, it is estimated that 393 participants will be needed to return after the intervention with ACS symptoms to detect a significant difference in pre-hospital delay time between the two groups (Cohen 1992). The current readmission rate among patients with ACS is between 10 and 14%. Therefore, in order to achieve a readmission sample of at least 393, it is estimated that at least 2,807 participants will need to be recruited. To maintain the statistical assumption of independence, data on patients' first subsequent readmission will be recorded for the study duration. In 2005, there were approximately 3,000 patients admitted and diagnosed with ACS across the research sites. It is estimated that approximately 50% of those who are admitted annually will be recruited to the study, given that a small proportion of patients will not meet the inclusion criteria and some will not be willing to participate. This means that there will be approximately 1,500 participants available per year. Therefore, data will be collected over a two-year period.

### **Randomisation process**

A random number generator will be used to generate the random sequences for each site, generating 50% control and 50% intervention within each random sequence. As patients are recruited to the study, they will automatically be given the next number in the sequence. The allocation to the control or the intervention group will be found in the relevant numbered, opaque, sealed envelope. When consent is obtained and baseline data collected, randomisation to the control or the intervention group will be divulged.

### **The Research Instruments**

The ACS Response Index will be used to collect data (Dracup *et al.* 2006). It comprises three sections:

- I. Knowledge, Attitudes and Beliefs about ACS;
- II. Control Attitudes Scale-Revised & the Multiple Affect Adjective Checklist
- III. Response Time Questionnaire.

It will be preceded by a socio-demographic and clinical characteristic questionnaire. Data will be collected at baseline, 3 months and 12 months from both groups. In addition, delay-time data will be collected on those who are readmitted to an ED with ACS symptoms (Table A).

Face validity will be determined by administering the questionnaire to two colleagues who are independent of this study, and four individuals over the age of 65 years. They will be asked to ascertain whether or not they can identify with the content and appropriateness of the questionnaire. Content validity will be established by a panel of experts with a background in cardiology. Internal consistency for the instrument was established using Cronbach's alpha with all three subscales above 0.70 (Riegel *et al.* 2007).

### **Ethical considerations**

Ethical approval will be sought from the research ethics committees of all five research sites. The researchers will uphold ethical principles in relation to human research. These will include the right to full disclosure, self-

determination, non-maleficence, privacy, anonymity and confidentiality. Written and verbal information will be provided about this study, and only then will informed consent be obtained. Gatekeepers will initially approach the patients, thereby avoiding any potential coercion to participate by the researchers. As assignment is through randomisation, each patient will have an equal chance of being assigned to the control or intervention group. Patients will be informed that they can withdraw from the study at any time, without consequence. As this is a randomised controlled trial, the intervention group is expected to benefit from the intervention. However, there is genuine uncertainty as to whether this will happen, as to date, most previous interventions aimed at reducing pre-hospital delay time have been unsuccessful.

### **Data collection and storage**

In keeping with the Data Protection Act 2003, data will be collected, stored and treated with strictest confidentiality and maintained for 5 years post trial completion. All hardcopy data will be stored in a locked cabinet in the School of Nursing & Midwifery, Trinity College Dublin. Data collection will be completed by December 2010.

### **Data analysis**

Data will be entered, cleansed and proofed throughout the study and on its completion. Major analyses will only be performed on completion of data collection. Data will be analysed using SPSS. As data on delay time is always markedly skewed, log transformation will be applied. Repeated measures ANOVA will be used to test the study hypotheses.

### **Data dissemination**

Dissemination of results will occur at the end of the project.

**Table A: Process for recruitment and follow-up**

<b>Prepare pack in advance of attending research site to include:</b>	
<ul style="list-style-type: none"> <li>• Patient eligibility form.</li> <li>• Participant information sheet.</li> <li>• Consent Form (2 copies). One for you and one for the patient.</li> <li>• Questionnaires: Clinical History, Socio-demographic &amp; ACS Response Index.</li> </ul>	<ul style="list-style-type: none"> <li>• Participant contact details form.</li> <li>• Sealed envelope with an opaque window (with study number revealed and randomisation group concealed).</li> <li>• Yellow sticker for chart.</li> <li>• Refrigerator magnet.</li> </ul>

