THE ACS RESPONSE-TIME INTERVENTION TRIAL

The effectiveness of an individualised educational intervention on knowledge, attitudes and beliefs about acute coronary syndrome: a randomised controlled trial

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Declaration

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Thesis Summary

Background: Acute coronary syndrome (ACS) refers to clinical symptoms, which when diagnosed are categorised into either heart attack or unstable angina. In Ireland, ACS is definitively diagnosed and treated in the hospital setting. Therefore, prompt attendance at the emergency department (ED) is essential for risk stratification and assignment of the appropriate cardiac intervention pathway. For those with an acute heart attack, it is ideal that myocardial perfusion is fully restored within 90 minutes of symptom onset. However, many people delay in seeking help for ACS symptoms. Delay may be associated with difficulty in recognition of and differentiating between the symptoms of ACS and other symptoms. Furthermore, information about ACS symptoms and the need to seek prompt treatment for them is not widely known or publicised. To date, a limited number of interventions have targeted knowledge, attitudes or beliefs about ACS. None of these were European studies. While the majority of interventions were successful, only a minority reported on the effect of their intervention on all three variables of knowledge, attitudes and beliefs.

Aim: The aim of this study was to test the effectiveness of a one-to-one individualised educational intervention on patients' knowledge, attitudes and beliefs about ACS.

Methods: This study was a randomised controlled trial conducted across five research sites in Dublin. Patients who were admitted to hospital with a diagnosis of ACS and who agreed to participate in the study (N=1,947), were randomised to the control (n=973) and intervention (n=974) groups. The ACS Response Index was used to collect data on knowledge, attitudes and beliefs about ACS at baseline and again at 3 months and 12 months for both groups. A total of 1,136 participants (control: 551, intervention: 585) completed the ACS Response Index at all three time-points and it was this cohort that were used in the study analyses. The intervention group received a 40-minute, one-to-one, individualised, educational intervention following the collection of baseline data.

The intervention was underpinned by Leventhal's self-regulatory model of illness behaviour and was delivered using the principles of motivational interviewing. The intervention was reinforced at one month and six months by telephone and post, respectively. Usual in-hospital education was provided to both groups.

Results: There was a significant effect of the intervention on mean knowledge (ANOVA, $p<0.001$), attitude (ANOVA, $p=0.003$) and belief (ANOVA, $p<0.001$) scores over time. Following the intervention, knowledge scores increased between baseline and 12 months in the intervention group, while they decreased simultaneously in the control group. Meanwhile attitudes increased in both groups from baseline to 3 and 12 months, but the increase was significantly greater in the intervention group, compared to the control group. Belief scores increased in both groups from baseline to 3 months, after which time they stabilised in the intervention group, but decreased slightly in the control group at 12 months. The increase in belief scores was greater in the intervention group, compared to the control group.

Conclusion: This is the first European randomised controlled trial to test this educational intervention and the first in Europe to demonstrate its effectiveness in improving knowledge, attitudes and beliefs about ACS. This is of major clinical significance, as individuals who have requisite knowledge, attitudes and beliefs about ACS symptoms and who rehearse the correct responses to them will have the ability to transfer this knowledge into action. Appropriate help-seeking behaviours can potentially improve prognosis and reduce mortality and morbidity among patients diagnosed with ACS.

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Glossary of Terms

For the purpose of this study interpretations of the following terms are:

- **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.
- **Attitude:** A way of thinking or feeling about something.
- **Baseline:** The time period following recruitment to the study when data were collected and prior to delivery of the educational intervention.
- **Belief:** A firmly held opinion.
- **Knowledge:** The information and skills a person acquires through education or experience.
- **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.
- **Study**: From Chapter 3 onwards, the term study refers to this current PhD study. It is used interchangeably with the word trial.
- **Thrombolysis**: The breaking down of blood clots, by pharmacological means (the administration of thrombolytics).
- **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.
- AHA: American Heart Association.
- ANOVA: Analysis of Variance.
- CABG: Coronary Artery Bypass Graft.
- CCU: Coronary Care Unit.
- 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.
- ESC: European Society of Cardiology.
- EU: European Union.
- GP: General Practitioner.
- IHF: Irish Heart Foundation.
- MATHs: Major Academic Teaching Hospitals.
- MI: Myocardial Infarction.
- NSTE-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.
- PPA: Per Protocol Analysis.
- RCT: Randomised Controlled Trial.
- SD: Standard Deviation.
- SPSS: Statistical Package for Social Sciences.

- STE-ACS: ST Segment Elevation Acute Coronary Syndrome.
- STEMI: ST Segment Elevation Myocardial Infarction.
- UA: Unstable Angina.

Chapter 1: Introduction

1.1 Introduction

This thesis provides details of a randomised controlled trial (RCT) that was conducted on patients who were diagnosed with acute coronary syndrome (ACS). Acute coronary syndrome is a serious and potentially life threatening condition, the management of which is time-dependent. If treatment is sought in a timely manner, the chances of reducing mortality, morbidity and complications of ACS are increased (Steg *et al*. 2012). In light of this, individuals should ideally present as soon as possible to the emergency department (ED) in the presence of unresolving ACS symptoms. This action is dependent on the individual having appropriate knowledge, attitudes and beliefs about ACS symptoms so that they can recognise and respond appropriately to them. Accordingly, the aim of this study was to test the effectiveness of an individualised educational intervention on knowledge, attitudes and beliefs about ACS. This chapter contextualises the condition of ACS within cardiovascular disease, its pathophysiology and management and its relevance to delay to treatment. The chapter also presents the importance of knowledge, attitudes and beliefs about ACS. It concludes with the study background and thesis overview.

Cardiovascular disease includes coronary heart disease (CHD) and stroke. This is a global health problem that accounts for approximately one third of deaths worldwide (Gray *et al*. 2008, Van de Werf *et al.* 2008). Within all European countries, cardiovascular diseases account for approximately 43% of all deaths in men and 55% in women (Graham *et al*. 2007). The problem of cardiovascular disease is no less serious in Ireland, where it is the single largest cause of death (Department of Health & Children 2010). In 2012, diseases of the circulatory system accounted for 32% (n=9,267) of all deaths (n=28,848) in Ireland. Of these, more than 50% (n=4,646) were directly attributed to CHD (Central Statistics Office 2013). The clinical presentations of CHD include silent ischaemia, stable angina, unstable angina, myocardial infarction (MI), heart failure and sudden death (Hamm *et al*. 2011). In 2012,

there were 2,278 deaths in Ireland from myocardial infarction (Central Statistics Office 2013). Acute coronary syndrome comprises MI and unstable angina.

1.2 Acute coronary syndrome

Acute coronary syndrome is categorised into one of three cardiac conditions: ST-segment elevation ACS (STE-ACS), non ST-segment elevation ACS (NSTE-ACS), or unstable angina (UA) (Kumar & Cannon 2009, Karras *et al*. 2013). ST-segment elevation ACS and NSTE-ACS are commonly known as a heart attack. Acute coronary syndrome is most commonly caused when an atherosclerotic plaque ruptures and precipitates thrombus formation (Van de Werf 2003, de Silva & Fox 2009). This can result in the sudden critical occlusion of a coronary artery with subsequent acute ischaemia (Cheng 2001). The resulting imbalance between oxygen supply and demand gives rise to the symptoms of ACS. If ischaemia is severe and persistent, myocardial necrosis occurs within approximately 2-4 hours (Thygesen *et al.* 2007, Libby *et al.* 2008, Hamm *et al*. 2011). The major adverse effects of ischaemia and necrosis are fatal dysrhythmias, heart failure and cardiogenic shock (Van de Werf *et al*. 2003, Anderson *et al.* 2007, Karras *et al.* 2013). Consequently, treatment is aimed at plaque stabilisation and the alleviation of ischaemia and symptoms (Sharma & Kaddoura 2005).

Many ACS-related deaths occur within the first few hours of symptom onset (Quinn 2005, Van de Werf *et al.* 2008, Steg *et al*. 2012). As a consequence of this, a significant number of people die before reaching the hospital (Quinn 2005, Steg *et al*. 2012). Most of these deaths are related to ischaemic complications of ACS, many of which could be prevented through interventions, such as early defibrillation (Finn *et al*. 2001, Coventry *et al.* 2013). In the short-term, the condition of ACS, its symptoms, and its complications can be effectively managed by the emergency medical services (EMS), provided they are summoned to assist the individual (Steg *et al.* 2012). Early intervention can reduce mortality and morbidity rates associated with ACS (Department of Health & Children 2010, Steg *et al.* 2012). Despite this, patients with ACS symptoms often delay getting to the hospital and benefiting from early medical intervention. In Ireland, a definitive diagnosis of ACS can only be made in

hospital. It is therefore imperative that individuals present to the ED as soon as possible for diagnosis and appropriate medical interventions (Asseburg *et al*. 2007, Perkins-Porras *et al*. 2009, MacKay *et al.* 2014). Best practice guidelines recommend transportation to the ED via the EMS (Steg *et al*. 2012).

Risk stratification algorithms have been developed to allow clinicians make timely decisions on appropriate treatment in ACS (Hamm *et al.* 2011). The pathway of treatment is dependent on the category of ACS diagnosis and separate guidelines are available for each category (Van de Werf *et al*. 2008). Time from symptom onset to treatment is important in all cases of ACS, but most particularly for those diagnosed with STE-ACS, where myocardial perfusion is occluded by plaque or thrombus. The immediate aims of treatment for STE-ACS are to re-establish coronary blood flow and to reduce the risk of recurrent thrombus formation (de Silva & Fox 2009). These are achieved through the use of reperfusion therapies.

Reperfusion therapies help to limit myocardial damage and preserve myocardial function (Verheugt *et al*. 2006, Steg *et al.* 2012). The reperfusion therapies most commonly used in the management of STE-ACS are primary percutaneous coronary intervention (PCI) and fibrinolysis (Health Service Executive 2012). It is generally accepted that primary PCI is the superior mode of reperfusion (Anderson *et al.* 2003, Keeley *et al.* 2003, Widimisky *et al*. 2003), provided it is performed expeditiously by an experienced team (Steg *et al.* 2012). The European Society of Cardiology (ESC) guidelines define expeditiously as <60 minutes from first medical contact (FMC) to PCI if the FMC was the primary PCI centre, or <120 minutes if FMC was the EMS or a non-primary PCI centre, providing the patient could be transported to a primary PCI centre within 120 minutes (Steg *et al*. 2012). In Ireland, this programme was established in September 2012 (Health Service Executive 2012). Primary PCI is effective in obtaining and preserving coronary artery patency and with less bleeding risks than fibrinolysis (Steg *et al*. 2012). However, where primary PCI cannot be performed within 120 minutes of FMC, fibrinolysis should be considered, particularly if it can be administered by the EMS or within 120 minutes of symptom onset (Bonnefoy *et al.*2009, Pinto *et al.* 2011). Regardless

of the method of reperfusion, the benefits rise exponentially if initiated within the first hour of symptom onset (Gusto 1993, Fox *et al*. 2007, Rosamond *et al.* 2007, Widimsky *et al.* 2010, Jernberg *et al*. 2011, McManus *et al*. 2011). Conversely, there is an inverse relationship between delay to the receipt of reperfusion and its beneficial effects (Tubaro *et al*. 2011, Health Service Executive 2012).

The majority of those who present with STE-ACS develop and are diagnosed with an ST-segment elevated myocardial infarction (STEMI). This is the most acute form of heart attack and many deaths occur from STEMI within the first few hours of onset (Steg *et al.* 2012). It is distinguished from NSTE-ACS by the presence of persistent ST-elevation, on the electrocardiograph (ECG). Those who present with NSTE-ACS are diagnosed with either unstable angina or a non ST-elevated myocardial infarction (NSTEMI) (Hamm *et al.* 2011).

The distinction between NSTEMI and unstable angina is based on the presence or absence of a rise in biomarkers (cardiac-specific troponins) that are released into the circulation when ischaemia is sufficiently severe to cause myocardial damage. In the presence of specific ECG changes and raised biomarkers, a diagnosis of NSTEMI can be made. Conversely, unstable angina is diagnosed through the presence of specific ECG changes with normal biomarkers (Kumar & Cannon 2009, Hamm *et al.* 2011).

Regardless of the category of NSTE-ACS, international guidelines highlight the importance of alleviating ischaemia and preventing the recurrence of adverse ischaemic events (Anderson *et al*. 2007, Hamm *et al.* 2011). Treatment with aggressive medical therapy is fundamental to achieving this goal. Individuals should also be scheduled for early PCI (within 4-24 hours of admission) or coronary artery bypass grafting (CABG), as required (Terkelsen *et al*. 2005, Kumar & Cannon 2009, Hamm *et al.* 2011). Prompt treatment is important to prevent the progression of ischaemia. There is also a risk of sudden death with NSTE-ACS, albeit to a lesser extent than those diagnosed with STE-ACS (Bassand *et al*. 2007, Gray *et al*. 2008). Although there are three categories of ACS, the symptoms of all categories can manifest similarly. Because of this,

individuals with ACS symptoms cannot determine for themselves which category of ACS they have (Ting *et al.* 2010). As category differentiation is reliant on ECGs and biochemical markers, patients with ACS symptoms must attend the ED promptly for risk stratification and diagnosis (Bassand *et al.* 2007, Kumar & Cannon 2009, Hamm *et al.* 2011).

1.3 Delay to treatment

Despite the need for early intervention, many individuals delay seeking treatment for ACS symptoms. Delay to treatment refers to the time-lag between the onset of ACS symptoms and the initiation of treatment in the ED. This time is often subdivided into pre-hospital and in-hospital delay. Pre-hospital delay refers to the time from acute symptom onset until arrival at the ED (Dracup *et al.* 2006, Løvlien *et al.* 2007) and is categorised into decision delay and transportation delay (Moser *et al.* 2006, Finn *et al.* 2007). Decision delay comprises the greatest portion of pre-hospital delay (Rasmussen *et al.* 2003, Riegel *et al.* 2007, O' Donnell *et al.* 2013). It is the time from acute symptom onset until the decision is made to seek medical assistance. Transport delay is the time taken from making the decision to seek treatment until arrival at the hospital (Finn *et al.* 2007, Khraim & Carey 2009, Khraim *et al.* 2009). In-hospital delay refers to the time from arrival at the ED until initiation of reperfusion (Finn *et al.* 2007).

Studies consistently report that patients delay longer than 2 hours before seeking treatment (Carney *et al.* 2002, Doyle *et al.* 2005, Moser *et al*. 2006, Goldberg *et al.* 2009, Mooney *et al*. 2014), and that significant proportions delay longer than six hours (Goldberg *et al.* 2002, DeVon *et al.* 2010a). Beyond these times, the benefits of reperfusion therapies are significantly reduced, with many patients becoming ineligible for treatment (Dracup *et al*. 2006, Steg *et al*. 2012). Despite the on-going problem of pre-hospital delay, the majority of prior interventions aimed at reducing pre-hospital delay time have failed to resolve the problem (Meischke *et al*. 1997, Luepker *et al*. 2000, Dracup *et al*. 2009, Mooney *et al.* 2012).

Longer pre-hospital delay times have been associated with failure to attribute ACS symptoms to a cardiac origin (Banks & Dracup 2006, Perkins-Porras *et al.* 2009, Fox-Wasylyshyn *et al.* 2010). Similarly, correctly attributing ACS symptoms to the heart can reduce pre-hospital delay time (Fukuoka *et al*. 2005, Quinn 2005, McSweeney *et al*. 2007, Kirchberger *et al*. 2012, McKee *et al*. 2013). Therefore, there is a need to disseminate information about ACS symptoms and how one should respond to them (Steg *et al*. 2012), as accurate knowledge, combined with appropriate attitudes and beliefs can shape how an individual interprets and responds to ACS symptoms (Jankowski *et al*. 2011).

As individuals with a previous ACS diagnosis are at high risk for a recurrence of ACS, it is of extreme importance that they are provided with information about ACS symptoms and what to do about them (Fox *et al.* 2007, Menzin *et al.* 2008, Fox *et al*. 2010, Hamm *et al.* 2011). Others at high risk for an ACS event are those people with established cardiovascular disease (Hamm *et al.* 2011). The need for these people to be equipped with relevant information is also well-recognised (Dracup *et al.* 1997a, Steg *et al*. 2012). Help-seeking behaviour could be improved through proper instruction and education, which develops knowledge, attitudes and beliefs (Kopec *et al.* 2010, Jankowski *et al.* 2011). Individuals who are adequately informed and who have positive attitudes and beliefs about seeking help for symptoms are more likely to make appropriate decisions (Dracup *et al.* 2008, Steg *et al.* 2012). However, it has been identified that information alone cannot change behaviour because of the interaction between knowledge and attitudes and beliefs (Ajzen & Fishbein 2005). This contextualises the importance of knowledge, attitudes and beliefs with respect to ACS symptoms and responses to them, as a deficit in these can contribute to increased pre-hospital delay time.

1.4 The relevance of knowledge, attitudes and beliefs to this study

According to the Oxford dictionary (2012), the term knowledge refers to the information and skills a person acquires through education or experience, an attitude is a way of thinking or feeling about something, while a belief is a firmly held opinion. The three terms can be independent of each other but they also

have an interdependent relationship with each other (McKinley *et al*. 2009, O'Brien *et al.* 2013). Consequently, they are often used interchangeably in the literature (Jensen & Moser 2008, Goulding *et al*. 2010). It has been suggested that an attitude is a "…state of readiness, a tendency to respond in a certain manner when confronted with a certain stimuli" (Oppenheim 2004 p.174). Attitudes are reinforced by beliefs (cognitive components) and attract strong feelings (emotional components), which can lead to particular behaviours (action tendencies) (Oppenheim 2004 p.175). Therefore, a person's behaviour can be explained by their attitudes and beliefs as "…their beliefs represent the information (correct or incorrect) that they have about the world" (Ajzen & Fishbein 1980 p. 79). The aim of this study is to examine the effectiveness of an individualised educational intervention on knowledge, attitudes and beliefs about ACS. The importance of this is rooted in the need for individuals to be exposed to information that can alter attitudes and beliefs and change behaviour.

1.5 Background to the study

This thesis is situated within the context of a larger research project called the ACS Response Time Intervention Trial. This multi-site RCT was devised by the ACS research team at the School of Nursing & Midwifery, Trinity College Dublin and was funded by the Irish Health Research Board. Its aim was to improve knowledge, attitudes and beliefs about ACS with a view to reducing pre-hospital delay time. From this project, two members of the ACS research team undertook separate strands as PhD studies. One PhD strand examined the effect of the intervention on patient pre-hospital delay time in the presence of ACS symptoms. The other PhD strand was the current study, on which this thesis is based. It examined the effect of the intervention on knowledge, attitudes and beliefs about ACS. Therefore, where the term study is used in this thesis, it refers to this current strand. The trial protocol and intervention content incorporated the objectives of both PhD studies. This is the first European educational intervention to target knowledge, attitudes and beliefs about ACS.

1.5.1 My unique contribution to the study

Although this study was part of the 'ACS Response Time Intervention Trial', I undertook ownership and total responsibility for the knowledge, attitude and belief component of the study. My unique contribution included:

- Making a significant contribution to the preparation and submission of the research proposal to the Health Research Board.
- Developing the trial protocol.
- The preparation and submission of applications for ethical approval.
- Selecting and training the interventionists with respect to patient recruitment, intervention delivery, data collection and data management.
- Providing information meetings with the gatekeepers and staff at each research site.
- Collecting baseline, 3 and 12 month data and delivering the educational intervention to participants recruited at one research site.
- Ensuring that the trial was conducted rigorously and that trial fidelity was upheld.
- Collating all data collected for this study. This included data inputting, data cleansing and proofing and data analysis.
- Local, national and international dissemination of the study results.

1.6 Overview of the dissertation

This thesis is divided into 6 chapters. Chapter 2 comprises the literature review, the thrust of which is centred on knowledge, attitudes and beliefs about ACS. Within this chapter, the importance of knowledge and recommended behaviours in ACS are discussed. As this study is an RCT in which an intervention is being tested, relevant prior interventions with a similar focus to this study are also reviewed. As a component of the literature review, previous strategies that were used in the education of patients are also addressed. The study aim, objectives and hypotheses are presented at the end of the literature review.

Chapter 3 presents the study methodology, which refers to the theoretical aspects of the study. Within this chapter, the criteria for RCT use and their

application are examined. Issues of importance, such as intervention design, intervention fidelity and the theoretical framework underpinning the educational intervention are discussed.

Chapter 4 details the research methods used in this study, including the day-to-day operationalisation of the study in the research sites. Details about access, sampling, recruitment, data collection, the research instruments and intervention delivery are provided. Ethical considerations and data analyses pertaining to this study are also presented in this chapter.

Chapter 5 presents the study's results. Consistent with the criteria for the reporting of RCTs, the CONsolidated Standards Of Reporting Trials (CONSORT) flow diagram is provided and can be located here. This diagram demonstrates the number of participants recruited, retained and those lost to study follow-up for the study duration.

Chapter 6 discusses and contextualises the study's results. An overview of the study processes and outcomes are appraised in the context of relevant literature. Factors that determined the outcomes of the hypotheses are also considered, in addition to the study's limitations. The clinical and statistical significance of this study is highlighted in this chapter. The concluding paragraphs incorporate the recommendations for future research.

Chapter 2: Literature Review

2.1 Introduction

Symptom onset is normally the first indicator of the presence of ACS. These symptoms can be continuous or intermittent; they can be of gradual or sudden onset and can vary in severity and intensity. Therefore, the ability to recognise and interpret symptoms, which is known as 'symptom recognition', is often less clear-cut than might be expected. This can pose major problems for individuals, as symptom ambiguity can contribute to delay in seeking help for symptoms (O'Donnell & Moser 2012, O'Donnell *et al.* 2014). Early help-seeking behaviour is important to facilitate the diagnosis and treatment of myocardial ischaemia in the shortest possible time. Knowledge, attitudes and beliefs are three influential factors that can guide symptom recognition and precipitate the initiation of help-seeking behaviour (Dracup *et al.* 2008, O'Brien *et al*. 2014). In light of this, it is important that individuals have sufficient knowledge to recognise ACS symptoms. In addition, positive attitudes and accurate beliefs about symptom management would help to reduce the consequences of delayed responses to ACS.

This literature review provides an overview of ACS symptoms and the recommended behaviour to take in their presence. Within this context, the role of knowledge, attitudes and beliefs are discussed. The purpose of this review is to provide evidence about desired and actual knowledge about ACS. In addition, those interventions that have previously been conducted with a view to improving knowledge, attitudes or beliefs about ACS will also be discussed. Furthermore, the optimum means by which patients can be educated will be presented, as this is thought to affect the means by which information is internalised (Rogers 1983).

This chapter is divided into three sections. These are preceded by a description of the search strategy that informed the content of this review. In the first section the reader is provided with an overview of ACS symptoms and the recommended responses to them. In the second section the literature

pertaining to public knowledge about ACS symptoms is reviewed. The third section critically appraises prior educational interventions that have been conducted in an effort to improve knowledge, attitudes or beliefs about ACS. Strategies known to enhance patient education are also included in the third section. The chapter concludes with the study's aim, objectives and hypotheses.

2.2 Search strategy

The literature search included published literature using the following databases: Pubmed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, Cochrane, Academic Search Premier and Google Scholar. Keywords used in the search included: acute coronary syndrome, acute myocardial infarction, heart attack, angina, myocardial ischaemia, coronary insufficiency. These were used in combination with knowledge, attitudes, beliefs, awareness, symptoms, help-seeking behaviour and responses to symptoms. Further combined searches were conducted to identify relevant educational interventions and patient education strategies. Keywords for these searches included educational intervention, patient education and education strategies. Additional searches of national and international websites, such as the Department of Health and Children, the Irish Heart Foundation and the European Society of Cardiology were completed. Reference lists were reviewed to identify any additional relevant literature. Literature was confined to that published in the English language and spanned the past 20 years (1994-2014). Quantitative and qualitative methodologies were included. Seminal literature, or studies of particular relevance to this research (some of which pre-date 1994), were also included.

Section I

2.3 Responses to ACS symptoms

In the presence of unresolved ACS symptoms, the recommended course of action is to promptly access the ED via the emergency medical services (EMS) (ambulance) (Steg *et al.* 2012, Irish Heart Foundation 2014). This action allows the individual to avail of the therapeutic modalities that limit ischaemia and

where appropriate, to restore myocardial perfusion (Van de Werf *et al.* 2008). Transportation to hospital by ambulance for acute cardiovascular events is associated with reduced pre-hospital delay time (Hutchings *et al*. 2004, Dracup *et al*. 2009, McKee *et al*. 2013). Those who summon the EMS receive earlier treatment, which results in improved outcomes by reducing myocardial tissue damage and necrosis (Canto *et al*. 2002, Hutchings *et al.* 2004, Moser *et al*. 2006, Song *et al*. 2008, Herlitz *et al*. 2010b). Additional benefits of ambulance use include the availability of advanced cardiac life support personnel and resuscitation resources. These are essential, given that approximately 50% of those who sustain ACS-related sudden death do so prior to hospital arrival (Lozzi *et al*. 2005, Rosamond *et al*. 2008).

Despite the imperative for prompt management of ACS, individuals with symptoms often fail to call the EMS (Lozzi *et al.* 2005, McGinn *et al*. 2005, Thuresson *et al.* 2007, Gartner *et al*. 2008, Dracup *et al*. 2009, McKee *et al.* 2013). Reasons for non-ambulance use include: a perceived lack of necessity, the belief that another mode of transport would be quicker, the advice of another person and emotions such as fear and embarrassment (Johansson *et al*. 2004b, Thuresson *et al.* 2008, Herlitz *et al*. 2010b). Researchers have reported that failure by patients to call the EMS is related to a lack of awareness of its benefits (Johansson *et al*. 2004b, Mathews *et al.* 2011). Indeed, for those who signal EMS assistance, the decision to do so is often delayed for at least one hour after symptom onset (Van de Werf *et al*. 2008).

As an alternative to responding appropriately, people use coping mechanisms such as the normalisation of symptoms, symptom denial, attribution to a less threatening cause and attempts at self-treatment (Nymark *et al.* 2014). Consequently, those who use these coping mechanisms arrive too late at the ED to reap the benefits of available reperfusion therapies. In the presence of unresolving symptoms, many contact their General Practitioner (GP) in the belief that this is the correct course of action (Pattenden *et al*. 2002, Johansson *et al.* 2004a). However, this action is associated with delayed presentation to hospital (Johansson *et al*. 2004b, O'Donnell *et al.* 2006, Mosley *et al*. 2011, Tubaro *et al*. 2011, McKee *et al.* 2013). The use of alternative coping

mechanisms, consultation with a GP and non-ambulance use highlight the need to increase public awareness with respect to correct ACS symptom management.

In ACS, help-seeking behaviour is triggered by the identification of symptoms as cardiac. In order to execute appropriate action, the individual must correctly appraise that their symptoms are of cardiac origin. This action can be delayed if the symptoms are unknown to the individual or if they present differently from what the individual expects. Interpretation of symptoms takes precedence over everything else in determining help-seeking behaviour (O'Donnell & Moser 2012), as the action taken is dependent on symptom knowledge and interpretation.

2.4 ACS symptoms

While ACS can manifest in a variety of ways, chest pain is the symptom most commonly associated with ACS (Johansson *et al.* 2004b, O'Donnell & Moser 2012). The anatomical position of the heart in the chest and the portrayal of an MI as a chest-clutching experience by the media, provide explanations for the association between chest pain and ACS. As the most common symptom associated with ACS, a frequency rate of between 73% and 95% has been reported (Johansson *et al.* 2004b, Ottesen *et al*. 2004, Fukuoka *et al*. 2005, Morgan 2005, King & McGuire 2007, Riegel *et al.* 2010, O'Donnell & Moser 2012, O'Donnell *et al*. 2012). Most public health educational materials focus on chest pain as the primary ACS symptom. Additional emphasis is placed on this symptom by listing it first and discussing it in depth. This implies that it is the symptom of greatest importance in MI (Ryan *et al*. 2007). However, it is only one of a range of possible symptoms, as the majority of people experience between four and five symptoms as part of their MI (Horne *et al*. 2000, O'Donnell *et al*. 2012). Other symptoms include shortness of breath, sweating, nausea or pain in the arm, neck, jaw or back (Hwang *et al*. 2009, El-Menyar *et al.* 2011, O'Donnell *et al.* 2012, Irish Heart Foundation 2014). As a complication of ACS, people can experience light-headedness or loss of consciousness (Steg *et al*. 2012, Irish Heart Foundation 2014). Symptoms can occur in isolation or in combination with each other.

During an ACS event, the majority of people present with some sort of symptom, although not necessarily chest pain. The proportion of those who present to hospital without chest pain ranges from one third in large cohort studies (Goldberg *et al*. 1998, Canto *et al*. 2000, Canto *et al*. 2007) to one fifth in smaller studies (Horne *et al*. 2000, Johansson *et al.* 2004a, Milner *et al*. 2004, Hwang *et al.* 2009, O'Donnell *et al*. 2012). The relative absence of chest pain among ACS patients was identified in the Global Registry of Acute Coronary Events (GRACE) study (Brieger *et al*. 2004). These investigators collected data on 20,881 ACS patients from 95 hospitals in 14 countries between 1999 and 2002. They reported that 8.4% (n=1,763) of patients presented to hospital without chest pain. Of these, 23.8% were not initially recognised as having ACS, as their primary presenting symptoms were dyspnoea (49.3%), diaphoresis (26.2%), nausea or vomiting (24.3%) and syncope (19.1%) (Brieger *et al*. 2004). The implication of this finding is that the range and variability of ACS symptoms is vast and in the absence of chest pain, medical professionals can encounter difficulties with reaching a differential diagnosis for ACS patients. It is therefore not unexpected that in the absence of chest pain, the public have difficulty in deciphering symptoms and attributing them to a cardiac cause.

Even in the presence of chest pain, symptom differentiation can be problematic, as the nature, onset and intensity of symptoms can be ambiguous and can differ within and between individuals. In a qualitative study, O'Donnell and Moser (2012) examined the illness presentation and help-seeking behaviour of 42 patients admitted to two Dublin hospitals with ACS. Following in-depth analysis of patient presentation descriptors, the researchers identified two discrete ACS symptom phenomena; slow-onset ACS and fast-onset ACS. According to these researchers, patients with fast-onset ACS can present with typical and atypical symptoms. However, irrespective of the symptoms, fast-onset ACS is always characterised by sudden, continuous and severe chest pain. Conversely, patients with slow-onset ACS can also present with typical or atypical symptoms, but their presentation is unique in so far as symptoms are of gradual onset, occur intermittently and are mild initially, but may intensify gradually.

Most patients (n=27) experienced slow-onset ACS, while only 15 patients experienced fast-onset ACS (O'Donnell & Moser 2012). However, all patients expected that ACS would resemble fast-onset ACS in terms of experiencing sudden, severe and continuous chest pain. Because of the incongruence between symptom expectation and symptom presentation, patients with slow-onset ACS reported difficulty in correctly associating their symptoms with a cardiac cause. As a result, they dedicated time to controlling their symptoms and normalising what they were feeling. Symptoms were often attributed to a pre-existing illness and when self-treatment efforts failed, these individuals had to re-appraise their symptoms. It was only as their symptoms began to resemble their expectation of ACS, that they sought help. Conversely, for those with fast-onset ACS, their illness presentation matched their expectation; thus they recognised the threatening nature of their symptoms and sought help. Minimal time was spent trying to control and cope with their symptoms. In light of these findings, O' Donnell and Moser (2012) suggest that the differentiation of the two categories of ACS could provide insight into the speed at which individuals seek help for ACS symptoms.

As a means of validating the slow-onset and fast-onset ACS concept, O'Donnell *et al*. (2014) tested these phenomena and their influence on pre-hospital delay using a quantitative methodology. A sample of ACS patients (N=893) were recruited from five Dublin hospitals and of these, 35% experienced fast-onset ACS while 65% experienced slow-onset ACS. This finding was reflective of their previous research (O'Donnell & Moser 2012). Patients diagnosed with NSTEMI were as likely to present with fast-onset ACS as slow-onset ACS. Patients presenting with slow-onset ACS were more likely to be diagnosed with unstable angina, whereas those presenting with fast-onset ACS were more likely to be diagnosed with STEMI. Those who experienced slow-onset ACS were significantly more likely to delay longer in getting to the ED than those who experienced fast-onset ACS (3.5 hours versus 2.0 hours $p<0.001$). This finding is not unexpected, as research suggests that people delay longer in accessing the ED when their symptoms are intermittent and less severe (Johansson *et al.* 2004a, McKinley *et al.* 2004, Banks & Dracup 2006, Noureddine *et al.* 2008, McKee *et al.* 2013).

The empirical finding by O'Donnell and Moser (2012) that symptom expectation was incongruent with symptom presentation was supported in prior research studies (Finnegan *et al.* 2000, Horne *et al*. 2000, Pattenden *et al*. 2002, King & McGuire 2007). However, the majority of these studies were conducted more than a decade ago. Studies were of both qualitative (Finnegan *et al.* 2000, Pattenden *et al*. 2002), and quantitative (Horne *et al*. 2000, King & McGuire 2007) methodologies. Those that were qualitative had sample sizes of 22 (Pattenden *et al*. 2002) and 207 (Finnegan *et al.* 2000), while those that were quantitative had sample sizes of 60 (King & McGuire 2007) and 88 (Horne *et al*. 2000).

In all studies (Finnegan *et al.* 2000, Horne *et al*. 2000, Pattenden *et al*. 2002, King & McGuire 2007), symptom expectation differed from reality in that the majority of participants experienced symptoms which were inconsistent with their perceptions. Differences related to: the type of symptoms that were experienced (Finnegan *et al.* 2000, Horne *et al.* 2000); symptom location (King & McGuire 2007); symptom severity (Pattenden *et al*. 2002, King & McGuire 2007); and the disparity between the lived experience of an MI and the media-driven Hollywood movie portrayal of this event (Finnegan *et al.* 2000, Pattenden *et al*. 2002, King & McGuire 2007). Individuals who have experienced an ACS event often favour a description of their symptoms which does not include the word pain. Fullness, tightness, heaviness, pressure, discomfort, crushing, burning, squeezing and sting have been used as descriptors of the sensation (King & McGuire 2007, Gray *et al.* 2008, O'Donnell & Moser 2012, Canto *et al.* 2014). In addition to O'Donnell *et al*. (2014), two other researchers identified an association between symptom expectation, symptom experience and rapid help-seeking behaviour (Horne *et al*. 2000, King & McGuire 2007). Although these studies (Horne *et al*. 2000, King & McGuire 2007) were relatively small, they offer insight into how an individual's interpretation of symptoms might contribute to their delay in reaching hospital.

It could be expected that those who have had a previous MI, should on a subsequent occasion, be able to identify that their symptoms are of cardiac origin and therefore have a shorter pre-hospital delay time. However,

researchers have demonstrated inconsistent results in this regard. Some researchers suggest that individuals who previously experienced an MI and those who had undergone recent cardiac procedures had shorter pre-hospital delay times (Sheifer *et al*. 2000, Gibler *et al.* 2002, Goldberg *et al*. 2002, McKee *et al*. 2013). However, this finding was not consistently reported (Dracup & Moser 1997, Johansson *et al*. 2004a) and may be explained by the presence of a different constellation of symptoms than previously experienced (Pattenden *et al.* 2002). Other possible explanations include attempts at symptom self-management, the presence of what is perceived to be an atypical MI symptom or the adaptation to living with chronic anginal pain (Alonzo & Reynolds 1998). The association between symptoms and the potential for their misinterpretation underscores the importance of individuals knowing the symptoms of ACS and how they can be different on a subsequent occasion, as well as knowing what to do in their presence.

2.4.1 Summary of ACS symptoms and responses to symptoms

Individuals who experience ACS symptoms and who associate these with ACS are more likely to attribute them to a cardiac cause. This attribution is determined by the nature, onset, duration and intensity of symptoms and the individual's pre-existing illness representations. These, together with symptom expectation and symptom presentation are dependent on knowledge, attitudes and beliefs about symptoms and the aetiology of those symptoms. This in turn determines how the individual labels and copes with their symptoms. The desired coping mechanism is that the individual would summon the EMS, who would then take them to the ED if symptoms were not resolving. Inconsistent with best practice, individuals sometimes revert to alternative coping mechanisms, which contribute to patient decision delay. Consequently, to deter people from using alternative coping strategies, they should know about the range and variability of ACS symptoms and how to respond appropriately to them. To determine the need for additional research into knowledge, attitudes and beliefs about ACS, it is important to ascertain what the public already know about these constructs.

Section II

2.5 What the public know about ACS

Knowledge of ACS symptoms and potential responses to them has been well researched. The most recent research in this area was conducted 5 years ago (Swanoski *et al.* 2012, Whitaker *et al.* 2012), while the oldest was 18 years ago (Goff *et al*. 1998). The majority of studies were carried out in the United States (Goff *et al*. 1998, Greenlund *et al*. 2004, Tullman & Dracup 2005, Dracup *et al*. 2008, Hwang *et al*. 2008, Swanoski *et al.* 2012), with two in Europe (Henriksson *et al.* 2012, Whitaker *et al.* 2012), one in Canada (Cytryn *et al.* 2009) and one in Thailand (Poomsrikaew *et al*. 2010). This section presents the literature pertaining to what the public know about ACS and the action they said they would take in its presence.

In 2012, two European researchers reported on knowledge levels of MI symptoms among the public (Henriksson *et al.* 2012, Whitaker *et al.* 2012). The studies were conducted in Sweden (Henriksson *et al.* 2012) and England (Whitaker *et al.* 2012). Whitaker *et al.* (2012) conducted a street survey on 302 people using open-ended questions, while Henriksson *et al.* (2012) used a sample of 418 patients who had no history of MI.

In England (Whitaker *et al.* 2012), only 75% of those surveyed correctly identified chest pain or chest discomfort as a symptom of ACS, compared to 98% in Sweden (Henriksson *et al.* 2012). The recognition of other symptoms also varied between these studies. Arm pain was correctly identified by 40% (Whitaker *et al.* 2012) and 85% (Henriksson *et al.* 2012), while 8% (Whitaker *et al.* 2012) and 65% (Henriksson *et al.* 2012) identified nausea as a symptom. The numbers who identified back pain were smaller, with only 3% (Whitaker *et al.* 2012) and 35% (Henriksson *et al.* 2012) correctly identifying this symptom. Otherwise, the researchers included different symptoms in their questionnaires. For example, Whitaker *et al.* (2012) identified that 35% of people knew that shortness of breath was an ACS symptom, while Henriksson *et al*. (2012) did not measure knowledge of that symptom.

The study that reported higher levels of symptom knowledge was the one that provided a list of potential symptoms, from which those surveyed could choose (Henriksson *et al.* 2012). Whitaker *et al.* (2012) used open-ended questions, where no options were provided. These differences in data collection methods may account for the reported differences in knowledge levels between the studies. In addition to assessing symptom knowledge, Henriksson *et al.* (2012) reported participants' intended actions if they suspected someone was experiencing symptoms of MI. In response to a scenario provided, 85% identified the need to phone 911 for an ambulance. However, when participants were asked the same question with respect to themselves experiencing the chest pain, only 75% reported the intended action of calling 911 (10% less) (Henriksson *et al.* 2012). This implies that people may be more willing to seek help for others than for themselves, which suggests the potential value of disclosing the presence of symptoms to another person. The non-disclosure of the presence of symptoms to a third party can extend pre-hospital delay time (Johansson *et al*. 2004a).

Two of the largest studies conducted to examine the public's knowledge of ACS symptoms were carried out in the US (Greenlund *et al.* 2004, Swanoski *et al*. 2012). Both studies used similar methodologies. The samples of 61,018 (Greenlund *et al.* 2004) and 103,262,115 (Swanoski *et al*. 2012) adults >18 years were identified using a state-based random digit-dialled telephone survey. From a pre-determined list of symptoms (5 correct, 1 incorrect/decoy symptom) on the Behavioral Risk Factor Surveillance Survey, participants in both studies were asked to identify which symptoms they would associate with ACS.

Greenlund *et al.* (2004) conducted their study in 17 US states and the US Virgin Islands in 2001. Swanoski *et al.* (2012) reported on data from three surveys which were carried out in 2005, 2007 and 2009 in 25 US states. As data comprised more than one study, Swanoski *et al.* (2012) used a composite score from all three surveys when reporting their results. Both researchers reported similar results. Chest pain or discomfort was recognised by 95% (Greenlund *et al.* 2004) and 93% (Swanoski *et al.* 2012), arm or shoulder pain by 89%

(Greenlund *et al.* 2004) and 87% (Swanoski *et al.* 2012), shortness of breath by 87% (Greenlund *et al.* 2004) and 85% (Swanoski *et al.* 2012), pain in the jaw, neck or back by 51% (Greenlund *et al.* 2004) and 54% (Swanoski *et al.* 2012) and feeling weak, lightheaded and faint by 65% (Greenlund *et al.* 2004) and 63% (Swanoski *et al.* 2012). When participants were asked to identify the first thing they should do if they thought someone was having a heart attack, 86% (Greenlund *et al.* 2004) and 87% (Swanoski *et al.* 2012) indicated that they would call 911.

Notwithstanding the high levels of knowledge reported by both researchers, 67% (Greenlund *et al.* 2004) and 58% (Swanoski *et al.* 2012) of participants incorrectly identified the decoy symptom as an ACS symptom. The use of one decoy symptom may have inflated the accuracy of results through guesswork. Despite their potential for an ACS event, individuals who were at high risk for a repeat event displayed no greater knowledge of ACS symptoms than those at low-risk in the study (Greenlund *et al.* 2004).