**Baseline (I = Intervention group, C= Control group)**

<b>Step taken</b>	<b>I</b>	<b>C</b>
Verify patient eligibility based on names given by gatekeeper.	x	x
Provision of written and verbal information & ascertain interest in trial.	x	x
Obtain and sign informed consent. Give one copy to the patient.	x	x
Decide best location for data collection (available room or bedside).	x	x
Collect baseline data (Patient contact details, demographic questionnaire & ACS Response Index).	x	x
Open randomisation envelope and inform patient of group.	x	x
<b>Control only</b> Remind participant to make contact if they are attended an ED with ACS-type symptoms. Give fridge magnet. Thank the patient for participating and inform them that they are welcome to avail of the intervention on completion of the study, by contacting you. Close the interview.		x
<b>Intervention only</b> After a short break, proceed with delivering the one-to-one educational intervention (in the presence of a family member if feasible). The intervention should take 40 minutes (30 minutes of prescribed script and the 10 minute individualised scenario and role-play session). The individualised component is based on the participant's current event and receptiveness to the intervention. Complete action plan and give this pink sheet to the patient with fridge magnet. Remind the participant to notify you if they are readmitted via ED with ACS-type symptoms and that you will be sending them the 3 and 12 month questionnaires. Arrange a potential suitable date and time for one-month follow-up phone call. Thank patient for participating and close the interview. Document field notes and prepare reports for monthly meetings.	x	
Put bright yellow sticker on front of medical notes to signify their enrolment in the study and prompt staff to notify the research team if participants are readmitted.	x	x
Verify data against medical notes. Reconcile any discrepancies with the participant.	x	x
<b>The interventionist must manage the collected data:</b> Separate file documents to ensure the participant contact details, eligibility and consent forms are stored separately from the questionnaires. Input data from the hardcopy of the questionnaire onto database. Cross-check the data on the hardcopy with inputted data. Save file using external hard drive provided for you to back up this data. File hardcopies of questionnaires in numerical order, separate from other data. Data-management – organise and update records with dates for follow-up.	x	x

**(I = Intervention group, C= Control group)**  
**1 month follow-up (Intervention group only)**

<b>Step taken</b>	<b>I</b>
Using the data-management system, identify the participants to whom the one month phone call is due.	
Telephone participant at the pre-scheduled time and call back until there is an opportunity to deliver the one month intervention.	x
Introduction.	
Check how they are and how they have been. Establish if they have been readmitted to an ED with ACS type symptoms since recruitment.	
Use pre-printed standardized protocol to reinforce the intervention.	
Update data-management system.	

**(I = Intervention group, C= Control group)**  
**6 month follow-up (Intervention group only)**

<b>Step taken</b>	<b>I</b>
<b>Intervention group only</b>	
Using the data-management system, identify the participants to whom reminder action plans are due to be distributed.	x
Prepare action plan sheets and letters for posting.	
Address and stamp each envelope and post.	
Update data-management system.	

**Readmission data (first readmission only – collect from time of enrolment to study end)**

<b>Step taken</b>	<b>I</b>	<b>C</b>
Check participants' readmission status when you are in communication (1, 3, 12 months).	x	x
Prior to study completion, contact all recruited participants (not known to be readmitted) to identify any missed readmissions.	x	x
For those who were readmitted, complete ACS Response Index (readmission) and confirm details against medical notes.	x	x
Update data-management system.	x	x

### 3 & 12 month follow-up

Step taken	I	C
<p>Using the data-management system, identify the participants to whom questionnaires are due to be distributed.</p> <p>Prepare questionnaires and letters for posting (personalise each letter). Enclose these with a stamped addressed envelope.</p> <p>Address and stamp each envelope and post.</p> <p>In the event of non-receipt of responses, telephone the participant to check that they received the package.</p> <p>For those who had mislaid it or not received it, resend the package, with consent.</p> <p>For those who had received it but had not returned it, kindly request that they might do so at their own convenience.</p> <p>A maximum of 2 reminder phone calls to each participant is recommended in an effort to retrieve the questionnaires.</p>	x	x
<p>On receipt of the completed questionnaires a courtesy phone call should be made to thank the participant for their correspondence and in the case of the 3 month questionnaires, to remind them that you will be sending the 12 month questionnaire in due course.</p>	x	x
<p>Input data from hardcopy of the questionnaire onto database.</p> <p>Cross-check the completed data between hardcopy and the database.</p> <p>Save changes to database using the external hard drive provided.</p> <p>File hardcopies of questionnaires in numerical order.</p> <p>Data-management – organise and update records with dates for follow-up.</p>	x	x

## References

Anderson H. & Willerson J. (1993) Thrombolysis in acute myocardial infarction. *The New England Journal of Medicine* **329** (10),703-709.

Bennett K., Kabir Z., Unal B., Shelley E., Crithley J., Perry I., Feely J. & Capewell S. (2006) Explaining the recent decrease in coronary heart disease mortality rates in Ireland,1985-2000. *Journal of Epidemiology and Community Health* **60**,322-327.

Bury G., Murphy A., Power R., Daly S., Mehigan C. & Walsh J. (1992) Awareness of heart attack signals and cardiac risk markers amongst the general public in Dublin. *Irish Medical Journal* **85**, 96-97.

Caldwell M.A. & Miaskowski C. (2002) Mass media interventions to reduce help-seeking delay in people with symptoms of acute myocardial infarction: time for a new approach? *Patient Education and Counseling* **46**(1), 1-9.

Clark AM., Barbour RS. & McIntyre PD. (2002) Preparing for change in the secondary prevention of coronary artery disease: A qualitative evaluation within a region in Scotland. *Journal of Advanced Nursing* **39**(6), 580-588.

Cohen J. (1992) A power primer. *Psychological Bulletin* **112**(1), 155-159.

Dempsey S., Dracup K. & Moser D. (1995) Women's decision to seek care for symptoms of acute myocardial infarction. *Heart and Lung* **24**(6), 444-456.

Department of Health and Children (1999) *Building Healthier Hearts. The Report of the Cardiovascular Health Strategy Group*. The Stationary Office, Dublin.

Department of Health and Children (2001) *First Progress Report of the Cardiovascular Health Strategy Group*. The Stationary Office, Dublin.

Department of Health and Children (2003) *Ireland's Changing Heart. Second Progress Report of the Cardiovascular Health Strategy Group*. The Stationary Office, Dublin.

Department of Health and Children (2006) *Reducing the Risk: A Strategic Approach. The Report of the Task Force on Sudden Cardiac Death*.

Department of Health and Children, Dublin

Erhardt L., Herlitz J., Bossaert L., Halinen M., Keltai M., Koster R., Marcassa C., Quinn T. & van Weert H. (2002) Task Force Report: Task force on the management of chest pain. *European Heart Journal* **23**, 1153-1176.

Fukuoka Y., Dracup K., Ohno M., Kobayashi F. & Hirayama H. (2005) Symptom severity as a predictor of reported differences of pre-hospital delay between medical records and structured interviews among patients with AMI. *European Journal of Cardiovascular Nursing* **4**(2), 171-176.

Gurwitz J.H., McLaughlin T.J., Willison D.J., Guadagnoli E., Hauptman P.J., Gao X. & Soumerai S.B. (1997) Delayed hospital presentation in patients who have had acute myocardial infarction. *Annals of Internal Medicine* **126**(8), 593-599.

Johansson I., Stromberg A. & Swahn E. (2004) Factors related to delay times in patients with suspected acute myocardial infarction. *Heart and Lung: Journal of Acute and Critical Care* **33**(5), 291-300.

Leventhal H., Meyer D. & Nerenz D. (1980) The common sense representation of illness danger. *Contributions to Medical Psychology* **2**, 7-30.

Leventhal H., Safer M.A. & Panagis D. (1983) The impact of communications on the self-regulation of health beliefs, decisions and behavior. *Health Education Quarterly* **10**, 4-28.



Leventhal H. & Cameron L. (1987) Behavioral theories and the problem of compliance. *Patient Education and Counseling* **10**, 117-138.

McKinley S., Dracup K., Moser D.K., Ball C., Yamasaki K., Kim C.J. & Barnett M. (2004) International comparison of factors associated with delay in presentation for AMI treatment. *European Journal of Cardiovascular Nursing* **3**(3), 225-230.

Moser D.K., Kimble L.P., Alberts M.J., Alonzo A., Croft J.B., Dracup K., Evenson K.R., Go A.S., Hand M.M., Kothari R.U., Mensah G.A., Morris D.L., Pancioli A.M., Riegel B. & Zerwic J.J. (2006) Reducing delay in seeking treatment by patients with acute coronary syndrome and stroke: a scientific statement from the American Heart Association Council on cardiovascular nursing and stroke council. *Circulation*. **114**(2), 168-182.

Norris R. (1998) on behalf of the United Kingdom Heart Attack Study (UKHAS) Collaborative Group. Fatality outside hospital from acute coronary events in three British health districts, 1994-1995. *British Medical Journal* **316**, 1065-1070.

O'Donnell S., Condell S., Begley C. & Fitzgerald T. (2006) Pre-hospital care pathway delays: gender and myocardial infarction. *Journal of Advanced Nursing* **53**(3), 268-276.

Sans S., Kesteloot H. & Kromhout D. on behalf of the task force (1997) The burden of cardiovascular diseases in mortality in Europe. Task Force of the European Society of Cardiology on Cardiovascular mortality and Morbidity Statistics in Europe. *European Heart Journal* **18**, 1231-1248.

Simoons M., Topol E., Califf R., Werf van de F., Armstrong P., Aylward P., Barash G., Bates E., Betriu A., Chesebro A., Col J., Bono D., Gore J., Gurci A., Hampton J. (1993) An international randomized trial comparing four thrombolytic strategies for acute myocardial infarction. *New England Journal of Medicine* **329**, 673-682.

United Kingdom Heart Attack Study (UKHAS) Collaborative Group (1998) Effect of time from onset to coming under care on fatality of patients with acute myocardial infarction: effect of resuscitation and thrombolytic treatment. *Heart* **80**, 114-120.

## Appendix 6: One month follow-up call



## ACS Response-Time Intervention Trial

### One month follow-up telephone call to the Intervention group.

Study number: \_\_\_\_\_

Date entered study: \_\_\_\_\_

Hello. May I please speak with (patient name).