Two researchers measured baseline knowledge levels about ACS prior to delivery of an intervention (Goff *et al*. 1998, Dracup *et al.* 2008). Goff *et al*. (1998) used a telephone survey to collect data on 1,294 participants across 20 US states. Data were collected using the Response Questionnaire, which comprised open-ended questions. These researchers (Goff *et al*. 1998) reported that 90% of the public identified chest pain or discomfort as a symptom of ACS. Arm pain and shortness of breath were identified by 67% and 51% of the sample, respectively. The scores for arm pain and shortness of breath were higher than the other study that used open-ended questions (Whitaker *et al*. 2012), but were lower than the studies that provided participants with a list of potential symptoms (Greenlund *et al.* 2004, Henriksson *et al.* 2012, Swanoski *et al.* 2012). Less than 10% of the total sample (N=1,294), had knowledge of four correct ACS symptoms, while only 3.1% knew at least six correct symptoms (Goff *et al*. 1998). This raises concern given that people generally experience up to five symptoms as part of their MI (Horne *et al*. 2000, O'Donnell *et al*. 2014). With respect to help-seeking behaviours, 89% indicated that they would call 911 to summon an ambulance in the event of ACS symptoms.

The study by Dracup *et al.* (2008) comprised samples from the US, Australia and New Zealand. These researchers used face-to-face interviews to collect data on 3,522 members of the public, all of whom had a diagnosis of coronary heart disease. Dracup *et al*. (2008) amended the instrument originally used by Goff *et al.* (1998) and renamed it 'The ACS Response Index'. This revised instrument included a list of correct and decoy ACS symptoms. Dracup *et al. (*2008) reported a mean knowledge score of 71% for their sample (range, 8%-100%), but did not report knowledge of individual ACS symptoms. To date, this is the only study that reported mean scores, thereby outruling the possibility of cross study comparisons. Of the sample (N=3,522), 44% scored less than 70%, which according to Dracup *et al*. (2008) was a low knowledge level. However, these researchers provided no rationale for their chosen benchmark of 70%. In addition to low knowledge levels, only 69% of this relatively high risk sample reported that they would call 911 in the event of ACS symptoms. This is a lower percentage than otherwise reported (Goff *et al.* 1998, Greenlund *et al.* 2004, Swanoski *et al.* 2012). Consistent with Greenlund *et al.* (2004), those with a history of MI or cardiac surgery were not found to display any greater knowledge level than those with no such history.

Tullmann and Dracup (2005) conducted a study similar to that of Dracup *et al. (*2008) with respect to its location and risk profile of the sample. Using the Response Questionnaire, Tullmann and Dracup (2005) measured knowledge of ACS symptoms on 115 older adults (65 years or older) who had a history of coronary heart disease. While the use of a small convenience sample may not demonstrate representativeness of the population of older adults at risk for ACS, these results should not be discounted as they lend support to other similar research. Consistent with other studies (Goff *et al.* 1998, Greenlund *et al.* 2004, Henriksson *et al.* 2012, Swanoski *et al.* 2012), the researchers reported that the majority of participants (99%) correctly identified chest pain or pressure as a symptom of ACS. More than 90% of those surveyed correctly identified that shortness of breath, arm or shoulder pain, palpitations and sweating were also ACS symptoms. Relative to other studies, knowledge levels were high with respect to these variables. However, more than one third of participants did not know that symptoms such as jaw pain, neck pain, back pain

and nausea were also symptoms indicative of ACS. As people of advancing age are less likely to experience chest pain and more likely to experience atypical symptoms (Brieger *et al.* 2004, Arslanian-Engoren *et al.* 2006, Hwang *et al.* 2009), these results highlight the need for specific education about this. In addition, participants with a prior history of MI had no greater knowledge of ACS than those with no prior history of an MI; a finding that was echoed elsewhere (Greenlund *et al*. 2004, Dracup *et al.* 2008). This highlights the need to target those members of the public who are at greatest risk for an ACS event (Hamm *et al.* 2011).

Hwang *et al.* (2008) used a combination of open-ended and structured questions to measure knowledge of ACS symptoms among a convenience sample of 116 Korean immigrants living in Chicago. Recruitment took place through Korean churches, markets and shops in central and suburban Chicago. Using a face-to-face administered questionnaire, participants were initially asked "*What do you think are the symptoms of a heart attack?"* In response to this open-ended question, reported knowledge levels were particularly low. Only 50% correctly identified at least one heart attack symptom, with only 15% of individuals correctly identifying two or more symptoms. Chest pain, which is generally the most commonly recognised symptom of ACS, was identified by only 33%.

The researchers (Hwang *et al.* 2008) proceeded to ask participants to identify possible ACS symptoms from a list of both correct and decoy symptoms. When presented with a list of ACS symptoms, participants showed greater signs of symptom recognition. On average, they recognised about half of all ACS symptoms, using this method. Furthermore, on this occasion 89% identified chest pain as an ACS symptom. These results are consistent with others whose participants were able to recall fewer symptoms when open-ended questioning was used, compared with when they were provided with a list (Zerwic 1998). In this study (Hwang *et al.* 2008), many participants were unaware that they should call 911 if an MI occurred. However, when the question was reworded to the same sample, 72% indicated that they would call 911 in the presence of ACS symptoms. This highlights how different responses

can be elicited from the same sample, depending on the method of questioning used.

Using a revised version of the instrument devised by Hwang *et al*. (2008), Poomsrikaew *et al*. (2010) measured knowledge of ACS symptoms in a convenience sample of 192 people in a street survey in Thailand. On average, participants identified more than half of all ACS symptoms from a list of correct and decoy symptoms. The most commonly known symptoms were fatigue (79.7%), chest discomfort (78%), dizziness (76%) and shortness of breath (71%). Conversely, nausea, indigestion and sweating were correctly identified by only 26%, 53% and 64% respectively. Given that participants were provided with a list of symptoms, the finding that 22% did not identify the classic chest discomfort as an ACS symptom, points to the need for education. This is further supported by the fact that half of all participants erroneously selected decoy symptoms as being ACS-related; a finding reflected elsewhere (Greenlund *et al.* 2004, Swanoski *et al.* 2012). Moreover, consistent with researchers who identified incongruence between symptom expectation and symptom presentation (Pattenden *et al*. 2002, King & McGuire 2007, O'Donnell & Moser 2012), 66.7% of participants in this study mistakenly believed that chest discomfort would be severe, sharp and stabbing.

Using qualitative research methods, Cytryn *et al.* (2009) explored the relationship between knowledge of ACS symptoms and the decision to act when faced with them. Participants (N=30) were recruited from a teaching hospital in Canada and included: 10 patients from a cardiac clinic, 10 patients from a diabetes clinic and 10 university personnel with no cardiac or diabetes history (the healthy group). Using semi-structured interviews, three scenarios which were based on progressively increasing familiarity of ACS symptoms, were read aloud to participants. The initial scenario provided a description of symptoms that were unrelated to ACS. The second comprised details of an unfamiliar ACS scenario, with vaguely familiar symptoms. The third was a familiar ACS scenario, which comprised proverbial symptoms, such as those demonstrated in a 'Hollywood Heart Attack'. For all scenarios, participants were instructed to think aloud so that their decision-making processes were

transparent. Participants were then interviewed about their knowledge of ACS symptoms, using an open-ended question.

In this study (Cytryn *et al.* 2009), individuals were more inclined to respond appropriately to the symptoms presented in the familiar scenario, such as the 'Hollywood heart attack' scenario. The sense of urgency relating to their actions also increased. Urgent actions included participants stating that they would call 911 or attend the ED. Correct response ranged from 33% for the unrelated scenario, to 50% for the unfamiliar ACS scenario, to 70% for the familiar ACS scenario. When responses were examined by group, the cardiac group had the highest frequency of urgent responses (73%), compared to the diabetic group (47%) and the healthy group (33%). There was also a trend that those who knew only one symptom reported urgent responses much less frequently. This indicates that increasing an individual's knowledge has the potential to positively influence their intentions to behave appropriately in the presence of ACS symptoms. The researchers (Cytryn *et al.* 2009) suggest that when cognitive methods of data collection and analysis are used, these may help illuminate the relationship between knowledge and action. The use of scenarios could play a role in the preparation of individuals for an event that might arise. This is an important consideration in the development of interventions that are designed to improve knowledge and alter attitudes and beliefs about seeking help in the presence of ACS.

Cytryn *et al.* (2009) reported ACS symptom knowledge to be low and participants primarily chose interventions that were inadequate to ensure rapid treatment. Similar to other studies (Goff *et al.* 1998, Greenlund *et al.* 2004, Tullman & Dracup 2005, Henriksson *et al.* 2012, Swanoski *et al.* 2012), chest pain was the most commonly reported symptom (93%), followed by dyspnoea (53%) and arm/jaw pain (47%). Seventeen percent of participants identified only one symptom, which was either chest pain (10%) or dyspnoea (7%). Most participants (60%) correctly identified three or more symptoms. These knowledge scores were low, relative to other studies (Goff *et al.* 1998, Greenlund *et al.* 2004). There was no significant difference between the groups with respect to the number of symptoms identified.

While the information from this study (Cytryn *et al.* 2009) supported other research results and provided information into future research requirements, the study was limited in some respects. Knowledge levels in this study may have been overestimated, as their measurement occurred after the scenarios were presented. Symptoms described in the scenarios may have provided cues to information that would have otherwise been unknown to participants.

For those studies reviewed in this section that measured intentions to call the EMS, the results were varied. In four studies, over 85% of participants stated that they would call 911 in the presence of ACS symptoms (Goff *et al.* 2004, Greenlund *et al*. 2004, Henriksson *et al.* 2012, Swanoski *et al*. 2012). Two researchers (Dracup *et al*. 2008, Hwang *et al*. 2008) reported results of 69% and 72%, respectively. For participants in the study by Cytryn *et al.* (2009), intentions to respond appropriately to ACS symptoms were dependent on their recognition that they were experiencing an ACS event. In this case, recognition was synonymous with the 'Hollywood heart attack'. This highlights how knowledge of ACS symptom presentation is important in determining intended actions.

With respect to the relationship between intentions to act and actual behaviour, this has been a focal point of interest in health psychology for many years (de Bruin *et al.* 2012). According to Sheeran (2000), intention is the key predictor of mental readiness for behavioural change. However, it is recognised that behavioural intentions do not always reliably lead to behavioural change (Orbell & Sheeran 1998, Sheeran 2002, Webb & Sheeran 2006, Ogden 2007). In order to determine how well intentions predicted behaviour in previous research, Sheeran (2002) carried out a meta-analysis of 10 meta-analyses. Analyses from 422 correlation studies demonstrated that on average, intentions accounted for 28% of variance in behaviour (Sheeran 2002). This suggests that with respect to correlation studies, intentions have a large effect on behaviour (Webb & Sheeran 2006). However, correlational evidence does not provide clear conclusions about whether intentions have a causal impact on behaviour. Furthermore, Webb and Sheeran (2006) contend that the use of cross-sectional designs in some correlational studies, render their reports of

intention and behaviour liable to bias and may inflate estimates of the effect of the relationship. To further explore this issue, Webb and Sheeran (2006) carried out a meta-analysis of 47 experimental studies, whereby intention was changed through intervention. Subsequent behaviour was then compared. Following analysis, the researchers reported that behavioural intentions have a significant impact on behavioural change, albeit to a smaller extent than that reported in correlational studies (Webb & Sheeran 2006). A more recent study (deBruin *et al*. 2012) supports the finding that intentions are good predictors of behaviour, and explain 25-30% of the variance, particularly if the person's self-regulatory capabilities are also increased. Based on the evidence provided by these analyses, it is reasonable to suggest that intention to behave in a particular way in the presence of ACS symptoms is a good predictor that the behaviour will be executed.

2.5.1 Summary of public knowledge about ACS

A total of 10 studies were reviewed in this section to identify what the public know about ACS. Evidence from the literature demonstrated that a large percentage of individuals would call 911 in the presence of ACS symptoms. Results from meta-analyses suggest that intentions to act in a particular way can be reflected in that behaviour (Webb & Sheeran 2006). With respect to ACS symptom knowledge, chest pain was the most commonly recognised symptom (Greenlund *et al*. 2004, Tullman & Dracup 2005, Hwang *et al*. 2008, Poomsrikaew *et al*. 2010, Henriksson *et al.* 2012, Swanoski *et al*. 2012, Whitaker *et al*. 2012), with knowledge levels ranging from 75% (Whitaker *et al*. 2012) to 99% (Tullman & Dracup 2005). However, knowledge of the constellation of other symptoms was lower than chest pain and varied between studies. For example, knowledge of nausea as an ACS symptom varied between 8% (Whitaker *et al*. 2012) and 65% (Henriksson *et al.* 2012), while knowledge of jaw pain ranged from 47% (Cytryn *et al*. 2009) to 54% (Swanoski *et al*. 2012). These poor knowledge levels can be problematic, as people often experience these other symptoms.

Generally, the researchers who used a pre-determined list of questions to assess knowledge (Greenlund *et al*. 2004, Tullman & Dracup 2005, Hwang *et*

al. 2008, Poomsrikaew *et al*. 2010, Henriksson *et al.* 2012, Swanoski *et al*. 2012), reported higher knowledge levels compared to those researchers who used open-ended questions (Goff *et al.* 1998, Hwang *et al*. 2008, Whitaker *et al*. 2012). A pre-determined list can provide cues to the individual that can result in an overestimation of their level of recognition in comparison to results obtained from unprompted recall. However, regardless of the method used, knowledge of ACS symptoms other than chest pain was notably inadequate.

The variation in study results might also be attributed to the use of different research methodologies and instruments. With the exception of the studies that used the Response Questionnaire (Goff *et al*. 1998, Tullman & Dracup 2005) and the Behavioral Risk Factor Surveillance System (Greenlund *et al*. 2004, Swanoski *et al.* 2012) to collect data, all other studies used different questionnaires with different sets of questions. There was lack of consistency among researchers with respect to the symptoms included in their checklist and categorisation of symptoms. Variations such as these make study comparisons more difficult.

Differences in data collection methods can also make it challenging to compare results between studies. Three large studies (Goff *et al*. 1998, Greenlund *et al*. 2004, Swanoski *et al*. 2012) accessed their populations via random digit-dialling telephone surveys. While this method is conducive to obtaining large sample sizes from varying geographical locations, results generated from random digit-dialling may be overestimated and represent a best-case scenario, as those who agree to participate may be better educated than those who refuse. While the same could be true for any large study, random digit-dialling has the potential to exclude those of lower socioeconomic status and those without a landline (Mosca *et al*. 2013). Higher education levels generally equate with higher socio-economic status. Consequently, the use of random digit-dialling may have influenced those studies' results. The exclusion of a particular cohort in society for whatever reason, threatens the external validity of a study's results. However, studies with large sample sizes (Goff *et al.* 1998, Greenlund *et al*. 2004, Dracup *et al.* 2008, Swanoski *et al.* 2012) have greater external validity in that they are more easily generalised to the population.

Irrespective of the methodological differences between studies, empirical evidence highlights the requirement for the public to be provided with information about ACS. This should include information on the range and variability of ACS symptoms, the potential for incongruence between symptom expectation and presentation and the correct responses to take in the presence of symptoms. As participants with a prior history of MI had no greater knowledge of ACS, than those with no prior history (Greenlund *et al*. 2004, Tullman & Dracup 2007, Dracup *et al.* 2008), this information is of particular relevance to those at high risk for developing ACS. The predominant means of public information dissemination is through educational interventions.

Section III

2.6 Interventions to increase ACS knowledge, attitudes or beliefs

The literature reviewed in the previous section demonstrated that public knowledge levels are generally inadequate and many ACS symptoms are unknown or go unrecognised. As requisite knowledge is the first and most important step to enabling individuals to identify and acknowledge ACS symptoms, the requirement for interventions aimed at increasing knowledge, attitudes or beliefs about ACS is supported. To date, a small number of interventions have been conducted to improve knowledge of ACS symptoms and help-seeking behaviour. In addition, some interventions targeted improvements in attitudes and beliefs about ACS. This section will review those interventions that reported on the measurement of knowledge, attitudes or beliefs about ACS. From this review, information will be gleaned with respect to what has been achieved to date, the means by which it has been achieved and the outstanding requirements for further research. The optimum means through which patient education can be provided will also be presented.

2.6.1 Prior interventions

A total of nine interventions targeted improvements in knowledge, attitudes or beliefs about ACS (Goff *et al*. 2004, Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, Bell *et al*. 2009, McKinley *et al*. 2009, DeVon *et al*. 2010b,

Gallagher *et al*. 2013, Mosca *et al*. 2013). These studies were conducted over a sixteen-year period; the earliest commenced in 1996 and the most recent was in 2012. They were all carried out in the United States, Australia or New Zealand. Six interventions were randomised controlled trials (Goff *et al*. 2004, Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009, DeVon *et al*. 2010b), two were pre-test, post-test designs (Bell *et al*. 2009, Gallagher *et al*. 2013) and one was a national awareness programme (Mosca *et al.* 2013). The purpose of all interventions was to improve knowledge of ACS symptoms and help-seeking behaviour, while some also incorporated the variables of attitudes and beliefs (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009). A summary of the intervention studies aimed at improving knowledge, attitudes or beliefs about ACS is outlined in Table 1.

Table 1: Summary of interventions aimed at improving knowledge, attitudes or beliefs about ACS

Author, setting, year conducted & design	**Intervention type**	**Sample**	**Selected concepts measured** **Research instrument**	**Selected results**
Goff *et al.* (2004) United States 1996-1997 Mass media RCT	18-month mass media & multi-component intervention in 20 communities. Symptom recognition and the need to act fast by calling 911.	Pre intervention: N=1,294 Post intervention: N=1,204	Knowledge of ACS symptoms using open-ended questions. Random digit telephone survey using the Response Questionnaire.	Knowledge of symptoms increased in intervention communities (p<0.001). No change in knowledge in comparison communities.
Meischke *et al*. (2004) United States 2001-2002 Individualised RCT	Information kit distributed to increase knowledge of ACS symptoms and the use of 911.	Over 65s (N=323) Intervention=176 Control =147	Knowledge of ACS symptoms and intentions to respond to symptoms. Telephone survey with open-ended questions.	No significant differences in knowledge of symptoms or intentions to call 911 between groups.
Buckley *et al*. (2007) Australia 2001 Individualised RCT	Individualised education and counselling intervention (40 minutes). Reinforced 1 month later.	History of CHD (N=200) Intervention=105 Control=95	Knowledge, attitudes and beliefs at baseline, 3 months and 12 months. The ACS Response Index.	The intervention significantly improved knowledge of ACS over time (p=0.02). No significant differences in attitudes and beliefs between groups over time.

Author, setting, year conducted & design	**Intervention type**	**Sample**	**Selected concepts measured** **Research instrument**	**Selected results**
Tullman *et al*. (2007) United States March - October 2001 Individualised RCT	Individualised education and counselling intervention (40-60 minutes). Reinforced 1 month later.	Over 65s with history of CHD (N=115). Intervention=58 Control=57	Knowledge, attitudes and beliefs at baseline and 3 months. The Response Questionnaire.	Significant increase in knowledge (p<0.001) and beliefs (p=0.002) in the intervention group compared to the control group at 3 months. No significant differences in attitudes between groups at 3 months.
Bell *et a*l. (2009) United States 2007 Pre-test, post-test	Group educational intervention (45-60 minutes).	Over 60s (N=693)	Knowledge of ACS symptoms and actions. The Behavioural Risk Factor Surveillance System.	Significant improvement in symptom knowledge (p<0.001). Significant improvement in knowledge of actions to take (p<0.001).
McKinley *et al.* (2009) United States, Australia & New Zealand 2001 – 2003 Individualised RCT	Individualised education and counselling intervention (40 minutes). Reinforced 1 month later.	History of CHD (N=3,522). Intervention=1,777 Control=1,745	Knowledge, attitudes and beliefs about ACS at baseline, 3 months and 12 months. The ACS Response Index.	Significant increase in knowledge (p=0.0005), attitudes (p=0.0005) and belief (p=0.0005) scores in the intervention group over time, compared to the control group. Knowledge, attitudes and beliefs were associated with improvements in the other**.**

Author, setting, year conducted & design	**Intervention type**	**Sample**	**Selected concepts measured** **Research instrument**	**Selected results**
DeVon *et al*. (2010b) United States Dec 2006-March 2008 Pilot RCT	Computerised slide presentation (5-15 minutes). Viewed 3 times pre discharge. Viewed at 2 and 4 months post discharge.	Patients with CHD for elective PCI (N=64) Intervention=32 Control=32	Knowledge of ACS symptoms and care seeking behaviour. An identified 20-item instrument.	Knowledge of ACS symptoms and care-seeking behaviour increased significantly in the intervention group, compared to the control group (p<0.001).
Gallagher *et al*. (2013) Australia. March 2010 to March 2011 Pre-test, post-test	Individualised educational intervention (15-25 minutes).	History of CHD (N=137)	Knowledge of ACS symptoms and actions. The ACS Response Index.	Significant improvement in mean symptom knowledge (p<0.0001). Significant improvement in knowledge of actions to take (p<0.001).
Mosca *et al.* (2013) USA 1997-2012 National mass media educational intervention	Mass media Intervention to increase awareness and educate the public about the hazzards of heart disease in women.	Women over 25 (N=>1000)	CVD risk and prevention. American Heart Association National telephone survey using random digit dialing with open-ended questions.	Significant increase in awareness of: nausea (p<0.0001) and shortness of breath as ACS symptoms since 1997 (p<0.05). Significant increase in awareness of heart disease as the leading cause of death in women since 1997 (p<0.001).
Legend: RCT- Randomised Controlled Trial, CHD- Coronary Heart Disease, PCI- Percutaneous Coronary Intervention, CVD- Cardiovascular Disease.				

One of the earliest interventions (Meischke *et al.* 2004) was an RCT designed to prepare those over 65 years of age for dealing with an MI, through improving their knowledge of and responses to MI symptoms (Table 1). In this study, sampling was divided into 30 geographical districts (research zones) in Washington; of these, 15 districts were randomised to the intervention zone and 15 districts were randomised to the control zone. Fire fighters delivered an information pack called the Heart Attack Survival Kit (HASK) to the homes of those over 65 years of age, in the 15 intervention zones (N=22,000). It was estimated that 11,000 individuals were provided with the information pack and one-to-one education by the fire fighters. For those who were not at home at the time of the visit (n=11,000), these individuals missed out on the one-to-one intervention, but the information pack was left on their door knob. Those who lived in the control zones received no pack and were not visited. Following the intervention, 1,000 participants were randomly telephoned to measure the effect of the intervention on knowledge. Of these, 323 participated (n=176 intervention zone, n=147 control zone). There were no significant post-intervention differences in knowledge of ACS symptoms or intentions to call 911 in response to symptoms, between participants in the intervention group and control group zones. This result might be explained by the low follow-up rate, the high refusal rate and the mixed intervention dose.

The Rapid Early Action for Coronary Treatment (REACT) trial was one of the largest intervention studies reported to date (Goff *et al*. 2004). This multi-city RCT tested the effectiveness of a community intervention programme on knowledge and awareness of ACS symptoms (Goff *et al*. 2004) and pre-hospital delay time (Luepker *et al*. 2000). To achieve this, 20 communities in the United States were pair-matched and included in the study. One community from each pair was randomised to receive an 18-month multi-component intervention, while its paired counterpart served as a comparison. A four-pronged intervention addressed different target audiences and included the following educational strategies: media based education that targeted all residences in the intervention

communities, professional education of relevant healthcare providers, direct patient education provided at clinics for individuals who had a history of or risk factors for coronary heart disease, and community groups that provided presentations, videos and printed material to organisations and cardiac rehabilitation groups. The 10 control communities received no organised education programme. A standardised, random digit-dialled telephone survey was used to determine the effectiveness of the mass media intervention on knowledge about ACS (n=30-60 adults in each community). At the end of the study, there was a low to modest increase in knowledge of 0.44 symptoms per individual in the intervention communities ($p<0.001$) and a 13.3% net increase ($p<0.001$) in the proportion of individuals who correctly reported more than three ACS symptoms.

Given the extent of the mass media campaign, the results were disappointing for the researchers (Luepker *et al*. 2000, Goff *et al*. 2004). Although the 18-month intervention appeared quite intense, the researchers purport that an intervention of greater intensity and longer duration may have been required to make a greater difference. As the REACT communities were not selected at random from all the communities in the US, the sample may not be representative of the entire US population.

In response to the on-going problem of limited knowledge of ACS symptoms and pre-hospital delay, Dracup *et al.* (2006) devised a study called PROMOTION (Patient Response tO Myocardial infarction fOllowing a Teaching Intervention Offered by Nurses). The names Dracup *et al*. or McKinley *et al*. were used on the publications arising from the PROMOTION study. This explains why these authors' names are used interchangeably in this literature review. The PROMOTION trial was a multi-site RCT that tested the effectiveness of an individualised educational intervention on knowledge, attitudes and beliefs about ACS (McKinley *et al.* 2009). Their intervention comprised of a 40-minute individualised education session using motivational interviewing techniques. It

was delivered at baseline and reinforced one month later. Two other researchers also used RCTs to test this same intervention (Buckley *et al.* 2007, Tullman *et al*. 2007). Data in all three RCTs were collected between the United States, Australia and New Zealand and all used a sample of individuals who had a coronary heart disease diagnosis (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al.* 2009). The three researchers reported on the variables of knowledge, attitudes and beliefs, although only two of them used the ACS Response Index to measure their outcomes (Buckley *et al.* 2007, McKinley *et al.* 2009).

Following the intervention, McKinley *et al.* (2009) reported significant increases in knowledge (p=0.0005), attitudes (p=0.0005) and beliefs (p=0.0005) about ACS in the intervention group, compared to the control group. Tullman *et al*. (2007) reported significant increases in knowledge (p<0.001) and beliefs (p=0.002) in the intervention group versus the control group, but not in attitudes, while Buckley *et al*. (2007) reported a significant improvement in knowledge (p=0.02) in the intervention group compared to the control group, but not in attitudes or beliefs. The use of the same intervention, research instrument and outcome measurement made it easy to draw comparisons between these studies.

Using a pre-test post-test design, Bell *et al*. (2009) carried out a community educational intervention at 40 centres in the US. The researchers aimed to improve recognition of MI symptoms on a sample (N=693) of older adults (> 60 years) who were enrolled in Georgia's Older American Act Nutrition Programme (OAANP). Following the pre-test, an educational intervention that comprised of eight sessions was delivered to participants. Three of these sessions included a focus on ACS. The post-test was delivered one to two months later. Following the intervention, significantly more participants (46%) correctly identified the five ACS symptoms on which they were instructed, compared to the pre-test result (29%) (p < 0.001). In addition, significantly more participants (92%) reported that

they would call 911 in the presence of ACS symptoms, compared to their pre-test result (84%) ($p < 0.001$).

One year later in the US, DeVon *et al.* (2010b) reported the results of an educational intervention, which they piloted using an RCT. This trial was called the '*Know & Go'* program. Although this was a pilot study, it was included in this review to inform future intervention research. The intervention differed from all others in that it was a computerised slide presentation that was delivered at baseline, 2 months and 4 months. It aimed to improve knowledge about CHD in a sample of patients who had undergone an elective PCI for coronary heart disease. On study completion (4 months), the intervention group scored significantly higher on the intervention post-test than the control group ($p<0.001$).

The most recently published intervention (Gallagher *et al.* 2013) was carried out in Australia between 2010 and 2011. A pre-test post-test design was used to test the effectiveness of the educational intervention on patients discharged from hospital with a diagnosis of CHD. The brief intervention (15-25 minutes) addressed knowledge deficits or misperceptions about ACS, as identified in the individual's pre-test assessment. Following the intervention, there were statistically significant improvements in knowledge of 11 of 14 MI symptoms ($p<0.0001$) and in reporting appropriate actions in the presence of symptoms ($p<0.001$).

The longest running national awareness intervention ('Heart Truth') was initiated in 2002 in an effort to reduce heart disease among women in the U.S (Long *et al.* 2008). The intervention, which focuses primarily on women aged 40-60 years, is on-going. The main goal of their intervention is to educate women about heart disease and to motivate them to talk to their doctors about how they can lower their risk for heart disease. It is conducted in partnership with the American Heart Association and other organisations dedicated to the health and well-being of women. The intervention consists of multiple components, including a national

media campaign, fact sheets, posters, conferences and videos, in addition to online resources. These resources provide women with information about heart disease and the steps they should take to reduce their CHD risk (Long *et al.* 2008). Because a number of publications have arisen from 'Heart Truth' over the years, the authors' names of Long *et al*., Christian *et al*. and Mosca *et al.* are used interchangeably when discussing their study.

Since its inception, triennial surveys have been carried out in 1997 (Mosca *et al*. 2000), 2000 (Mosca *et al*. 2004), 2003 (Mosca *et al*. 2006), 2006 (Christian *et al*. 2007), 2009 (Mosca *et al*. 2010) and 2012 (Mosca *et al*. 2013). The aim of these studies was to track trends in women's awareness and perceptions of heart disease. As the national awareness intervention commenced in 2002, the first two studies, which were carried out in 1997 (Mosca *et al*. 2000) and 2000 (Mosca *et al*. 2004), served as baseline comparisons for the studies carried out from 2003 onwards. All studies were a replication of each other with respect to the survey, methods and sampling procedures used. More than 1,000 individuals comprised the sample in each of the six studies. Different individuals were surveyed at each time point.

Data from these triennial surveys enable comparisons to be drawn between the study outcomes over 15 years. Since 1997, awareness of heart disease as the leading cause of death in women has almost doubled (30% versus 56%; $p<0.001$). Similarly, knowledge of symptoms such as nausea (10% versus 18%; $p<0.0001$) and shortness of breath have improved significantly (33% versus 38%; $p<0.05$), notwithstanding that there is still room for improvement. Conversely, knowledge of chest pain as a symptom of MI was less well known in 2012 than it was in 1997 (56% versus 67% $p<0.0001$). While results from the Heart Truth campaign support the benefits of ongoing education through mass media, in comparison to other studies, symptom knowledge was quite low. For example, most other researchers have reported knowledge levels of chest pain as ranging from between 73% and 95% (Morgan 2005, King & McGuire 2007, Riegel *et al*.

2010, O'Donnell *et al*. 2012). However, the collection of data using open-ended questions (Mosca *et al*. 2000, 2004, 2006, 2010, 2013), as opposed to a pre-determined list of symptoms, may account for the noted differences in knowledge scores across studies.

Most researchers reported successful study outcomes following their intervention with respect to improving knowledge, attitudes or beliefs about ACS (Goff *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, Bell *et al*. 2009, McKinley *et al*. 2009, DeVon *et al*. 2010b, Gallagher *et al*. 2013, Mosca *et al*. 2013), albeit to varying degrees. One researcher (Meischke *et al*. 2004), reported no effect of their intervention. In order to evaluate the validity of the reported results and to determine study strengths and limitations, the studies are reviewed collectively below.

2.6.2 Study designs

Six of the nine intervention studies were RCT designs (Goff *et al*. 2004, Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009, DeVon *et al*. 2010b). Of these, four used individualised educational interventions (Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009), one was conducted using a mass media intervention (Goff *et al*. 2004), while one used a computerised slide presentation (DeVon *et al*. 2010b). In all cases, the intervention was delivered to the intervention group only. Of the three non-RCTs, one of the pre-test post-test interventions was also an individualised educational intervention (Gallagher *et al*. 2013), while the other was delivered in a group setting (Bell *et al*. 2009). The national awareness programme (Mosca *et al.* 2013) was a mass media intervention. Randomised controlled trials are the most robust method for evaluating intervention effectiveness (Torgerson & Torgerson 2008, Grove *et al*. 2013, Jaarsma *et al.* 2014). Randomly assigning individuals to receive the intervention removes any in-built bias and increases internal validity (Jadad & Enkin 2007, Drennan 2013). On the other hand, results from a pre-test post-test design cannot be legitimately presumed to illustrate cause and effect, as participants' knowledge may have changed as a result of

other factors (Grove *et al*. 2013). Consequently, those studies that used an RCT design to measure the effect of their intervention were considered to be the most reliable, on the proviso that other aspects of their study were equally trustworthy.

2.6.3 Populations targeted: age and risk status

Each intervention targeted different age groups and populations. For some researchers, age did not comprise their inclusion/exclusion criteria (Buckley *et al.* 2007, McKinley *et al*. 2009, DeVon *et al*. 2010b, Gallagher *et al.* 2013). One study targeted the public and collected data on all individuals over 18 years (Goff *et al*. 2004). Others focused specifically on those over 65 years (Meischke *et al*. 2004, Tullman *et al.* 2007, Bell *et al*. 2009). Women aged between 40 and 60 years were the primary focus of the educational intervention carried out by Mosca *et al*. (2013). Of the three studies whose interventions focused on those over 65 years (Meischke *et al*. 2004, Tullman *et al.* 2007, Bell *et al*. 2009), one did not demonstrate any significant effect of the intervention (Meischke *et al*. 2004). Although memory loss may not be directly related to age, given that only 60% of the sample in the study by Meischke *et al*. (2004) remembered receiving the intervention, the results may be explained in part by poor memory among this cohort. The other researchers who also targeted their intervention on those over 60 (Bell *et al*. 2009) and 65 years (Tullman *et al.* 2007) demonstrated significant effects of their interventions on some (Tullman *et al.* 2007) or all (Bell *et al*. 2009) of the variables measured. As intervention outcomes were measured relatively soon after the intervention in both studies (one and two months after the intervention), this may account for the positive effect of the intervention in these studies.

With respect to risk status, five studies specifically focused on individuals who had a history of CHD (Buckley *et al.* 2007, Tullman *et al.* 2007, McKinley *et al*. 2009, DeVon *et al*. 2010b, Gallagher *et al.* 2013). Consequently, their intervention was aimed at those who were at high risk for developing ACS (McKinley *et al*. 2009). The three studies whose interventions focused on those over 65 years (Meischke *et al*. 2004, Tullman *et al.* 2007, Bell *et al*. 2009), also

targeted an at risk sample, by virtue of their age. Of those studies that used mass media interventions (Goff *et al.* 2004, Mosca *et al*. 2013), one (Mosca *et al*. 2013) directed their intervention messages at a specific target group that they felt was at risk for ACS. The other (Goff *et al.* 2004), exposed all members of the intervention communities to the same intervention messages, regardless of age or risk status. Mass media messages are limiting in that there is no way to determine which individuals embrace or internalise the information, as each person may feel the message is targeting somebody else (Lefler & Bondy 2004).

Although both researchers (Goff *et al.* 2004, Mosca *et al*. 2013) reported a significant effect of their intervention with respect to knowledge levels, their outcomes were not as good as anticipated. Goff *et al.* (2004) reported a low-to-modest increase in knowledge of ACS symptoms, while Mosca *et al*. (2013) reported a significant increase in some symptoms and a significant decrease in others. Consequently, mass media interventions that are not focused on an at-risk group may not be an ideal method of disseminating pertinent information. While Mosca *et al*. (2013) targeted an at-risk group in their mass media intervention, outcome data were collected on all women over 25 years. The rationale for this is unclear and may have impacted on the study results. Intervention messages that focus on individuals who are at-risk and who identify with that risk are more likely to internalise the information (Taylor 2006). This supports the value of targeted interventions.

2.6.4 Intervention methods

Six interventions used individualised education approaches to deliver their intervention messages (Goff *et al*. 2004, Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009, Gallagher *et al*. 2013). Four of these were exclusively individualised (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009, Gallagher *et al*. 2013), while two researchers used a dual approach (Goff *et al*. 2004, Meischke *et al*. 2004). The individualised component of the intervention delivered by Goff *et al*. (2004) was confined to a small number of high-risk individuals who attended clinics, while all others were recipients of

mass media intervention messages. The individualised education provided by Meischke *et al*. (2004) was delivered only to those individuals in the intervention group who happened to be at home when the interventionist visited (50%). For all other intervention group participants, an information pack containing the intervention message was left on the doorknob of the participants' homes. As intervention fidelity is optimised when all participants receive the same dose of the intervention (Bellg *et al.* 2004), fidelity in the study by Meischke *et al.* (2004) was not optimised.

Bell *et al*. (2009) and DeVon *et al.* (2010b) delivered standardised interventions, with no individualisation. These were in the form of a group teaching session (Bell *et al*. 2009) or a computerised slide presentation (DeVon *et al.* 2010b). Interventions that are individualised provide an opportunity for the interventionist to focus on the specific needs of the participant. This is particularly important for those at risk of symptom development (Thuresson *et al.* 2008, Jankowski *et al.* 2011). Five of the interventions that reported successful post intervention outcomes used some individualised component of intervention delivery (Goff *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009, Gallagher *et al*. 2013). Consequently, this is something that should be considered for future interventions.

2.6.5 Content of the interventions

The core message underpinning the majority of interventions was ACS symptom recognition and the need to access care rapidly by calling the EMS in the presence of symptoms (Goff *et al*. 2004, Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009, Bell *et al*. 2009, DeVon *et al*. 2010b, Gallagher *et al*. 2013). In general, the information was similar and included detail on the range and variability of typical and atypical symptoms. The focus of the mass media intervention reported by Mosca *et al*. (2013) was slightly different in that its main aim was to educate women about their risk for heart disease and to provide tools for them to take action against risk factors. This included information on ACS symptoms.

While knowledge is known to be a main factor in ACS symptom recognition, attitudes influence an individual's confidence in their ability to seek help, while accurate beliefs about the action to take are central to the execution of appropriate responses to symptoms (Ajzen & Fishbein 1980, McKinley *et al.* 2009). Four researchers targeted attitudes and beliefs in their interventions (Goff *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009). As higher knowledge scores have been independently associated with more appropriate attitudes and beliefs (McKinley *et al*. 2009, O'Brien *et al*. 2013), the inclusion of all three components in educational interventions is important in the context of ACS.

Three researchers incorporated cognitive, social and emotional factors that may affect an individual's ability to seek help promptly into their intervention (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009). These researchers also provided supporting documentation for participants to take home as a reminder of the symptoms of ACS and what to do in their presence (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009). Supporting information included a personalised action plan and fridge magnet (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009). Gallagher *et al*. (2013) also provided an action plan fridge magnet for their participants to take home. An information pack was provided by Meischke *et al*. (2004), while those who used mass media approaches distributed leaflets and pamphlets (Goff *et al*. 2004, Mosca *et al*. 2013). No supporting literature was given to those who received the intervention in the form of a computerised information slide show (De Von *et al*. 2010) or the group education session (Bell *et al*. 2009). The benefit of providing supporting documentation for patients to take home has been reported (Arnold *et al*. 2009, Commodore-Mensah & Dennison Himmelfarb 2012) and is something that warrants consideration in future interventions.

2.6.6 Intervention duration, reinforcement and length of time to post-test

Intervention duration varied across the studies. The intervention of shortest duration ranged from 5-15 minutes (DeVon *et al.* 2010b) and was reinforced at 2 and 4 months post discharge. Post-intervention tests were administered at 4 months, which was immediately after the final reinforcement. This timing may have inflated the intervention effect, as researchers who collect data shortly after intervention delivery or reinforcement, increase the risk of recall bias (DeVon *et al*. 2010b). In addition, administration of post-tests varied by group, with the intervention group tested on the computer and the control group tested over the phone. This may also have had implications for the noted between group differences following the intervention.

Three studies used the same interventions and their durations ranged from 40 minutes (Buckley *et al.* 2007, Tullman *et al.* 2007, McKinley *et al*. 2009), to 1 hour (Tullman *et al.* 2007). Intervention messages were reinforced one month later by telephone (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009) and the intervention effect was measured 3 months later by three of the researchers (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009) and 12 months later by two of the researchers (Buckley *et al.* 2007, McKinley *et al*. 2009). All researchers reported a significant effect of the intervention on knowledge, attitudes or beliefs. The two studies (Buckley *et al.* 2007, McKinley *et al*. 2009) that measured and sustained their intervention effect at 12 months follow-up could determine that their intervention effect would remain stable over time. Despite the advantage of longitudinal outcome measurement, few researchers have adopted this approach.

The exact duration of the intervention by Gallagher *et al*. (2013) was unclear, as the 15 to 25 minute description was a combination of data collection and intervention delivery. No further educational reinforcement was provided. Post intervention effectiveness was measured six to eight weeks later, on completion of the cardiac rehabilitation programme. The educational intervention delivered

by Bell *et al*. (2009) comprised eight sessions in total, however only three of these covered material on ACS. Each session was of 45-60 minutes duration. As participants only attended approximately 75% of the sessions (6 sessions) and with ACS discussed on three occasions, the actual dose of the ACS aspect of the intervention is unclear. The intervention effect was measured four to eight weeks after the final education session, which although consistent with Gallagher *et al*. (2013), is earlier than reported in other studies (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009). Consequently, the dose effect of the intervention was still potentially high at post-test in both studies (Bell *et al*. 2009, Gallagher *et al*. 2013).

Meischke *et al*. (2004) did not disclose the length of time afforded to delivering the face-to-face component of their intervention. Some participants only received the information pack which was left on the door knob for the individual to self-administer. Consequently, it is unknown whether or not the intervention pack was read (Meischke *et al*. 2004). The duration between intervention delivery and outcome data collection was not outlined. Consequently, there is no way to determine if participants' knowledge of symptoms and intentions to act in response to them would differ if recorded at another point in time. This study did not demonstrate any significant effect of the intervention.

With respect to mass media interventions (Goff *et al*. 2004, Mosca *et al*. 2013), the intervention campaigns were reinforced over an 18-month (Goff *et al*. 2004) and 12-year (Mosca *et al*. 2013) period. Both researchers provided detailed accounts of the sequencing of their intervention (Raczynski *et al*. 1999, Long *et al*. 2008), the dose of which was high for those who internalised it. However, with mass media interventions there is no way to regulate or determine which individuals take on board the disseminated messages.