Hello. My name is: \_\_\_\_\_. I'm a research nurse at \_\_\_\_\_ (Hospital). I met you a month ago at the hospital when you agreed to take part in a study about delay in seeking treatment following heart symptoms. I am phoning to follow up on the teaching session you received. Does it suit you to talk now?

(If no) schedule a follow-up phone call, thank and close.

(If yes). Proceed

Icebreaker: e.g. how have you been since your discharge from hospital?

From this, establish if the patient had attended A&E for heart-related symptoms?

Tick appropriate box	Yes	No
Have you attended A&E for heart related symptoms?		

(If yes) complete Response-Time Questionnaire (Readmission)

I'd like to go over a couple of points related to the teaching session you had. Do you recall that the main goal is to promote early treatment of possible heart attack symptoms?

Yes  No

Specifically we want to prevent heart attacks from happening, or stop them before they can do severe damage. Right now patients wait any length from

hours to days before receiving the care they need to restore blood flow to the heart muscle. The average length of time is between 2 and 6 ½ hours. The goal is to shorten that to 1 hour for every patient. This means one hour from the first symptom to the time that the blood flow is restored to the heart. There are many reasons people “delay” in seeking and receiving care.

Do you recall any of these reasons from the teaching session?

Yes    No

(tick the ones the patient remembers and reiterate the ones the patient doesn't mention)

- Many patients are not sure of the symptoms of a heart attack, and do not believe that the symptoms they are experiencing are serious.
- Sometimes patients delay because they are embarrassed and don't want to draw attention to themselves or bother others.
- Sometimes care is delayed by family or friends.
- A big reason for delay is calling your doctor for advice. By taking the time to make the phone call, waiting for the doctor to be relayed the message and receiving advice, precious minutes are wasted.

(If the patient is African-American) A patient's ethnicity sometimes leads to a delay in care. African Americans may receive care less quickly than Caucasians. African Americans have more heart attacks at a younger age than Whites due to a higher incidence of high blood pressure.

(If the patient is Hispanic) A patient's ethnicity sometimes leads to a delay in care. Hispanics may receive care less quickly than Caucasians. Hispanics have heart attacks at younger ages because of higher incidence of diabetes.

(If the patient is female) Women may have greater delays in care than men. And, sometimes, women don't realize they could have a heart attack.

(If the patient is less than 50 years old) Age is a cause of delay in treatment. The very young often don't believe that they could have a heart attack.

(If the patient is greater than 70 years old) Age may be a cause of delay in treatment. People over 70 may have aches and pains that lead to further delays in care.

Do you have diabetes?

Yes  No

(If yes)

Diabetics often suffer delays in treatment because they do not feel pain with heart attacks. Just like a diabetic can have less feeling in their feet and legs, they can have nerve damage to their heart muscle as well. This lack of sensation leads to more severe heart attacks going undetected.

(If no, continue)

Fear causes many people to delay seeking care. They don't want to be having a heart attack, so they wait to see if it will "go away." While they wait, muscle is dying due to lack of oxygen.

Anxiety can cause us to think less clearly, and make excuses about what is happening to our bodies. The anxiety related to a possible heart attack, or the care that will be necessary, causes many people to delay seeking the care they need.

There are many benefits to arriving at the hospital early after symptoms start.

Hospitals have treatments to restore the blood supply to the heart

By getting to the hospital in time to use these therapies, patients experience many benefits. Do you remember any of them from the teaching session?

(Tick the ones the patient remembers and reiterate the ones the patient doesn't mention)

- Greater chance of survival
- Better quality of life after recovery
- Less complications (heart failure, irregular heart rhythms)

Have you ever had a heart attack?

Yes  No

(If yes) What were your symptoms? (Listen and use reflective statements to incorporate the patient's answer into the rest of the teaching. Tick which symptoms they experienced)

- Chest discomfort or pain, may radiate to left arm, neck, jaw, teeth
- Pain or heaviness in the left arm, or both arms
- Shortness of breath
- A sense of dread (something is wrong, but don't know what it is)
- Feeling cold and clammy, or sweaty
- Feeling nauseated or vomiting, or a feeling of heart burn
- Feeling faint or light-headed
- Fatigue
- Discomfort in any area from your nose to your naval

(If no, continue)

Just to review, typical symptoms of a heart attack include:

- Chest discomfort or pain, may radiate to left arm, neck, jaw, teeth
- Pain or heaviness in the left arm, or both arms
- Shortness of breath
- A sense of dread (something is wrong, but don't know what it is)

Other symptoms which may occur are:

- Feeling cold and clammy, or sweaty
- Feeling nauseated or vomiting or a feeling of heart burn
- Feeling faint or light-headed
- Fatigue
- Discomfort in any area from your nose to your naval.

Do you recall what to do if you think you are having a heart attack? (tick the ones the patient remembers and reiterate the ones the patient doesn't mention)

Recognise how you might feel about a possible heart attack.

- Stop and Rest
- Take your GTN (angina spray) as instructed
- Let someone know what is happening
- If symptoms continue for more than 15 minutes, act immediately
- Phone 999 or 112 for an ambulance wherever you are.