2.6.7 Outcome measures

A number of outcome measures were used to assess knowledge, attitudes or beliefs across the eight intervention studies. Three researchers used the ACS

Response Index to collect data on knowledge, attitudes and beliefs for their study (Buckley *et al.* 2007, McKinley *et al*. 2009, Gallagher *et al*. 2013). The questionnaire comprised closed and Likert scale questions. Validity and reliability of this instrument has been reported (Buckley *et al.* 2007, Riegel *et al.* 2007, McKinley *et al*. 2009). An earlier version of the ACS Response Index was used by two researchers (Goff *et al.* 2004, Tullman *et al*. 2007) and comprised of open and closed questions. Goff *et al.* (2004) did not report on the psychometric properties of their instrument, although Tullman *et al*. (2007) reported on its reliability. Bell *et al.* (2009) used the Behavioural Risk Factor Surveillance System (BRFSS) which comprised a pre-determined list of six symptoms, including one decoy symptom. This instrument has been used widely in other studies and has been shown to be valid and reliable (Greenlund *et al.* 2004, Bell *et al.* 2009, Swanoski *et al*. 2012). The remaining researchers (Meischke *et al*. 2004, DeVon *et al*. 2010b, Mosca *et al*. 2013), used bespoke questionnaires to assess ACS knowledge. Some used closed questions (DeVon *et al*. 2010b), while others used open-ended questions (Meischke *et al*. 2004) and others again included a mixture of both (Mosca *et al*. 2013). Of these three researchers (Meischke *et al*. 2004, DeVon *et al*. 2010b, Mosca *et al*. 2013), only DeVon *et al*. (2010b) reported on the validity and reliability of their questionnaire. However, the repeated use of the same questionnaire on six occasions by Mosca and colleagues (2013) supports its reliability (Polit & Beck 2010). Moreover, the use of the same questionnaire across studies is beneficial as it allows comparisons to be drawn between results.

2.6.8 Interventionist preparation and intervention delivery

Interventions were delivered by specifically recruited interventionists (Buckley *et al.* 2007, Tullman *et al.* 2007, McKinley *et al*. 2009, DeVon *et al.* 2010b), cardiac rehabilitation program coordinators (Gallagher *et al*. 2013), fire-fighters (Meischke *et al*. 2004) or well educated people who were not necessarily health professionals (Bell *et al.* 2009). With the exception of the mass media interventions (Goff *et al*. 2004, Mosca et al. 2013) and two other studies (Bell *et al.* 2009, DeVon *et al.* 2010), all researchers reported the provision of specific

training to their interventionists (Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al.* 2007, McKinley *et al*. 2009, Gallagher *et al.* 2013). Where more than one person delivers an intervention or collects data, the issue of equivalence must be addressed in the form of inter-rater reliability testing (Watson 2013). Only one study addressed this issue, which increases the reliability of their intervention delivery (McKinley *et al.* 2009).

In all studies, intervention delivery was supported by either: a 27 page flip chart manual (Buckley *et al.* 2007, Tullman *et al.* 2007, McKinley *et al*. 2009); a one page educational tool (Gallagher *et al.* 2013); a red flyer in the shape of a door hanger (Meischke *et al*. 2004); mass media materials (Goff *et al*. 2004, Mosca *et al*. 2013); a computer (DeVon *et al.* 2010b); or a curriculum (Bell *et al.* 2009). Interventionist training and the use of a standardised manual in delivering intervention messages are paramount in upholding intervention fidelity (Sidani & Braden 2011). The studies that endorsed these factors in the delivery of their intervention, demonstrated greater fidelity to their intervention. As the study by DeVon *et al*. (2010b) was administered by computer, with no individualised or interpersonal component, lack of training was not viewed as a limitation.

In addition to the preparation of interventionists, all studies (Goff *et al*. 2004, Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al.* 2007, McKinley *et al*. 2009, Gallagher *et al*. 2013, Mosca *et al*. 2013) with the exception of Bell *et al.* (2009) and DeVon *et al.* (2010b), referred to the preparation of data collectors. Furthermore, all of the RCTs (Goff *et al*. 2004, Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al.* 2007, McKinley *et al*. 2009, DeVon *et al*. 2010b) addressed the issue of blinding their data collectors, which minimises bias in those collecting data (Friedberg *et al.* 2010). This affirms the credibility of these studies' results.

2.6.9 Sample size and sampling

Sample sizes varied across the nine interventions and ranged from 64 (De Von *et al*. 2010) to 3,522 (McKinley *et al.* 2009). Only one study reported a power analysis calculation for estimating their sample size (Gallagher *et al*. 2013). Power analysis calculations are necessary to verify the validity of the statistical conclusions reached (Polit & Beck 2010), yet some studies made no reference to this (Buckley *et al.* 2007, Tullman *et al*. 2007, Bell *et al.* 2009, DeVon *et al*. 2010b). The study by DeVon *et al*. (2010b) was a pilot study which explains its small sample size of 64. However, in light of this, their results should be interpreted with caution. In two studies, sample size was calculated based on the study's primary aim, which was to reduce pre-hospital delay (Goff *et al.* 2004, McKinley *et al.* 2009). It is therefore likely that these large studies (N=1,294 & N=3,522 respectively) were adequately powered for secondary data analysis. However, the diversity in sample sizes and the inadequacy of details with respect to power analysis in some studies are limitations to the interpretation of their results.

Two researchers used different samples at each data collection time-point which meant that baseline and post intervention data were not recorded on the same individuals (Goff *et al*. 2004, Mosca *et al*. 2013). One researcher measured post intervention data only (Meischke *et al.* 2004). Six researchers measured pre and post intervention data on the same individuals for their study duration (Buckley *et al.* 2007, Tullman *et al*. 2007, Bell *et al.* 2009, McKinley *et al*. 2009, DeVon *et al*. 2010b, Gallagher *et al*. 2013). The collection of baseline and post intervention data from the same individuals reduces threats to internal validity and provides more accurate measurements of an intervention effect (Grove *et al.* 2013, Gray 2014). Consequently, this is something that should be considered in future interventions.

2.6.10 Theoretical underpinnings

All researchers referred to the theoretical/conceptual framework that underpinned their intervention (Goff *et al.* 2004, Meischke *et al*. 2004, Buckley *et al.* 2007,

Tullman *et al*. 2007, Bell *et al.* 2009, McKinley *et al*. 2009, Mosca *et al.* 2013). Some researchers used a combination of behaviour change theories to include social cognitive theory, the health belief model, the theory of reasoned action, diffusion theory, the theory of planned behaviour, and social marketing theory (Goff *et al.* 2004, Bell *et al.* 2009, Gallagher *et al*. 2013, Mosca *et al*. 2013). It is important that educational interventions are underpinned by a sound theoretical framework (Craig *et al.* 2008, Borelli 2011). One researcher referred to a conceptual framework that was based on results from a meta-analysis, which identified factors that contributed to increased enrolement and adherence to cardiac rehabilitation (DeVon e*t al.* 2010b). As this conceptual framework was not previously tested, its effectiveness as a framework has yet to be determined.

The theoretical underpinning most commonly used was Leventhal's self-regulatory model of illness behaviour (Goff *et al.* 2004, Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009). This was also the framework that underpinned four of the interventions that resulted in positive outcomes for knowledge, attitudes or beliefs (Goff *et al.* 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009). From a methodological perspective, these studies were strong.

2.6.11 Intervention results

Six of the nine researchers reported statistically significant positive effects of their interventions on knowledge of ACS symptoms (Goff *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, Bell *et al.* 2009, McKinley *et al*. 2009, DeVon *et al*. 2010b, Gallagher *et al*. 2013). One researcher (Meischke *et al*. 2004), reported no improvement in post-intervention knowledge levels about ACS, while another (Mosca *et al.* 2013) reported improvements in some symptoms. Of the three researchers who reported on attitudes and beliefs (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009), only one (McKinley *et al*. 2009) reported a statistically significant positive effect of their intervention on attitudes. With respect to beliefs, two researchers (Tullman *et al*. 2007, McKinley *et al*. 2009) reported statistically significant positive effects of their interventions on this

variable. This suggests that the cognitions of attitudes and beliefs may be harder to change than knowledge (Goulding *et al.* 2010).

Sample sizes differed considerably among those studies that measured attitudes and beliefs. The sample sizes were 3,522 (McKinley *et al*. 2009), 200 (Buckley *et al.* 2007) and 112 (Tullman *et al*. 2007). Although none of the three researchers disclosed details of their study's power analysis calculations, the sample size used by McKinley *et al*. (2009) was very large. Conversely, the small sample sizes used by Buckley *et al*. (2009) and Tullman *et al*. (2007) may have resulted in the studies being insufficiently powered to demonstrate a significant effect of the intervention on all three variables. As all three variables of knowledge, attitudes and beliefs have been reported to be co-dependent on each other (McKinley *et al*. 2009), the inclusion of all three components in educational interventions is warranted.

2.6.12 Summary of interventions

In consideration of the results of previously conducted interventions, the eight studies that reported statistically significant post intervention improvements (Goff *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, Bell *et al.* 2009, McKinley *et al*. 2009, DeVon *et al*. 2010b, Gallagher *et al*. 2013) were similar in many respects. The majority were RCTs (Goff *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009, DeVon *et al*. 2010b) and most interventions provided individualised education (Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009, DeVon *et al*. 2010b, Gallagher *et al*. 2013). One (Goff *et al*. 2004) used an individualised component in conjunction with a mass media intervention. In the case of all interventions, some (Goff *et al*. 2004, Tullman *et al*. 2007) or all of the samples (Buckley *et al.* 2007, Bell *et al.* 2009, McKinley *et al*. 2009, DeVon *et al*. 2010b, Gallagher *et al.* 2013) were at risk for future ACS events. The theoretical framework most commonly used was Leventhal's self-regulatory model of illness behaviour. This was used alone (Tullman *et al*. 2007, Buckley *et al.* 2007, McKinley *et al*. 2009), or in conjunction with another framework (Goff *et al.* 2004).

While intervention designs provide one potential reason for successful outcomes, the effectiveness of interventions may be attributable to other factors. One factor that warrants consideration is the means by which patient education is provided. The role of effective teaching strategies in optimising the education of cardiovascular patients has been acknowledged in the literature (Commodore-Mensah & Dennison Himmelfarb 2012, Gallagher *et al.* 2013) and will be presented next.

2.7 Strategies to optimise patient education

Key education strategies for hospitalised cardiovascular patients were reported in a systematic review by Commodore-Mensah and Dennison Himmelfarb (2012). The studies included in the review were conducted between 2000 and 2010 and included patient populations admitted with a broad range of cardiovascular conditions such as ACS, heart failure, stroke and congenital heart disease. Of the 25 studies that met the inclusion criteria, 20 were RCTs, and 5 were quasi-experimental designs. Modes of education delivery included face-to-face and multimedia formats. The former comprised of individualised and standardised education, while the latter included DVDs or computer education. Teaching was supplemented using written material or a wallet card. Most studies included multi-faceted approaches.

Of the educational strategies used, individualised education was widely provided and was promoted as an effective strategy in the provision of patient education (Blank & Smithline 2002, Hajek *et al.* 2002, Lichtman *et al.* 2004, Levetan *et al.* 2005, Dracup *et al.* 2006, Mohiuddin *et al*. 2007, Sørlie *et al*. 2007, Arnold *et al.* 2009). Of the five studies that demonstrated improved healthcare utilisation outcomes (Kalra *et al.* 2004, Anderson *et al.* 2005, Koelling *et al.* 2005, Mohiuddin *et al*. 2007, Jack *et al*. 2009), the majority delivered individualised education and all used multiple modes of delivery.

Nine of the ten studies that measured the intervention effect on knowledge levels reported significant improvements in that variable (Enzenhofer *et al.* 2004, Lichtman *et al.* 2004, Gwadry-Sridhar *et al*. 2005, Stromberg *et al*. 2006, Lowe et al. 2007, Steffenino *et al*. 2007, Williams *et al*. 2007, Tait *et al.* 2009, Chan *et al*. 2010). The study that was unsuccessful in improving knowledge (Hoffmann *et al.* 2007) had provided an intervention using computer generated tailored information about stroke. The researchers (Hoffmann *et al.* 2007) suggest that a multi-component intervention such as supplementing written information with verbal communication or patient counselling may have been more effective in improving knowledge. Furthermore, the researchers acknowledge that the study sample of 133 may not have been adequately powered to detect a modest effect in knowledge (Hoffmann *et al.* 2007).

Interventions that measured behavioural or clinical outcomes were less likely to demonstrate effectiveness (Commodore-Mensah & Dennison Himmelfarb 2012). Outcome measurements included for example, medication or self-care compliance. Of the four studies that measured knowledge and behavioural outcomes, none demonstrated a significant effect on both knowledge and behaviour (Lichtman *et al.* 2004, Gwadry-Sridhar *et al*. 2005, Stromberg *et al*. 2006, Hoffmann *et al.* 2007). Commodore-Mensah and Dennison Himmelfarb (2012) suggest that although knowledge is pre-requisite for behavioural change, it may not be sufficiently strong to change behaviour (Oppenheim 2004, Bodenheimer 2005). Lack of success in changing behaviour in these studies may be attributed to the individual having a condition that is asymptomatic, such as hypercholesterolaemia. Consequently, they may lack understanding of the importance of their behaviour in complying with medication use (Lichtman *et al.* 2004).

Commodore-Mensah and Dennison Himmelfarb (2012) reported that education strategies that fit with the individual's learning style, cognition and motivation are more likely to increase the probability that the patient will act in accordance with

the education. According to the educational psychologist Jean Piaget (1896-1980), the motivation to learn is based on the cognitive principle of disequilibrium. This is the first step in the learning process, whereby the individual identifies a need to learn (Piaget 1973). An unpleasant state of disequilibrium occurs when new information cannot be fitted into the individual's pre-existing schemas. Equilibration is the force that drives the learning process, as the individual seeks to restore balance through learning (Piaget 1973).

The motivation to learn further originates from the development of discrepancy in the individual. This refers to the identification of the need for change by the individual in order to meet their personal goals (Dart 2011, Miller & Rollnick 2013). This process often arises when the individual experiences a sense of discomfort and perceives inconsistencies in their thinking, beliefs or actions (Festinger 1957, deVries 2008, Syx 2008). In the context of ACS, a dissonance may arise when there is disequilibrium between symptom expectation and symptom presentation, or where information messages are incongruent with pre-existing knowledge, attitudes or beliefs about ACS. Once dissonance is experienced, individuals are motivated to make changes by the need to regain consistency (Festinger 1957, Syx 2008).

It has been suggested that patient education should commence with an evaluation of learning needs (Fredericks *et al*. 2010), and should include health literacy levels (Dewalt *et al*. 2004). To further enhance the absorption of information, consideration should be afforded to the means by which information is delivered. Ideally a combination of verbal and written material should be provided as a patient education strategy (Gallagher *et al.* 2013). This can be achieved through the use of tailored interventions.

The majority of learning occurs visually, with smaller proportions gained from the other senses (Lopez 2005). Visual teaching aids with a blend of text and graphics should therefore be provided (Gallagher *et al.* 2013). While ACS may occur at

any age, it is most likely to occur in those over 65 years (Graham *et al.* 2007). In light of the complications of ageing, large print should be used (Gallagher *et al.* 2013), and tone of voice altered according to auditory needs (Tullman *et al*. 2007). Consideration should also be given to the rapidity with which information is delivered.

According to Commodore-Mensah and Dennison Himmelfarb (2012), hospitalisation is an ideal time for education to occur, as individuals are particularly susceptible to learning during this time. While education is normally delivered immediately prior to discharge in usual care, research has shown that patients prefer their education to be as close to the event as possible (Tilly *et al.* 1987). Furthermore, it has been suggested that cardiac patients are more receptive to interventions if they are targeted immediately following their MI or health threat event (Weinman *et al*. 2001, Petrie *et a*l. 2002). Nonetheless, as patients are subjected to physical and mental stressors following an ACS event, it is important that education is not over burdensome for them. Commodore-Mensah and Dennison Himmelfarb (2012) identified that following ACS events, the maximum time spent educating patients at any one time was 40 minutes (Blank & Smithline 2002, Sørlie *et al*. 2007). These studies imply that prolonged periods of in-hospital patient education should be avoided.

Only a few studies provided education, which they reinforced on another occasion. As interventions that include follow-up sessions are generally more effective (Artinian *et al.* 2002, Buckley *et al.* 2007, McKinley *et al.* 2009, Commodore-Mensah & Dennison Himmelfarb 2012), this is also worth considering as a patient education strategy.

2.7.1 Summary of educational strategies

Patient education can be optimised through the provision of individualised education. The individualisation of teaching enables the teacher to take cognisance of the individual's learning style, literacy level, motivation to learn and their level of discrepancy. This approach facilitates the tailoring of teaching to the

individual and is considered most favourable. Furthermore, teaching is thought to be more effective when one form of information is supplemented with another. With respect to the provision of education to the older generation, consideration should be afforded to the deterioration of the senses. For patients with ACS, teaching should take place as close to the event as possible, but should not be over burdensome in terms of duration. Ideally, information should be reinforced on at least one occasion.

2.8 Conclusion

The literature review revealed that responses to ACS symptoms are dependent on adequate knowledge, attitudes and beliefs. There is a requirement for improvements in these constructs because with the exception of chest pain, knowledge of the constellation of other ACS symptoms tends to be inadequate. However, ACS symptoms can be difficult to decipher and a definitive ACS diagnosis is not always straightforward. This can pose difficulties for health care providers as well as the public. The nature and onset of symptoms can provide cues about ACS, depending on whether they are categorised as fast-onset or slow-onset ACS. As a consequence of symptom misattribution and inadequate knowledge, help-seeking behaviour is prolonged and EMS use can be delayed or foregone. Other factors that influence help-seeking behaviour include knowledge levels, pre-existing illness representations and attitudes and beliefs about symptoms and their aetiology. The literature suggests that individuals would readily seek assistance via the EMS, if they identified the symptoms as cardiac, or felt that their symptoms warranted this recourse.

To date, nine educational interventions targeted knowledge, attitudes or beliefs about ACS. The majority of studies were RCTs and most were successful in improving knowledge and attitudes or beliefs. Of the RCTs that were successful, most were based on Leventhal's self-regulatory model of illness behaviour. Previous research enabled the identification of important considerations in intervention development. These included the targeting of individuals who are at

risk for ACS, as opposed to the entire population. While some used mass media interventions, the majority of researchers adopted the approach of individualised educational interventions.

This literature review identified what is known about knowledge in ACS and reviewed those interventions previously conducted with a view to informing future research. Empirical evidence from this review identified that a gap in knowledge exists among the public with respect to ACS. As ACS can manifest in a variety of ways, the public should be aware of the range and variability of all ACS symptoms and the action to be taken in their presence. Evidence yielded from this review also provided insights into strategies for effective patient education.

No prior educational intervention about ACS has been conducted in Ireland or in Europe. While some of the interventions comprised of samples from more than one country, none of these samples were European. This underscored the need to develop an educational intervention aimed at improving knowledge, attitudes and beliefs about ACS in Ireland. The majority of previously successful interventions were tested using RCT designs. On this basis, and on the wide recognition that RCTs are of sound methodology, an RCT design was considered for this study.

With respect to the means by which individualised education could be delivered, the literature identified that education while in hospital is most beneficial. Furthermore, learning should be contextualised to the individual's needs and should include an awareness of motivation, literacy and cognition levels. It is ideal that information be reinforced, as opposed to over burdening the individual with intense once-off teaching. Special consideration should be given to the fact that individuals learn using a variety of senses, particularly sound and visual. For this reason, written and verbal education is most effective.

This collective information signalled the necessity to develop an individualised educational intervention, that would focus on all three variables of knowledge, attitudes and beliefs and which would be tested using an RCT. The inclusion of all three variables was of particular importance as they are interdependent, yet most previous researchers focused on knowledge only. Recommended strategies for patient education and the strengths of prior interventions have provided insights into the best means by which knowledge, attitudes and beliefs about ACS could be improved. Accordingly, the development of this intervention was informed by this current review. From this, the study aim, objectives and hypotheses were developed.

2.9 Aim of the study

The aim of this study was to test the effectiveness of an individualised educational intervention on knowledge, attitudes and beliefs about ACS.

2.10 Study objectives and hypotheses

1. To determine whether there was a difference in ACS patients' knowledge about ACS facts and symptoms between those randomly assigned to the control group and those randomly assigned to the intervention group.

   Hypothesis: Following the educational intervention, patients assigned to the intervention group will demonstrate greater knowledge about ACS facts and symptoms at 3 months and 12 months, than those assigned to the control group.

2. To determine whether there was a difference in ACS patients' attitudes towards symptom recognition and confidence in their own ability to instigate appropriate help-seeking behaviour between those randomly assigned to the control group and those randomly assigned to the intervention group.

Hypothesis: Following the educational intervention, patients assigned to the intervention group will demonstrate better attitudes towards symptom recognition and confidence in their own ability to instigate appropriate help-seeking behaviour, at 3 months and 12 months, than those assigned to the control group.

3. To determine whether there was a difference in ACS patients' beliefs about what constitutes appropriate responses to ACS symptoms between those randomly assigned to the control group and those randomly assigned to the intervention group.

   Hypothesis: Following the educational intervention, patients assigned to the intervention group will demonstrate more accurate beliefs about what constitutes appropriate responses to ACS symptoms, at 3 months and 12 months, than those assigned to the control group.

Chapter 3: Methodology

3.1 Introduction

The importance of undertaking this study was underpinned by the literature review, which highlighted the global problem of limited knowledge, attitudes and beliefs about ACS and the importance of prompt help-seeking behaviour. Moreover, no prior educational intervention about ACS has been conducted in Europe, which provided further impetus for the pursuance of this study. Consequently, the aim of this study was to test the effectiveness of an individualised educational intervention on knowledge, attitudes and beliefs about ACS. Empirical evidence strengthened the need for the intervention to be individualised and delivered during hospitalisation, to patients at risk for an ACS event. The strengths and weaknesses of previous interventions informed the choice of intervention for this study, as did those educational strategies that were found to be effective. As this study is part of the ACS Response Time Intervention Trial, the intervention targeted knowledge, attitudes and beliefs about ACS, with the intention of improving behaviour and thereby reducing pre-hospital delay time.

This chapter presents the methodological aspects of this study and its philosophical underpinning. An RCT design was identified as the most appropriate for this study. The rationale for its use, and its principles and benefits are outlined, along with the criteria of randomisation, concealment of group allocation, minimisation of trial bias and intervention fidelity. The choice of intervention and the theoretical framework on which the intervention was based are also presented. The chapter concludes with an overview of the principles of motivational interviewing, which were used in the delivery of this intervention.

3.2 Philosophical and theoretical perspective underpinning the study

The overall purpose of research is to discover the truth about the phenomenon under investigation. Research is guided by three fundamental elements, namely ontology, epistemology and methodology (Wainwright 1997, Rolfe 2013). Ontology refers to what exists, epistemology is the relationship between the inquirer and that being studied, while methodology is the means by which the enquirer obtains knowledge (Wainwright 1997, Hanson *et al.* 2005, Sarantakos 2013). These facets are inextricably linked and collectively constitute a paradigm (Sarantakos 2013). Paradigms influence the questions posed by the researcher and the methods employed to answer them (Morgan 2007).

Researchers and authors have traditionally subscribed to the division of the scientific status of knowledge generation into two main paradigms (Crotty 1998, Gray 2014). These contrasting paradigms are the interpretivist-inductive-qualitative approach and the positivist-deductive-quantitative alternative (Duffy 1985, Corner 1991, Pierce 2013). From an epistemological perspective, these are often referred to as constructionism and objectivism, respectively (Crotty 1998). Constructionism asserts that knowledge is generated through social interaction and reflection, while objectivism is the epistemological stance that reality exists objectively and independent of conscious thought (Crotty 1998, Matthews & Ross 2010). The philosophical and theoretical perspective underpinning this study was determined by the study aim, objective and hypotheses. As the study is rooted in objectivism, it is grounded in the positivist paradigm.

3.2.1 Objectivism

Objectivism comprises a deductive and quantitative approach to research and is situated within the positivist paradigm. Objectivism is epistemologically consistent with the aim of this study, in which hypotheses were tested to identify cause and effect relationships. According to the positivist paradigm there is a single reality

and relationships are determined through objective, deductive measurement and quantitative analyses (Firestone 1987, Matthews & Ross 2010). Unlike constructionism, within the positivist paradigm the researcher's relationship with the social world and the social phenomena under investigation is objective (Matthews & Ross 2010). Historically, positivism has been the dominant paradigm underpinning healthcare research and has attained credibility through its rigorous control of variables, precise measurement, statistical analyses and use in clinical and academic circles (Grove *et al.* 2013). Given the aim of this study and the nature of intervention delivery and testing, objectivity and credibility were fundamental. Objectivity is attained through the rigorous control of variables (Weaver & Olsen 2006), while credibility is established through the employment of large sample sizes, rigorous statistical testing of hypotheses, prediction and control (Lincoln & Guba 1985). As the aim of this study was to test the effectiveness of an educational intervention, an RCT was selected as the chosen research design.

3.3 Research design: randomised controlled trial

Randomised controlled trials are experimental designs in which participants are randomly allocated to two or more groups to test a specific treatment (intervention). One group receives the intervention while the other (the control or comparison group) receives usual treatment, a placebo or no treatment at all. Both groups are followed up at specific times to identify the effectiveness of the intervention (Jadad & Enkin 2007, Torgerson & Torgerson 2008, Grove *et al.* 2013).

3.3.1 Rationale for selecting a randomised controlled trial

Randomised controlled trials are considered the 'gold standard' method for determining the effectiveness of interventions in health and social science research (Torgerson & Torgerson 2008, Gerrish & Lacey 2010, Hutchison & Styles 2010, Grove *et al*. 2013). Their strengths include the rigorous control of variables, which enable investigators to isolate and quantify the impact of an intervention. This makes RCTs the strongest method for supporting a

hypothesised correlation between an independent and dependent variable (Jadad & Enkin 2007, Hoy 2010, Singh *et al.* 2011, Schulz *et al.* 2010). Further strengths of RCTs include the minimisation of the potential for bias. This is dependent on the trial conforming to specific RCT criteria. When these criteria are upheld, it can be deduced with confidence that observed differences in outcomes between the intervention and control groups are due to the intervention (Sidani & Braden 2011). Conclusions drawn from methodologically sound RCTs have high credibility and can provide empirical support for the implementation of changes in health care, education and public policy (Watson *et al.* 2002, DePoy & Gitlin 2005, Torgerson & Torgerson 2008).

As this study was health-care based and has potential clinical and health policy implications, it was important that it conformed to the highest research standards. This is important in nursing, where it is recognised that nursing practice should be underpinned by the highest form of evidence (Corry *et al.* 2013). Accordingly, an RCT was selected as the design for this study, as it provides the strongest level of all research evidence (LoBiondo-Wood & Haber 2010, Grove *et al.* 2013).

3.4. Classification of randomised controlled trials

Randomised controlled trials can be classified according to how participants are exposed to the intervention, the number of participants in the study, and whether the investigators and participants know which aspect of the intervention is being assessed. This RCT was classified according to how participants were exposed to the intervention. Within this classification, there are three categories: the crossover, factorial and parallel designs (Jadad & Enkin 2007).

A crossover design refers to the successive administration of the intervention to all study participants, the order of which is determined at random. In a factorial design, investigators can compare two or more experimental interventions, either together or separately. Conversely, in a parallel design, each group of participants is exposed to only one of the study interventions. This is the most

frequently used design, where the two groups differ by virtue of the intervention delivered (Jadad & Enkin 2007, Grove *et al.* 2013). A parallel design was used in this study, where one group was exposed to the intervention, while the other served as the control group.

3.5 Randomised controlled trial criteria

In order to be considered methodologically sound, it is elementary that RCTs conform to the following criteria: a rigorous randomisation process for the allocation of participants to the study groups, concealment of group allocation, the minimisation of trial bias and strict adherence to intervention fidelity (Jadad & Enkin 2007, Sidani & Braden 2011). In the absence of such adherence, there is potential for study outcomes to be flawed or misinterpreted and for policies or procedures to be inappropriately implemented (Jadad & Enkin 2007). Consequently, these criteria must be adhered to throughout the study to ensure that the RCT is executed rigorously.

3.5.1 Randomisation

Randomisation is the process of allocating trial participants to either the control or the intervention group (Sidani & Braden 2011, Pierce 2013). This process ensures that each participant has an equal chance of being in either group (Altman 2006), which eliminates the potential problem of selection bias (Torgerson & Torgerson). Thus, randomisation maximises the probability that group characteristics are comparable at baseline (DePoy & Gitlin 2005, Kunz *et al.* 2007, Sidani & Braden 2011). Furthermore, randomisation allows investigators to isolate and quantify the effect of the intervention (Jadad & Enkin 2007). While randomisation produces comparable groups, the groups are rarely, if ever, identical. Therefore, even with randomisation, there is a small probability that group differences can still occur due to chance. A study that is sufficiently powered will help protect against this, and in the event of group differences arising, these differences can be controlled for using statistical methods (Torgerson & Torgerson 2008, Singh *et al*. 2011).

Block randomisation

Randomisation can be generated in several ways; from flipping a coin to using a computer generated random number sequence. This latter method is preferable (Jadad & Enkin 2007, Torgerson & Torgerson 2008). To counteract the potential for an imbalance in group size, simple computer generated randomisation can be created in multiple blocks (Altman 2006, Jadad & Enkin 2007). With this method, each block contains an equal number of intervention and control allocations. However, the order in which the interventions are assigned in each block is randomised (Jadad & Enkin 2007).

Should a trial terminate prematurely, the use of block randomisation offers the advantage of ensuring the numbers assigned to each group are similar, as the researcher may stop recruitment at the end of a block. Even if this is not possible, this method ensures that groups cannot be unbalanced by more than half the block size (Jadad & Enkin 2007). Regardless of the method of randomisation chosen, investigators should adhere to two principles; to define the rules that govern allocation at the study outset and to follow those rules for the study duration (Jadad & Enkin 2007).

3.5.2 Concealment of group allocation

Successful randomisation is contingent on concealment of group allocation from both the participants and those recruiting them (Kunz 2007, Gerrish & Lacey 2010). Concealment protects against trial bias and is necessary until group allocation occurs. A Cochrane systematic review conducted by Kunz (2007) reported that trials with inadequate concealment of allocation tended to over-estimate treatment effects. Concealment can be accomplished using sequentially-numbered, opaque, sealed envelopes (SNOSE). With this method, the randomised number is visible through a window in the envelope, but the group allocation is concealed (Singh *et al.* 2011).

3.5.3 Minimising bias in randomised controlled trials

Trial bias is an important consideration, as it can threaten the validity and trustworthiness of an RCT (Polit & Beck 2010). Randomisation and concealment of group allocation do not protect against all types of trial bias (Jadad & Enkin 2007). Bias can be introduced by anyone associated with the trial, including the person determining eligibility and recruiting participants, the person administering and the person receiving the intervention, the data analyst or those involved in the dissemination of the results (Jadad & Enkin 2007, Gerrish & Lacey 2010). When designing an RCT, measures should be taken to protect against the introduction of selection bias, ascertainment bias and attrition bias.

Selection bias

Selection bias refers to the means by which potentially eligible individuals are accepted or rejected for participation in a trial or to the fraudulent allocation of group assignment when recruited (Jadad & Enkin 2007). Selection bias is of concern in research because of its potential effect on distorting the study outcomes (Grove *et al*. 2013). However, it should not arise if randomisation and concealment of group allocation is properly adhered to.

Ascertainment (observation) bias

Ascertainment bias occurs when the results of a trial are prejudiced, either knowingly or unknowingly, by knowledge of study group allocation (Jadad & Enkin 2007, Gerrish & Lacey 2010). The development of blinding in a trial refers to the concealment of group allocation from all those involved in the trial for as long as possible (Grove *et al*. 2013). Blinding is adopted to avoid bias caused by subjective judgment in evaluating, analysing and reporting data due to knowledge of group allocation (Jadad & Enkin 2007). However, blinding is not always possible in a trial (Friedberg *et al*. 2010) and although it is important in reducing bias, it is considered less so in trials where outcome data are objective (Day & Altman 2000).

Attrition bias

Ideally, all participants in an RCT would complete the trial and all outcome measures would be obtained. However, due to attrition and missing data, it is rarely possible to include 100% of participants in the final analyses (Jadad & Enkin 2007, Torgerson & Torgerson 2008). High levels of attrition have the potential to cause a Type II error, thereby failing to detect a significant effect in a population when one exists (Warner 2008, Field 2011). Attrition bias can limit the generalisability of the trial's results (Polit & Beck 2008) and if not adequately addressed, can compromise the quality of research outcomes (Polit & Beck 2010). A low rate of returns of postal questionnaires is considered to be a form of attrition bias (Edwards *et al.* 2002b). To minimise this potential, the following strategies have been suggested: the inclusion of a 'thank you' statement at the end of the questionnaire, a return address on the back of the envelope, the inclusion of a personalised note and a stamped addressed envelope (Edwards *et al*. 2002a, Torgerson & Torgerson 2008, Gerrish & Lacey 2010).

Per protocol analysis

Regardless of participant retention efforts, it is inevitable that some level of attrition will occur in all trials, particularly among those that are on-going (Jadad & Enkin 2007). Some studies employ a per protocol analysis (PPA) to address this issue and to minimise attrition bias. This decision should be made *a priori*, in order to maximise the likelihood of obtaining a valid conclusion from data analyses (Kruse *et al*. 2002, Grove *et al.* 2013). With PPA, participants' outcomes are analysed according to the treatment they received and the availability of their follow-up data (Torgerson & Torgerson 2008, Gerrish & Lacey 2010). Those lost to follow-up should never be ignored and an explanation is warranted with respect to reasons for exclusion from analyses (Schulz *et al.* 2010). Torgerson and Torgerson (2008) assert that if attrition rates are similar between both arms of a trial, then the probability of attrition bias is minimised. Nonetheless, it cannot be assumed that both groups are similar, so analyses should be performed that compares the characteristics of participants who

remained in the study with those who were lost to follow-up (Torgerson & Torgerson 2008, Gerrish & Lacey 2010).

3.5.4 Intervention fidelity

Almost all interventions are complex interventions. Complex interventions are those that are made up of various interconnecting parts that can act both independently and interdependently (Medical Research Council 2000, Campbell *et al*. 2007, Aranda 2008). Intervention fidelity is an integral component of complex interventions and has been highlighted as a concern in intervention research in recent years. Fidelity refers to the methodological strategies used to ensure the interventionist delivers the intervention consistently, competently and accurately, through strict adherence to a specified protocol and design (Judge Santacroce *et al*. 2004, Sidani & Braden 2011, Grove *et al*. 2013).

Fidelity is important in all intervention-based research, but particularly so for those concerned with implementing behavioural change (Campbell *et al*. 2013, Grove *et al.* 2013). Reporting fidelity measures is imperative in all published work, as it allows the reader to judge the quality of the trial and to replicate the intervention, if so desired (Resnick *et al*. 2005, Spillane *et al.* 2007). Furthermore, it can furnish intervention developers with an insight into the factors that may have influenced study outcomes (Murphy & Gutman 2012). Careful consideration of fidelity increases scientific confidence that changes in the dependent variable can be accredited to the independent variable (Bellg *et al*. 2004, Borelli *et al.* 2005, Borelli 2011).

Ensuring treatment fidelity in complex interventions is not without its challenges and there is a need for researchers to determine at the study design phase, the methods they will use to assess and monitor intervention fidelity (Smith *et al.* 2006, Spillane *et al.* 2007). The Treatment Fidelity Workgroup of the National Institutes of Health Behaviour Change Consortium (Bellg *et al.* 2004) and others (Spillane *et al.* 2007, Sidani & Braden 2011) have provided best practice guidelines that can be applied to maximise intervention fidelity. These include

intervention design, training procedures, delivery of the intervention in addition to receipt and enactment of intervention skills in real life settings (Bellg *et al*. 2004, Spillane *et al.* 2007, Sidani & Braden 2011).

Intervention design

Fidelity of intervention design refers to the factors, which should be considered when designing an intervention to ensure that the intervention is reflective of its theoretical base and fully operational (Bellg *et al*. 2004, Borrelli 2011). During this phase, a standardised intervention manual should be devised and procedures to measure the 'dose' of the intervention established (Bellg *et al.* 2004). Intervention 'dose' refers to the frequency, duration and number of contacts to be administered, in addition to the intervention content (Bellg *et al*. 2004, Grove *et al*. 2013). Consistent with this, a trial protocol should be devised to clearly specify the dose of the intervention to be administered to each participant. A plan to address possible setbacks in intervention implementation, such as interventionist attrition, should also be created (Bellg *et al.* 2004).

Selection and training of the interventionists

The interventionist is pivotal to the successful implementation of the intervention and its fidelity. The nature of the interaction between the participant and interventionist can positively contribute to the participant's motivation to engage in and adhere to the intervention (Fuertes *et al.* 2007, Sidani & Braden 2011). Consequently, the selection and training of interventionists cannot be underestimated (Sidani & Braden 2011). Although there are no specific guidelines to stipulate the necessary attributes to be considered during recruitment, it has been suggested that certain factors should be taken into account. These include personality style, competence in terms of formal training and experience and congruence between the interventionist and the participant with respect to socio-demographic characteristics (Sidani & Braden 2011).

The foundation for successful training and its fidelity hinges on standardising training and training providers (Spillane *et al*. 2007). Devising an interventionist training manual and engaging the same training providers helps to ensure that training is consistent among interventionists (Bellg *et al.* 2004). Furthermore, it enhances the potential for equivalence of delivery of the intervention across research sites, where more than one research site is used (Borrelli 2011). Post-training skills acquisition levels should be monitored to ensure that training was successful (Bellg *et al.* 2004). Refresher training sessions facilitate on-going coaching to minimise 'drift' in skills, the importance of which cannot be underestimated (Johnson & Remien 2003, Borelli 2011).

Delivery of the intervention

Processes to monitor and ensure that the intervention is delivered as intended, are imperative for intervention fidelity (Bellg *et al.* 2004, Spillane *et al*. 2007). This is of particular importance in multi-site trials, where variations in intervention delivery can occur (Oakley *et al*. 2006). In addition to training, a number of strategies can optimise intervention fidelity with respect to the interventionist and their delivery of the intervention. Strategies include the use of an intervention manual that is user-friendly (Borrelli 2011) and supported by a detailed script (Friedberg *et al*. 2010). In addition, the provision of a trial protocol to ensure interventionist awareness of the mandatory requirement to deliver an identical intervention to each participant with respect to content, frequency and duration. Where an intervention is given to only one group, there is a requirement to keep the randomised groups separate to minimise the risk of contamination between the groups (Bellg *et al*. 2004).

Process evaluation is an important step in ensuring that the interventionist has adhered to the intervention manual and trial protocol. Some authors (Bellg *et al*. 2004, Borrelli 2011) consider audiotaping or observing intervention sessions to be the gold standard in process evaluation. Others (Sidani & Braden 2011) recognise that this can sometimes be difficult or inappropriate and suggest

alternative strategies such as self-report evaluations and field notes. While trial fidelity is very important, very rigid procedures are not always appropriate, particularly where interventions are centred on individuals (Craig *et al.* 2008). In light of this, flexibility is often required, depending on the context, setting or individual (Leventhal & Friedman 2004).

Receipt and enactment of intervention skills

Receipt of the intervention involves the process of verifying the participant's comprehension of the intervention (Bellg *et al*. 2004, Borrelli 2011, Sidani & Braden 2011). Suggested strategies to assess for the receipt of treatment skills include questioning before and after the intervention, problem solving and skill demonstration (Bellg *et al*. 2004). On the other hand, enactment of intervention skills refers to the methods of monitoring and improving the participant's ability to enact the intervention in a real-life setting (Bellg *et al*. 2004, Borrelli 2011). This can be achieved through the observation of *in-vivo* interactions, such as role play. Additional measures include maintaining contact with participants using follow-up telephone calls or letters (Bellg *et al*. 2004).

3.6 Quality and reporting of randomised controlled trials

Critical appraisal and interpretation of an RCT is only possible if the trial is described thoroughly and accurately in research reports and published articles. The CONSORT guidelines were devised (Begg *et al*. 1996) and subsequently revised (Altman *et al*. 2001, Schulz *et al*. 2010) to develop uniform methods of reporting on clinical trials and to enable researchers to improve on the quality of reporting. Current guidelines comprise a 25-item checklist of essential items that should be included when researchers are reporting RCTs. The checklist includes an illustration that demonstrates the flow of participants through the trial (Schulz *et al*. 2010).

3.7 Framing the intervention

The choice of framework for this intervention was based on the aim of the ACS Response Time Intervention Trial, which was to improve knowledge, attitudes and beliefs about ACS with a view to reducing pre-hospital delay time in the presence of ACS symptoms. As this intervention was a complex intervention, there was a requirement that it would be theoretically-based. This was particularly important, as theory-based interventions designed to change behaviour are most effective (Hafner & Kirscht 1970, Petrie *et al*. 2002). It was endeavoured that the theoretical framework would bridge the gap between knowledge acquisition and the translation of this knowledge into the adoption of appropriate health behaviours. Self-regulatory models can bridge this gap between knowledge acquisition and the adoption of appropriate behaviours (Maes & Karoly 2005, de Ridder & de Wit 2006). It was considered that improvements in knowledge would positively influence attitudes and beliefs about help-seeking behaviours. Furthermore, adherence is most effective among interventions that increase self-regulatory capabilities (de Bruin *et al.* 2012). It has been suggested that self-regulatory models provide the basis for all purposeful action (Bandura 1991). Therefore, an intervention that was based on self-regulation was considered in the context of this study.