- If you do not have access to 999, have someone take you to the nearest full-service Emergency Department.
- Do not stop to call your doctor.
- Do not stop to call friends or family.
- Rest until help arrives.

Do you have any questions about the teaching program or heart attacks in general?

(If yes) answer them.

(If no) Thank you so much for your time. I will be phoning you again in 2 months, after I have posted you the same questionnaire that you completed in the hospital.

Thank and close the call.



## Appendix 7: Six month intervention reinforcement



**ACS RESPONSE TIME INTERVENTION TRIAL**

School of Nursing & Midwifery,  
Trinity College Dublin,  
24 D'Olier Street,  
Dublin 2

Dear

I hope that this letter finds you well.

Thank you for completing the three month questionnaire, which will assist us with our on-going study. I am now sending you a small reminder about the action to take should you have any "heart warning" signs or symptoms.

You will be able to use this reminder to re-cap on the typical symptoms that you may have and how to deal with them.

**REMEMBER:**

The purpose of our study is to encourage people **NOT TO DELAY** if they experience heart symptoms.

I will send you the final questionnaire in 6 months time and in the meantime, I wish you well.

Thank you so much for your participation. It is much appreciated.

Yours sincerely

---

Mary Mooney  
Research Nurse

## WHAT TO DO IF YOU HAVE ONE OR MORE HEART WARNING SYMPTOMS?

**1. You may experience some or all of these symptoms:**

- Chest discomfort, heaviness or pain
- Arm pain or ache
- Pain radiating to your neck, jaw, arms or shoulder blades
- Shortness of breath
- Sweating
- Nausea and/or indigestion
- A sense of dread
- Discomfort in any area from your nose to your navel



**2. If symptoms are present:**

- Stop and Rest
- Take your GTN spray as directed: \_\_\_\_\_
- Let someone know what is happening



**3. If the symptoms continue longer than 15 minutes, phone 999 or 112 for an ambulance.**

- Don't wait
- Don't hesitate
- ***IF IN DOUBT LET A&E CHECK IT OUT***

**If you experience any heart symptoms and go to A&E please record below**

Date:	Time:
I had some or all of the above symptoms: Yes                      No	
I took GTN spray at:	
Pain persisted beyond 15 minutes:    Yes:                      No:	
I phoned ambulance at :	
Ambulance arrived at:	
I got to A&E at:	
If you attend hospital with heart symptoms please leave a message to inform the researcher - 085 51381267	

## Appendix 8: Ethical Approval Letters

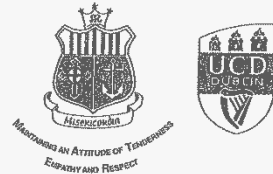


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SIÚRACHA NA TRÓCAIRE

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*Not for prescription purposes*

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Dr Declan Sugrue  
Consultant Cardiologist  
Mater Misericordiae University Hospital  
Eccles Street  
Dublin 7

05<sup>th</sup> November 2007

Our Ref: 1/378/1125

**RE: The effectiveness of a structured educational intervention on the length of pre hospital delay in patients at risk of acute coronary syndrome  
Patient Information Leaflet, Version 6 19/08/07  
Consent Form, Version 6 19/08/07**

Dear Dr Sugrue

I acknowledge receipt of your correspondence dated 19<sup>th</sup> October 2007 clarifying the points addressed in my letter to you of 25<sup>th</sup> July 2007 and enclosing a revised Patient Information Leaflet and Consent Form (Version 6 19/08/07) for the above research study to be carried out at the Mater Misericordiae University Hospital.

This correspondence has been noted and the revised Patient Information Leaflet and Consent Form have been approved. Approval to proceed with this research study at the Mater Misericordiae University Hospital is now granted; this approval is valid until 25<sup>th</sup> July 2009.

It is your responsibility to adhere to the study protocol without deviation (unless it has been agreed by the Research Ethics Committee), to submit annual reports setting out the progress of the research (giving details of the number of participants who have been recruited, the number who have completed the study and details of any adverse events etc.) and to notify the Research Ethics Committee when the research is concluded.

Yours sincerely

Dr Harry Frizelle  
Chairman Research Ethics Committee

c.c. Dr Gabrielle McKee, Senior Lecturer, School of Midwifery, Trinity College  
Ms Anne Carrigy, Director of Nursing, Mater Misericordiae University Hospital

Directors: Mr. John Morgan (Chairman), Fr. Kevin Doran, Mr. Eamon Clarke, Mr. Don Mahony,  
Sr. Margherita Rock, Mr. Martin Cowley, Mr. Kevin O'Malley, Mrs. Anne Carrigy, Mr. Brian Conlan,  
Sr. Eugene Nolan, Dr. Anthony Clarke, Mr. Kevin Murphy, Dr. Nuala Healy.

Registered in Ireland No. 351402 Charity No. CHY203 Registered Office: Eccles Street, Dublin 7.