3.8 Self-regulation

Self-regulation is framed within Social Cognitive Theory (Bandura 2004). Social Cognitive Theory is underpinned by the belief that human behaviour, motivation and well-being are regulated through the person's belief in their own self-efficacy, goals and outcome expectations (Bandura 2004). Broadly speaking, self-regulation refers to the thoughts, feelings and actions that individuals adopt in order to attain their personal goals (Carver & Scheier 1998). It is achieved through the individual modifying his/her environment and making on-going behavioural changes, as necessary (Boekaerts *et al*. 2000, Maes & Karoly 2005, de Ridder & de Witt 2006). Self-regulatory theory views 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 & Scheier 1982).

3.8.1 Origins of self-regulation

One of the first self-regulatory theories was cybernetic control theory, which was developed by Carver and Scheier (1982). This theory originated from the mechanics of a machine and its chief mechanism of control is the operation of a cyclical feedback loop. With respect to humans, self-regulation is a far more complex process. However, the principles of the theory can also be applied to human behaviour (Carver & Scheier 1982). Unlike mechanistic processes, humans use the cyclical feedback loop process to appraise goal-setting, monitor progress towards the achievement of goals and take action to reduce discrepancies that arise between the individual's current state and the standard needed to achieve their goals (Carver & Scheier 1982, de Ridder & de Wit 2006). The reduction of discrepancies between goal-setting and goal achievement is dependent on behaviour, such as compliance with a health recommendation and the person's cognitive representation of their current status and the goal or plan that they have for changing it (Leventhal & Cameron 1987). In the presence of self-regulation, individuals become active decision-makers who determine their own outcomes and actions in terms of health behaviours, while in its absence, the person is helpless when faced with a health threat (Baumeister 2005).

The individual's goals and their actions are contingent on the person's context and characteristics (Carver 2004). Carver and Scheier (1982) theorised that in self-regulation, goals are organised hierarchically and altered in accordance with the individual's sense of self and commitment to the goals. Self-awareness and self-monitoring are crucial to the understanding of self-regulation, as the individual's interpretation of progress determines what further action is required and taken. Self-regulation is unique in that it involves regulation of the self, by the self, as opposed to the regulation of predominantly external influences (Leventhal *et al.* 2003).

3.8.2 Common characteristics

There are a number of theoretical approaches to self-regulation. These vary with respect to the principles that they emphasise or the mechanisms to which they subscribe (de Ridder & de Wit 2006). Irrespective of their focus, all theories share the two common characteristics of goal-setting and emotional and cognitive processes (Cameron & Leventhal 2003).

The first characteristic of goal-setting is initiated through the conscious or unconscious selection or activation of goals (Maes & Karoly 2005). In self-regulation, the individual chooses his or her own goals; a process known as autonomous regulation. These goals emanate from the individual and are set because they are of personal importance to them. Research reports suggest that individuals who are supported to engage in autonomous goal-setting tend to be more motivated to fulfil their goals (Williams *et al*. 1998). However, the development of autonomous regulation often requires the support of health care providers (Maes & Karoly 2005). The appraisal and revision of goals and strategies is determined by the feedback loop system that is characteristic of self-regulation.

The second common feature of self-regulation is concerned with the management of emotional responses (Carver & Scheier 1998). Emotional responses are intricately linked with cognitive processes in the attainment of goals and are central to motivation (Bandura 2005, de Ridder & de Wit 2006). The management of emotions plays a major role in determining and directing goal-setting strategies (de Ridder & de Wit 2006). Through the feedback loop system, goal-related outcomes are appraised cyclically and depending on these outcomes, new goals may be developed or previously developed goals revised.

While the literature does not readily explain the rationale for goal-setting, it has been suggested that the motivation to set goals in the first instance relates to the need for survival and a feeling of normality (sense of self) (Carver & Scheier 1996). The presence of ACS symptoms is an example of a goal-setting trigger. In

this situation, the individual may view the illness experience (symptoms) as a threat to their health and therefore, their safety. Consequently, they may adopt a number of strategies to achieve their goal. The success or failure of these strategies is determined through the feedback loop system. If this adopted approach is successful, then the individual's self-belief in their ability to deal with the threat is likely to increase. This self-belief is referred to as self-efficacy and is based on self-confidence (Bandura 1977, de Ridder & de Witt 2006). Self-efficacy is a component of self-regulation and according to Bandura (1977) it is an indicator for motivation to make behavioural change. Its presence strengthens the process of goal-setting and can influence an individual's motivation and behaviour (Bandura 1986, Bandura 1999). Consequently, many self-regulatory models incorporate self-efficacy as a means of understanding or predicting goal focused behaviour (Leventhal *et al*. 1983, Brownlee *et al*. 2000).

Self-regulation therefore incorporates motivation, goal-setting, self-efficacy, cognition and emotion. As this study was focused on an intervention aimed at improving help-seeking behaviour, through improved knowledge, attitudes and beliefs about ACS, a model of self-regulation was considered appropriate. According to the social cognitive theory of self-regulation, individuals develop the capacity to successfully manage their behaviours by proceeding through a series of regulatory skill levels (Zimmerman 2000). Furthermore, self-regulatory models are thought to enhance the effectiveness of interventions designed to change health-related behaviour (Abraham *et al.* 1998).

Leventhal's self-regulatory model of illness behaviour (1980) encompasses these important facets, together with an explicit devotion to the role of coping with emotions in the presence of a health threat (Leventhal *et al.* 1980). It was therefore felt that this could be a suitable framework to underpin the current intervention, as these were important and applicable issues in this study.

3.9 Assessing the suitability of Leventhal's self-regulatory model of illness behaviour

Leventhal's self-regulatory model of illness behaviour is founded on the principles of social cognitive theory. This model is one that provides an explicit link between illness cognitions, coping behaviours and strategies (Leventhal *et al*. 1980, Hagger & Orbell 2003). According to this model mental representations of actual or potential health threats trigger coping procedures for dealing with those threats. Coping strategies are determined by the way the health threat is perceived and goals that are set to deal with them. Responses to the health threat are evaluated through the feedback loop system. The dimensions of the representation are considered in terms of labeling, timeline, causes, consequences and cure (de Ridder & de Wit 2006). In the presence of a health threat, the individual's responses are based on their illness prototypes, together with their coping abilities. Motivation and self-efficacy levels also play a role in responses to symptoms. Therefore, the incorporation of coping in this model and the means by which it is addressed, appraised and re-appraised in the presence of a health threat rendered it suitable as a framework for this study. The rationale for its use was further strengthened through its theoretical foundations.

Leventhal's self-regulatory model of illness behaviour offers a framework that can effectively guide interventions designed to change behaviour and thereby improve appropriate help-seeking behaviour among individuals experiencing ACS symptoms (Leventhal *et al*. 1983, Petrie *et al.* 2002, Meischke *et al*. 2004, Bunde & Martin 2006, Dracup *et al.* 2006). It has been extensively tested and used successfully in previous studies (Zerwic *et al.* 2007, Noureddine *et al.* 2008, Dracup *et al*. 2009, Nymark *et al.* 2009, Farquharson *et al*. 2012, O'Donnell & Moser 2012, Dullaghan *et al.* 2014). In addition, Leventhal's self-regulatory model of illness behaviour has been identified as the framework of choice for the majority of studies that examine responses to ACS symptoms (Baxter & Allmark 2013). Most importantly, previous interventions designed to improve knowledge, attitudes and beliefs about ACS were underpinned predominantly by Leventhal's

self-regulatory model of illness behaviour (Goff *et al.* 2004, Meischke *et al*. 2004, Buckley *et al*. 2007, Tullman *et al*. 2007, McKinley *et al.* 2009).

Despite the strengths of the model, it has been negatively critiqued for its emphasis on perception and rationality. The model focuses on conscious intentional behaviour but does not address the wide-ranging automatic actions that can arise in the face of a health threat. There is an assumption within the model that people actively respond cognitively and emotionally, although not automatically, to a health threat (de Ridder & de Wit 2006). This critique was not considered an obstacle to using this model, as the intended intervention for this study will clearly stipulate the actions to be taken in the face of a health threat.

While Leventhal's self-regulatory model of illness behaviour incorporates theory about coping in the face of a health threat, it has been suggested that it offers little information about how to remain on track during the ongoing maintenance of goals (de Ridder & de Wit 2006). In the context of this study, it was planned that the intervention would be reinforced at intervals following its delivery. Therefore, this deficit could potentially be addressed through the follow-up of participants, thereby enabling them to remain on track.

A further critique of Leventhal's self-regulatory model of illness behaviour, relates to its limited application among culturally and linguistically diverse groups (Murray *et al.* 2000, Sahin-Hodoglugil *et al.* 2003). This did not deter the use of the model in the context of this Irish study. In recent years, Ireland has become increasingly multi-cultured and, to a less extent, more linguistically diverse. However, multi-cultural groups represent a small minority of the total population. Furthermore, by the nature of ACS onset, most of the intended recipients of the intervention in this study would be older than the age of the majority of immigrants to Ireland.

The components of Leventhal's self-regulatory model of illness behaviour and its applicability to the current study rendered it a suitable framework for the intervention. This decision was further justified by its wide adoption in prior research studies. Due consideration was also afforded to the limitations of this model, none of which were viewed to be sufficiently strong to preclude its use in the current context.

3.10 Leventhal's self-regulatory model of illness behaviour

Leventhal's self-regulatory model of illness behaviour (Figure 1) provides a theoretical structure for explaining and understanding an individual's interpretations of and responses to ACS symptoms and how they self-regulate during this process (Zerwic 1998, O'Donnell & Moser 2012, Scott *et al*. 2013). The actions taken are guided by the individuals own 'common-sense' construction of the health threat, which they use to form an illness representation. These are influenced by the individual's knowledge, attitudes and beliefs.

Combinations of internal and environmental factors influence the illness representation. Internal factors include the person's characteristics, such as their demographic attributes, their current knowledge and their past experiences of health and illness, all of which determine their current attitudes and beliefs. Environmental factors refer to the signals, messages and reactions they receive from others such as: family members, the media, physicians, or other people by whom they are influenced. Internal and environmental factors contribute individually and collectively to the individual's ability to cope with a health threat and to the action taken in response to it.

In accordance with the model, the individual undergoes a three-stage adaptation process (1) the cognitive representation of the health threat (2) the development of an action plan or coping strategies and (3) the appraisal stage (Figure 1). Each stage has a cognitive and an emotional component, which exist in parallel to each other. The cognitive system deals with the perceived threat, while the

emotional system manages the emotions aroused by the perceived threat. Responses depend on the individual's cognition, coping and appraisal of the health threat. Illness representations, coping plans and appraisal rules are constructed using episodic memories, which are autobiographical memories of the persons past experience and semantic memories which reflect abstract or conceptual knowledge about concepts (Leventhal & Cameron 1983). Making sense and finding ways to create consistency between conflicting semantic and episodic knowledge about a health threat is a key issue for compliance in the long term.

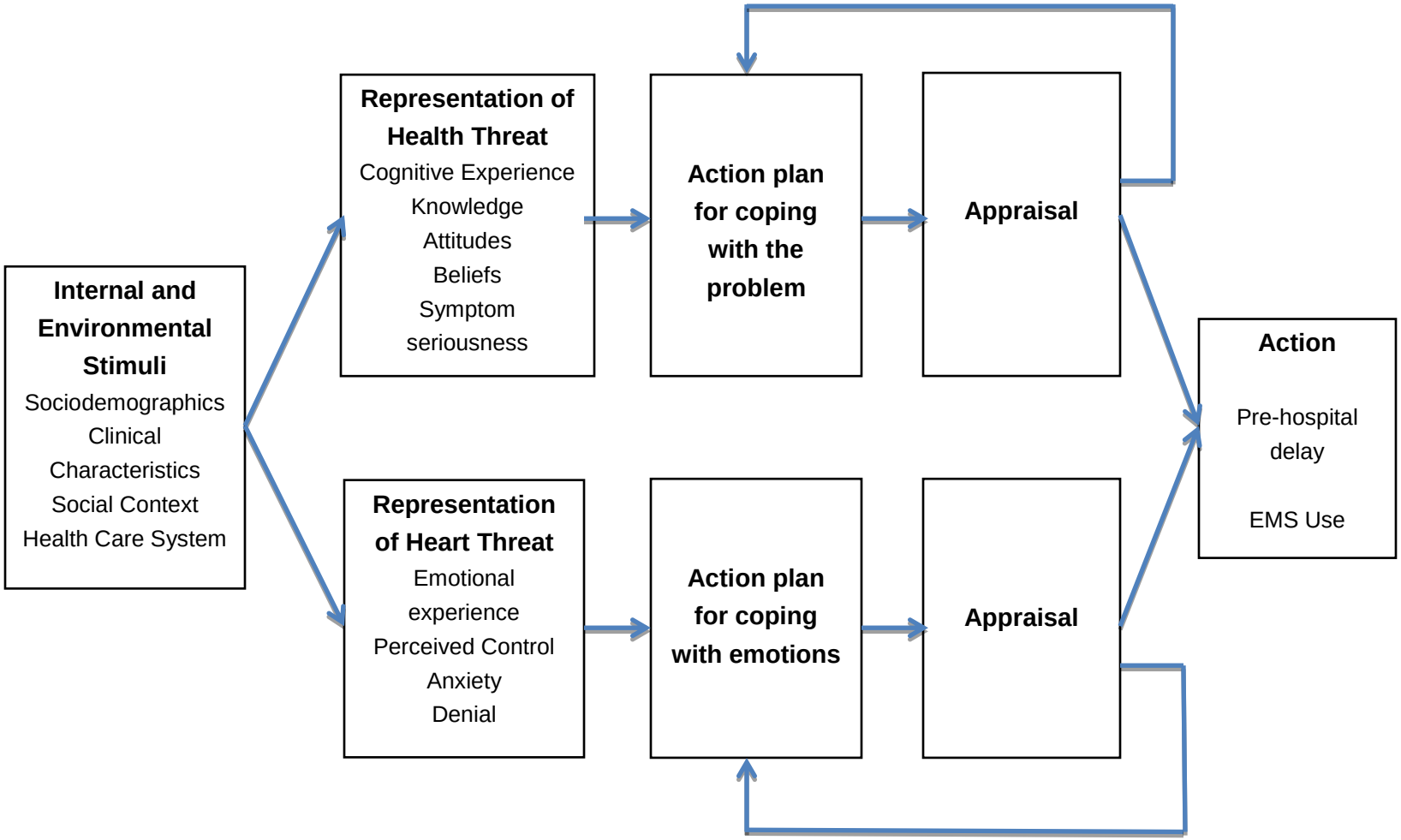

Figure 1: Leventhal's self-regulatory model of illness behaviour

3.10.1 The cognitive representation of the health threat

During the cognitive representation stage, an individual's response to a health threat is determined by their interpretation of that threat (Leventhal & Cameron 1987). This is strongly influenced by their pre-existing knowledge, attitudes and beliefs about the illness representation (Dracup *et al*. 2006). Illness representations are structured around or dependent upon five factors or 'domains', which are labelled as: identity, cause, consequences, timeline and control (Table 2) (Leventhal 1970, Leventhal *et al*. 1983, Leventhal *et al*. 2003, Leventhal *et al*. 2010, O'Donnell & Moser 2012).

Table 2: Five content domains of a health threat

Domain	**Identity/ Label**	**Cause**	**Consequences (expected outcome)**	**Timeline (duration)**	**Control/ Cure**
Representation.	Perceived identity of illness based on symptoms experienced	Based on episodic & semantic memory and opinions from others.	Beliefs regarding how the illness will impact on their lifestyle and well-being.	Perceived chronicity of the illness.	The degree to which the illness can be cured or controlled.

When the individual experiences symptoms, they *label* their health threat according to how they perceive these symptoms and according to the knowledge they have about the illness and its symptoms. Their belief about the perceived *cause* of the health threat is dependent on information retrieved from their episodic or semantic memory of a health threat and their experience of same. It is also influenced by external stimuli such as the opinions of those with whom they engage. The perceived *consequences* of the threat are determined by their sense of vulnerability to the health threat, along with how it might affect them physically, socially and economically (for example, sudden death, loss of work time). The individual's belief with respect to a likely *time-line* or sense of health threat duration is established. This may be determined by the persistent or episodic nature of symptoms. As time progresses, these beliefs are re-evaluated and from this, the potential for the threat to be controlled, cured or

prevented from progressing is assessed (Leventhal 1970, Leventhal *et al*. 1998, O'Donnell & Moser 2012).

From a cognitive perspective, progression through these domains provides the individual with mental schemas of the origin, impact, and potential outcome of the representation. Individuals who during this progression, correctly affiliate their symptoms with their pre-existing illness representation, are more likely to respond appropriately (Figure 2). Equally, a mismatch of symptoms to an illness representation may provide an explanation for individuals who delay in seeking help in response to a health threat (Figure 3) (O'Donnell & Moser 2012, Scott *et al.* 2013). Concurrent with this cognitive response, the individual also has an emotional response to the health threat, both of which can influence each other (Figure 1). Emotions include fear, anxiety, perceived control, embarrassment, and denial. Responses to these emotions can therefore be determined by the individual's cognition. Objectively represented health threats are controlled through cognitively controlled processes, while the subjectively represented health threats are controlled emotionally (Leventhal *et al*. 1984). These inter-related factors may ultimately affect how the individual copes in the next phase of the model (Dracup *et al*. 2003, Moser *et al.* 2007).

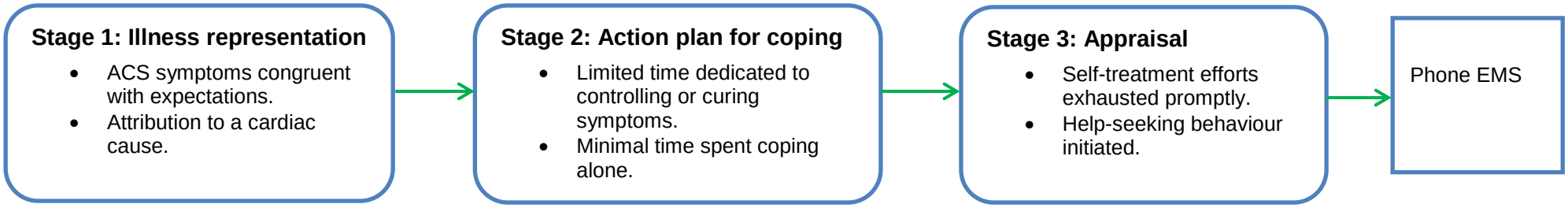

Figure 2: Appropriate appraisal, coping and action

(*adapted from O'Donnell & Moser 2012*)

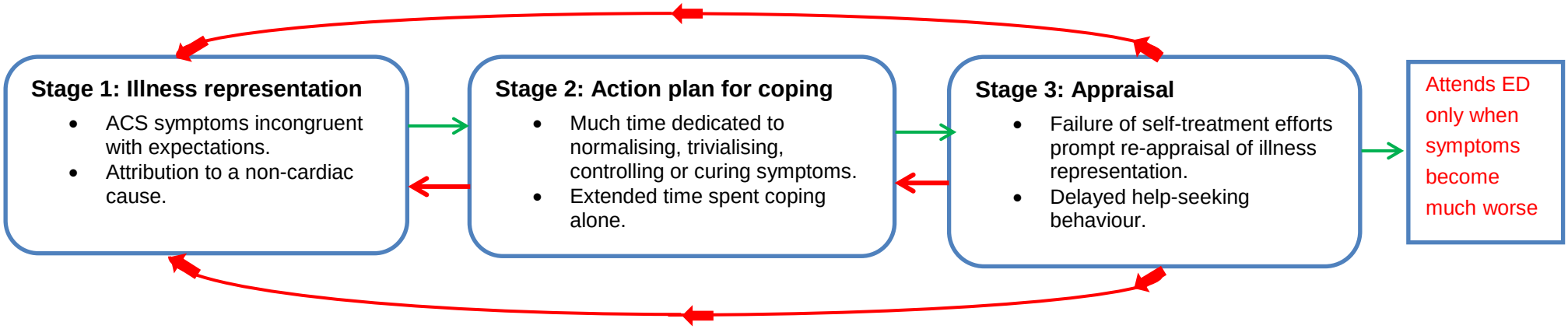

Figure 3: Inappropriate appraisal, coping and action

(*adapted from O'Donnell & Moser 2012*)

3.10.2 The coping/action plan stage

Once an illness representation is made, coping strategies follow at cognitive and emotional levels (Leventhal *et al*. 1980). This is known as the action plan stage, as an action plan for coping with the problem is devised and initiated (Figure 1). Emotional coping strategies may vary from the normalisation or trivialisation of symptoms to the minimisation of factors that inhibit the ability to act or the acknowledgement of symptom denial. The selected coping strategy is determined by the individual's interpretation of the symptoms experienced, the extent to which these are perceived as serious and the emotions experienced during the cognitive phase; all of which are dependent on the individual's knowledge, attitudes and beliefs about the health threat.

If the individual does not perceive their symptoms to be a health threat, then their motivation to engage in any coping action is limited. Similarly, if symptoms are mislabelled to a non-cardiac cause, then coping strategies are less likely to be appropriate. For example, if due to limited knowledge of symptoms, an individual fails to identify his/her symptoms as cardiac-related, but instead attributes them to a non-cardiac cause, such as indigestion, then he or she may take an antacid and spend prolonged time waiting for symptoms to resolve (Figure 3) (Dracup *et al.* 2006). Conversely, someone with appropriate knowledge, attitudes and beliefs about ACS may accurately perceive their symptoms to be cardiac-related and spend limited time controlling or curing symptoms (Figure 2).

3.10.3 The appraisal stage

The appraisal stage is used to evaluate the effectiveness of the action plan. During this time the individual appraises the actions taken and their effectiveness in reducing or eliminating the health threat. A central feature of the model is the feedback loop, whereby the individual can review, reassess and reappraise their progress (Figure 1). This feedback loop system enables the person to gauge the success or not of their coping actions. If insufficient progress has been made, the person may re-evaluate the situation and alter their plan of coping accordingly. This may result in the creation of a new coping

strategy, thus forming a self-regulatory feedback loop (Lau-Walker 2006). Additional plans may be made to cope with and control emotions.

Using Leventhal's self-regulatory model of illness behaviour, it was expected that through the process of self-regulation participants in this study would, in the presence of a health threat, correctly affiliate their symptoms with ACS and acknowledge their seriousness. In addition to this accurate cognition, participants would be cognisant of the need to acknowledge the concurrent emotional response and begin to take control of their emotions. It was endeavoured that, as opposed to spending time controlling or curing their symptoms (Figure 3), the individual would instead seek treatment promptly by telephoning the EMS (Figure 2). Consequently, appropriate help-seeking processes would be initiated through the cognitive, emotional and social domains.

3.11 The choice of intervention

Leventhal's self-regulatory model of illness behaviour was the framework of choice for the current intervention. The literature review provided insight into previously conducted interventions and their strengths and limitations. The target intervention was one that would improve knowledge, attitudes and beliefs about ACS, with a view to reducing pre-hospital delay time in the presence of ACS symptoms. From the literature reviewed, there was one intervention which closely reflected the aim and objectives of this study (McKinley *et al*. 2009). This intervention (McKinley *et al*. 2009) used a multi-site RCT to test an educational intervention that was underpinned by Leventhal's self-regulatory model of illness behaviour (Leventhal 1970, Leventhal *et al.* 1983, Leventhal & Cameron 1987). The intervention was individualised and incorporated motivational interviewing techniques, while addressing the role of emotions in response to a health threat. Their intervention was therefore considered potentially suitable for replication in the current study.

Despite the similarities between the study by McKinley *et al*. (2009) and the current study, it was not automatically assumed that their intervention would be suitable for transfer to the Irish context. Its suitability was considered in light of

the intended research setting. The intervention reported by McKinley *et al.* (2009) was written in the English language, which obviated the need for translation. This was significant, as context or meaning can be lost where translation between languages is required. In addition, the wording, explanations and graphics used in the previously conducted intervention were clear and could be easily understood among the Irish population. Furthermore, the intervention content was based on international research and was delivered using motivational interviewing techniques. In light of this evaluation, a decision was made to seek permission from the original authors (McKinley *et al.* 2009) to replicate their intervention in Ireland and to adopt their research instruments. Permission was granted on both accounts.

The content of the intervention is detailed in Chapter 4. In brief, the intervention comprised a 40-minute individualised, one-to-one education session delivered to patients who were randomised to the intervention group, following admission to an ED with an ACS event. Motivational interviewing principles were used in the delivery of the intervention.

3.12 Motivational interviewing

Motivational interviewing is a specific client-centred counselling style designed to engage ambivalent patients in the process of behavioural change (Miller & Rollnick 2002, Watkins *et al*. 2007, Thompson *et al*. 2011). Given that the aim of the intervention was to improve knowledge, attitudes and beliefs about ACS with a view to reducing pre-hospital delay time, this technique was considered appropriate. As this study and that of McKinley *et al*. (2009) were framed within a self-regulatory model, the use of motivation was paramount. Goal-setting and progress appraisal are determined by the individual's level of motivation. These are components of Leventhal's self-regulatory model of illness behaviour. Since its inception in 1983 various authors have written about motivational interviewing and while there is variation in the terminology used, the underlying principles of motivational interviewing remain unchanged (Miller & Rollnick 2002, Rollnick *et al*. 2008, Dart 2011, Miller & Rollnick 2013).

Four broad guiding principles underlie motivational interviewing techniques. These are expressing empathy, rolling with resistance, developing discrepancy and building self-efficacy (Miller & Rollnick 2002, Levensky *et al.* 2007, Dart 2011). Expressing empathy refers to the ability of the interventionist to understand the participant's perspective and feelings (Miller & Rollnick 2002), through reflective listening (Dart 2011, Thompson *et al*. 2011). This facilitates the participant to feel comfortable sharing their thoughts and experiences (Miller & Rollnick 2013). Central to this core principle is the ability of the interventionist to remain non-judgmental and to expect the participant to be ambivalent about his or her current health status.

The interventionist's ability to help the participant create goals and explore their motivation to change, without telling them what to do or what not to do is referred to as developing discrepancy (Rollnick *et al*. 2008, Dart 2011, Thompson *et al.* 2011). This principle is based on dissonance theory whereby a discrepancy or discomfort occurs when the individual's 'ideal' self is not synonymous with their 'current' self (Festinger 1957). Thus, individuals strive for congruence between their current and ideal self. When there is sufficient discrepancy between the two, a stimulus to learn is evoked and the participant's own motivation to change their behaviour is stimulated in order to achieve a state of congruence.

Rolling with resistance requires the interventionist to suppress their initial desire to oppose the participant's resistance to change and instead explore their motivation for change. This is an important component of self-regulation where the individual sets his/her own goals, which must be respected. This principle is acknowledged as one of the most difficult to accomplish (Dart 2011). For many healthcare professionals, there is a tendency to advise patients about the correct measures to take for good health. As most people resist persuasion when they are ambivalent about change, challenging the participant's negative thoughts will only result in building further resistance. Consequently, rolling with resistance promotes feelings of acceptance and engagement, which are central to the promotion of behavioural change (Dart 2011).

Empowerment is important in supporting self-efficacy. Participants are empowered through an exploration of what has previously worked for them or through the provision of hope that such change is possible (Hohman 2012). Furthermore, participant outcomes improve when they are active collaborators in their plan of care. This is consistent with Leventhal's self-regulatory model of illness behaviour. The provision of positive reinforcement is central to self-efficacy, whereby the participant makes an effort to take an active role in the behavioural change process (Rollnick *et al*. 2008, Dart 2011, Thompson *et al.* 2011). These four principles were applied to the cognitive, emotional and social aspects of the intervention.

3.13 Summary

The aim of this study was to test the effectiveness of an individualised educational intervention on knowledge, attitudes and beliefs about ACS. Set within the positivist paradigm, an RCT research design was selected, as it was considered to be the most appropriate for this study. The methodological considerations associated with RCTs were discussed. These include randomisation, the minimisation of trial bias and an adherence to intervention fidelity. Given that this was a complex intervention designed to change behaviour, a theoretical framework was a pre-requisite. Leventhal's self-regulatory model of illness behaviour was the framework chosen. This decision was based on its successful use in prior research, its unique inclusion of coping in the face of a health threat and its applicability to this study. The selected intervention was a replication of one previously designed and delivered in a multi-site RCT. The means by which the intervention was delivered and the framework applied to it are described in Chapter 4, together with details about how this RCT was conducted.

Chapter 4: Methods

4.1 Introduction

This chapter presents the research methods used to conduct this RCT. It details the content of the educational intervention and the means by which it was delivered in the research sites. As with any parallel design RCT, only the intervention group received the intervention. Therefore, a description of what constitutes usual care is also provided. Detail on research access, sampling, recruitment, data collection and implementation of the trial protocol are presented along with the ethical considerations and data analyses procedures. To maximise the quality, completeness and accuracy of reporting the operationalisation aspects of this study, the CONSORT checklist (Schulz *et al*. 2010) was used.

4.2 The intervention

Participants randomised to the intervention group received the one-to-one, individualised educational intervention after baseline data were collected. Where feasible, a family member or significant other was invited to be present during intervention delivery. In addition to reducing pre-hospital delay time, the intervention aimed at improving participants' (1) knowledge about ACS facts and symptoms (2) attitudes towards symptom recognition and confidence in their own ability to instigate appropriate help-seeking behaviour and (3) beliefs about what constitutes appropriate responses to ACS symptoms. In an effort to achieve this, the content of the intervention addressed informational, emotional and social factors related to ACS. These factors parallel the cognitive, emotional and environmental components of Leventhal's self-regulatory model of illness behaviour. The selected intervention was a replication of one that had been designed and previously delivered in a multi-site RCT (McKinley *et al*. 2009). The exact content of the intervention is presented in Appendix 1.

4.2.1 Selection of interventionists

Interventionists were recruited to assist with the implementation of the trial. Criteria for selection included registration with An Bord Altranais as a general

nurse (RGN), with cardiovascular experience a desirable attribute. Proficiency in the use of a computer and competent organisational skills were also deemed important. During selection interviews, consideration was given to ascertaining whether or not the applicant perceived the intervention and the trial protocol to be credible and consistent with his/her own values. This 'buy in' was considered mandatory to the successful delivery of the intervention. As this was an individualised educational intervention, candidates' interpersonal skills were also appraised.

4.2.2 Training of interventionists

A detailed training schedule was developed to maximise fidelity of operational procedures. Training was provided by a registered general nurse (RGN) who had previously delivered this same intervention in another multi-site RCT and who had also trained other RGN's to deliver the intervention. The trainer produced a compact disc (CD) and a digital videodisc (DVD) demonstrating the expert interventionist delivering the intervention. The CD and DVD were designed to be used in the initial training of the interventionists and for on-going reinforcement during the trial.

Training was provided on patient recruitment, data collection, data management and intervention delivery. An interventionist training manual (Appendix 2) was devised and comprised the trial protocol (Appendix 3), intervention manual (Appendix 1), CD recording of the intervention, along with the lecture notes used during training. Each interventionist was furnished with a copy of the interventionist training manual and instructed to deliver the intervention precisely, according to the manual and the trial protocol. This was a mandatory requirement so that the intervention would be delivered with consistency across the sites. Furthermore, they were advised to listen to the CD recording monthly, at minimum. Following the training sessions, interventionists' skills acquisition levels were evaluated. This was achieved through questioning and role-play.

4.2.3 Intervention delivery

The intervention manual and the trial protocol determined how, where, when and to whom the intervention was delivered. The manual was presented in flipchart form, in a white A4 folder that bore the study name and logo on the

front cover. Using recommended patient educational strategies, the intervention script was presented in the form of large print text with colourful graphics. Each interventionist delivered the intervention content using the pre-established script. This information was pitched at the participant's level of understanding.

To minimise the risk of contamination between the randomised groups, consideration was given to the location that best suited intervention delivery in the hospital. Where possible, the day room was selected, as it afforded most privacy. When circumstances precluded this, the intervention was delivered at the bedside. In these circumstances care was taken to confine intervention delivery to the relevant patient. This was achieved by closing the bedside curtains, sitting close to the participant, without invading their space, and speaking quietly.

The intervention took 40 minutes to deliver; 30 minutes of prescriptive education and 10 minutes of rehearsal of the intervention messages, during which time scenarios were used (Table 3). Intervention delivery time was approximate, as it was dependent on the participant's level of uptake of the intervention. Each interventionist was responsible for documenting and self-reporting their intervention delivery at monthly team meetings. These meetings were attended by the PI of the project and the ACS team. Meetings also provided an opportunity to clarify intervention-related queries and to minimise 'drift' in skills through reinforcing the intervention.

Table 3: Overview of educational intervention

Time	Intervention component	Rationale for inclusion
2 minutes	Introduction to the study.	To engage participants with the intervention and to 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. *Complete action plan*.	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 and close.	To enhance retention of the main educational intervention messages. Give documentation – wallet card, action plan. Arrange one month follow-up. Closure, thank and depart.

4.2.4 Content of the educational intervention

Information/Cognitive

The intervention began with a reminder about the aim and purpose of the study. Consistent with Leventhal's self-regulatory model of illness behaviour, the intervention addressed the cognitive representation of a health threat in an effort to improve participants' knowledge, attitudes and beliefs about ACS. Colourful graphics that illustrated the process of coronary occlusion supported the education with respect to how an MI occurs. Information was provided about how reperfusion therapies restore blood flow to the myocardium and how maximum benefit can be obtained if individuals reach the ED within one hour of symptom onset (also known as 'the golden hour'). Participants were informed that many people miss out on the best possible outcomes because they delay too long before seeking care.

Central to this, information was provided on the range of symptoms that can be experienced during ACS. Typical ACS symptoms such as chest pain, chest tightness and chest discomfort were highlighted together with left arm discomfort and breathlessness. Participants were informed that pain could radiate to the arm, neck or jaw. Less typical symptoms such as sweating, nausea, fatigue and intrascapular discomfort were also emphasised. This information was fundamental to the overall intervention message, as individuals who are unaware of all potential ACS symptoms may fail to recognise these, if they arose. Consequently, they may overlook the requirement for urgent treatment. Participants were also advised that symptom onset may be gradual or intermittent, rather than the classic, stereotypical 'Hollywood heart attack'. Furthermore, they were informed of the possible variability in symptom presentation among different groups, for example, women, older people and those with diabetes. This educational message was tailored to the individual in question.

Participants were reminded of their risk for a recurrent ACS event and how another event may not manifest in the same way as a previous one. In an effort to improve their beliefs about what constitutes appropriate response to ACS symptoms, participants were instructed about the appropriate action to take in the event of symptom recurrence. This included ceasing activity in the presence of symptoms, informing another person about what is happening, self-administering prescribed nitrates and calling 999 or 112 for an ambulance, if symptoms persist beyond 15 minutes. As many people perceive consultation with a GP to be the correct course of action when they experience ACS symptoms, this misperception was clarified.

Emotional issues

Participants were advised about the role of emotions when ACS symptoms are present. It was acknowledged that these emotions could affect their ability to recognise and cope with symptoms, which could ultimately delay their presentation for treatment. To help overcome the threat posed by emotional barriers, participants were assisted with anticipating and recognising their

emotional responses to ACS symptoms. The reference to the role of emotions was consistent with Leventhal's self-regulatory model of illness behaviour.

The discussion centred on the consequences of trivialising or normalising symptoms. The role of emotions such as fear, denial, anxiety and embarrassment were discussed in this context. Participants were also alerted to the fact that symptom attribution to a non-cardiac cause is common and can cause a delay in seeking care. As all participants had experienced a recent ED admission and had recounted their story in advance of the intervention session, their recent ACS experience was incorporated into the intervention message. In addition, negative past experiences were acknowledged and reconciled with the intervention message that the rewards of promptly seeking treatment prevailed all else. Messages were positive (i.e. the preservation of heart muscle and the increased chance of survival), as opposed to negative (i.e. possibility of sudden death). Positive messages are considered potentially more effective (Dracup *et al*. 1997b).

During the final ten minutes of the intervention, emotional issues were further addressed using scenarios and the principles of motivational interviewing. Individualised scenarios that most closely resembled the participant's age, gender and lifestyle were administered. Role play was used to assist participants with anticipating emotions that they might experience in the presence of ACS symptoms. Their responses provided information about their receipt of the intervention and their receptiveness to change. Using reflective statements, the interventionists recounted aspects of the participant's event, which demonstrated reflective listening. At all times, the participant's perspective was acknowledged and where difficulties arose with aspects of the intervention, solutions were sought through seeking an understanding of the participant's knowledge, attitudes and beliefs. Where inaccuracies were identified, participants were guided through the appropriate actions to take. It was considered that this would increase the likelihood of them responding appropriately to a health threat in the future (Leventhal *et al.* 2010). Further scenarios were administered, as required. Positive feedback was provided with respect to those aspects of the intervention that they accurately enacted in the

scenarios and role-play. It was envisaged that this would help to improve their levels of self-efficacy.

It was intended that the rehearsal of responses to the possible recurrence of ACS symptoms would also improve participants' sense of control on a subsequent occasion. The perception of control over an illness equates with self-efficacy and can positively impact on the cognitive and emotional strategies used in symptom appraisal. It was expected that by providing participants with confidence in their ability to act appropriately, their level of anxiety would simultaneously reduce (Moser *et al*. 2009).

Social factors/Environmental stimuli

Participants were requested to identify the person they would most likely call upon for help if they experienced unresolving ACS symptoms. Where feasible, and with the participant's consent, that 'designated' individual was welcomed to attend the intervention. The purpose of their attendance was to develop their appreciation of the significance of ACS symptoms and the associated help-seeking phenomena (Leventhal *et al.* 2010). Participants were advised that if they experienced unresolving symptoms, they should consult immediately with this designated individual. This person would act as the external stimulus in encouraging the participant to use the steps recommended in the intervention. It was endeavoured that the use of scenarios would assist the designated individual in dealing with the emotions involved in witnessing a possible ACS event and enhance the likelihood that they would respond appropriately in the future.

Consistent with Leventhal's self-regulatory model of illness behaviour, an individualised action plan (Appendix 1) was provided for each participant to take home. This action plan delineated the symptoms of ACS and the actions the participant should take in their presence. Other specific details such as the name and phone number of the person they would call if symptoms occurred were also recorded on the action plan. Participants were asked to place the action plan in a prominent position in their home. A refrigerator magnet bearing the study name and logo was also given, with which to secure the action plan to

their refrigerator. The action plan was printed on pink paper so that it could be easily located if the participant chose to store it elsewhere. A wallet card with the main intervention messages was also given to each participant (Appendix 1).

4.2.5. Following the intervention

Following delivery of the intervention, the main information messages were summarised. Participants were thanked for their participation in the study and a potentially suitable date and time for follow-up was arranged. Participants were also reminded of the next steps in the data collection process, which was the completion of the 3 and 12 month questionnaires. The interview was closed with a final expression of gratitude.

Intervention group only

Participants from the intervention group were telephoned one month after the intervention was delivered, to reinforce the main points from the intervention (Appendix 4). This also served as an opportunity to assess participants' comprehension and internalisation of the intervention. Six months following the intervention, a letter was posted to participants together with a copy of the action plan (Appendix 5).

4.3 Usual care for both groups

Participants in both groups received usual in-hospital care. Prior to undertaking this study, time was dedicated to ascertaining what constituted 'usual care' in each research site, with respect to pre-discharge education for ACS patients. There was an element of variability within and across research sites. This variability depended on whether patients were discharged from the ward or the coronary care unit. Regardless of discharge location, information was primarily delivered by the nurse. Depending on the patient's diagnosis, additional information was provided by the cardiac rehabilitation (CR) nurse and/or the designated percutaneous coronary intervention (PCI) nurse.

Usual pre-discharge education always included information on typical ACS symptoms, while atypical symptoms were frequently but not always addressed. Information was also provided about the patient's presenting diagnosis and its

associated management. Booklets, pamphlets and leaflets were made widely available to patients and contained information on specific conditions, risk factor management, resumption of daily activities and medications. Written information was supplemented with verbal information. With respect to medication information, patients were given detailed education about nitrate use. This included its effects, side effects, benefits and uses. Advice was more focused on nitrates than on any other medication, although information on a range of medications was provided.

The educational intervention provided in this study differed from usual care with respect to the content and delivery of the education provided. With respect to cognitive factors, the intervention provided detailed descriptions of the range and variability of ACS symptoms and the impact that pre-hospital delay can have on the treatments available. This concept of timeliness, which was referred to as the golden hour in the intervention, was not described as part of usual care. The role of emotions was not referred to in the descriptions of what constituted usual care from the research sites. The only reference to social factors was the advice to tell somebody if symptoms were persistent. The emphasis in usual care was primarily focused on cognitive factors. The intervention message differed from this in that it incorporated cognitive, emotional and social factors. Furthermore, in the descriptions of usual care, there was no reference to individualising patient education or to assessing the extent to which information was absorbed. These aspects were addressed within the intervention through role play and scenario provision.

4.4 Research setting and sample

4.4.1 The research sites and gaining patient access

The research sites were selected because they had EDs and coronary care units (CCUs), which catered for patients with ACS. Following informal discussions, an information letter and a copy of the research proposal was sent to the directors of nursing and one consultant cardiologist in each of the five Major Academic Teaching Hospitals in Dublin (MATHs). Access was granted to all sites, subject to ethical approval. One part-time research nurse/ interventionist was assigned to each research site. This individual was

responsible for patient recruitment, delivery of the intervention and the follow-up of participants within his/her own research site.