**Ethics and Medical Research Committee**

ELM PARK, DUBLIN 4

Tel. (01) 2774117 Fax (01) 2838123 email: joan.mcdonnell@ucd.ie

22/10/07

Dr. Gabrielle McKee,  
Snr Lecturer,  
School of Nursing & Midwifery,  
Trinity College,  
24 Dolier Street,  
Dublin 2.

**Re: The Effectiveness of a Structured Educational Intervention on the Length of Pre-hospital Delay in Patients at Risk of Acute Coronary Syndrome: A Randomised Controlled Trial.  
Protocol. Patient Informed Consent Form. Vs 3 18/10/07. Letters to Consultants and Director of Nursing. Questionnaires.**

Dear Dr. McKee,

Thank you for the revised documents and clarifications which were requested prior to issuing approval for this study at the Ethics and Medical Research Committee meeting held on Wednesday 5<sup>th</sup> September 2007.

Following review of your clarifications outlined in your covering letter dated 12<sup>th</sup> October, 2007 and the revised documentation this study is now approved.

Yours sincerely,

Professor D. Veale,  
Chairman,  
Ethics and Medical Research Committee

**Ethics (Medical Research) Committee - Beaumont Hospital  
Notification of ERC/IRB Approval**

**Investigator:** Dr. T. Gumbrielle  
**Protocol No.:** 07/46  
**Protocol Title:** The effectiveness of a Structured Educational Intervention on the length of pre-hospital delay in Patients at risk of Acute Coronary Syndrome (ACS)

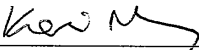
**Ethics Committee Meeting Date:** 29<sup>th</sup> June 2007  
**Final Approval Date:** 6<sup>th</sup> September 2007

**From:** Ethics (Medical Research) Committee - Beaumont Hospital, Beaumont, Dublin 9

**Documents Reviewed**

<b>Document and Date</b>	<b>Date Reviewed</b>	<b>Approved</b>
<b>Application 07/46, Signed T. Gumbrielle, 20/7/07</b>	6/9/07	Yes
<b>GP Letter, Version 1, 20/7/07</b>	6/9/07	Yes
<b>Flow Chart of Experimental Protocol, Version 2, 20/7/07</b>	6/9/07	Yes
<b>Patient Information Leaflet Version 2, 20/7/07</b>	6/9/07	Yes
<b>Consent Form, Version 2, 20/7/07</b>	6/9/07	Yes
<b>Detail of Participants, Version 2, 20/7/07</b>	6/9/07	Yes
<b>Background Beaumont Version 1</b>	6/9/07	Yes
<b>Eligibility Checklist Beaumont Version 1</b>	6/9/07	Yes
<b>Socio-Demographic Information Beaumont Version 1</b>	6/9/07	Yes
<b>Clinical History Beaumont Version 1</b>	6/9/07	Yes

Response Questionnaire Beaumont Version 1	6/9/07	Yes
Patient Advisory Take Home Form Beaumont, Version 1	6/9/07	Yes
Delay Time Questionnaire Beaumont Version 1	6/9/07	Yes
Curriculum Vitae: - T. Gumbrielle	Pending	Pending


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 Professor Kieran Murphy  
 ERC/IRB – Convenor's Signature  
 Approval # 1, dated 6<sup>th</sup> September 2007



THIS NOTE/PAPER MUST NOT BE USED FOR  
PSEUDO-IDENTIFICATION

SJH/AMNCH Research Ethics Committee Secretariat  
Dan Lynch Ph: 4142860 email: Dan.Lynch@amnch.ie  
Ursula Ryan Ph: 4142342 email: Ursula.Ryan@amnch.ie  
Secretariat Fax 4142371



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Dr. Gabrielle McKee  
Senior Lecturer  
Director of Undergraduate Teaching & Learning  
School of Midwifery  
Trinity College Dublin  
24 D'Olier Street  
Dublin 2

June 27th 2007.

**Re: The Effectiveness of a Structured Educational Intervention on the Length of  
Pre Hospital Delay in Patients at Risk of Acute Coronary Syndrome.**

*Please quote this reference in any follow up to this letter: 2007/06/14 Chairman's  
Action.*

Dear Dr. McKee,

Thank you for your recent submission of the above proposal to the SJH/AMNCH  
Research Ethics Committee.  
The Chairman, having reviewed your proposal has, on behalf of the Committee, given  
ethical approval to the proposed study.

Yours sincerely,

**Daniel R. Lynch,**  
Secretary,  
SJH/AMNCH Research Ethics Committee

## Appendix 9: Patient Information Leaflet



The University of Dublin, Trinity College

Faculty of Health Sciences

School of Nursing & Midwifery

24 D'Olier Street, Dublin 2.

Tel: + 353 1 8962692 Fax: + 353 1 8963001 <http://www.nursing-midwifery.tcd.ie/>

### Patient Information Leaflet

#### 1. Title of study: ACS Response-Time Intervention Trial.

#### 2. Introduction:

We are asking for your help with a study that we are carrying out to find out the benefits of giving an extra teaching session to patients who have had heart symptoms. We want to find out if patients who get this extra information are more likely to get medical help early if they get these symptoms again. The hospital and consultants have given us permission, to carry out this study at the hospital and we would like you to take part. If you do not want to take part in the study, this will not affect your care in any way.