4.4.2 Preparing the clinical staff

In preparation for commencement of the trial, information meetings were held with the clinical nurse managers and nursing staff at each research site. Gatekeepers were identified from the CCUs and cardiology wards, as this is where recruitment took place. An overview of the study was presented along with a detailed description of the role of the gatekeeper in screening patients for eligibility. Within each site, protocols for access to patients and case notes were devised and agreed with the gatekeeper. Gatekeepers were reassured that patient care would not be compromised because of the study. Time was invested in briefing staff about the purpose of the study and the significance of their input in making it possible.

4.4.3 The study sample

The population of interest for this study was all patients admitted through the EDs of the research sites with a provisional diagnosis of ACS, as detailed in their medical notes. Patients were recruited to the study using purposive sampling and were selected based on stringent inclusion and exclusion criteria, which were determined *a priori*. This information was imparted to the gatekeepers, who provided initial screening for patient eligibility. The gatekeepers compiled a list of interested and eligible patients, which they gave to the interventionists daily. This process helped to minimise selection bias, as the interventionist had no control over the names provided by the gatekeeper.

Inclusion and exclusion criteria

Patients were considered eligible for the study if they:

- had a provisional diagnosis of ACS,
- were stable and planning for discharge,
- could read, understand and converse in English,
- had a telephone and were willing to participate in the study.

Patients were excluded from participation in the study if they:

- resided in an institutional setting,
- had serious complicating co-morbidities,
- had a profound learning disability,
- had a major or uncorrected hearing loss,
- had an untreated malignancy or neurological disorder that impaired cognition.

Rationale for inclusion and exclusion criteria

A good command of the English language was required so that participants could understand the intervention, complete the questionnaires at the various study time-points (baseline, 3 and 12 months) and to strengthen the likelihood that true consent to participate in the study was obtained. As participants in the intervention group were telephoned one month after the intervention, it was necessary that they had a telephone and no major hearing impairment.

Patients were excluded from the study if they had a profound learning disability or a neurological disorder that impaired cognition, as these conditions would have inhibited their understanding of the intervention. In an effort to reduce participant burden, those with untreated malignancies or complicating co-morbidities were excluded from the trial. Those residing in institutional settings were also excluded, as they would not have the primary decision-making authority about when and how to seek medical assistance if they experienced ACS symptoms.

4.4.4 Sample size

When conducting and evaluating quantitative research, it is important that the sample size is adequate to test the research hypothesis (Devane *et al.* 2004, Burns & Grove 2010). Consistent with the CONSORT statement (Schulz *et al.* 2010), the means by which a sample size is determined must be made explicit. With respect to this study, the sample size was initially calculated for the ACS Response Time Intervention Trial, of which knowledge, attitudes and beliefs is a component. In order to determine if the sample size was adequately powered to test the hypotheses in this study, G* Power 3.1 (Faul *et al.* 2009) was used. In

addition, previously published data on knowledge, attitudes and beliefs (McKinley *et al.* 2009) were used to calculate the anticipated difference between the groups (effect size).

Using data from McKinley *et al.* (2009), mean knowledge scores for the control and intervention groups were 69.77 and 72.46 respectively, with a mean standard deviation of 11.95 for the control group. This represented an effect size of 0.225. Given this effect size, an alpha of 0.05 and assuming the use of repeated measures ANOVA using 2 groups (control and intervention) and 3 repetitions (baseline, 3 months & 12 months), it was estimated that a sample size of 174 was required to achieve sufficient power (1-beta) to show a significant difference, if one truly existed (95% power).

Using data from McKinley *et al.* (2009), mean attitude scores for the control and intervention groups were 14.65 and 15.04 respectively, with a mean standard deviation of 2.51 for the control group. This represented an effect size of 0.155. Given this effect size, an alpha of 0.05 and assuming the use of repeated measures ANOVA using 2 groups (control and intervention) and 3 repetitions (baseline, 3 months & 12 months), it was estimated that a sample size of 364 was required to achieve sufficient power (1-beta) to show a significant difference, if one truly existed (95% power).

Using data from McKinley *et al.* (2009), mean belief scores for the control and intervention groups were 23.08 and 23.47 respectively, with a mean standard deviation of 3.39 for the control group. This represented an effect size of 0.115. Given this effect size, an alpha of 0.05 and assuming the use of repeated measures ANOVA using 2 groups (control and intervention) and 3 repetitions (baseline, 3 months & 12 months), it was estimated that a sample size of 658 was required to achieve sufficient power (1-beta) to show a significant difference, if one truly existed (95% power). Therefore, the sample size required to test the three study hypotheses was 658.

4.5 The research instruments

The research instruments used in this study were adopted from Dracup *et al.* (2006) and McKinley *et al*. (2009). The primary instrument, the ACS Response Index, was used to measure the study outcomes (Appendix 6). This was preceded by a clinical history and socio-demographic questionnaire, which was used to characterise the sample. The ACS Response index was specifically developed to measure knowledge, attitudes and beliefs about ACS and responses to symptoms (Dracup *et al*. 2006, Riegel *et al*. 2007). Furthermore, it measures cognitive, emotional and social factors, which are consistent with Leventhal's self-regulatory model of illness behaviour (Dracup *et al.* 2006, Leventhal 1970).

4.5.1 Clinical history and socio-demographic questionnaire

The purpose of this 27-item questionnaire was to describe the sample with respect to the following categorical information: gender, age, ethnicity, education level, marital status, employment and financial status along with level of health insurance and number of dependents. Data were obtained on participant's previous cardiac history, co-morbidities, cardiac risk factors, weight, height, level of physical activity and intention to attend a cardiac rehabilitation programme (Appendix 6). Information was derived from the participant and the medical notes and was recorded by the interventionist. As the questionnaire contained commonly recorded, factual, demographic information, it was not open to varied interpretation. However, it was reviewed for readability by two independent lay individuals who had no medical background, and the content was deemed appropriate.

4.5.2 The ACS Response Index

The ACS Response Index is comprised of two sections (Appendix 6):

I. *Knowledge, Attitudes and Beliefs about ACS.*
II. *Response Time Questionnaire.*

For the purpose of this study, only the first section of the ACS Response Index was used. This section is entitled baseline questionnaire and it assessed knowledge, attitudes and beliefs about ACS. The second section of the ACS

Response Index measured responses to ACS symptoms and was used in the measurement of the pre-hospital delay time aspect of the ACS Response Time Intervention Trial.

Knowledge, attitudes and beliefs about ACS

The ACS Response Index was originally devised in the United States. In light of this, a minor amendment was made to one question, to contextualise it to the Irish setting. This amendment related to the following: "Heart disease is the most common cause of death in women in the United States" was changed to: "Heart disease is the most common cause of death in women in Ireland". The questionnaire was administered at baseline (prior to randomisation) and again at 3 and 12 months following randomisation. Knowledge, attitudes and beliefs were divided into three subscales, all of which were scored separately. Responses correctly answered were awarded one point on the database, whereas incorrect responses were awarded a score of zero. Consistent with this, decoy symptoms were reverse coded. The questionnaire measured cognitive and emotional aspects of ACS symptom presentation. The results yielded at the various time-points were indicative of participants' uptake of the intervention across these domains (Leventhal *et al.* 1983).

Knowledge about ACS facts and symptoms

Knowledge was measured on a dichotomous scale by items 1 and 2 of the baseline questionnaire (Appendix 6). Using a 'true' or 'false' option, participants were asked to respond to five questions about ACS facts. For example, "Hospitals have treatments that reduce the damage done when a heart attack *occurs"*, true or false? This was followed by a list of 21 pre-defined ACS symptoms (e.g. shortness of breath), from which participants were asked to correctly identify those symptoms that they would associate with a heart attack, using a 'yes' or 'no' option. Six decoy symptoms (e.g. arm paralysis) were included to account for the possibility that persons would answer 'yes' to all items. Knowledge scores were calculated by adding up the number of correct responses. The total combined knowledge score could range from 0 to 26 (5 facts and 21 symptoms). The higher the score obtained, the higher the

knowledge about ACS. For ease of comparison with other studies, the score was converted to a percentage.

Attitudes about seeking assistance in the presence of ACS symptoms

Attitudes were measured using a four-point Likert-type scale by items 3.1-3.5 in the baseline questionnaire (Appendix 6). It comprised of five items which measured participants' attitudes towards symptom recognition and confidence in their ability to instigate appropriate help-seeking behaviour in themselves or others, if ACS was suspected. The Likert scale responses of 'not at all' 'little sure' 'pretty sure' or 'very sure' were recoded with assigned numerical values ranging from 1 to 4. Scores were added together to form an attitudinal composite scale. Potential scores ranged from 5 to 20. The higher the score, the better the participant's attitude towards recognising ACS symptoms and initiating appropriate help-seeing behaviour in themselves or others. The attitude score was reflective of the participant's level of self-efficacy, which is a component of self-regulation.

Beliefs about appropriate responses to ACS symptoms

Beliefs were also measured using a four-point Likert-type scale by items 4.1-4.9 of the baseline questionnaire (Appendix 6). The beliefs scale had nine items that recorded participants' beliefs about appropriate responses to ACS symptoms, such as getting to the hospital as soon as possible in the presence of unresolved chest pain, not being embarrassed to go to hospital if a heart attack was suspected and using an ambulance to get to the ED. The Likert scale responses of 'strongly agree' 'agree' 'disagree' and 'strongly disagree' were recoded with assigned numerical values, ranging from 1 to 4. The scores were added together to form a combined belief scale. The potential range of scores on the belief questionnaire was between 9 and 36. A high score indicated more accurate beliefs with respect to the appropriate responses to take in the event of ACS symptoms arising.

4.6 Validity and reliability of the ACS Response Index

The validity of an instrument refers to the degree to which it measures what it is intended to measure (Gerrish & Lacey 2010, Polit & Beck 2010), whereas

reliability denotes the consistency of those measures (Grove *et al.* 2013). With respect to data collection instruments, these issues must be addressed as they are fundamental to the evaluation, quality and accuracy of trial outcomes (Polit & Beck 2010).

4.6.1 Validity

The validity of the ACS Response Index was established by Riegel *et al*. (2007). These researchers (Riegel *et al*. 2007), used a panel of five nurse experts to establish content validity, while construct validity was established using exploratory factor analysis. Discriminant validity was then assessed. In addition, the ACS Response Index has been widely used in other studies that measured knowledge, attitudes and beliefs about ACS and is therefore well validated (Buckley *et al.* 2007, Dracup *et al*. 2009, McKinley *et al*. 2009). In the context of this trial, issues of face and content validity were considered.

Face validity refers to the extent to which the questionnaire appears to be valid through the eyes of the researcher or another person, normally the participant (Lobiondo-Wood & Haber 2006, Grove *et al*. 2013). Determining face validity of a questionnaire is important, as its suitability is related to its utility (Bannigan & Watson 2009). In this study, face validity was determined through the administration of the questionnaire to four lay individuals who were over 65 years of age. Each person readily identified with the questionnaire content and the rationale for using it.

Content validity refers to the scope of the research instrument and requires that the instrument contains sufficient and appropriate items to adequately measure the area of interest (Wodarski & Hopson 2012, Watson 2013). For this trial, a panel of four experts judged the ACS Response Index for content validity. One of these was an academic with a background in cardiology. The remaining three were registered general nurses; one was an advanced nurse practitioner in cardiology while two were coronary care nurses. The experts were asked to evaluate the clarity and relevance of the questions and to consider whether they adequately addressed the phenomena of interest. As the questionnaire originated in the United States, they were also asked to comment on the

language contained in the questionnaire and its adequacy for the Irish context. While the content validity index is often used to establish content validity, judgment by an expert panel is also acceptable (Polit & Beck 2008). In this study, content validity was based on feedback from the panel of experts. The panel considered the research instrument to be understandable and highly relevant.

4.6.2 Reliability

The ACS Response Index has been established internationally as a reliable instrument (Riegel *et al*. 2007) and has been successfully used in studies measuring knowledge, attitudes and beliefs about ACS (Buckley *et al.* 2007, Dracup *et al.* 2008, McKinley *et al*. 2009). Internal consistency is one means by which reliability can be established. It examines the extent to which the items in a scale consistently measure the same characteristics (Polit & Beck 2008, Gerrish & Lacey 2010, Watson 2013). The most commonly used statistical method for assessing this is Cronbach's coefficient alpha (Polit 2010, Field 2011, Watson 2013). Values range from 0 to 1, with higher levels indicating greater reliability (Watson 2013). A coefficient of 0.7 is considered to be an adequate measure of reliability, although measures of 0.8 or greater are preferable (Polit & Beck 2008, Watson 2013). With respect to the ACS Response Index, Riegel *et al.* (2007) reported internal consistency reliability coefficient alphas of 0.82 for knowledge, 0.71 for attitudes and 0.74 for beliefs. Meanwhile Buckley *et al*. (2007) reported internal consistency reliability coefficient alphas of 0.65, 0.77 and 0.71 for attitudes and 0.55, 0.64 and 0.60 for beliefs at baseline, 3 months and 12 months respectively.

In this study, reliability of the ACS Response Index was determined by calculating Cronbach's alphas (α) of all three subscales. Measurements specific to this study were: 0.85 (knowledge), 0.65 (attitudes) and 0.63 (beliefs). Therefore, the knowledge scale indicated a high level of reliability, while the attitude and belief scales indicated moderate levels of reliability (Polit & Beck 2010). Although attitude and belief values were not as high as desired, this may be due to the fact that Cronbach's alpha values are sensitive to the number of items on a scale. With scales of less than 10 items, it is common to find

Cronbach's alpha values to be lower than anticipated (Pallant 2010). This was the case in this study, where the number of items on the attitude and belief scales was 5 and 9 respectively. With respect to inter-rater reliability, this was established through role play during interventionist training.

4.7 Pilot Study

The benefits of undertaking a pilot study are numerous and its use is endorsed in intervention research (Grove *et al*. 2013). The first two weeks of this RCT were dedicated to the pilot study and during this time, 34 patients were recruited across the five research sites. The pilot study permitted testing the research instruments for ease of administration, the time taken to do so and the comprehensibility and appropriateness of their use in a patient with ACS (Gerrish & Lacey 2010, Grove *et al.* 2013). It provided an opportunity to assess and subsequently refine operational procedures, such as recruitment and intervention delivery (Polit & Beck 2008). Finally, potential pitfalls of the study were identified (Polit & Beck 2008, Grove *et al*. 2013).

Results of the pilot study showed that there were no reports of lack of clarity with respect to the questionnaires or other written documentation, such as the participant information sheet. Data collection took approximately 30 minutes to complete for each participant. While the administration process was relatively straightforward, this was somewhat longer than originally anticipated. The duration was dependent on the participant's personality and their desire to engage in discourse.

The pilot study highlighted the potential for a number of patients to be lost to recruitment. This was due to a 24-hour consideration period, which was obligatory before consent could be obtained and data collected. This meant that patients who expressed an interest in participating could not have their data collected until 24 hours later. These patients, who were available at the initial briefing about the study, were often unavailable 24 hours later. Their unavailability was related to interventions (such as angiogram or angioplasty), discharge from hospital or transfer to another hospital. Patients frequently requested permission to complete the questionnaire at the time of information

giving, instead of 24 hours later. However, this was not possible as ethical approval had not been sought for this at the time of the pilot study.

Each interventionist invested a significant amount of time developing relationships and communicating with nursing, medical and administrative staff. Gerrish & Lacey (2010) emphasise the importance of building a rapport with all staff, particularly the gatekeeper, whose support is fundamental to the smooth running of the study. Much time was spent discussing and resolving any queries with respect to the gatekeepers role in screening patients for eligibility, the provision of information and ascertaining patient interest in the RCT. Overall no major issues emerged and by the end of the fortnight, staff in all research sites appeared to positively embrace the study and the presence of the interventionist in their environment.

On completion of the pilot study, the ACS team met to discuss and evaluate all aspects of the trial. There was consensus among the five interventionists that a change to the 24-hour consent consideration period was warranted. A decision was made to re-apply to each ethics committee requesting, with rationale, a change to the consent protocol. Ethical approval for this amendment was granted and the change was implemented from January 2008. This change meant that informed consent could be obtained at the time of recruitment. As there were no changes to the questionnaires or delivery of the intervention, data collected during the pilot study were included in the final analyses.

4.8 Trial protocol

4.8.1 Patient recruitment

Patient recruitment to the study took place between November 2007 and October 2009 in the coronary care units and cardiology wards of the participating sites. A flow diagram of patient recruitment and follow-up is presented in Figure 4. Gatekeepers provided the interventionists with a list of potentially interested patients. These patients were subsequently approached and their eligibility and interest in hearing more information about the study was verified. This usually occurred within 2 to 4 days of the patient's admission. Verbal and written information was provided and all questions were answered. If

the patient was willing to proceed with the study, informed consent was obtained and the participant was provided with a copy of the consent form. The CONSORT checklist (Schulz *et al.* 2010) for this study can be located in Appendix 7.

Randomisation

A computerised random number generator was used to randomly allocate 250 participants to the control group and 250 to the intervention group in each research site. Using block randomisation, each random sequence was further sub-divided into blocks of 20. Within each block of 20, there were 10 participants assigned to the intervention group and 10 to the control group. While the numbers were generated sequentially, the allocations of intervention and control assignments were totally random.

Concealment of group allocation

Sequentially-numbered, opaque, sealed envelopes were used as the means of group concealment. The study number was visible through a window in the envelope, but the allocation to the intervention or control group was concealed. Thus, there was no way of knowing the group allocation associated with the random number. Pre-prepared envelopes were filed in numerical order from 1-500, ready for allocation. As patients were recruited to the study, they were automatically given the next number in the sequence. This process further precluded the potential for selection bias as the group to which the patient was randomised was never revealed to the interventionist or the participant until informed consent was obtained and baseline data collected.

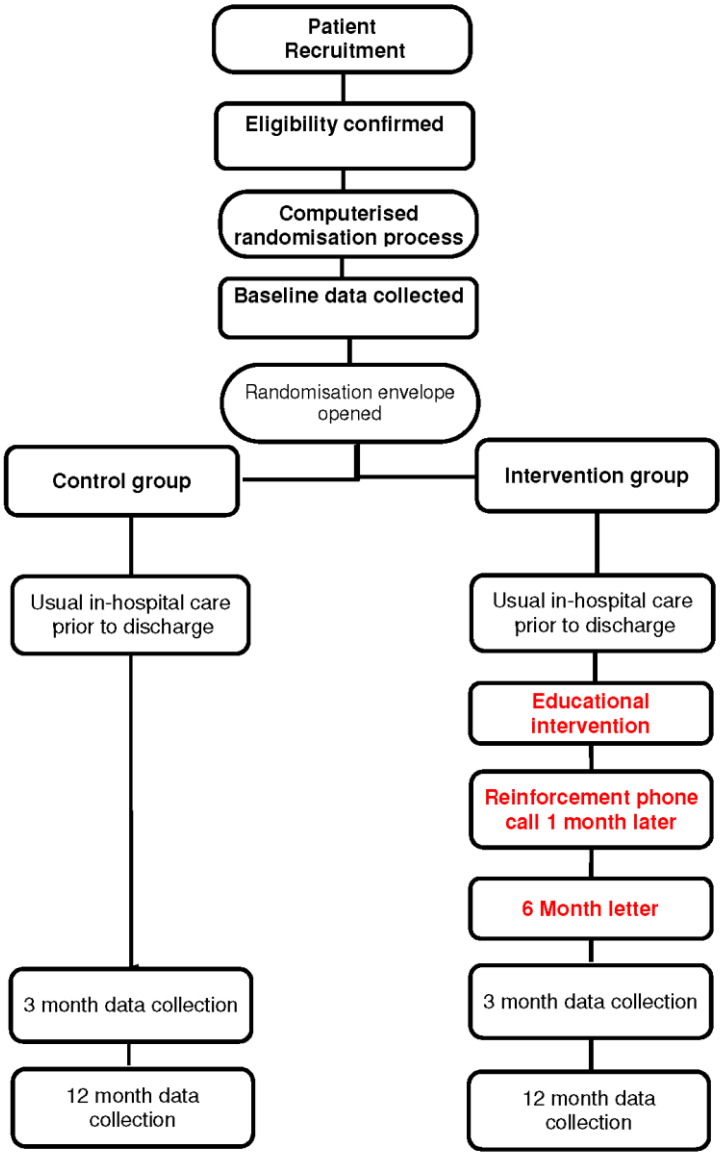

Figure 4: Flow diagram of patient recruitment and follow-up

Blinding

Due to the educational nature of the intervention, it was not possible for the interventionist or participant to be blinded to the randomised group. Furthermore, the interventionist was responsible for reinforcing the intervention at one and six months. Therefore, knowledge of randomised group was necessary for intervention delivery.

Blinding was executed in the collection of 3 and 12 month outcome data as postal questionnaires were identified by study number only and contained no identifiable reference to group allocation. In addition, these questionnaires measured objective data. Clinical staff were not made aware of participant group allocation, which avoided any temptation by them to provide additional information to the control group, beyond that of usual care. These measures maximised the use of blinding in this study.

4.8.2 Baseline data collection

Baseline data collection preceded the revelation of group allocation. Data were collected through face-to-face interviews, using pen and paper. When participants were comfortable and happy to begin, each question was read aloud and time was given for them to follow what was being read on the identical copy they had been provided with. Participants were instructed to choose the responses that most closely reflected their opinion. Their selected responses were then recorded on the questionnaire on which their study number was written. If the participant demonstrated any ambiguity in their understanding of a question, the question was re-read for clarification. On completion of the interview, demographic and clinical information were checked against their medical notes and inconsistencies were reconciled with the participant.

Participants who were randomised to the control group were thanked for their participation and reminded of the next steps in the data collection process, which was the completion of the 3 and 12 month questionnaires. A refrigerator magnet with the study logo and name was provided to remind them of the study. The interview was closed with a final expression of gratitude.

4.8.3 Follow-up

Knowledge, attitudes and beliefs were measured at 3 and 12 months after recruitment. The baseline questionnaire was again administered at these time-points, but it was labelled according to the relevant time-point (3 month or 12 month) (Appendix 6). Questionnaires were posted to participants in both groups. Those who had not returned their questionnaire within two weeks of distribution were telephoned to check if they had received it. During the call, their interest in remaining in the study was ascertained and on-going consent confirmed. Participants often requested that the questionnaire be resent to them, if they had mislaid or forgotten to complete it. Occasionally participants requested that the questionnaire be completed over the telephone. These requests were upheld. On receipt of completed questionnaires, participants were telephoned to thank them for their on-going assistance and to advise them of the next step in the data collection process.

4.8.4 Methods of minimising attrition bias

Strategies were employed to minimise attrition bias in this study. These involved efforts to minimise the extent of missing data through maximising the number of returned completed questionnaires. Attempts to limit attrition bias were made through the inclusion of a stamped addressed envelope and a return address on the back of each envelope. This helped to ensure that undelivered questionnaires could be returned to the interventionist. In addition, a personalised message was written on each standardised letter that was sent to participants at 3 and 12 months. Personalised notes included for example, good wishes sent to a new grandchild or a get-well message to a participant's ill spouse. This helped to increase the likelihood that participants would return their completed questionnaires through the maintenance of a good rapport. The follow-up courtesy telephone call provided an opportunity to rectify any missing data that were noted on returned questionnaires. These approaches helped to minimise the extent of missing data. Strategies were consistent across randomised groups.

Per protocol analysis

A decision was made *a priori* to employ a per protocol analysis (PPA) to address missing data. Therefore, only participants who completed questionnaires at all three time-points and who had no missing data were included in the analyses. Specific details of participants who were lost to follow-up and the rationale for same are provided in the CONSORT flow diagram in Chapter 5.

4.9 Ethical considerations

The importance of conducting research 'ethically' is recognised internationally as an essential component of all research (Fry & Johnstone 2008, Macfarlane 2009). This study conformed to the international ethical standards of the Nuremberg Code (1949), the Belmont Report (The National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research 1979) and the Declaration of Helsinki (World Medical Association 2004). In addition, as this was a nursing-based study, the ethical research guidelines of the nursing regulatory body (An Bord Altranais 2007) were adhered to. Ethical approval to conduct this study was sought and obtained from the ethics committees at the five research sites (Appendix 8). The following section discusses how the ethical principles of Respect, Beneficence (including non-maleficence) and Justice were upheld throughout this study.

4.9.1 The principle of respect

Autonomy and self-determination

The principle of respect for persons encompasses the right to autonomy, the right to self-determination and the right to full-disclosure, all of which are the fundamental building blocks on which informed consent is based (An Bord Altranais 2007, Polit & Beck 20010, Dooley & McCarthy 2011). Autonomy and self-determination refer to the recognition by the researcher that the person has the right to freely choose if they wish to participate in the study (Polit & Beck 2010). To uphold the right to autonomy, patients were initially approached and briefed about the study by a gatekeeper, who ascertained their interest in participating. It was explicitly stated that non-participation would have no impact on their nursing or medical care and that involvement in the study was not a component of their in-hospital care. In an effort to enhance their autonomy and

self-determination, patients were made aware that the interventionist was not employed by the research site. This helped to address any ethical concerns with respect to coercion.

Informed consent

Full disclosure is a pre-requisite to autonomy, self-determination and obtaining informed consent. In order to be considered valid, informed consent must incorporate full disclosure (Holm & Madsen 2009, Scott 2013) and the participant must demonstrate comprehension of the information received (Burns & Grove 2011, Scott 2013). To facilitate full-disclosure, those who expressed an interest in the study were provided with clear, unambiguous, verbal and written information about the study (Appendix 9). When designing participant documentation such as the participant information sheet and consent form, consideration was given to the content, font, layout, length, and accuracy of each item. In addition, the documents were tested for readability against current Irish adult literacy guidelines and Flesch readability statistics. Amendments were made to each draft and on repeat testing the scores were deemed appropriate at 64.9 (Flesch Reading Ease score) and 8.5 (Flesch-Kincaid Grade level).

The provision of clear information enabled participants to make an informed and considered judgment about whether or not to participate in the study. The voluntary nature of participation was emphasised, as was the freedom to withdraw from the study at any time, without explanation or consequence. Informed consent (Appendix 10) was only obtained when it was clear that the information about the study was understood.

Consent should be viewed as a process as opposed to an outcome (Jadad & Enkin 2007), as was the case in this study. Participants' receptiveness to the one month telephone call and the return of the 3 and 12 month questionnaires were taken as on-going consent. When participants failed to return a questionnaire, they were contacted by telephone and on-going consent was checked verbally. A maximum of two telephone messages were left for each

participant with whom verbal contact could not be made and the questionnaires were resent on one occasion only.

4.9.2 The principles of beneficence and non-maleficence

The ethical principle of beneficence mandates that researchers have an obligation to do good for others, while preventing or minimising risk or harm (non-maleficence) (Fry & Johnstone 2008, Polit & Beck 2010, Purtilo & Doherty 2011, Scott 2013). There was an expectation that the educational intervention would improve knowledge, attitudes and beliefs among ACS patients in the intervention group. This had the potential to reduce their pre-hospital delay time and associated mortality and morbidity. However, this benefit was not guaranteed. If the intervention was unsuccessful, those in the intervention group were not going to be harmed in any way by the information they received, as participants from both groups received 'usual' in-hospital care. While the control group were not expected to benefit from participation, their involvement in the study posed no threat or harm to them.

In the study, any participant who appeared tired, stressed or upset was given the opportunity to postpone or cancel data collection. This was underpinned by the recommendation that from an ethical perspective, researchers should take cognisance of the psychological and physical comfort of patients and where necessary, reschedule data collection (Fitzsimons & Strachan 2012). Furthermore, care delivery and visitors were given priority over the needs of the study. This often meant returning to a participant a second or a third time to complete data collection. In some cases, it resulted in the patient not being included in the study, despite the fact that theoretically they fulfilled the study eligibility criteria. Non-maleficence was addressed using these measures.

4.9.3 The principle of justice

The principle of justice requires that participants are selected fairly, so that the burdens and benefits of the research are distributed fairly (Smith Iltis 2006, Macfarlane 2009). Much debate has ensued over the years with respect to the ethics of RCTs and how randomisation deprives half the study population of a potentially better treatment (Freedman *et al.* 1987). Consistent with ethical

guidelines, randomisation in this study was computer generated, therefore all participants had an equal chance of being assigned to either group.

Equipoise is the ethical requirement that the researcher is genuinely uncertain as to whether one treatment is better than the other (Smith Iltis 2006, Gerrish & Lacey 2010, Scott 2013). Within this study there was an expectation that the intervention would improve knowledge, attitudes and beliefs and reduce pre-hospital delay time for participants in the intervention group. However, there was genuine uncertainty as to whether this would happen, as most previous interventions that aimed to reduce pre-hospital delay time were unsuccessful. Thus equipoise was established in this RCT. It has been suggested that where clinical equipoise exists, there is no ethical concern with respect to randomisation (Freedman *et al*. 1987, Lilford 2003).

For ethical reasons control groups are rarely used in nursing research (Burns & Grove 2013). This was not a concern in this study, as both groups received usual in-hospital care. The educational intervention provided additional information, delivered by an individual (interventionist) who was not employed by the hospital. The control group was therefore not deprived of any care that would normally be provided outside the study. Furthermore, all participants in the control group were informed that if, on completion of the study, they wished to avail of the intervention, they could do so.

Protection of privacy and confidentiality

Justice was also upheld through the protection of participant privacy and confidentiality. Meticulous attention was paid to the handling of paper and electronic records. Data were collected and stored in keeping with the Data Protection Act (Government of Ireland 2003). During data collection, all hardcopy data were stored in locked cabinets in a secure location. The study number allocated to each participant was recorded on the participant's contact details form. This number was the only identifying link feature to their corresponding questionnaires. Participant contact details were stored with the consent and eligibility forms in a locked cabinet. Questionnaires, which were identified only by study number, were stored separately. Electronic data were

password protected and only the relevant interventionist knew their own individual password.

Nursing and medical staff were aware of the research sites and those patients who participated in the study. This was obvious through the role of the gatekeeper and the process of data collection at the bedside. However, nursing and medical staff are bound by their code of professional practice, which includes confidentiality, and were therefore not at liberty to disclose the identities of participating patients. Group allocation was concealed from all staff members and specific details obtained during the course of data collection were never disclosed, which further maintained confidentiality. Confidentiality of the research sites was maintained through number coding. Publications have not and will not include any identifying data about individuals or the research sites.

On completion of the study, all hardcopy records were returned to and are currently kept in a locked filing cabinet in the School of Nursing & Midwifery, Trinity College Dublin. Five years following completion of the study (2015), all non-anonymised hardcopy data will be shredded.

4.10 Developing and maintaining the database

A database was developed specifically for this study using the Statistical Package for Social Sciences (SPSS Inc. Chicago IL) version 16. This programme was updated annually as new versions were made available. The database contained the merged data from the five research sites. A codebook was developed and maintained, to clarify the meaning of labels and their units of measurement for response options, the importance of which has been emphasised by Pallant (2010). Data at all time-points were collected using a paper copy of the questionnaire. Each interventionist entered her own data onto the database.

4.10.1 Quality checks

Accuracy of data entry was ongoing throughout the study. The database was screened for outliers, invalid responses and missing data for each variable, periodically during the study. Missing data were represented by a 999 code. On

completion of the study and data entry, further cleansing and proofing of data took place. More than 10% of the original hard copy questionnaires from each site were randomly checked against the inputted data and monitored for accuracy of data entry. Amendments to missing or incorrect data were made as appropriate. The rate of error was less than 1%. Frequencies and scatter plots were viewed to identify additional outliers and incorrectly inputted data. Where discrepancies were noted, data were checked against the original questionnaires and amendments were made, as necessary. No participants were excluded from analyses on this basis. On completion of cleansing and proofing, the database was 'locked' and no further amendments were permitted.

4.11 Data analysis

Data were analysed using Predictive Analytics Software (PASW) version 18. No inferential analyses were carried out until data collection was complete, to prevent bias and preserve the false positive error rate. For all statistical analyses, an alpha of 0.05 was set to control for the Type 1 error rate (Warner 2008).

4.11.1 Descriptive Statistics

Descriptive statistics were generated to describe the demographic and clinical characteristics of the entire sample and to examine the equality of the randomised groups. Between-group characteristics were analysed and compared using chi-square tests for categorical data, and are presented as raw numbers and percentages. Independent samples *t*-tests were used to analyse and compare continuous data, the results of which are presented as means and standard deviations. For all *t*-tests, Levene's test for equality of variances was tested to ensure that the variability of scores for each group was similar. When the assumption of homogeneity of variance was violated (indicated by a significant result) this suggested that the variances of scores between groups were not equal. In this situation the result reported was that of equal variances not assumed.

The assumption of normality of distribution was assessed by examining histograms and *p*-*p* plots for each continuous variable. For non-normally distributed variables, a Mann Whitney *U* test was used to compare medians.

According to Field (2011) it is not uncommon for scales measuring psychological attributes to be abnormally distributed. Thus, for knowledge, attitude and belief scores at baseline, the mean, median and interquartile range scores were reported. Raw numbers and percentages were used to present the results of individual questions from the ACS Response Index at baseline and study end (12 months). Knowledge scores were presented sequentially, from the most well-known to the least well-known symptoms. At all three time-points the unadjusted mean scores, standard deviation and confidence intervals were calculated. These are presented in the appropriate appendices.

4.11.2 Analysis of variance (ANOVA)

Repeated measures analysis of variance (ANOVA) was used to test whether there was a difference in ACS patients' knowledge, attitudes and beliefs about ACS between those randomly assigned to the control and intervention groups at 3 and 12 months after the intervention. This procedure was chosen over multiple *t*-tests, as the mean scores for the same people were being tested on more than two occasions (Pallant 2007, Polit & Beck 2010) and the use of multiple *t*-tests increases the probability of making one or more Type I errors (Polit & Beck 2010, Field 2011). This is a false positive error, whereby one can conclude that there is a difference between the groups, when there is none (Pallant 2007, Polit & Beck 2010).

Assumptions of ANOVA

The initial step involved testing that the general assumptions of ANOVA were met. This included ensuring that the dependent variable was measured using a continuous level variable and that random assignment to the control or intervention group occurred (Pallant 2007, Field 2011). Any differences between randomised groups at baseline were adjusted for at the analysis stage. A further assumption of ANOVA refers to independence of observation and measurement. In repeated measures designs, scores in the intervention group are expected to be non-independent for a given participant, but measurement between participants should be independent (Pallant 2007, Polit & Beck 2010), as was the case in this study.

The assumption of normality of distribution was assessed by examining histograms for each dependent variable and they appeared to be approximately normally distributed. The Central Limit Theorem asserts that with sufficiently large sample sizes, sampling distributions of means are normally distributed, regardless of the distributions of variables (Tabachnick & Fidell, 2007). Furthermore, distribution is considered normal when the mean, trimmed mean and the median are nearly equal (Tabachnick & Fidell, 2007), as was the case for each of the knowledge, attitude and belief variables used in this study's analyses.

Another assumption of ANOVA is the assumption of sphericity and the homogeneity of variances. This assumption tests that the variance in the groups being compared, is equal in the population (Polit & Beck 2010, Field 2011). For every case of ANOVA, this was tested using Mauchly's test. When this assumption is violated, the suggestion is that the variances of scores between the groups are not equal. In this situation, SPSS produces a choice of three corrections, which can be applied to produce a valid *F*-ratio (Field 2011). The first two options include the application of either the Greenhouse-Geisser correction or Huynh-Feldt correction. Another option is to use multivariate test statistics, which are not dependent on the assumption of sphericity. Stevens (2002) advocates the use of a univariate approach when there is a small violation of sphericity (>0.7). As the violation of sphericity was minimal in the analyses in this study, a decision was made to report the Greenhouse-Geisser corrected result. However, it is worth noting that the effect of the intervention in this study, remained statistically significant at $p<0.001$, in all three options. Furthermore, it is noteworthy that analysis of variance is reasonably robust to violations of this assumption; provided the sample size is reasonably large and groups sizes are somewhat similar (Pallant 2007, Polit & Beck 2010). This was the case in this RCT.

Repeated measures ANOVA

Three separate repeated measures ANOVAs were used to analyse each dependent variable in turn. Dependent variables were: knowledge scores at baseline, 3 and 12 months for the first repeated measures ANOVA; attitude scores at baseline, 3 and 12 months for the second repeated measures ANOVA; and belief scores at baseline, 3 and 12 months for the third and final repeated measures ANOVA.

Comparison of mean scores from the ACS Response Index were analysed with group assignment (with two levels, control and intervention) as the independent variable for each ANOVA. Covariates that were significantly different between the groups at baseline (age, education level, employment status, health insurance status and the presence of diabetes) were adjusted for within the model.

ANOVA results are presented as estimated marginal means and confidence intervals, for each dependent variable separately, after adjusting for covariates. Due to the number of primary hypotheses being tested (three), a Bonferroni adjustment was made and the significance level was reset for these analyses at $p \leq 0.0167$. Effect size was calculated and reported using partial eta squared (η^2). This statistic indicates the proportion of variance of the dependent variable that is explained by the independent variable (Pallant 2007). A result of $\eta^2=.01$ was considered a small effect size, $\eta^2=.06$ a moderate and $\eta^2=.14$ a large effect size, as guided by Cohen (1988) (Pallant 2007, Polit & Beck 2010). The results of these analyses are presented in Chapter 5.

4.12 Summary

This chapter detailed the methods used to conduct this parallel design RCT, which was carried out across five Dublin hospitals. The control and intervention groups received usual care and in addition, the intervention group received the educational intervention. The 40-minute educational intervention was individualised, used motivational interviewing techniques and was based on Leventhal's self-regulatory model of illness behaviour. The aim of the intervention was to improve knowledge, attitudes and beliefs about ACS, with a

view to reducing pre-hospital delay time in the presence of ACS symptoms. The focus of the intervention was on symptom recognition, symptom self-management and in the event of unresolved symptoms, the need to seek treatment promptly by calling the EMS who would arrange transport to the nearest ED.

The ACS Response Index was used to collect data. This questionnaire, which was administered at baseline (prior to the intervention) and at 3 months and 12 months following recruitment, captured cognitive, emotional and social responses to symptoms. For the duration of the trial, every effort was made to ensure that the intervention was delivered consistently within and across the research sites. An emphasis on interventionist training, the development of the trial protocol and the use of the intervention manual helped to ensure the adequacy of this process. The study conformed to national and international research ethics and trial regulatory guidelines. The principles of respect, beneficence, non-maleficence and justice were viewed as fundamental in the conduct of this trial.

Chapter 5: Results

5.1 Introduction

This chapter presents the results of the study, the aim of which was to test the effectiveness of an individualised educational intervention on ACS patients' knowledge, attitudes and beliefs about ACS. The hypotheses tested whether following the educational intervention, those randomly assigned to the intervention group demonstrated: greater knowledge about ACS facts and symptoms; better attitudes towards symptom recognition and confidence in their own ability to instigate appropriate help-seeking behaviour; and more accurate beliefs about what constitutes appropriate responses to ACS symptoms, compared to those assigned to the control group. Data were compared at baseline, 3 months and 12 months.

The chapter is divided into three sections. The first section provides an overview of patient recruitment to the study (N=1,947), together with details of study attrition (n=811). The second section presents data on the 'study cohort', which refers to those individuals who completed and returned the ACS Response Index at all three time-points; baseline, 3 months and 12 months (N=1,136). Analysis and discussion will focus on these participants. Demographic and clinical characteristics are presented by randomised group, to provide a profile of the study cohort. Comparisons between the study cohort (N=1,136) and those who were lost to follow-up or whose data were incomplete (n=811) is then presented. This section also presents baseline knowledge, attitude and belief scores. These scores are presented as mean or median scores and as frequencies and percentages for the separate subscales.

The third section presents the results of the testing of the study hypotheses. The effect of the educational intervention on knowledge, attitudes and beliefs about ACS is presented using repeated measures analysis of variance (ANOVA). These scores are presented as adjusted mean scores at 3 and 12 months and as frequencies and percentages for the separate subscales at 12 months.

Section I

5.2 Recruitment and attrition of the total sample

Between 1st November 2007 and 31st October 2009, 2,703 patients with a provisional diagnosis of acute coronary syndrome were assessed for study eligibility (Figure 5). Of these, 662 (24.4%) did not fulfill the inclusion criteria. In cases where patients were excluded for more than one reason, only the primary reason was recorded. Reasons included: being unwell, unstable or confused (n=166; 6.1%); declining to participate in the study (n=142; 5.2%); the presence of a serious co-morbidity (n= 117; 4.3%); an inability to understand or communicate in the English language (n=64; 2.3%); living in an institution (n=57; 2.1%); a cognitive impairment (n=37; 1.3%); and the absence of a telephone, the presence of deafness or some other random reason (n=79; 2.9%) (Figure 5).

In total, 2,041 patients were enrolled in the study and were randomly assigned to either the control (n=1022) or intervention (n=1019) group. However, of those enrolled, 94 (3%) did not have a final diagnosis of ACS and were thus excluded from the study. Consequently, data on 1,947 participants were available for baseline analysis (973 control; 974 intervention). Follow-up data were collected from both groups at two time-points (3 and 12 months) until the 30th November 2010 (Figure 5).

5.2.1 Follow-up at one month

At one month, participants who received the educational intervention at baseline (n=974) were telephoned in order that the educational intervention be reinforced. Ninety-nine percent (n=960) were contactable and remained willing to embrace the intervention. The 1% lost to follow-up resulted from: the researcher being unable to contact the participant (n=4), the participant withdrawing from the study (n=6), or the participant was deceased (n=4) (Figure 5).

5.2.2 Follow-up evaluation at 3 months

The first follow-up evaluation was conducted 3 months after participants were recruited to the study. A total of 74% (n=1,436) of the total eligible baseline sample completed and returned the ACS Response Index at this time (n=714; control) (n=722; intervention). The 26% lost to follow-up at this time resulted from: the researcher being unable to contact the participant (n=473; 24%), the participant withdrawing from the study (n=12; 1%), or the participant was deceased (n=12; 1%) (Figure 5).