#### 3. What will happen to me if I agree to take part in the study?

The research nurse will already have talked to you briefly about the study. She will check to see if you are suitable to be in the study and will help you in the filling out of a consent form. If you are willing to be part of the study, you will be picked by chance to be in one of two groups: the "control group" that gets the usual care or the "study group" that gets an extra teaching session as well as the usual care.

In this study, you will be asked to help us in the following ways. Before you are discharged, the "study group" and the "control group" will fill out some surveys (the research assistant will help you with this). These will be repeated 2-3 times over the next two years, by post and/or telephone. The surveys will ask you questions about the following:

- **Personal Details:** Medical history, date of birth, age, etc. These questions will be filled out before you are discharged with the help of the research assistant. To help in the filling out of the surveys the researcher will look at your case notes. The case notes will also hold a note showing that you are taking part in this study.
- **Questions about your anxiety, beliefs and understanding of cardiac disease:** you will fill out these questions before you are discharged with the help of the research assistant. They will also be filled out at 3 and 12 months. At these times, the surveys will be posted to you and you may send them back or the research assistant will phone you and you can fill them out over the telephone. This should take about 30 minutes. Along with this, if you are in the "study group" the researcher will phone you one month after discharge to see how you are getting on.
- **Readmission:** If you are admitted to hospital again within the next one to two years with heart symptoms you will be asked to phone the research assistant **after admission** and answer some questions about your symptoms before you were admitted, how and when you got to hospital etc.

**4. Benefits:** Responding quickly to heart symptoms improve health outcomes. The aim of this study is to see if an extra teaching session positively influences how a person responds to their heart symptoms if they occur again. We would hope to find that those who were chosen by chance to be in the "study group" might respond quicker to heart symptoms if they re-occur. The results of this study will be used to inform and improve health care for future patients.



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**5. Risks:** There are no likely risks from taking part in this study.

**6. Taking part in the study:** In order to be part of the study, we need the patients to be alike in certain ways.

To be in the study

- You must have a diagnosis of acute heart disease as defined by this study. The nurse and research assistant will ask you some questions and check your case notes.
- You must have a telephone so that we can complete the questionnaires after your discharge.
- You should be able to read, understand and speak English.
- You must be willing to take part.

Unfortunately, you will not be able to be in the study:

- If you live in a home, hospital etc.
- If you have some other illness(s) as defined by the study.
- If you have a major or uncorrected hearing loss.
- If you have a profound learning disability.

**7. Privacy:**

All information that we get during the study will be treated with full privacy. As it is our aim to make recommendations to improve practice, study results may appear in paper form or be presented at conferences. However, neither the hospital nor the patients will be identifiable, as results will be reported in a group manner. At all times your identity will remain private. The researcher knows your name at the start, but you will be given a code, which replaces your name on all information given. Your name will never appear beside any information that we get from you. Although the code and your name are linked, this is for administration purposes only and your information will remain secret at all times.

**8. What if something goes wrong:** There is no likely risk with taking part in this study. This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

**9. Taking part in this study is your own choice:** If you decide not to take part or withdraw from the study later this will not affect your hospital care in any way.

**10. Stopping the study:** In some cases, as with all research studies, the research team may stop you taking part in the study at any time without your consent.

**11. Permission:** The study has Research Ethics Committee approval from this hospital.

**12. Further information:** You can get more information or answers to your questions about the study, your taking part in the study, and your rights, from Mary Mooney. Mary can be contacted by telephone at 085-1381267 or by email at [mooneyma@tcd.ie](mailto:mooneyma@tcd.ie). If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

*Thank you for taking the time to consider being part of this study*

# Appendix 10: Consent Form



**The University of Dublin, Trinity College**  
Faculty of Health Sciences  
**School of Nursing & Midwifery**  
24 D'Olier Street, Dublin 2.  
Tel: + 353 1 8962692 Fax: + 353 1 8963001 <http://www.nursing-midwifery.tcd.ie/>

## Consent Form

**Title of study: ACS Response-Time Intervention Trial**

**Researchers:** Dr.Gabrielle McKee, Professor Debra Moser, Dr.Sharon O'Donnell, Ms.Mary Mooney & Ms.Frances O'Brien

I understand that I am taking part in a study whereby I will be in either a 'study' or 'control' group. If I am picked for the 'control group', I will get the usual teaching from the hospital staff. If I am picked for the 'study group' as well as the usual education, I will get an extra teaching session. This extra session is planned to promote early presentation to hospital in the event of future heart symptoms.