5.2.3 Follow-up evaluation at 12 months

The second follow-up evaluation occurred 12 months after recruitment to the study. In total, 63% (n=1,235) of the baseline sample completed and returned the ACS Response Index at this time (n=597; 30% control) (n=638; 33% intervention). The additional 11% lost to follow-up from the 3-month data collection point, resulted from: the researcher being unable to contact the participant (n=171; 9%), the participant withdrawing from the study (n=8; <1%), or the participant was deceased (n=22; 1%) (Figure 5).

5.2.4. Missing data

During the data cleansing and proofing process, it was identified that 8% (n=99) of these questionnaires had some data missing (n=46 control; n=53 intervention). Due to the inferential statistics being used in the study analyses, participants with an incomplete data set could not contribute to these analyses. Analyses was therefore completed on 58% (N=1,136) (n=551; control) (n=585; intervention) of the total sample (Figure 5). This sample is referred to as the ‘study cohort’.

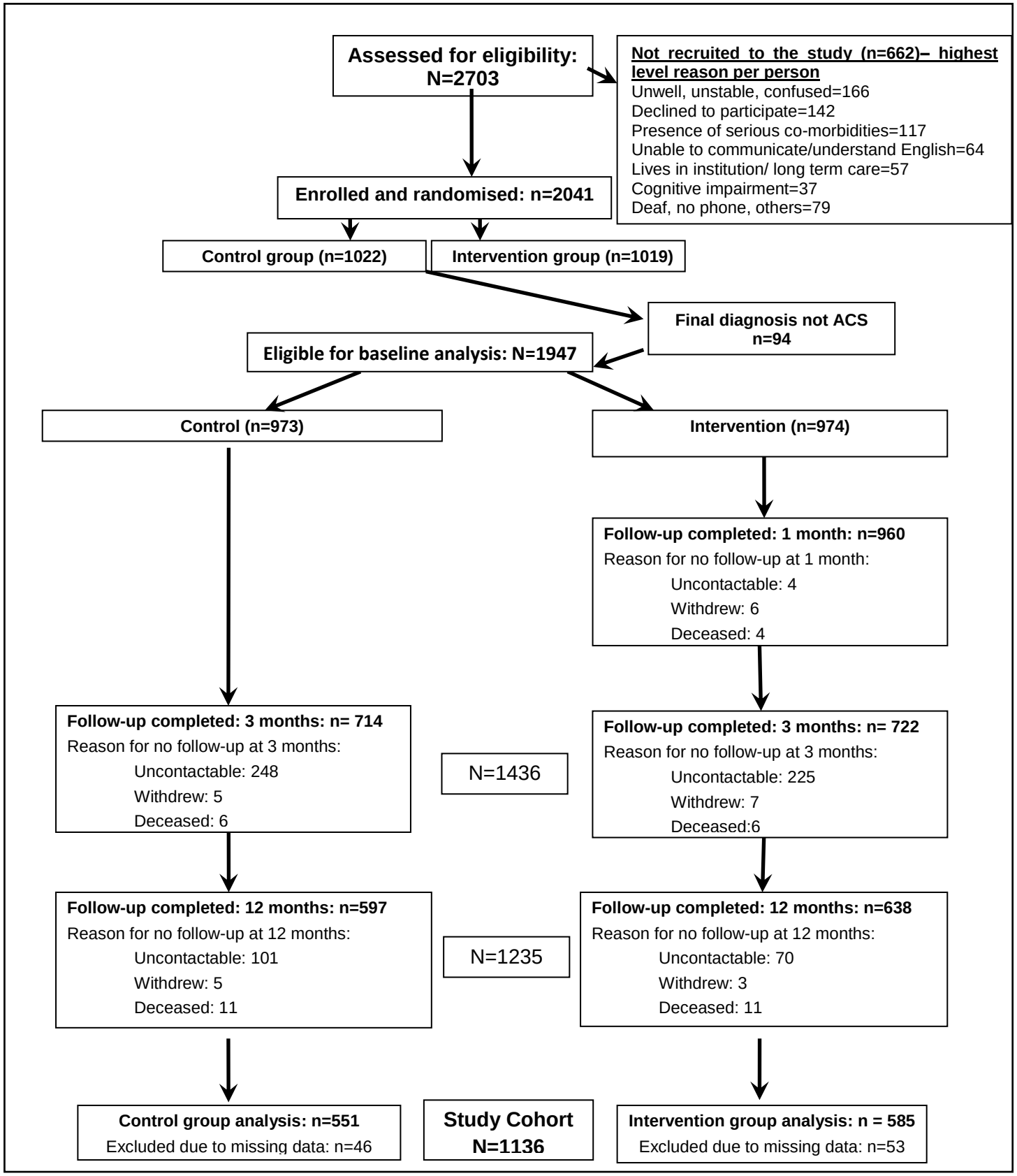

Figure 5: Consort flow diagram

Section II

5.3 The study cohort

A total of 1,136 participants completed questionnaires at all three time-points (baseline, 3 months and 12 months). Analysis and discussion will focus on these participants and they will be referred to as the 'study cohort'. The study was adequately powered, given that a sample size of 658 was required to achieve sufficient power (1-beta) to show a significant difference between groups, if one truly existed (95%).

5.3.1 Demographic characteristics

The mean age of the study cohort was 63.57 (SD ± 11.2) years, with an equal number of participants under (n=568; 50%) and over (n=568; 50%) 65 years of age. Age was approximately normally distributed as demonstrated from the histogram (Figure 6). The majority of the sample was Irish (n=1102; 97%) and male (n=820; 72.2%). Approximately two-thirds (n=771; 67.9%) were married or living with their significant other, while the remainder (n=365; 32.1%) were single, widowed or divorced. From an educational perspective, 35.7% (n=405) had little formal or primary education, 44.8% (n=509) had either commenced or completed second level while 19.5% (n=222) had attained third level status. Less than half (n=470; 41.4%) were employed, students or looking after the home, while 58.6% (n=666) were retired, unemployed or in receipt of a disability allowance. Most participants (n=901; 90.2%) considered themselves to be either comfortable financially (n=276; 27.6%) or to have enough money to make ends meet (n=625; 62.6%). However, 9.8% (n=98) believed that they did not have enough money to make ends meet. Just over one third of participants (n=413; 36.9%) had private health insurance, while the majority (n=707; 63.1%) did not (Table 4).

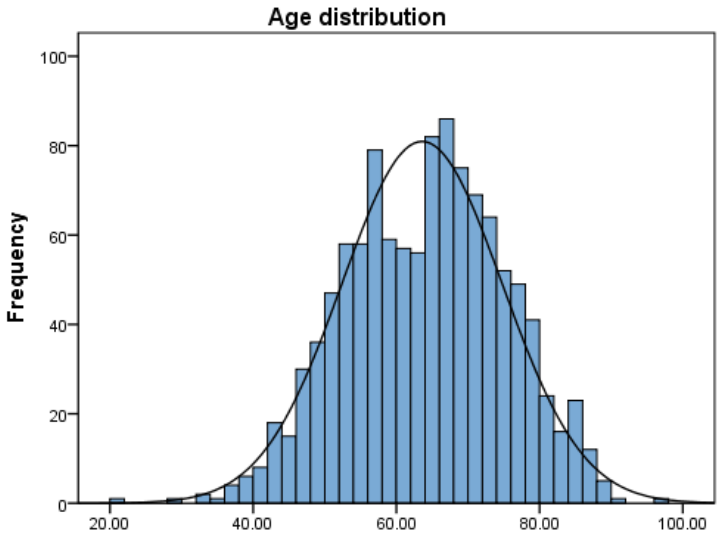

Figure 6: Histogram showing mean age of the study cohort

A comparison of the demographic characteristics of the randomised groups was completed and the following significant differences were noted. The mean age of participants in the control group was significantly higher than the mean age of participants in the intervention group (64.31 versus 62.88; χ^2, p=0.03). With respect to education, the distribution of participants across the different education subdivisions was significantly different between the control and intervention groups (χ^2, p<0.01). More participants from the control than intervention group had little formal/ primary education (38.7% versus 32.8%) and had completed second level education (46.1% versus 43.6%), compared to the intervention group. Conversely, more participants in the intervention group had completed third level education, compared to those in the control group (23.6% versus 15.2%).

A higher percentage of participants in the control group were unemployed, retired or in receipt of a disability allowance (62.6% versus 54.9%; χ^2, p=0.01) and did not have private health insurance (67.1% versus 59.5%; χ^2, p=0.01), compared to those in the intervention group (Table 4).

Table 4: Comparison of study cohort demographics

Characteristics	Overall (N=1136) n(%)	Control (n=551) n(%)	Intervention (n=585) n(%)	*P* value*
Age	63.57±11.19	64.31±11.22	62.88 ±11.13	0.03*
Gender				0.53
Male	820 (72.2)	393 (71.3)	427 (73.0)	
Female	316 (27.8)	158 (28.7)	158 (27.0)	
Marital status				0.80
Single/widowed/divorced	365 (32.1)	175 (31.8)	190 (32.5)	
Married/living with significant other	771 (67.9)	376 (68.2)	395 (67.5)	
Education				<0.01*
Little formal/primary	405 (35.7)	212 (38.7)	192 (32.8)	
Second level	509 (44.8)	254 (46.1)	255 (43.6)	
Third level	222 (19.5)	84 (15.2)	138 (23.6)	
Employment status				0.01*
Employed/student/looking after home	470 (41.4)	206 (37.4)	264 (45.1)	
Unemployed/retired/disability	666 (58.6)	345 (62.6)	321 (54.9)	
Financial status				0.43
Comfortable	276 (27.6)	125 (25.8)	151 (29.4)	
Enough to make ends meet	625 (62.6)	310 (63.9)	315 (61.3)	
Not enough to make ends meet	98 (9.8)	50 (10.3)	48 (9.3)	
Health insurance				0.01*
No private health insurance	707 (63.1)	361 (67.1)	346 (59.5)	
Private health insurance	413 (36.9)	177 (32.8)	236 (40.5)	

Legend: Values represent frequencies (percentages) or means ± standard deviation. Age was compared between groups using an independent samples *t*-test. The remaining categorical variables were compared using chi-square test. * Hypothesis test indicates significance at $p<0.05$ level.

5.3.2 Clinical characteristics

With respect to presenting diagnosis, 28.9% (n=329) of participants were diagnosed with ST-elevation myocardial infarction (STEMI), 34.1% (n=387) with non-ST-elevation myocardial infarction (NSTEMI) and 37% (n=420) with unstable angina. Approximately one third had a history of angina (n=396; 34.9%) and/or myocardial infarction (n=352; 31%), many of whom had interventions including PTCA (n=300; 26.4%) and coronary artery bypass surgery (n=157; 13.8%). Two thirds (n=752; 66.2%) had a family history of cardiovascular disease, while 15.5% (n=176) had diabetes. A large proportion had a diagnosis of hypercholesterolaemia (n=827; 72.8%) and/or hypertension (n=686; 60.4%). Just over a quarter of participants (n=323; 28.4%) smoked at the time of admission to hospital. Comparison between the randomised groups revealed that there were significantly more participants with diabetes in the control group compared to the intervention group (18% versus 13.2%; χ^2, p=0.03) (Table 5).

Table 5: Comparison of study cohort clinical characteristics

Characteristics	Overall (N=1136) N(%) yes	Control (n=551) n(%) yes	Intervention (n=585) n(%) yes	*P* value*
Diagnosis				0.13
STEMI	329 (28.9)	150 (27.2)	179 (30.6)	
NSTEMI	387 (34.1)	181 (32.9)	206 (35.2)	
Unstable angina	420 (37.0)	220 (39.9)	200 (34.2)	
History of Angina	396 (34.9)	200 (36.3)	196 (33.5)	0.32
Previous MI	352 (31.0)	173 (31.4)	179 (30.6)	0.77
Previous PTCA	300 (26.4)	145 (26.3)	155 (26.5)	0.95
Previous CABG	157 (13.8)	81 (14.7)	76 (13.0)	0.40
Family history of heart disease	752 (66.2)	356 (64.6)	396 (67.7)	0.27
Diabetes	176 (15.5)	99 (18.0)	77 (13.2)	0.03*
Hypercholesterolaemia	827 (72.8)	406 (73.7)	421 (72.0)	0.51
Hypertension	686 (60.4)	331 (60.1)	355 (60.7)	0.83
Current smoker	323 (28.4)	162 (29.4)	161 (27.5)	0.48

Legend: Values represent frequencies (percentages). All categorical variables were compared using chi-square test. * Hypothesis test indicates significance at $p<0.05$ level. STEMI = ST segment elevated myocardial infarction; NSTEMI = non-ST segment elevated myocardial infarction; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; CABG = coronary artery bypass graft.

5.3.3 Comparisons between study cohort and those lost to follow-up

Demographic (Table 6) and clinical characteristics (Table 7) were compared between the study cohort (N=1136) and participants who were either lost to follow-up at 12 months or whose data were incomplete (n=811). The following significant differences were noted. More of the study cohort than those lost to follow-up were married or living with a significant other (67.9% versus 62.8%), while less were single, widowed or divorced (32.1% versus 37.2%) (χ^2, p=0.02), (Table 6). With respect to financial status, more of the study cohort than those lost to follow-up were comfortable financially (27.6% versus 20.8%). Conversely more of those lost to follow-up than the study cohort had either enough to make ends meet (65.8% versus 62.6%) or not enough to make ends meet (13.4% versus 9.8%) (χ^2, p<0.01). More of the study cohort than those lost to follow-up had private health insurance (36.9% versus 31.0%) versus no private health insurance (63.1% versus 69.0%) (χ^2, p=0.01), (Table 6). In addition more of those lost to follow-up were smokers (37.7% versus 28.5%; χ^2, p <0.01), (Table 7).

Table 6: Demographic comparison of study cohort and those lost to follow-up

Characteristics	Study cohort (N=1,136) N (%)	Lost to follow-up (n=811) n (%)	*P* value
Group randomisation			0.12
Control	551 (48.5)	422 (52.0)	
Intervention	585 (51.5)	389 (48.0)	
Age	63.6±11.2	62.65 ± 12.3	0.09
Gender			0.84
Male	820 (72.2)	582 (71.8)	
Female	316 (27.8)	229 (28.2)	
Marital status			0.02*
Single/widowed/divorced	365 (32.1)	302(37.2)	
Married/living with significant other	771(67.9)	509 (62.8)	
Education			0.31
Little formal/primary	405 (35.7)	310 (38.2)	
Second level	509 (44.8)	362 (44.6)	
Third level	222(19.5)	139 (17.1)	
Employment status **(n=1136 versus 809)			0.11
Employed/student/looking after home	470 (41.4)	364 (45.0)	
Unemployed/retired/disability	666 (58.6)	445 (55.0)	
Financial status **(n=999 versus 707)			<0.01*
Comfortable	276 (27.6)	147 (20.8)	
Enough to make ends meet	625 (62.6)	465 (65.8)	
Not enough to make ends meet	98 (9.8)	95(13.4)	
Health payment method **(n=1120 versus 791)	707 (63.1)	546 (69.0)	0.01*
No Private health insurance	413 (36.9)	245 (31.0)	
Private health insurance			

Legend: Values represent frequencies (percentages) or means ± standard deviation (SD).Age was compared between groups using an independent samples *t*-test. The remaining categorical variables were compared using chi-square test. * Hypothesis test indicates significance at $p<0.05$ level. **Some missing data.

Table 7: Clinical characteristic comparison of study cohort and those lost to follow-up

Characteristics	Study cohort (N =1,136) N (%)	Lost to follow-up (n=811) n (%)	*P* value
Diagnosis			0.05
STEMI	329 (29.0)	219 (27.0)	
NSTEMI	387 (34.1)	320 (39.5)	
Unstable angina	420 (37.0)	272 (33.5)	
Previous MI	352 (31.0)	233 (28.7)	0.28
History of Angina	396 (34.9)	266 (32.8)	0.34
Previous PTCA	300 (26.4)	215 (26.5)	0.96
Previous CABG	157 (13.8)	102 (12.6)	0.42
Diabetes	176 (15.5)	142 (17.5)	0.24
Family history of heart disease	752 (66.2)	524 (64.4)	0.47
Hypercholesterolaemia	827 (72.8)	564 (69.5)	0.12
Hypertension	686 (60.4)	478 (58.4)	0.39
Current smoker	323 (28.5)	306 (37.7)	< 0.01*

Legend: Values represent frequencies (percentages). All categorical variables were compared using chi-square test. * Hypothesis test indicates significance at $p<0.05$ level. STEMI = ST segment elevated myocardial infarction; NSTEMI = non-ST segment elevated myocardial infarction; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; CABG = coronary artery bypass graft.

5.4 Baseline knowledge, attitude and belief scores for the study cohort

5.4.1 Knowledge of ACS at baseline

The knowledge scale included 5 questions about ACS facts (Table 8) and 21 questions about participants' perceptions of ACS symptoms (Table 9). Participants' mean score on the knowledge scale at baseline was 17.6 ± 3.7 (range = 7 to 25), which when converted to percent was 67.9% ± 14.2% (range = 26.9% to 96.2%). Knowledge scale scores showed a moderate negative skew on histogram (Figure 7). Median knowledge score was calculated at 69.23 with an interquartile range (IQR) of 57.69 - 76.92. There were no significant differences between the randomised groups at baseline with respect to knowledge of ACS (Mann Whitney *U* test, *p*=0.166).

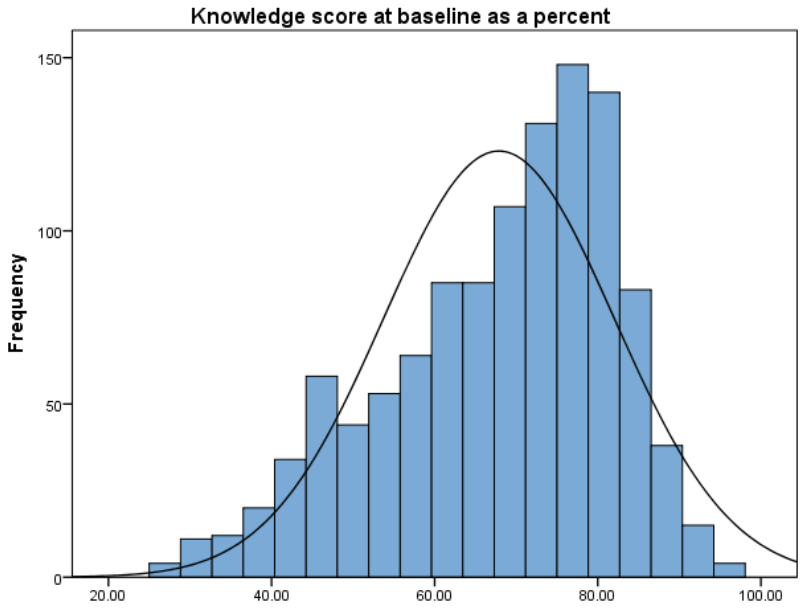

Figure 7: Histogram showing mean knowledge scores of the study cohort

Analysis of participants' knowledge of individual ACS facts demonstrated only one significant difference between the randomised groups (Table 8). Significantly more participants in the control group knew that almost all heart attacks occur in people over the age of 65 years, compared with participants in the intervention group (38.3% versus 31.5%; χ^2, p=0.02).

Table 8: Knowledge of ACS facts at baseline

Statement:	Total (n=1136) N (%)correct	Control (n=551) n (%)correct	Intervention (n=585) n (%)correct	*P* value
Heart disease is most common cause of death in women in Ireland.	381 (33.5)	193(35.0)	188(32.1)	0.30
Almost all heart attacks occur in people over age 65 years.	395 (34.8)	211(38.3)	184(31.5)	0.02*
Hospitals have drugs that reduce damage when a heart attack occurs.	999 (87.9)	490(88.9)	509(87.0)	0.32
Most people benefit from taking two puffs of GTN immediately they experience heart attack symptoms.	995 (87.6)	493(89.5)	502(85.8)	0.06
The location/size of a heart attack can vary depending on which blood vessel in the heart is blocked.	1006 (88.6)	493(89.5)	513(87.7)	0.35

Legend: Values represent frequencies (percentages) of correct answers. Variables were compared using chi-square test. * Hypothesis test indicates significance at p<0.05 level.

With respect to participants' knowledge of individual ACS symptoms, the five most commonly known symptoms were: chest pain/pressure/tightness (n=1126; 99.1%), arm/shoulder pain (n=1030; 90.7%), chest discomfort (n=1002; 88.2%), shortness of breath (n=974; 85.7%) and palpitations (n=912; 80.3%) (Table 9).

Analysis demonstrated only two significant differences between the groups. Significantly more participants in the intervention group, compared to the control group, correctly identified that loss of consciousness/fainting was a symptom of ACS (intervention 67% versus control 61.3%; χ^2, p=0.046), and that cough was not a symptom of ACS (intervention 84.1% versus control 77.9%; χ^2, p=0.01) (Table 9).

Table 9: Knowledge of ACS symptoms at baseline

Symptom of heart attack:	Total (N=1136) N (%)correct	Control (n=551) n (%)correct	Intervention (n=585) n (%)correct	*P* value
Chest pain/pressure/tightness	1126 (99.1)	545(98.9)	581(99.3)	0.47
Arm or shoulder pain	1030 (90.7)	501(90.9)	529(90.4)	0.77
Chest discomfort (heaviness, burning, tenderness)	1002 (88.2)	488(88.6)	514(87.9)	0.71
Shortness of breath/difficulty breathing	974 (85.7)	469 (85.1)	505 (86.3)	0.56
Lower abdominal pain (stomach pain) **	943 (83.0)	449(81.5)	494(84.4)	0.19
Cough**	921 (81.1)	429(77.9)	492(84.1)	0.01*
Palpitations/rapid heart rate	912 (80.3)	439(79.7)	473(80.9)	0.62
Weakness/fatigue	824 (72.5)	387(70.2)	437(74.7)	0.09
Sweating	807 (71.0)	377(68.4)	430(73.5)	0.06
Headache**	796 (70.1)	380(69.0)	416(71.1)	0.43
Pale, ashen, loss/change of color	761 (67.0)	358(65.0)	403(68.9)	0.16
Loss of consciousness/fainting	730 (64.3)	338(61.3)	392(67.0)	0.04*
Slurred speech**	658 (57.9)	320(58.1)	338(57.8)	0.92
Dizziness/lightheadedness	653 (57.5)	306(55.5)	347(59.3)	0.20
Neck pain	640 (56.3)	301(54.6)	339(57.9)	0.26
Heartburn/indigestion/stomach problem	629 (55.4)	305(55.4)	324(55.4)	0.99
Nausea/vomiting	580 (51.1)	274(49.7)	306(52.3)	0.39
Jaw pain	564 (49.6)	272(49.4)	292(49.9)	0.85
Arm paralysis (unable to move arm) **	456 (40.1)	230(41.7)	226(38.6)	0.29
Back pain	422 (37.1)	211(38.3)	211(36.1)	0.44
Numbness/ tingling in arm or hand**	292 (25.7)	148(26.9)	144(24.6)	0.39

Legend: Values represent frequencies (percentages) of correct answers. Variables were compared using chi-square test. * Hypothesis test indicates level of significance at $p<0.05$ level. **indicates distractor symptoms.

5.4.2 Attitudes and beliefs about ACS at baseline

In measuring attitudes and beliefs, participants' attitudes towards symptom recognition, confidence in their own ability to instigate appropriate help-seeking behaviour and beliefs about what constitutes appropriate responses to ACS symptoms were examined. The mean scores on the attitudes and beliefs scales of the ACS Response Index at baseline were 14.2 ± 2.8 (range 5 to 20) and 27.5 ± 3.2 (range 18 to 36) respectively. The histogram for attitudes showed a very slight negative skew (Figure 8), while that for beliefs showed a very slight positive skew (Figure 9). Median attitude score was 14.0 with an IQR of 13.0 – 16.0. Median belief score was 27.0 with an IQR of 25.0 – 29.0. There were no significant differences between the randomised groups at baseline with respect to attitudes (*t*-test, *p*=0.747) (Table 10), or beliefs (*t*-test *p*=0.482) (Table 11).

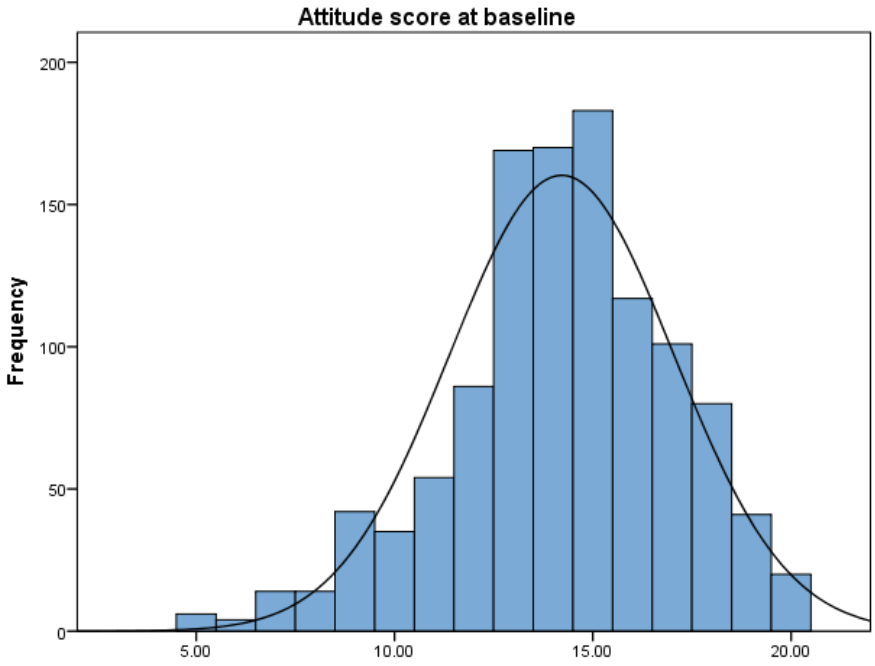

Figure 8: Histogram showing mean attitude scores of the study cohort

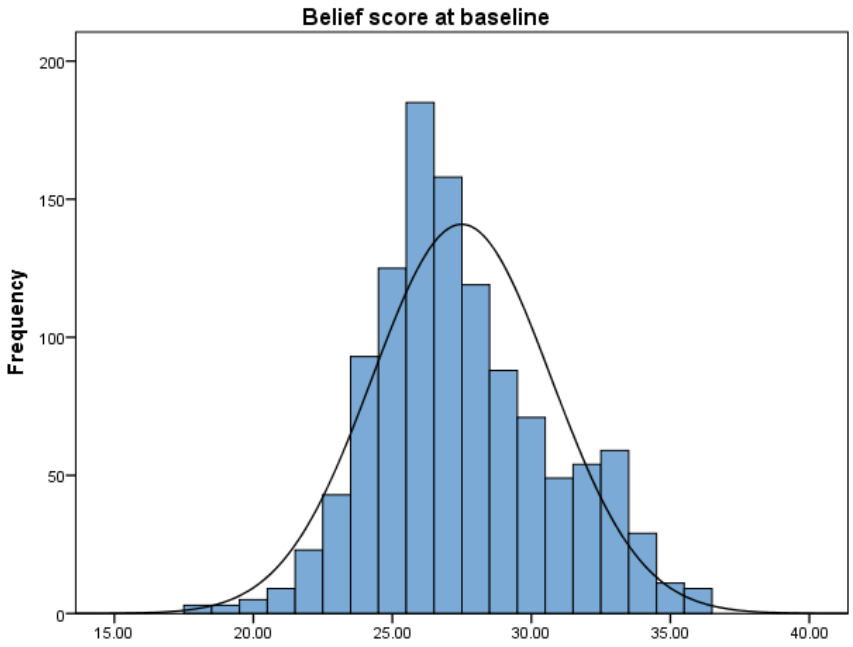

Figure 9: Histogram showing mean belief scores of the study cohort

Analysis of participants' responses to the individual items on the attitude and belief subscales demonstrated no significant differences between the control and intervention group at baseline (Tables 10 and 11 respectively).

Table 10: Attitudes at baseline

How sure are you that you could:	Total (N=1136) N (%)	Control (n=551) n (%)	Intervention (n=585) n (%)	*P* value
Recognise symptoms of heart attack in someone else				0.73
Not at all	209(18.4)	103(18.7)	106(18.1)	
Little sure	322(28.3)	163(29.6)	159(27.2)	
Pretty sure	527(46.4)	250(45.4)	277(47.4)	
Very sure	78(6.9)	35(6.4)	43(7.4)	
Recognise symptoms of heart attack in yourself				0.41
Not at all	73(6.4)	42(7.6)	31(5.3)	
Little sure	177(15.6)	83(15.1)	94(16.1)	
Pretty sure	594(52.3)	289(52.5)	305(52.1)	
Very sure	292(25.7)	137(24.9)	155(26.5)	
Tell difference between symptoms of heart attack and other medical problems				0.11
Not at all	228(20.1)	102(18.5)	126(21.5)	
Little sure	413(36.4)	192(34.8)	221(37.8)	
Pretty sure	393(34.6)	210(38.1)	183(31.3)	
Very sure	102(9.0)	47(8.5)	55(9.4)	
Get help for someone if you thought they were having a heart attack				0.96
Not at all	31(2.7)	15(2.7)	16(2.7)	
Little sure	82(7.2)	42(7.6)	40(6.8)	
Pretty sure	590(51.9)	286(51.9)	304(52.0)	
Very sure	433(38.1)	208(37.7)	225(38.5)	
Get help for yourself if you thought you were having a heart attack				0.25
Not at all	32(2.8)	18(3.3)	14(2.4)	
Little sure	98(8.6)	41(7.4)	57(9.7)	
Pretty sure	565(49.7)	286(51.9)	279(47.7)	
Very sure	441(38.8)	206(37.4)	235(40.2)	

Legend: Variables were compared using chi-square test. * Hypothesis test indicates significance at $p<0.05$ level.

Table 11: Beliefs at baseline

How strongly do you agree or disagree:	Total (N=1136) N (%)	Control (n=551) n (%)	Intervention (n=585) n (%)	*P* value
I'd be embarrassed to go to hospital if I thought I was having a heart attack				0.99
Strongly agree	58(5.1)	28(5.1)	30(5.1)	
Agree	175(15.4)	84(15.2)	91(15.6)	
Disagree	519(45.7)	253(45.9)	266(45.5)	
Strongly disagree	384(33.8)	186(33.8)	198(33.8)	
If I thought I was having a heart attack I'd wait until I was very sure				0.90
Strongly agree	39(3.4)	20(3.6)	19(3.2)	
Agree	200(17.6)	93(16.9)	107(18.3)	
Disagree	623(54.8)	302(54.8)	321(54.9)	
Strongly disagree	274(24.1)	136(24.7)	138(23.6)	
If I'm having chest pain & I'm not sure it's a heart attack I should go to hospital				0.51
Strongly agree	265(23.3)	135(24.5)	130(22.2)	
Agree	780(68.7)	368(66.8)	412(70.4)	
Disagree	88(7.7)	47(8.5)	41(7.0)	
Strongly disagree	3(0.3)	1(0.2)	2(0.3)	
If I thought I was having a heart attack I would go to the hospital right away				0.40
Strongly agree	446(39.3)	207(37.6)	239(40.9)	
Agree	624(54.9)	309(56.1)	315(53.8)	
Disagree	62(5.5)	34(6.2)	28(4.8)	
Strongly disagree	4(0.4)	1(0.2)	3(0.5)	
Most people who have a heart attack have crushing, severe chest pain				0.37
Strongly agree	150(13.2)	76(13.8)	74(12.6)	
Agree	571(50.3)	285(51.7)	286(48.9)	
Disagree	338(29.8)	159(28.9)	179(30.6)	
Strongly disagree	77(6.8)	31(5.6)	46(7.9)	
If I have chest pain for > 15 minutes I should get to hospital as soon as possible				0.17
Strongly agree	459(40.4)	230(41.7)	229(39.1)	
Agree	609(53.6)	286(51.9)	323(55.2)	
Disagree	54(4.8)	31(5.6)	23(3.9)	
Strongly disagree	14(1.2)	4(0.7)	10(1.7)	
If I thought I was having a heart attack I'd rather have someone drive me than ambulance come to my home				0.86
Strongly agree	115(10.1)	59(10.7)	56(9.6)	
Agree	335(29.5)	162(29.4)	173(29.6)	
Disagree	408(35.9)	200(36.3)	208(35.6)	
Strongly disagree	278(24.5)	130(23.6)	148(25.3)	
Most people who think they are having a heart attack should drive themselves to the hospital				0.22
Strongly agree	7(0.6)	2(0.4)	5(0.9)	
Agree	28(2.5)	14(2.5)	14(2.4)	
Disagree	376(33.1)	197(35.8)	179(30.6)	
Strongly disagree	725(63.8)	338(61.3)	387(66.2)	
Women rarely have heart attacks				0.92
Strongly agree	5(0.4)	2(0.4)	3(0.5)	
Agree	246(21.7)	118(21.4)	128(21.9)	
Disagree	685(60.3)	337(61.2)	348(59.5)	
Strongly disagree	200(17.6)	94(17.1)	106(18.1)	

Legend: Variables were compared using chi-square test. * Hypothesis test indicates significance at $p<0.05$ level.

Section III

5.5 The effect of the intervention on knowledge, attitudes and beliefs

To examine the effect of the intervention, repeated measures ANOVA was conducted. Comparison of scores from the ACS Response Index for the intervention and control groups were analysed in three separate repeated measures ANOVA's (knowledge, attitudes and beliefs). Between-group baseline differences (age, education level, employment status, health insurance status and diabetes) were controlled for during analysis by including them as independent variables. Tables and figures for these adjusted mean scores are presented below. The unadjusted mean scores for knowledge, attitudes and beliefs are presented in Appendix 11.

Preliminary assumption testing of the assumption of normality of distribution demonstrated some element of skewness of distribution. However, the data were approximately normally distributed which meant that it was amenable to analysis using ANOVA. Mauchly's test of sphericity indicated that the assumption of sphericity was violated in each repeated measures ANOVA for knowledge (χ^2, (2)= 219.425, p<0.001), attitudes (χ^2, (2)= 61.024, p<0.001) and beliefs (χ^2, (2)= 52.804, p<0.001). As the violation of sphericity was minimal in these analyses, with epsilon close to 1 for knowledge (0.848), attitudes (0.949) and beliefs (0.956), the Greenhouse-Geisser corrected result was reported.

5.5.1 Knowledge

Intervention effect on knowledge scores over time

The study hypothesis was accepted for knowledge. Repeated measures ANOVA demonstrated that the intervention had a significant effect on knowledge about ACS over time, F (df 2, 1886) = 16.313, p<0.001 (partial η2= 0.014), while controlling for the confounding variables of age, education level, employment status, health insurance status and diabetes.

Through observing the plots (Figure 10) and the estimated marginal mean scores (Table 12), it was noted that knowledge scores among the intervention

group remained the same between baseline and 3 months but they increased from 3 months to 12 months. Knowledge scores among the control group decreased from baseline to 3 months and decreased further from 3 months to 12 months (*p*= <0.001) (Table 12 and Figure 10).

Table 12: Knowledge scores across time by group (adjusted)

Knowledge (%)	Control (n=551)	Intervention (n=585)	*P* value
	Estimated Marginal Mean (CI)	Estimated Marginal Mean (CI)	
Baseline	68.6 (67.1-70.1)	68.9 (67.5-70.3)	
3 months	65.3 (64.2-66.4)	68.9 (67.8-70.0)	<0.001
12 months	64.9 (63.7-66.1)	69.9 (68.7-71.0)	

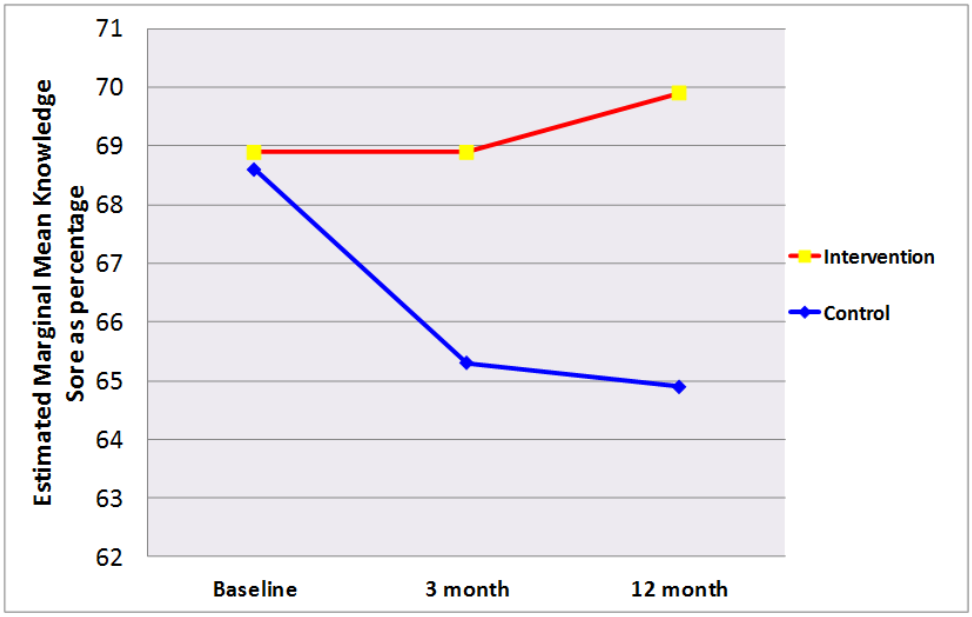

Figure 10: Knowledge scores across time (adjusted)

Although there were differences between the intervention and control groups at baseline with respect to age, education levels, employment status, health insurance status and the presence of diabetes, these factors had no impact on the change in knowledge scores between the groups following the intervention. After adjusting for baseline differences, analysis demonstrated significant differences in knowledge scores, between the groups over time.

Knowledge scores of individual questions on the ACS Response Index

Irrespective of randomised group, more participants demonstrated greater knowledge of ACS facts between baseline (Table 8) and 12 months (Table 13), with one exception. Compared to their baseline score, fewer participants at 12 months knew that almost all heart attacks occur in people over the age of 65 years. Significantly more participants in the control group correctly answered this question, compared to the intervention group (34.5% versus 27.2%; χ^2, p =0.01), (Table 13).

Significantly more participants in the intervention group correctly identified that most people benefit from taking two puffs of GTN (nitrates) immediately when they experience heart attack symptoms (92.6% versus 89.1%; χ^2, p=0.04), (Table 13).

Table 13: Knowledge of ACS facts at 12 months

Statement:	Control n(%)correct (n=551)	Intervention n(%)correct (n=585)	*P* value
Heart disease is most common cause of death in women in Ireland	243(44.1)	286(48.9)	0.11
Almost all heart attacks occur in people over age 65 years	190(34.5)	159(27.2)	0.01*
Hospitals have drugs that reduce damage when a heart attack occurs	493(89.5)	521(89.1)	0.82
Most people benefit from taking two puffs of GTN immediately they experience heart attack symptoms	491(89.1)	542(92.6)	0.04*
The location/size of a heart attack can vary depending on the artery	498(90.4)	545(93.2)	0.09

Legend: Values represent frequencies (percentages) of correct answers. Variables were compared using chi-square test. * Hypothesis test indicates significance at p<0.05 level.

Using a chi-square test, participants' knowledge of ACS symptoms at 12 months was evaluated. Significantly more participants in the intervention group compared with the control group correctly knew that the following were ACS symptoms; arm or shoulder pain (intervention 95.0% versus control 90.7%; p=0.005), shortness of breath (intervention 93.2% versus control 86.2%; p<0.001), chest discomfort (intervention 90.6% versus control 82.4%; p<0.001), palpitations (intervention 85.5% versus control 78.9%; p=0.004), weakness/ fatigue (intervention 74.5% versus control 63.2%; p<0.001), sweating (intervention 76.8% versus control 61.5%; p<0.001), loss of consciousness/fainting (intervention 68.9% versus control 56.6%; p<0.001), dizziness/lightheadedness (intervention 58.6% versus control 48.6%; p=0.001), neck pain (intervention 76.1% versus control 49.5%; p <0.001), heartburn/ indigestion/stomach problems (intervention 60.7% versus control 46.5%; p<0.001), nausea and vomiting (intervention 55.9% versus control 38.7%; p <0.001), jaw pain (intervention 76.2% versus control 57.9%; p <0.001) and back pain (intervention 53.3% versus control 34.1%; p <0.001) (Table 14).

With respect to the inclusion of distractor symptoms, significantly more participants in the control group correctly identified that the following were not symptoms of ACS: lower abdominal pain (control 77% versus intervention 68.9%; p =0.002), headache (control 79.7% versus intervention 73.5%; p =0.01), slurred speech (control 55.4% versus intervention 46.8%; p=0.004), arm paralysis (control 35.6% versus intervention 27.2%; p =0.002) and numbness and tingling of the arm/hand (control 23.4% versus intervention 11.8%; p<0.001) (Table 14).

Table 14: ACS symptom knowledge at 12 months

Symptom of ACS:	Control n(%) correct (n=551)	Intervention n(%) correct (n=585)	*P* value
Chest pain/pressure/tightness	542(98.4)	577(98.6)	0.71
Arm or shoulder pain	500(90.7)	556(95.0)	0.005*
Shortness of breath/difficulty breathing	475(86.2)	545(93.2)	<0.001*
Chest discomfort (heaviness, burning, tenderness)	454(82.4)	530(90.6)	<0.001*
Lower abdominal pain (stomach pain) **	424(77.0)	403(68.9)	0.002*
Cough **	452(82.0)	471(80.5)	0.51
Palpitations/rapid heart rate	435(78.9)	500(85.5)	0.004*
Weakness/fatigue	348(63.2)	436(74.5)	<0.001*
Sweating	339(61.5)	449(76.8)	<0.001*
Headache **	439(79.7)	430(73.5)	0.01*
Pale, ashen, loss/change of color	404(73.3)	464(79.3)	0.18
Loss of consciousness/fainting	312(56.6)	403(68.9)	<0.001*
Slurred speech **	305(55.4)	274(46.8)	0.004*
Dizziness/lightheadedness	268(48.6)	343(58.6)	0.001*
Neck pain	273(49.5)	445(76.1)	<0.001*
Heartburn/indigestion/stomach problem	256(46.5)	355(60.7)	<0.001*
Nausea/vomiting	213(38.7)	327(55.9)	<0.001*
Jaw pain	319(57.9)	446(76.2)	<0.001*
Arm paralysis (unable to move arm) **	196(35.6)	159(27.2)	0.002*
Back pain	188(34.1)	312(53.3)	<0.001*
Numbness/tingling in arm or hand**	129(23.4)	69(11.8)	<0.001*

Legend: Values represent frequencies (percentages) of correct answers. Variables were compared using chi-square test. * Hypothesis test indicates significance at $p<0.05$ level. **indicates distractor symptoms.

5.5.2 Attitudes

Intervention effect on attitude scores over time

The study hypothesis was accepted for attitudes. Repeated measures ANOVA demonstrated that the intervention had a significant effect on the change in attitude scores over time, F (df 2, 2111) = 6.009, *p*=0.003, (partial η2= 0.005), while controlling for the confounding variables of age, education level, employment status, health insurance status and diabetes.

Through observing the plots (Figure 11) and the estimated marginal mean scores (Table 15), it was noted that attitudes increased in both groups from baseline to 3 and 12 months, but they increased significantly faster and to a greater extent in the intervention group, compared to the control group.

Table 15: Attitude scores across time by group (adjusted)

Attitude	Control (n=551)	Intervention (n=585)	*P* value
	Estimated Marginal Mean (CI)	Estimated Marginal Mean (CI)	
Baseline	14.3(14.0-14.6)	14.3 (14.0-14.6)	
3 months	14.5 (14.2-14.8)	14.9 (14.6-15.2)	0.003
12 months	14.7 (14.4-14.9)	15.3 (15.0-15.5)	

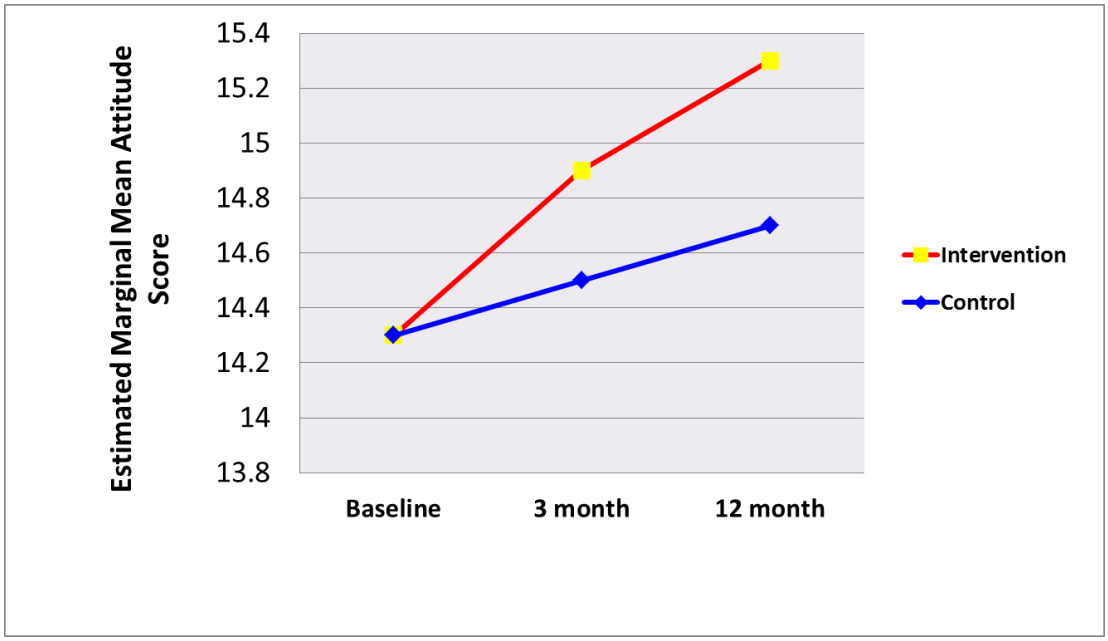

Figure 11: Attitude scores across time (adjusted)

Although there was a difference between the intervention and control groups at baseline with respect to age, education levels, employment status, health insurance and presence of diabetes, these factors had no impact on the differences in attitude scores between the groups following the intervention. After adjusting for baseline differences, analysis demonstrated significant differences in the change in attitude scores, between the groups over time.

Attitude scores of individual questions on the ACS Response Index

The effect of the intervention on the proportions of the responses (not at all, little sure, pretty sure, very sure) to the individual items on the attitude subscale at 12 months was then tested, using a chi-square test (Table 16). For the purposes of presenting the results in the text below the pretty sure and very sure responses were combined.

There were significant differences between the intervention and control group with respect to their attitudes towards ACS. Significantly more participants in the intervention group compared to the control group were pretty sure or very sure that they could recognise the signs and symptoms of a heart attack in someone else (72% versus 62%; $p<0.001$) and in themselves (90.1% versus 82.2%; $p<0.001$). Significantly more participants in the intervention group were also pretty sure or very sure that that they could differentiate between a heart attack and other medical problems (64.1% versus 58.5%; $p=0.01$) and that they could get help for someone else if they thought they were having a heart attack (90.9% versus 86.5%; $p=0.04$).

Table 16: Attitudes with respect to ACS at 12 months

How sure are you that you could:	Control % (n=551)	Intervention % (n=585)	*P* value
Recognise the symptoms of a heart attack in someone else			<0.001*
Not at all	37(6.7)	13(2.2)	
Little sure	172(31.2)	151(25.8)	
Pretty sure	306(55.5)	375(64.1)	
Very sure	36(6.5)	46(7.9)	
Recognise the symptoms of a heart attack in yourself			<0.001*
Not at all	18(3.3)	7(1.2)	
Little sure	80(14.5)	51(8.7)	
Pretty sure	309(56.1)	323(55.2)	
Very sure	144(26.1)	204(34.9)	
Tell the difference between symptoms of heart attack and other medical problems			0.01*
Not at all	58(10.5)	30(5.1)	
Little sure	171(31.0)	180(30.8)	
Pretty sure	272(49.4)	316(54.0)	
Very sure	50(9.1)	59(10.1)	
Get help for someone if you thought they were having a heart attack			0.04*
Not at all	15(2.7)	5(0.9)	
Little sure	59(10.7)	48(8.2)	
Pretty sure	285(51.7)	306(52.3)	
Very sure	192(34.8)	226(38.6)	
Get help for yourself if you thought you were having a heart attack			0.13
Not at all	11(2.0)	11(1.9)	
Little sure	70(12.7)	53(9.1)	
Pretty sure	281(51.0)	290(49.6)	
Very sure	189(34.3)	231(39.5)	

Legend: Variables were compared using chi-square test. * Hypothesis test indicates significance at $p<0.05$ level.

5.5.3 Beliefs

Intervention effect on belief scores over time

The study hypothesis was accepted for beliefs. Repeated measures ANOVA demonstrated that the intervention had a significant effect on the change in belief scores over time, F (df 2, 2125) = 8.932 $p<0.001$, (partial $\eta 2= 0.008$), while controlling for the confounding variables of age, education level, employment status, health insurance status and diabetes.

Through observing the plots (Figure 12) and the estimated marginal mean scores (Table 17), it was noted that belief scores increased in both groups from baseline to 3 months, after which it remained stable in the intervention group at 12 months, but decreased slightly in the control group. The increase was significantly greater in the intervention group compared to the control group.

Table 17: Belief scores across time by group (adjusted)

Beliefs	Control (n=551)	Intervention (n=585)	*P* value
	Estimated Marginal Means(CI)	Estimated Marginal Means(CI)	
Baseline	27.7(27.4-28.0)	27.7 (27.4-28.0)	
3 months	28.9 (28.6-29.3)	29.7 (29.3-30.0)	<0.001
12 months	28.8 (28.4-29.1)	29.7 (29.3-30.0)	

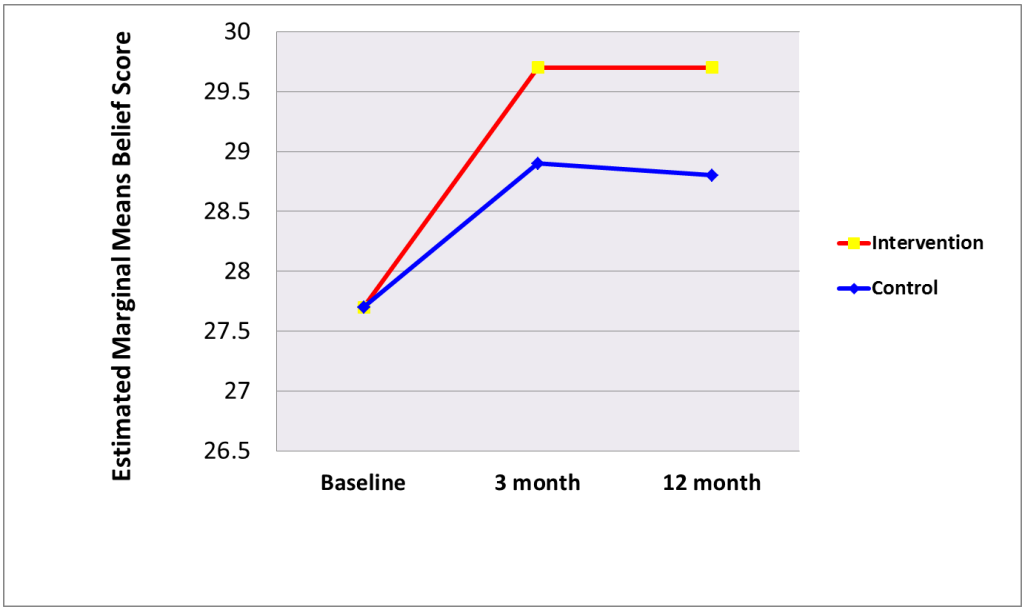

Figure 12: Belief scores between groups across time (unadjusted)

There was also a significant effect of education on the change in belief scores over time *F* (df 4, 2125) =3.580 *p*=0.007 (partial η2= 0.006). On examination of the interaction graph (Appendix 12, Figure 13), mean belief scores increased from baseline to 3 months, regardless of education level. For participants in the lower education group, belief scores increased slightly more from 3 to 12 months, while scores reduced slightly from 3 to 12 months in those who had some second level education and beyond.

There was a significant effect of health insurance on the change in belief scores over time F= (df 2, 2125) 4.681 *p*=0.010, (partial η2= 0.004). Irrespective of

health insurance status, mean belief scores increased from baseline to 3 months. However, for those with private health insurance it reduced slightly between 3 and 12 months, while it remained the same in those with no private health insurance (Appendix 12, Figure 14).

Although there was a difference between the intervention and control groups at baseline with respect to age, education levels, employment status, health insurance and presence of diabetes, these factors had no impact on the differences in belief scores between the groups following the intervention. After adjusting for baseline differences, analysis demonstrated significant differences in the change in belief scores between the groups over time.

Belief scores of individual questions on ACS Response Index

Using a chi-square test, the effect of the intervention on the proportions of the responses (strongly agree, agree, disagree, strongly disagree) to the individual items on the belief subscale at 12 months was tested (Table 18). There were significant differences between the intervention and control group with respect to their beliefs about ACS. Significantly more participants in the control group than the intervention group, strongly agreed that most people who have a heart attack have crushing severe chest pain (control 23.8% versus intervention 16.8%, $p<0.001$). Conversely, significantly more participants in the intervention group than the control group, strongly agreed that they should get to the hospital right away if they thought they were having a heart attack (intervention 68.7% versus control 60.6% $p=0.03$), if they had chest pain that lasted for more than 15 minutes (intervention 67.4% versus control 61.0%, $p=0.01$), or if they had chest pain, but were not sure if it was a heart attack (intervention 51.5% versus control 41.1%, $p=0.002$). Consistent with the aforementioned belief, significantly more participants in the control than intervention group, strongly agreed or agreed that they would wait until they were very sure that they were having a heart attack before going to hospital (control 19.6% versus intervention16.2%, $p=0.01$).

With respect to transportation to hospital, significantly more participants in the control group than the intervention group, strongly agreed or agreed that they would prefer someone to drive them to the hospital than have an ambulance

come to their home (control 35.9% versus intervention 26.3% p=0.001). Significantly more participants in the intervention group compared to those in the control group, strongly disagreed that women rarely have heart attacks (intervention 46.2% versus control 39.7%, p=0.002).

Table 18: Beliefs about ACS at 12 months

How strongly do you agree or disagree:	Control % (n=551)	Intervention % (n=585)	*P* value
I'd be embarrassed to go to hospital if I thought I was having a heart attack			0.12
Strongly agree	29(5.3)	34(5.8)	
Agree	89(16.2)	74(12.6)	
Disagree	200(36.3)	193(33.0)	
Strongly disagree	233(42.3)	284(48.5)	
If I thought I was having a heart attack I'd wait until I was very sure			0.01*
Strongly agree	21(3.8)	31(5.3)	
Agree	87(15.8)	64(10.9)	
Disagree	197(35.8)	184(31.5)	
Strongly disagree	246(44.6)	306(52.3)	
If I'm having chest pain & I'm not sure it's a heart attack I should go to hospital			0.002*
Strongly agree	228(41.1)	301(51.5)	
Agree	297(53.9)	255(43.6)	
Disagree	20(3.6)	16(2.7)	
Strongly disagree	6(1.1)	13(2.2)	
If I thought I was having a heart attack I would go to hospital right away			0.03*
Strongly agree	334(60.6)	402(68.7)	
Agree	193(35.0)	163(27.9)	
Disagree	16(2.9)	11(1.9)	
Strongly disagree	8(1.5)	9(1.5)	
Most people who have a heart attack have crushing, severe chest pain			<0.001*
Strongly agree	131(23.8)	98(16.8)	
Agree	181(32.8)	189(32.3)	
Disagree	188(34.1)	200(34.2)	
Strongly disagree	51(9.3)	98(16.8)	
If I have chest pain for >15 minutes I should get to hospital as soon as possible			0.01*
Strongly agree	336(61.0)	394(67.4)	
Agree	160(29.0)	135(23.1)	
Disagree	19(3.4)	9(1.5)	
Strongly disagree	36(6.5)	47(8.0)	
If I thought I was having a heart attack I'd rather have someone drive me than ambulance come to my home			0.001*
Strongly agree	79(14.3)	52(8.9)	
Agree	119(21.6)	102(17.4)	
Disagree	160(29.0)	167(28.5)	
Strongly disagree	193(35.0)	264(45.1)	
Most people who think they are having a heart attack should drive themselves to hospital.			0.40
Strongly agree	20(3.6)	16(2.7)	
Agree	6(1.1)	7(1.2)	
Disagree	114(20.7)	102(17.4)	
Strongly disagree	411(74.6)	460(78.6)	
Women rarely have heart attacks			0.002*
Strongly agree	10(1.8)	20(3.4)	
Agree	72(13.1)	44(7.5)	
Disagree	250(45.4)	251(42.9)	
Strongly disagree	219(39.7)	270(46.2)	

Legend: Variables were compared using chi-square test. * Hypothesis test indicates significance at $p<0.05$ level.

5.6 Chapter summary

This chapter presented the results of the educational intervention on participants' knowledge, attitudes and beliefs about ACS. The hypotheses tested whether following the educational intervention, patients assigned to the intervention group demonstrated: greater knowledge about ACS facts and symptoms; better attitudes towards symptom recognition and confidence in their own ability to instigate appropriate help-seeking behaviour; and more accurate beliefs about what constitutes appropriate responses to ACS symptoms, compared to those assigned to the control group. Data were compared at baseline, 3 months and 12 months. Fifty-eight per cent (N=1,136; control=551, intervention=585) of the baseline study sample (n=1,947) completed the ACS Response Index at all three time-points (baseline, 3 and 12 months) and were used in the study analyses. Given that a sample size of 658 was required to show a significant difference between groups if one existed, the study was adequately powered (95%).

Mean knowledge, attitude and belief scores were similar at baseline between the control and intervention groups. Following the educational intervention, there was a significant difference in knowledge (ANOVA, $p<0.001$), attitude (ANOVA, $p=0.003$) and belief (ANOVA, $p<0.001$) scores, between the groups over time. Knowledge scores in the intervention group remained the same between baseline and 3 months but they increased from 3 months to 12 months. Knowledge scores among the control group decreased from baseline to 3 and 12 months. Attitudes increased in both groups from baseline to 3 and 12 months, but the increase was significantly greater in the intervention group, compared to the control group. Belief scores increased in both groups from baseline to 3 months, after which they remained stable in the intervention group but decreased slightly in the control group at 12 months. The increase was significantly greater in the intervention group compared to the control group. Therefore, the study hypotheses for knowledge, attitudes and beliefs about ACS were accepted.

Chapter 6: Discussion

6.1 Introduction

The aim of this study was to test the effectiveness of an individualised educational intervention on knowledge, attitudes and beliefs about ACS. It was intended that following the intervention, the intervention group would have greater knowledge about ACS facts and symptoms, better attitudes towards symptom recognition and help-seeking behaviours and more accurate beliefs about what constitutes appropriate responses to symptoms, than the control group. As there was a significant effect of the intervention on these variables, over time, the study hypotheses were accepted. To synopsise the effect of the intervention, knowledge scores increased in the intervention group between baseline and 12 months, while they decreased simultaneously in the control group. Meanwhile, attitudes increased in both groups but they increased significantly faster and to a greater extent in the intervention group, compared to the control group. Beliefs increased in both groups from baseline to 3 months, after which time they stabilised in the intervention group, but decreased slightly in the control group. The increase was significantly greater in the intervention group compared to the control group.

This study is the first RCT in Europe to test this intervention and to report on knowledge, attitudes and beliefs about ACS. It is also the first European study to demonstrate the effectiveness of the intervention on all three constructs. From an international perspective, this is just one of two studies where an intervention was found to positively influence the three constructs of knowledge, attitudes and beliefs. Consequently, it has the potential to reduce mortality and morbidity associated with ACS. In this chapter, the study's baseline and post intervention results are discussed in the context of relevant literature. The originality of this study and reasons for its success are also presented. The implications of the intervention for clinical practice, education and future research are outlined, together with the study limitations. The chapter concludes with recommendations for future practice, education and research.

6.2 The effect of the intervention

The intervention in this study was effective in improving knowledge, attitudes and beliefs about ACS. The effect of the intervention was reflected through an increase in knowledge scores in the intervention group with a concurrent decrease in knowledge in the control group, between baseline and 12 months (p<0.001). Attitude levels increased in both groups, but the increase was significantly greater in the intervention group, compared to the control group (p=0.003). Meanwhile beliefs increased in both groups from baseline to 3 months, after which time they stabilised in the intervention group, but decreased slightly in the control group. The increase in belief scores was significantly greater in the intervention group compared to the control group (p<0.001).

The effect of the intervention is of major clinical significance as individuals with good knowledge of ACS symptoms, who rehearse the correct responses to them, will have the ability to transfer this knowledge into action in the presence of a health threat. In the case of this intervention, the targeted action was to expedite help-seeking behaviour in the presence of ACS symptoms. Therefore, any improvement in knowledge attitudes and beliefs about ACS is an important first step towards achieving this aim.

6.3 Baseline results

Despite being diagnosed with ACS, many participants in this study had poor knowledge, attitudes and beliefs about ACS at baseline. Similar findings to this have been reported in non-European populations (Buckley *et al*. 2007, McKinley *et al.* 2009). In this study, mean knowledge scores based on collective symptom recognition were reported, in addition to scores for individual items. The provision of both mean and individual scores makes a significant contribution to the body of nursing and research knowledge. Some researchers reported knowledge of individual ACS symptoms, without including mean scores (Goff *et al*. 1998, Tullman & Dracup 2005, Hwang *et al*. 2008, Cytryn *et al.* 2009, Henriksson *et al*. 2012, Swanoski *et al.* 2012, Whitaker *et al.* 2012). Meanwhile, others reported mean knowledge scores only (Buckley *et al*. 2007, Dracup *et al*. 2008, McKinley *et al*. 2009). With respect to attitudes and beliefs about ACS, a limited number of researchers have published in this area and of those that did

(Buckley *et al*. 2007, McKinley *et al.* 2009), mean scores were reported in isolation. Consequently, the inclusion of both mean and individual items in this study makes an important contribution to the body of knowledge, while providing valuable information for other researchers, irrespective of their mode of measurement.

In this study, the mean baseline knowledge score was 68.9%. Relative to other researchers, this result was mid-range. Buckley *et al*. (2007) reported a mean knowledge score of 63%, while McKinley *et al.* (2009) reported a mean score of 71%. These researchers (McKinley *et al.* 2009) suggested that mean knowledge scores of less than 70% are low. However, further research is warranted to validate this suggestion given that these researchers were the only ones to provide this definition.

With respect to knowledge of individual symptoms, the findings from this study echo those of other researchers (Goff *et al*. 1998, Tullman & Dracup 2005, Hwang *et al*. 2008, Cytryn *et al.* 2009, Henriksson *et al*. 2012, Swanoski *et al.* 2012, Whitaker *et al.* 2012). Symptoms of ACS, such as chest pain, arm pain or shortness of breath were well-recognised in this Irish population. However, knowledge was poor with respect to other symptoms such as nausea and jaw pain. This is not an unexpected finding, given that these symptoms are considered minor, relative to those dramatic symptoms associated with the 'Hollywood Heart Attack' (Finnegan *et al*. 2000, King and McGuire 2007, O'Donnell *et al.* 2012). Hollywood-style symptoms are widely publicised and readily recognised. Conversely, those that are less widely publicised tend to be less well known by the public (Dracup *et al.* 2008, Hwang *et al*. 2008, Cytryn *et al*. 2009, Henriksson *et al*. 2012, Swanoski *et al*. 2012).

The mean attitude and belief scores among participants in this study were also midrange when compared to those of other researchers. Previously reported attitude scores (measured out of 20) were 14.6 (McKinley *et al.* 2009) and 13.9 (Buckley *et al*. 2007). For this Irish cohort, the attitude score was 14.3. With respect to the belief construct (measured out of 36) the mean score in this study was 27.7. Buckley *et al*. (2007) reported a mean belief score of 29.5, while the

score of 22.8, reported by McKinley *et al*. (2009) was considerably lower. Therefore, the mean attitude and belief scores in this study compared well with others who used the same research instrument (Buckley *et al*. 2007, McKinley *et al.* 2009). While a benchmark of 70% has been suggested as an acceptable knowledge score, researchers have not defined acceptable scores for attitudes and beliefs.

With respect to the results of the individual items on the attitude subscale at baseline in this study, one in five individuals lacked confidence about recognising the presence of heart attack symptoms in the future. More than half expressed an attitude of doubt in their own ability to differentiate between a heart attack and other medical problems. The implication of this is that many individuals may deliberate inappropriately before acknowledging the need to seek help. However, the lack of published research on individual subscale items precludes comparison beyond what is presented here.

To contextualise the results of the individual items on the belief subscale in this study, almost all participants believed that they should get to the hospital as quickly as possible if they had chest pain that lasted more than 15 minutes. While this would improve prognosis and reduce mortality and morbidity, it is contingent on the presence of chest pain, as opposed to any other symptom that could arise. While chest pain is regarded as the hallmark symptom of ACS (Canto *et al*. 2007), it is imperative that individuals appreciate that ACS can occur without typical chest pain or discomfort (Canto *et al.* 2007). It has been reported that of those who present to hospital with ACS, up to 30% do not have chest pain (Canto *et al*. 2000, Horne *et al.* 2000, Milner *et al.* 2004, Canto *et al.* 2007). The findings from this study and others underscore the requirement to clarify to the public generally, and to ACS patients specifically, those symptoms that constitute an ACS event, and how these should be managed. Such information would serve to improve knowledge, attitudes and beliefs about ACS, thereby enhancing help-seeking behaviour.

6.4 Post intervention results

The baseline knowledge level of less than 70% in this study reinforced the need for the current educational intervention. According to Ting & Bradley (2009), in order for an intervention to be effective, a pre-existing knowledge gap in the targeted group should exist. This provides one explanation for the effectiveness of the intervention on knowledge scores. The collection of baseline data may have reinforced for participants their level of dissonance when their knowledge about ACS was challenged (Festinger 1957, deVries 2008). Consequently, an attempt to resolve dissonance and restore balance may have provided the stimulus to learn at the outset of the intervention. The fact that learning occurred was evidenced through the significant effect of the intervention.

Following the intervention, knowledge scores increased by 1% in this study. This was comparatively lower than knowledge scores reported by other researchers who used the same intervention and research instrument. Increases of 2% (McKinley *et al.* 2009) and 8.2% (Buckley *et al.* 2007) were previously reported. Consistent with the finding for knowledge scores, the researchers (Buckley *et al.* 2007) who started with the lowest baseline attitude score increased by the most following their intervention. These researchers reported an increase of 1.6 points in attitudes at 12 months. In this study, there was a one point increase in attitudes, while McKinley *et al.* (2009) had an increase of less than one point at the same data collection point. The increase across the three studies was relative to their starting points at baseline. However, with respect to the increased scores by Buckley *et al.* (2007), it is likely that increases are more easily achieved where results are lower to begin with.

Changes in post-intervention belief scores were inconsistent across the three studies. In this study, there was an increase of two points (27.7-29.7) from baseline to 12 months. McKinley *et al.* (2009) reported an increase of one point, although their baseline level was considerably lower (22.8-23.8) than in this study. Buckley *et al.* (2007) reported a baseline score of 29.5, which was higher than others. Following their intervention, there was an increase of over three

points to 32.8, which was also higher than other post-intervention results. Despite this, there was no significant difference (p=0.30) in attitudes or beliefs between the intervention and control groups over time (Buckley *et al*. 2007). The lack of intervention effect reported by Buckley *et al*. (2007) may be due to the small and possibly inadequately powered sample size. In this current study, the intervention was effective across the three constructs of knowledge, attitudes and beliefs.

The use of a rigorous design to test the intervention in this study provides confidence that the observed differences in outcomes between the control and intervention groups were due to the intervention. The adoption of a robust study design in the form of an RCT provided unequivocal evidence for the acceptance of the study hypotheses. Randomised controlled trials are considered the 'gold standard' method for testing the effectiveness of interventions (Torgerson & Torgerson 2008, Gerrish & Lacey 2010, Grove *et al.* 2013). While the RCT design validated the study outcomes, the unique contribution of many factors contributed to the success of the intervention. These include the use of an appropriate theoretical framework to underpin the intervention, the intervention content, its recipients and the means by which the intervention was delivered. The contribution of these aspects to the success of the intervention will be discussed below.

6.4.1 The theoretical framework

Theory-based interventions are considered to be of sound underpinning (Bellg *et al*. 2004, Craig *et al.* 2008, Borelli 2011, Commodore-Mensah & Dennison Himmelfarb 2012) and superior to those that are not theory-based (Hafner & Kirscht 1970, Petrie *et al*. 2002, Fridlund *et al.* 2014). Usual in-hospital education tends to be disease specific, with less focus on theory and more on practical skills (Bodenheimer *et al.* 2002, Petrie *et al*. 2002, Timmins 2005, Maloney & Weiss 2008). In this study, both groups received usual in-hospital education, therefore the receipt of a theoretically-based educational intervention differentiated the control and intervention groups. The provision of education to the intervention group using a theoretical framework that incorporated cognitive, emotional and social factors extended beyond what was delivered in usual care.

Previous interventions that targeted knowledge, attitudes or beliefs about ACS were underpinned by a theoretical framework (Goff *et al.* 2004, Meishke *et al.* 2004, Buckley *et al*. 2007, Tullman *et al.* 2007, Bell *et al.* 2009, McKinley *et al.* 2009, Mosca *et al*. 2013). Five of these were based on Leventhal's self-regulatory model of illness behaviour (Goff *et al*. 2004, Meishke *et al.* 2004, Buckley *et al*. 2007, Tullman *et al*. 2007, McKinley *et al*. 2009). As most of these researchers reported successful intervention outcomes (Goff *et al*. 2004, Buckley *et al*. 2007, Tullman *et al*. 2007, McKinley *et al.* 2009), the use of Leventhal's self-regulatory model of illness behaviour in this study enhanced the potential for the effectiveness of this intervention.

6.4.2 The intervention content

Targeting cognitive aspects

Strategies to enhance cognition in this intervention were based on previously successful interventions and on strategies known to enhance patient education. Consistent with recommendations (Dewalt *et al*. 2004, Boyde *et al*. 2009, Fredericks *et al.* 2010), education should begin with an informal assessment of knowledge. This assessment can be the catalyst for the development of discrepancy or dissonance, which is an important stimulus for learning (Festinger 1957, deVries 2008, Syx 2008).

A combination of patient education strategies has been found to be most effective in improving knowledge and behavioural outcomes (Fredericks *et al.* 2010). Previously successful interventions included a range of strategies to enhance their intervention outcomes such as the provision of written and verbal information (Johnson & Sandford 2005, Friedman *et al*. 2011, Gallagher *et al.* 2013). Written information included an action plan (Buckley *et al*. 2007, McKinley *et al*. 2009) and a wallet card (Gallagher *et al.* 2013), both of which outlined ACS symptoms and how to manage them. In addition to verbal information, recipients of the intervention in this study were provided with an action plan and wallet card to take home. This written information served as another means of information reinforcement.

Reinforcement of information is thought to produce outcomes that are more resistant to extinction in the short and long term (Passer & Smith 2008). The reinforcement of intervention messages was shown to be successful in previous studies (Artinian *et al.* 2002, Buckley *et al*. 2007, Tullman *et al*. 2007, McKinley *et al.* 2009, DeVon *et al*. 2010b, Gallagher *et al.* 2013). According to psychologists, reinforcement increases the likelihood of an appropriate response (Skinner 1971, Taylor 2006) and the more frequently information is recalled, the more likely it is to be retained (Gagne 1970). In this study, the main intervention messages were reinforced on two occasions; at one month and six months after recruitment. Consequently, these aforementioned approaches were included in this intervention. This intervention was further strengthened through the use of an intervention manual that was previously used in successful interventions (Buckley *et al*. 2007, McKinley *et al*. 2009).

Targeting emotional aspects

The ability to cope with a health threat is dependent not only on cognition, but also on the individual's emotions. One of the strengths of Leventhal's self-regulatory model of illness behaviour is its inclusion of coping mechanisms in the face of a health threat (Leventhal *et al*. 1980, de Ridder & de Witt 2006). However, a range of emotions such as fear, embarrassment, denial and anxiety can be triggered in response to ACS symptoms. Both coping and emotions play a role in responses to symptoms and are affected by knowledge, attitudes and beliefs. During the intervention, emotions and attitudes were targeted through increasing participants' levels of self-efficacy, thereby promoting their self-regulatory capacity. It was acknowledged that each individual's emotions, responses and coping mechanisms differ in the presence of a health threat. The intervention focused on minimising barriers that are known to reduce self-efficacy. These include concerns about health care systems and their availability, affordability, acceptability and accessibility (Dracup *et al.* 2006, Scanlon *et al*. 2006, Elzawawy *et al*. 2008, Kaur *et al*. 2008). For example, with respect to accessibility, individuals can falsely believe that in the presence of ACS symptoms, GP consultation is the correct course of action (Pattenden *et al.* 2002) and that GP services are more accessible than ED services (Leslie *et*

al. 2000, Ruston *et al.* 2001, Dracup *et al*. 2006, Alonzo 2007). Misperceptions such as these were reconciled during the intervention, when participants were informed that the ED was available and accessible to them in the presence of ACS symptoms.

Emotions were further targeted in this study using the principles of motivational interviewing. One means by which this was achieved was through the expression of empathy where reflective statements were used to convey an understanding of the kinds of emotions that participants had experienced. With respect to cardiovascular health, motivational interviewing has also been successfully used in previous interventions (Brodie & Inoue 2005, Riegel *et al*. 2006, Watkins *et al.* 2007, Brodie *et al*. 2008, Everett *et al*. 2008, Thompson *et al*. 2011). Thompson *et al*. (2011) suggest that patients with chronic illness are more receptive to motivational interviewing, than those with an acute illness. As one third of participants in the intervention group had experienced a previous cardiac event, they may have had a perception of chronicity. When this perception was combined with motivational interviewing, there was increased potential to positively influence the study outcomes. Patients' expressions of intentions to change during motivational interviewing sessions have been associated with improved outcomes (Watkins *et al.* 2007, Thompson *et al*. 2011).

An individual's level of self-efficacy is thought to have the greatest impact on actual outcomes (Webb & Sheeran 2006). From the attitudes of the intervention group in this study, there was evidence of their sense of control over responses to ACS symptoms. Given that the intervention was underpinned by self-regulation theory and that participants expressed confidence in their ability to recognise and seek help for themselves and others, it was expected that their intentions would translate into behaviours consistent with these intentions. It has been suggested that adherence to intentions is most effective among interventions that increase self-regulatory capabilities (de Bruin *et al.* 2012). Self-regulatory capability can be achieved through the development of knowledge and skills that permit confident and effective responses to barriers that could otherwise impede goal attainment (de Bruin *et al.* 2012).

Targeting social aspects

As the intervention targeted knowledge, attitudes and beliefs, the social component of this study was centred on the role that other individuals can play when symptoms are disclosed to them. Leventhal's self-regulatory model of illness behaviour helped to improve attitudes about normalising the disclosure of symptoms to another individual. The beneficial effect of entrusting another individual with responsibility in the presence of symptoms has been acknowledged in the literature (Yarzebski *et al*. 1994, Horne *et al*. 2000, Gartner *et al.* 2008). Furthermore, the awareness that another individual could offer help and support about symptoms is known to positively influence help-seeking behaviour (Herlitz *et al.* 2010a). During the intervention, the role of the third party was emphasised. This was important because an understanding of one's role and the expectations associated with that role are important factors in the enhancement of learning and its application (Gagne 1970). Consequently, the focus on cognitive, emotional and social factors that impact on knowledge, attitudes and beliefs enhanced the acceptance of the study hypotheses.

6.4.3 The intervention recipients

This study differed from all previous interventions that targeted knowledge, attitudes or beliefs about ACS, with respect to the sample used (Goff *et al.* 2004, Meischke *et al*. 2004, Buckley *et al*. 2007, Tullman *et al*. 2007, Bell *et al*. 2009, McKinley *et al.* 2009, DeVon *et al*. 2010b, Gallagher *et al.* 2013). To be included in this study, an ACS diagnosis was a pre-requisite; a criterion which differed from previous studies, where inclusion criteria ranged from a diagnosis of coronary heart disease (Buckley *et al*. 2007, Tullman *et al*. 2007, Bell *et al.* 2009, McKinley *et al.* 2009, DeVon *et al*. 2010b, Gallagher *et al.* 2013) to no diagnosis required (Goff *et al.* 2004, Meischke *et al*. 2004, Mosca *et al*. 2013). Therefore, relative to the samples included in previous studies, the sample in this study was at higher risk for a future cardiac event.

It is widely known that individuals with a previous cardiac diagnosis are more susceptible to future ACS events (Anderson *et al.* 2007). However, those at high risk for a cardiac event can underestimate or reject their risk status and these individuals are often reticent to change their health behaviours (Weinstein

& Klein 1995, Ayanian & Cleary 1999, Weinstein 1999). Studies that examined the relationship between patients' perceived and actual risk of cardiovascular disease (CVD) reported a tendency towards inappropriate optimism (Weinstein 1999). An accurate risk perception is central to shaping appropriate responses to a health threat (Furze *et al*. 2003, Smith *et al.* 2006, Webster & Heeley 2010).

To target perceptions of invulnerability to a future health threat, participants were informed about their risk for a future ACS event. The relevance of this information may have influenced their uptake and internalisation of the intervention message, as messages are more salient and meaningful for those who identify themselves as being at risk for a recurrent event (Weinstein 1999, Taylor 2006). Percutaneous coronary intervention is the predominant and preferred treatment for patients with STE-ACS (HSE 2012). However, extended pre-hospital delay times have been associated with patients who have undergone PCI (McKee *et al*. 2013). This may be because following PCI, patients no longer feel vulnerable to an ACS event, as PCI can be mistakenly viewed as a curative intervention (Eastwood 2001, Dracup *et al.* 2008). This affirms the importance of educating all ACS patients about their predisposition to heart disease, irrespective of their care pathway.

Unlike the majority of previous educational interventions (Goff *et al.* 2004, Meischke *et al.* 2004, Buckley *et al*. 2007, Tullman *et al*. 2007, Bell *et al*. 2009, McKinley *et al.* 2009, Gallagher *et al.* 2013, Mosca *et al*. 2013), the intervention recipients in this study were hospitalised at the time of intervention delivery. The period of hospitalisation after an ACS event has been recognised as the optimum time to deliver educational interventions aimed at behavioural change, as this is when individuals as most susceptible to learning (Auer *et al*. 2008, Commodore-Mensah & Dennison Himmelfarb 2012). Furthermore, it has been suggested that cardiac patients are more receptive to interventions if they are targeted immediately following their heart attack or health threat event (Weinstein 1989, Weinman *et al*. 2001, Petrie *et a*l. 2002). The intervention in this study was generally delivered within 2-4 days of their ACS event. As intervention delivery was sufficiently close to their event, this optimised the potential that this timing contributed to the noted improvement in knowledge,

attitudes and beliefs about ACS. The allowance of 2-4 days following admission provided the participant with time to adjust to their event and to restore some level of health equilibrium. None of the previous recipients of educational interventions were targeted within 96 hours of their ACS event (Goff *et al*. 2004, Meischke *et al*. 2004, Buckley *et al.* 2007, Tullman *et al*. 2007, McKinley *et al*. 2009, DeVon *et al*. 2010b, Gallagher *et al*. 2013, Mosca *et al*. 2013). This is the first study to do so, which contributes to the originality of this study.

6.4.4 The delivery mechanism

This intervention was standardised, yet individualised to each participant's personal context and their unique ACS experience. It has been reported that individualised health-related educational interventions tend to be more effective than those that are non-individualised (Fletcher 1987, Lauver *et al.* 2002, Ryan & Lauver 2002, Suhonen *et al*. 2008, Commodore-Mensah & Dennison Himmelfarb 2012). Furthermore, individualised interventions have been known to increase the chance of behavioural modification (Strecher *et al*. 2002, Alm-Roijer *et al.* 2006, Jensen *et al*. 2009). While there is a relative scarcity of empirical evidence to support and evaluate the impact of individualised interventions, it has been suggested that an individualised approach to teaching is well suited to those at greatest risk of symptom development (Caldwell & Miaskowski 2002, Thuresson *et al.* 2008, Jankowski *et al.* 2011).

With respect to ACS, previously successful interventions were based on individualised approaches (Buckley *et al*. 2007, Tullman *et al*. 2007, McKinley *et al.* 2009, DeVon *et al*. 2010b, Gallagher *et al.* 2013). Furthermore, individualised interventions were reported to have been read more frequently and remembered better (De Vries & Brug 1999, Skinner *et al.* 1999, Ryan & Lauver 2002). Rogers (1983) contends that information will be meaningful and internalised if it is holistically relevant to the person. This infers that individualised interventions are superior to those that are non-individualised. Thus, the individualisation of the intervention in this study contributed to its successful outcomes.

Intervention uptake can diminish if it is demanding of time or effort (Conn *et al.* 2001, Aranda 2008). It has been suggested that interventions of less than one-hour duration are suited to the clinical area and are less likely to tire participants (Cleary *et al*. 2012). In this intervention, the 40 minutes spent with the participant was sufficiently long to facilitate assimilation of the intervention message, yet short enough to prevent apathy and fatigue. Consequently, the most successful interventions are those that are individualised and do not exceed one hour duration. The use of these strategies positively strengthened the effect of the intervention in the current study.

6.5 The control group

Given the success of the educational intervention among the intervention group, the decline in knowledge scores among the control group is most likely attributable to their non-receipt of the intervention. While the most commonly recognised symptoms were known by both groups, subtle or atypical symptoms were less familiar to the control group. Commonly known ACS symptoms are widely advertised through the media. However, these are not always internalised, as people tend to normalise unpleasant information (Alonzo & Reynolds 1997). In this study, the intervention group was protected against normalising unpleasant information, as the intervention reinforced their vulnerability for a future event. Furthermore, the intervention included all potential ACS symptoms including those that are not easily located within the public realm. This may have contributed to the differentiation in outcomes between the two groups.

While knowledge scores among the control group decreased, their attitude and belief scores increased. The pattern of change in attitude and belief scores among the control group mirrored that of the intervention group. However, the change was greater among the intervention group. It is likely that the hospital admission experience impacted similarly on all participants' attitudes and beliefs about attending the ED on a subsequent occasion for ACS symptoms. While these experiences are unlikely to alter knowledge levels, the admission experience would impact on their attitudes and beliefs with respect to their intentions to seek treatment in the future. This helps to explain the change in

attitudes and beliefs in both groups and the significant difference between the groups.