I understand that all information obtained during the study will be treated as strictly private. It will be used for the purpose of the study and for no other reason. Only the researchers will have the names of the people in the study. I understand that the general study results may appear in paper form with the permission from the hospital and consultants concerned, but neither the hospital nor the person taking part in the study will be identifiable. I am aware that I may withdraw from this study at any time.

### DECLARATION:

I have read, or had read to me and understand 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.

I understand I may withdraw from the study at any time.

**PARTICIPANT'S NAME:**.....

**PARTICIPANT'S SIGNATURE:**..... **Date:**.....

**Statement of investigator's responsibility:** I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

**RESEARCHERS SIGNATURE:**..... **Date:**.....

## **Appendix 11: Peer reviewed publications from this study**

### **Papers**

Mooney M., McKee G., Fealy G., O' Donnell S., O' Brien F., Moser D. (2014) A Randomised Controlled Trial to Reduce Pre-Hospital Delay Time in Patients with Acute Coronary Syndrome. *Journal of Emergency Medicine*. In press, Available on line: <http://dx.doi.org/10.1016/j.jemermed.2013.08.114>.

McKee G., Mooney M., O' Donnell S., O' Brien F., Biddle M. & Moser D. (2013) Multivariate analysis of predictors of pre-hospital delay in acute coronary syndrome. *International Journal of Cardiology* **168** (3), 2706-2713.

Mooney M., McKee G., Fealy G., O'Brien F., O' Donnell S. & Moser D. (2012) A review of interventions aimed at reducing pre-hospital delay time in acute coronary syndrome: What has worked and why? *European Journal of Cardiovascular Nursing* **11**(4), 445-453.

Mooney M., O' Brien F., McKee G., O' Donnell S. & Moser D. (2014) Ambulance Use in Acute Coronary Syndrome: A Cross-Sectional Study. Submitted to *Annals of Emergency Medicine* (currently under peer review).

### **Press release**

Irish Times Newspaper, Health Supplement, April 2014.

Irish Examiner Newspaper, April 2014.

## Conferences

Mooney M., McKee G., O'Brien F., O' Donnell S. & Moser D. (2012) An intervention to alter help-seeking behaviour and reduce pre-hospital delay time in patients diagnosed with Acute Coronary Syndrome (ACS). British Cardiovascular Society Annual Conference, Manchester. May 28–30. *Heart*, **98**(1), A69 (doi:10.1136/heartjnl-2012-301877b.122).

Mooney M., McKee G., O' Donnell S., O' Brien F. & Moser D. (2012) The impact of an educational intervention on patient behaviour in presenting with Acute Coronary Syndrome (ACS): a randomised controlled trial. European Society of Cardiology Congress, Munich, Germany. August 25-29 *European Heart Journal, Book of Abstracts*, **33**, 444-445.

Mooney M., McKee G., O'Brien F., O' Donnell S. & Moser D. (2011) An RCT to test the effectiveness of an educational intervention on pre-hospital delay time in patients with acute coronary syndrome (ACS). *12th Annual Interdisciplinary Research Conference. School of Nursing and Midwifery, Trinity College Dublin.* November 9th-10<sup>th</sup>, Book of Abstracts, pg.74.

Mooney M., McKee G., O'Brien F., Fealy G., O' Donnell S. & Moser D. (2011) A randomised controlled trial to test an intervention aimed at reducing pre-hospital delay in acute coronary syndrome. European Society of Cardiology Congress, Paris. August 27-31. *European Heart Journal, Book of Abstracts*, **1**(Suppl. 1), 2337.

Mooney M., O'Brien F., McKee G., Fealy G., O' Donnell S. & Moser D. (2011) Unchanging times: acute coronary syndrome pre-hospital delay times in an Irish

population. *4th Annual Multidisciplinary Research, Clinical Audit & Quality Improvement Seminar*, May 19<sup>th</sup>, St. James's Hospital, Dublin,

Mooney M., O'Brien F., McKee G., Fealy G., O' Donnell S. & Moser D. (2011) Irish pre-hospital delay-times in acute coronary syndrome: an ongoing dilemma. 11th Annual Spring meeting on Cardiovascular Nursing. Brussels, Belgium. April 1-2. *European Journal of Cardiovascular Nursing, Book of Abstracts*, **10**(Suppl. 1), 35.

Mooney M., O'Brien., McKee G., Fealy G., O'Donnell S. & Moser D. (2010) From whom do people with ACS symptoms seek advice before going to the emergency department? *Irish Nurses Cardiovascular Association*. October 7<sup>th</sup>, Sligo.

Mooney M., McKee G., Moser D., O'Brien F., Fealy G. & O' Donnell S. (2009) A study to determine the length of time that patients delay before presentation to accident and emergency with acute coronary syndrome. 9th Annual Spring meeting on Cardiovascular Nursing, Dublin, Ireland. April 24-25. *European Journal of Cardiovascular Nursing, Book of Abstracts*, **8**, (Suppl. 1), S9.