6.6 Intentions versus behaviours

Knowledge, attitudes and beliefs impact on help-seeking behaviour. Improvements in these three constructs can translate into the prompt recognition of ACS symptoms, the initiation of help-seeking behaviour and consequently, a reduction in patient pre-hospital delay time. In this study, more participants in the intervention group, compared to the control group, responded with the intention of behaving in accordance with the components of the intervention. Furthermore, with reference to the other research strand associated with the ACS Response Time Intervention Trial, there was evidence that intentions were translated into behaviours, as more participants from the intervention group presented more promptly to the ED with ACS symptoms (Mooney *et al*. 2014). The researchers (Mooney *et al*. 2014) reported that there was a significant difference in pre-hospital delay time between the control and intervention group following the intervention ($p \leq 0.001$). The post-intervention pre-hospital delay time difference between the control and intervention group was 5.4 hours. Furthermore, more participants from the intervention group disclosed their symptoms more promptly to another individual and less consulted with a GP in the presence of symptoms, both of which were components of this intervention. In the absence of adequate knowledge, attitudes and beliefs about ACS, these outcomes may not have been realised.

6.7 Implications for clinical practice, education and future research

The aim of this study was to test the effectiveness of the intervention on knowledge, attitudes and beliefs about ACS. Based on its positive outcomes, the aim is now to translate the study results into clinical practice. This is an essential step, as the advancement of nursing practice is dependent on a sound evidence base (Corry *et al.* 2013, Jaarsma *et al*. 2014). Nursing research and clinical practice are therefore interdependent. Well-conducted clinically based studies in general and RCTs in particular, provide empirical evidence for change. In the case of this study, there is scope for what is referred to as translational research, where research findings can be translated and applied in clinical practice.

It is widely known that patient decision-delay is the primary reason for failure to seek and receive timely treatment for ACS symptoms (O'Donnell *et al.* 2014). Lack of knowledge is one factor that contributes to patient decision-delay (Jankowski *et al.* 2011). This study makes a major contribution to clinical practice as greater knowledge, better attitudes and more accurate beliefs about ACS culminate in appropriate help-seeking behaviour. Consequently, this study has the potential to reduce ACS-related mortality and morbidity. The incorporation of this intervention into usual care in clinical practice would empower individuals to seek help promptly in the face of ACS symptoms. Furthermore, the adoption of theoretically-based information in usual care would benefit all patients with ACS.

Patient education is elementary to good nursing practice (Albarran *et al*. 2013). With respect to cardiovascular health, patient education is dependent on learning that can exert change in knowledge, attitudes, skills and behaviours, which ultimately has the potential to improve health status and outcomes (Rankin & Stallings 2001). Cardiovascular nurses dedicate many hours to the provision of education, which often focuses on self-management and improvements in well-being (Norekval *et al.* 2007). The effect of this intervention was sufficiently strong to support its adoption into practice. The intervention

took approximately 40 minutes to deliver and could easily be administered by nurses in coronary care units, as a component of usual care.

Based on this study's results, it is reasonable to suggest that responses to ACS symptoms are likely to be more appropriate among those whose knowledge levels about ACS are at least adequate. The significant difference in attitudes and beliefs between the groups may have originated from, among other things, the focus on increasing knowledge during the intervention, as these three constructs are interdependent (McKinley *et al*. 2009, O'Brien *et al.* 2013).

Considering the admission rate outlined in the CONSORT for this study (Figure 5), many patients could benefit from receipt of this intervention annually, if it is incorporated into usual care. The literature suggests that individuals generally consult with another person in the presence of ACS symptoms (McKinley *et al*. 2004). In light of this, there is potential for this intervention to impact beyond the direct recipients of the intervention, as lay individuals who consult with the recipients would also benefit from the advice to act in accordance with the components of the intervention. In due course, this has the potential to save lives and improve or maintain health, which would reduce health resource expenditure.

In addition to the potential contribution of this study to clinical practice and patient education, this study can also contribute to future research. From a clinical perspective, the nurses in the research sites demonstrated an interest in this research and were keen to hear about the study outcomes. This may have had the effect of generating their enthusiasm in clinical research. The outcomes of this study have the potential to reach a wide audience and to make a global difference across the developed world. However, its impact is contingent on the intervention being adopted in practice. To maximise this potential, the results of the study have been and will continue to be disseminated. The means by which this dissemination has taken place to date is outlined in Appendix 13.

6.8 Study limitations

While this RCT has improved participants' knowledge, attitudes and beliefs about symptom recognition and appropriate help-seeking behaviour in ACS, some limitations are acknowledged:

Threats to external validity

- As part of the exclusion criteria, patients who were clinically unstable were not eligible to participate in the study. Consequently, the effect of the educational intervention on this cohort remains unknown.

- Only 58% of participants completed the questionnaires at all three time-points. The remaining 42% were excluded from analyses (as per the Consort flow diagram). Therefore, only data on a percentage of the total population were included.

- The sample in this study was quite homogenous in that 97% was Irish. Therefore, the results may not be generalisable to other nations. Similarly, as the study was conducted in five urban hospitals, the effect of the intervention cannot be generalised to rural settings.

Threat to internal validity

- Despite the strict randomisation protocol outlined in the methods chapter, the control and intervention groups differed at baseline with respect to age, education level, employment status, health insurance and presence of diabetes. These differences were due to chance and were controlled for in the analyses.

6.9 Study conclusion and recommendations

This is the first European RCT to target and demonstrate the effectiveness of an intervention on participants': knowledge about ACS facts and symptoms; attitudes towards symptom recognition and confidence in their own ability to instigate appropriate help-seeking behaviour; and beliefs about what constitutes appropriate responses to ACS symptoms. Furthermore, this effectiveness was sustained for at least one year. The acceptance of the study hypotheses was

substantiated through the use of a robust RCT. Other study strengths include a well-defined ACS population and a well-powered sample, in addition to the use of a reliable and well validated data collection instrument and educational intervention. The success of the intervention was optimised through the use of an appropriate theoretical framework to underpin the intervention, the content of the intervention, its recipients and the means by which the intervention was delivered.

With respect to the theoretical framework, the concepts of self-regulation and self-efficacy were addressed through the emphasis on cognitive, emotional and social factors. The intervention promoted the adoption of self-regulatory procedures as a means of coping and controlling actions and reactions to a health threat. It was endeavoured that this would result in appropriate help-seeking behaviour in the presence of ACS symptoms. It is likely that the high-risk sample and the emphasis on their risk for a future event increased the saliency of the intervention message for the intervention group. With respect to delivery of the intervention, the individualised approach and the fact that the intervention reflected important aspects of educational psychology further contributed to the study outcomes.

The acceptance of the study hypotheses suggests that help-seeking behaviours can be modified, which can potentially improve prognosis and reduce mortality and morbidity among patients diagnosed with ACS. As an outcome of the ACS Response Time Intervention trial, it can be inferred that knowledge, attitudes and beliefs play important roles in the reduction of pre-hospital delay time. However, the long-term success of the study will be dependent on the implementation of this educational intervention into clinical practice. Meanwhile, the following recommendations arise from this RCT:

6.9.1 Recommendations for clinical practice

- Ideally, this 40-minute educational intervention should be replicated in full, using one-to-one individualised teaching by a designated nurse, for all patients admitted to hospital with an ACS diagnosis.

- If economic resources preclude the employment of a designated nurse to deliver the intervention, then it is recommended that the intervention be incorporated into usual care for ACS patients. Furthermore, special emphasis should be placed on the extent of their risk and vulnerability for a future ACS event.

6.9.2 Recommendations for education

- Due to limited knowledge of the range and variability of ACS symptoms by participants at baseline, the dissemination of educational messages to the public that incorporate this information is recommended. This would also help to reduce incongruence between symptom expectation and presentation for those who experience ACS symptoms for the first time. Consistent with symptom knowledge, the public should be educated about the appropriate action to take in the presence of symptoms and information messages should foster positive attitudes and beliefs about help-seeking behaviour.

- The principles of motivational interviewing were incorporated into intervention delivery and may have been a factor in the study's success. Despite the fact that this technique has gained credibility as a means of behavioural change, it is not currently part of undergraduate general nurse education programmes or postgraduate cardiovascular nursing programmes. It is therefore recommended that motivational interviewing techniques be considered for inclusion in nursing and health science curricula.

6.9.3 Recommendations for future research

- As there is limited research pertaining to knowledge, attitudes and beliefs about ACS, it is recommended that further research be conducted into these phenomena. It is further recommended that researchers disseminate these results in full, to include scores for knowledge, attitudes and beliefs.

- It is recommended that mean and individual subscale items for each variable of knowledge, attitudes and beliefs are included in research reports.

- There is no empirical evidence to support or determine what constitutes acceptable knowledge scores. This needs to be substantiated through research to provide a benchmark for future studies.

- In order to determine the effectiveness of this intervention on a rural population, it is recommended that the intervention be delivered and tested in a rural setting.

- As the vast majority of the study sample was Irish, it is recommended that this study be replicated outside Ireland, to test the effectiveness of the educational intervention throughout Europe and beyond.

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Appendix 1: The Intervention Manual

The Intervention Manual

ACS Response-Time Intervention Trial

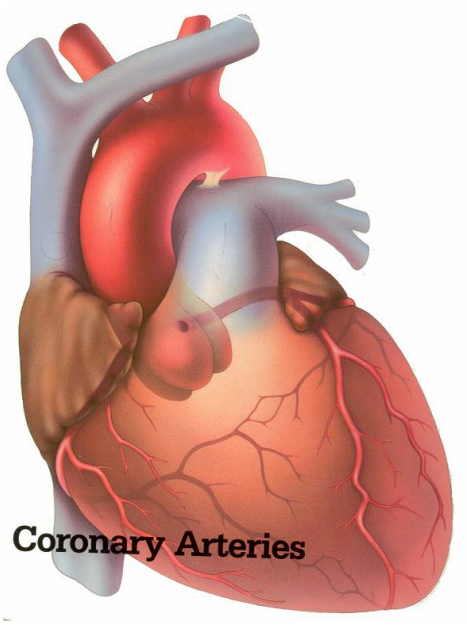
Intervention PowerPoint slides and associated script.

- 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.

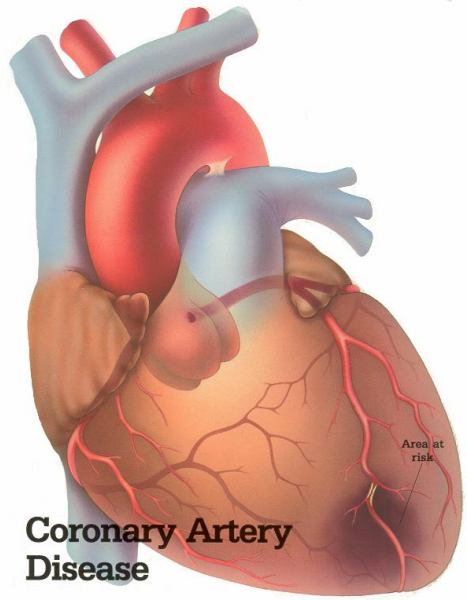
The aim of this study is to teach patients how to recognise common heart symptoms and the benefits of seeking care early (to promote early response to heart symptoms).

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

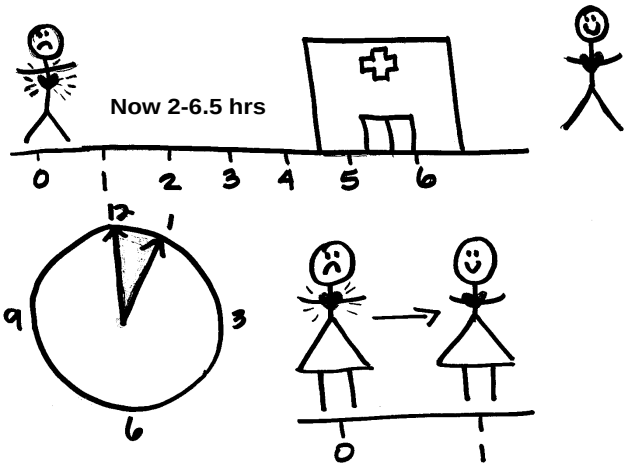
By getting to the hospital quickly, patients spend the <u>first hour near trained personnel</u> with <u>emergency equipment</u> to treat the life threatening complications, which often lead to sudden death within the first hour of a heart attack. Remember, you are at increased risk of another event and 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/ pain/tightness 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

- Intrascapular pain
- 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.

<u>Common sites for chest pain</u>

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

<u>What to do when you think you are having a heart attack.</u>

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 HESTITATE

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?

Scenarios for patients to consider (males)

1. A 36 year old man began to feel "not well" as he was getting ready for work in the morning. He felt heaviness in his chest and began to feel slightly nauseated. He thought he might be coming down with the flu. As the day progressed he felt the heaviness in his chest become more intense and he began to feel cold and clammy.

   What do you think he should do?

2. You are out to lunch with your friend, who is a 68 year old man. He tells you that he began to feel chest pain about 30 minutes ago and now feels like he can't get enough air to breathe. What would you do?

   Scenario continued: He tells you that he thinks he has the flu and is going to drive himself home so that he can go to bed. What do you think about his plan? What would you tell him to do?

Scenarios for patients to consider (females)

1. A 40 year old woman was finishing her evening shift as a telephone operator. During the last two hours she has had some discomfort in her chest which she thought was due to sitting in one position for so long. As she walked to her car the discomfort became worse and spread up to her jaw. She noticed she was breathless and felt as though there was something wrong.

   What do you think she should do?

2. You are playing cards with your friend, who is a 68 year old woman. She tells you that she began to feel chest pain about 30 minutes ago and now she feels lightheaded and nauseated. What would you do?

   Scenario continued: She tells you that she thinks she has the flu and is going to drive herself home to take some medication and rest. What do you think about her plan? What would you tell her to do?

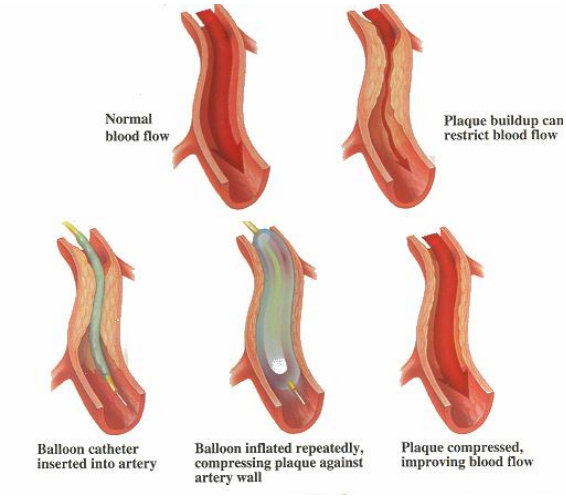
Rehearsal of response to heart attack symptoms

(Individually tailor for each person's age, gender, medical history and social circumstances).

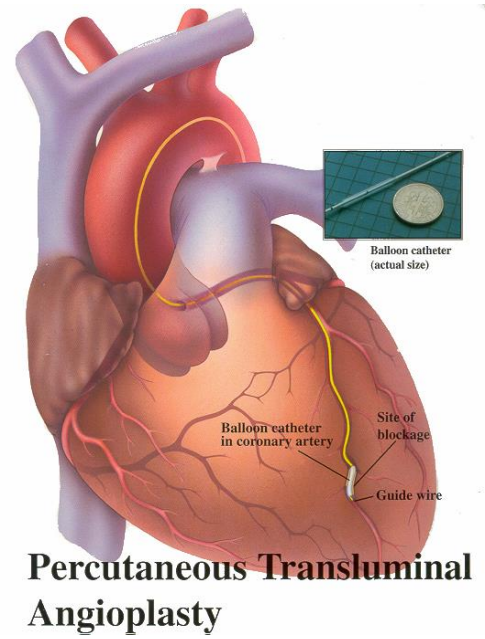
1. You wake up at 3:00 am with a dull ache in your chest. You don't want to wake anyone up so you lie in bed waiting for the pain to go away. Finally, you get up and take some antacid medication from the bathroom medicine cabinet. It doesn't seem to help. What should you do next?

2. You had a big Thai dinner about two hours ago and now you feel nauseated and have a pain that comes and goes right here (point to lower sternum). The pain continues to come and go but for the last 30 minutes has become quite severe. What do you do next?

Percutaneous Transluminal Coronary Angioplasty (PTCA)



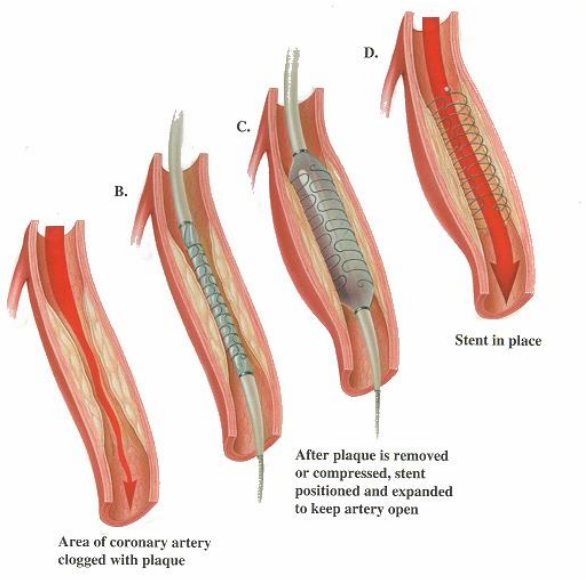
This diagram shows a normal coronary artery with smooth walls. Next to it is an artery that is narrowed because of plaque build-up. The angioplasty catheter is threaded into the narrow artery, the balloon is blown up and the vessel wall made larger by the pressure exerted by the balloon. Angioplasty is very effective but frequently these arteries reclose in a short period of time.



Percutaneous Transluminal Angioplasty

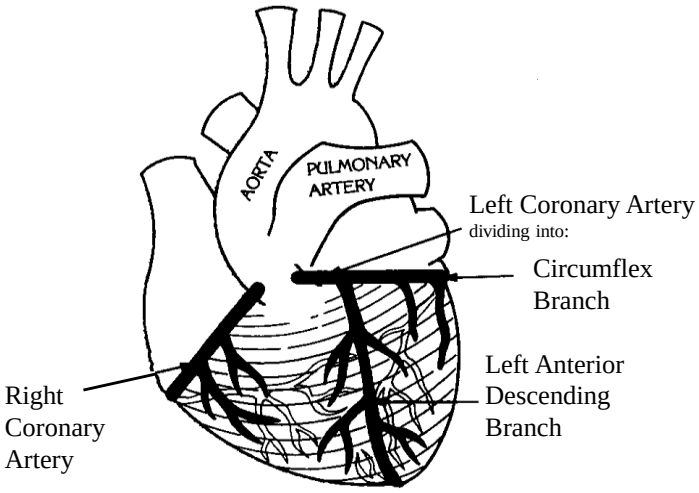
Percutaneous Transluminal Angioplasty is a procedure in which a small catheter is threaded from an artery in the groin to the blocked portion of the artery in the heart.

PTCA and Intracoronary Stenting

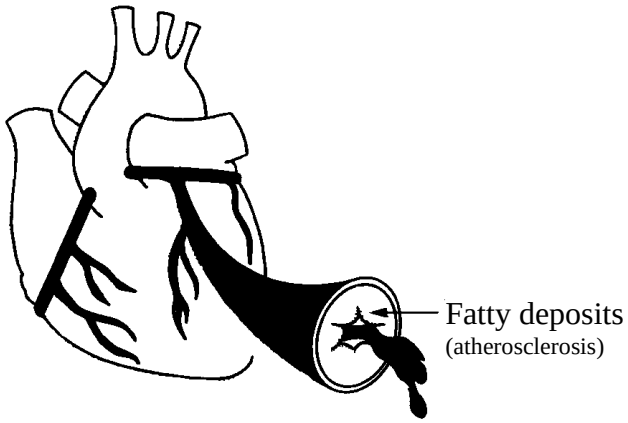


Over the past few years coronary artery stents have been perfected and are used as a kind of scaffolding to keep the arteries open after angioplasty. This diagram shows you how an angioplasty catheter is used to introduce the narrowed stent into the artery. When the angioplasty balloon is inflated, the 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.

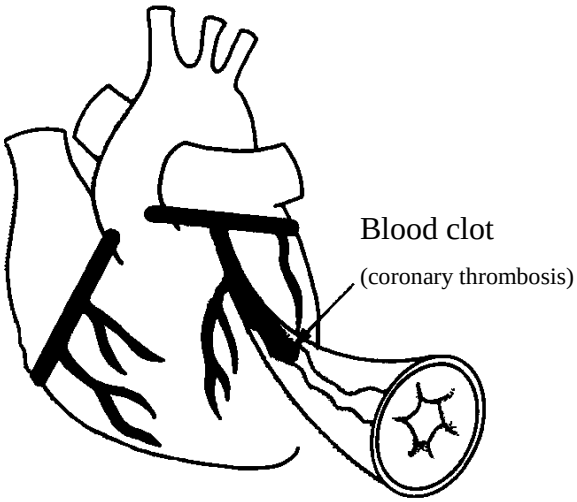
Blood supply to the heart



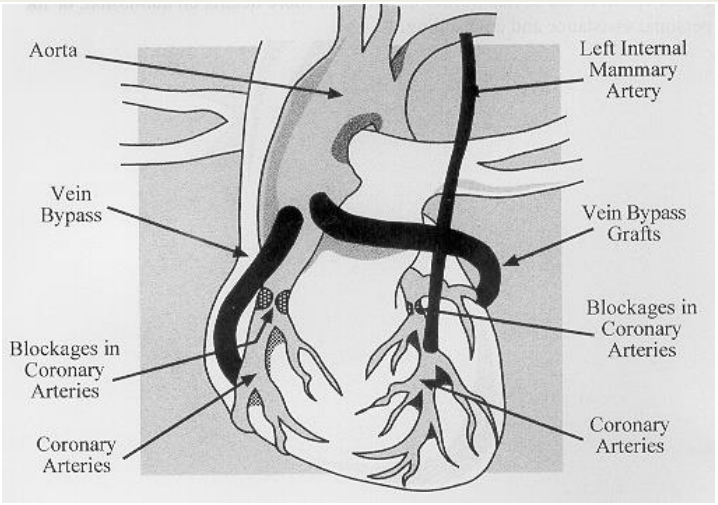
Atherosclerosis



Blockage of the coronary arteries

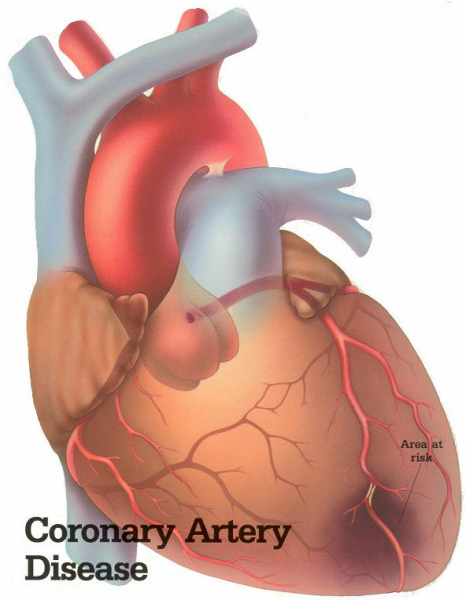


Coronary bypass surgery



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?

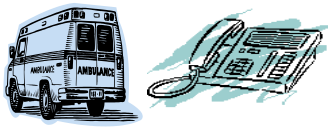
1. You may experience <u>some</u> or all of these symptoms:

- 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, <u>phone 999 or 112 for an ambulance.</u>

- 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 58200925

Wallet card

WHAT TO DO IF YOU HAVE ONE OR MORE HEART WARNING SYMPTOMS?

Don't wait
Don't hasitate
IF IN DOUBT
LET A&E
CHECK IT

1.If symptoms are present:
- Stop and rest
- Take your GTN spray as directed
2. Let someone else know what is happening
3. If the symptoms continue longer than 15 minutes, phone 999 or 112 for an ambulance

You may experience <u>some</u> 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 our navel

ACS RESONSE-TIME INTERVENTION TRIAL

Appendix 2: 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

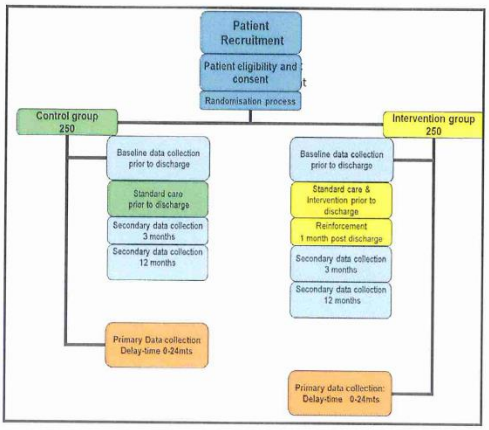
- Principle Investigator
  - Dr Gabrielle McKee
- ACS Research Team, School of Nursing and Midwifery, Trinity College Dublin.
  - Dr Sharon O'Donnell, Prof Debra Moser, Mary Mooney and Frances O'Brien.

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.

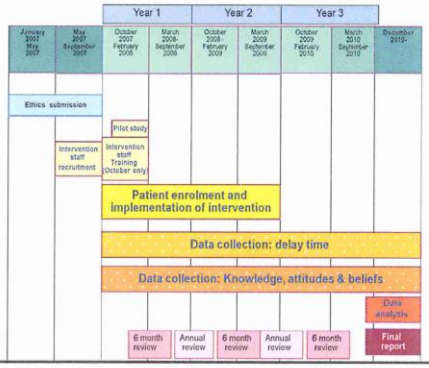
  Information, emotional issues, social factors, action plan, individualisation.

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

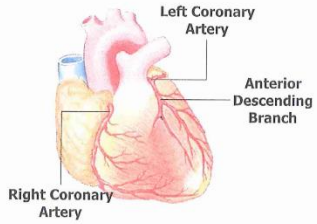
- Cells require constant O2 & Nutrients.
- If perfusion is reduced, cells become irreversibly injured.
- Cell death takes a finite period.
- Complete necrosis takes 4-6 hours.
- Collateral perfusion helpful

(Alpert et al. 2000)

Causes

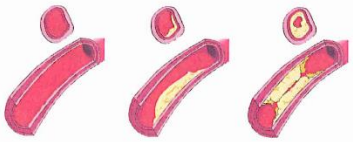
Reduced blood flow due to

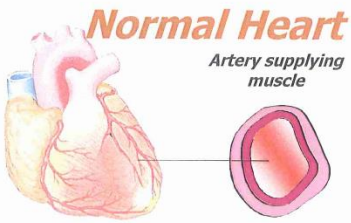
- Atherosclerosis
- Embolus
- Thrombus
- Arterial spasm
- Shock or Haemorrhage

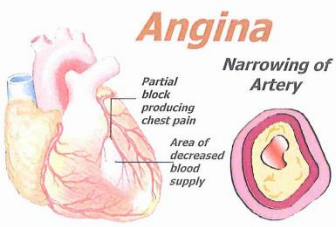


Causes of Heart Disease

- 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)

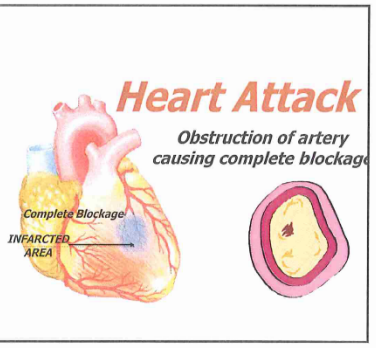
Types of Infarcts

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:** O2, 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: Retaplase–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 O2 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 MVO2 - eg. Hypertrophy
- Pericarditis
- Pulmonary embolus
- Oesopageal 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 O2 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 02 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 O2 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.

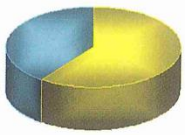
Acute Coronary Syndrome:

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.

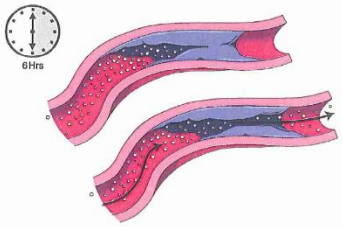
Most deaths occur within 1 hour of symptoms onset



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



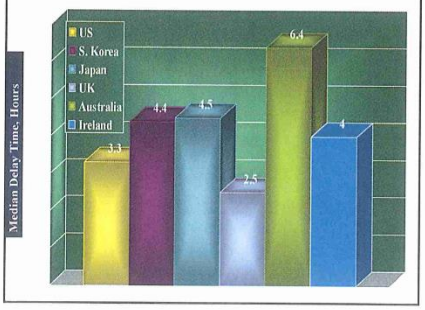
A Global Epidemic of Delay

- 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.

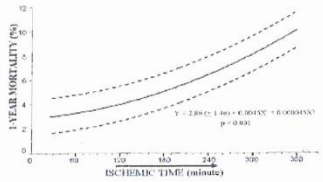
Delay in Seeking Treatment

- Median delay times 2 - 6.4 hours
  - NRMI = 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

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

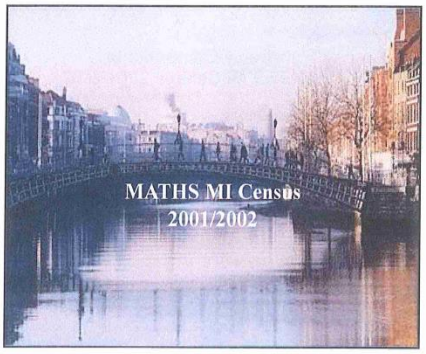
- Data were collected on 29,398 (reference) and 31,645 (intervention) patients presenting to A&E's with suspected acute CHD.
- Hospitalized during the intervention period with a CHD-related discharge diagnosis
  - 9801 reference patients
  - 10563 intervention patients

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

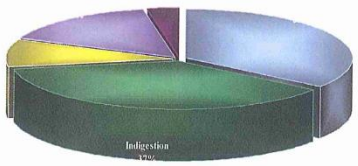
- Baseline ambulance use in all 20 communities: 33%
- Ambulance use increased steadily and significantly in the intervention communities (16%/yr)
- Mean trend in ambulance use in reference communities did not change
- Net effect: 20% increase in ambulance use in intervention vs. reference communities



The MATHS MI Census 2001-2002

- 1-year Prospective Myocardial Infarction Census
- Duration: December 1st 2001 - November 30th 2002
  - Site: 6 Major Academic Teaching Hospitals in Dublin

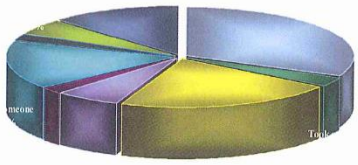
Symptom Attribution



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

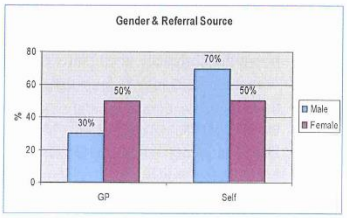
Patient Initial Response to Event



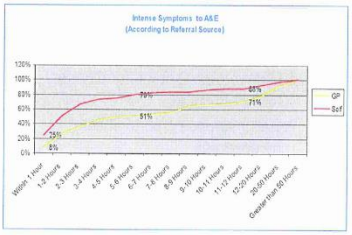
Seeking Expert Help

- 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

Referral Source



Pre-hospital Delays (Referral Source)



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.

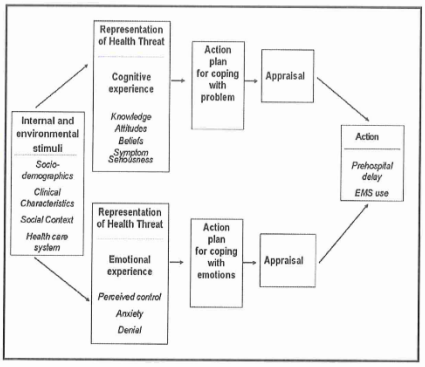
Seven Steps to Survival

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.

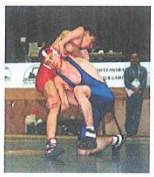
What is Known about Health Behaviors?

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)

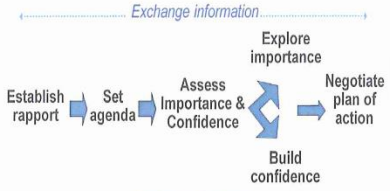
Brief Motivational Counseling "Dancing, not wrestling"



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

General Strategy



Source: Rollnick, Mason & Butler (1999).

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

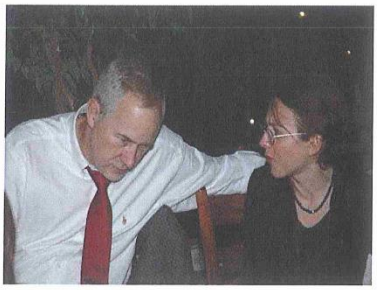
Roll with Resistance

- Avoid "yes, but…"
- Avoid "premature focus" on change
  - pushing ahead too soon
- Avoid simple solutions
- Avoid advice giving

Support Self-Efficacy

Social Cognitive Theory

- Cognitive factors
  - Self-efficacy*
    - Personal maste
    - Vicarious experiences
    - Verbal persuasion
    - Physiologic state
- Environmental factors
  - Social & Structural



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 patent 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 3: Trial Protocol

ACS Response-Time Intervention Trial

The effectiveness of a structured educational intervention in improving knowledge, attitudes and beliefs about acute coronary syndrome and reducing pre-hospital delay time in patients at risk for 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 (Erhardt *et al.* 2002, Johansson *et al.* 2004a, 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.* 2004a, 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 improving knowledge, attitudes and beliefs about ACS, thereby reducing patient pre-hospital delay time among patients who present to an ED with ACS symptoms.

Hypotheses

Following the intervention:

- 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.

- 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.

Outcome measures

- Knowledge, attitude and belief scores at baseline, 3 months and 12 months.
- 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.

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 size

For the measurement of pre-hospital delay time

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.

For the measurement of knowledge, attitudes and beliefs

The sample size required to test the hypotheses for knowledge, attitudes and beliefs was calculated using previously published data (McKinley *et al.* 2009) and G* Power 3.1 (Faul *et al.* 2009).

Using data from McKinley et al. (2009), mean knowledge scores for the control and intervention groups were 69.77 and 72.46 respectively, with a mean standard deviation of 11.95 for the control group. This represented an effect size of 0.225. Given this effect size, an alpha of 0.05 and assuming the use of repeated measures ANOVA using 2 groups (control and intervention) and 3 repetitions (baseline, 3 months & 12 months), it was estimated that a sample size of 174 was required to achieve sufficient power (1-beta) to show a significant difference, if it truly existed (95% power).

Using data from McKinley et al. (2009), mean attitude scores for the control and intervention groups were 14.65 and 15.04 respectively, with a mean standard deviation of 2.51 for the control group. This represented an effect size of 0.155. Given this effect size, an alpha of 0.05 and assuming the use of repeated measures ANOVA using 2 groups (control and intervention) and 3 repetitions (baseline, 3 months & 12 months), it was estimated that a sample size of 364 was required to achieve sufficient power (1-beta) to show a significant difference, if it truly existed (95% power).

Using data from McKinley et al. (2009), mean belief scores for the control and intervention groups were 23.08 and 23.47 respectively, with a mean standard deviation of 3.39 for the control group. This represented an effect size of 0.115. Given this effect size, an alpha of 0.05 and assuming the use of repeated measures ANOVA using 2 groups (control and intervention) and 3 repetitions (baseline, 3 months & 12 months), it was estimated that a sample size of 658 was required to achieve sufficient power (1-beta) to show a significant difference, if it truly existed (95% power).

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 one section on knowledge, attitudes and beliefs about ACS and the other on responses to symptoms. 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

Prepare pack in advance of attending research site to include:	
• Patient eligibility form. • Participant information sheet. • Consent Form (2 copies). One for you and one for the patient. • Questionnaires: Clinical History, Socio-demographic & ACS Response Index.	• Participant contact details form. • Sealed envelope with an opaque window (with study number revealed and randomisation group concealed). • Yellow sticker for chart. • Refrigerator magnet.

Baseline (I = Intervention group, C= Control group)

Step taken	**I**	**C**
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
Control only 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
Intervention only 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 enrolement 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
The interventionist must manage the collected data: 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.	x	x

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.		

(I = Intervention group, C= Control group)

1 month follow-up (Intervention group only)

Step taken	**I**
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. 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.	x

(I = Intervention group, C= Control group)

6 month follow-up (Intervention group only)

Step taken	**I**
Intervention group only Using the data-management system, identify the participants to whom reminder action plans are due to be distributed. Prepare action plan sheets and letters for posting. Address and stamp each envelope and post. Update data-management system.	x

Readmission data (first readmission only – collect from time of enrolement to study end)

Step taken	**I**	**C**
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
Using the data-management system, identify the participants to whom questionnaires are due to be distributed. Prepare questionnaires and letters for posting (personalise each letter). Enclose these with a stamped addressed envelope. Address and stamp each envelope and post. In the event of non-receipt of responses, telephone the participant to check that they received the package. For those who had mislaid it or not received it, resend the package, with consent. For those who had received it but had not returned it, kindly request that they might do so at their own convenience. A maximum of 2 reminder phone calls to each participant is recommended in an effort to retrieve the questionnaires.	x	x
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.	x	x
Input data from hardcopy of the questionnaire onto database. Cross-check the completed data between hardcopy and the database. Save changes to database using the external hard drive provided. File hardcopies of questionnaires in numerical order. Data-management – organise and update records with dates for follow-up.	x	x

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Appendix 4: 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 the 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 5: 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

_____
Frances O'Brien
Research Nurse

WHAT TO DO IF YOU HAVE ONE OR MORE HEART WARNING SYMPTOMS?

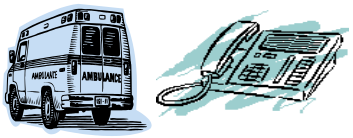
1. You may experience <u>some</u> or all of these symptoms:

- 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, <u>phone 999 or 112 for an ambulance.</u>

- 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 58200925

Appendix 6: 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
Cardiac history			
Angina	☐	☐	☐
MI	☐	☐	☐
PTCA	☐	☐	☐
Stent	☐	☐	☐
CABG	☐	☐	☐
Valve surgery	☐	☐	☐
Co-morbidities			
Diabetes mellitus	☐	☐	☐
Peripheral vascular disease	☐	☐	☐
Stroke	☐	☐	☐
Current known cardiac risk factors			
Positive family history of CHD	☐	☐	☐
Current smoker	☐	☐	☐
History of smoking	☐	☐	☐
Hypercholesterolaemia	☐	☐	☐
Hypertension	☐	☐	☐
Do you intend to attend cardiac rehabilitation programme?	☐	☐	If no why not

Physical activity questionnaire	Days/week	Hrs./day	Mins./day	None
Vigorous activity				☐
Moderate activity				☐
Walking				☐
Sitting				☐

Weight ☐ stones ☐ pounds ☐ KG

Height ☐ feet ☐ inches or metres ☐ **BMI** ☐

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
☐ Unemployed
☐ Retired
☐ Student
☐ Looking after home or family
☐ 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
☐ Private Health Insurance
☐ Don't know
☐ Social health insurance (PRSI)
☐ Uninsured
☐ 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.	☐	☐
b.	Most heart attacks occur in people over age 65.	☐	☐
c.	Hospitals have treatments that can reduce the damage of a heart attack.	☐	☐
d.	The location and size of a heart attack can vary depending on which blood vessel in the heart is blocked.	☐	☐
e.	Most patients benefit from taking two puffs of GTN spray immediately if they experience heart attack symptoms.	☐	☐

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)	☐	☐
2.	Arm pain or shoulder pain	☐	☐
3.	Arm paralysis (unable to move arm)	☐	☐
4.	Back pain	☐	☐
5.	Chest pain/pressure/tightness	☐	☐
6.	Chest discomfort (heaviness, burning, tenderness)	☐	☐
7.	Cough	☐	☐
8.	Dizziness, light-headedness	☐	☐
9.	Headache	☐	☐
10.	Heartburn/indigestion/stomach problem	☐	☐
11.	Jaw pain	☐	☐
12.	Loss of consciousness/fainting	☐	☐
13.	Nausea/vomiting	☐	☐
14.	Neck pain	☐	☐
15.	Numbness/tingling in arm or hand	☐	☐
16.	Pale, ashen, loss/change of colour	☐	☐
17.	Palpitations/rapid heart rate	☐	☐
18.	Shortness of breath/difficulty breathing	☐	☐
19.	Slurred speech	☐	☐
20.	Sweating	☐	☐
21.	Weakness/fatigue	☐	☐

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?	☐ 1	☐ 2	☐ 3	☐ 4
3.2 How sure are you that you could recognise the signs and symptoms of a heart attack in yourself?	☐ 1	☐ 2	☐ 3	☐ 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?	☐ 1	☐ 2	☐ 3	☐ 4
3.4 How sure are you that you could get help for someone if you thought they were having a heart attack?	☐ 1	☐ 2	☐ 3	☐ 4
3.5 How sure are you that you could get help for yourself if you thought you were having a heart attack?	☐ 1	☐ 2	☐ 3	☐ 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.	☐ 1	☐ 2	☐ 3	☐ 4
4.1 Most people who have heart attacks have crushing, severe chest pain.	☐ 1	☐ 2	☐ 3	☐ 4
4.3 Women rarely have heart attacks	☐ 1	☐ 2	☐ 3	☐ 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.	☐ 1	☐ 2	☐ 3	☐ 4

	Strongly agree	Agree	Disagree	Strongly disagree
4.5 I would be embarrassed to go to the hospital if I thought I was having a heart attack but I wasn't.	☐ 1	☐ 2	☐ 3	☐ 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.	☐ 1	☐ 2	☐ 3	☐ 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.	☐ 1	☐ 2	☐ 3	☐ 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.	☐ 1	☐ 2	☐ 3	☐ 4
4.9 If I thought I was having a heart attack, I would go to the hospital right away.	☐ 1	☐ 2	☐ 3	☐ 4

	Much less likely	Somewhat less likely	About the same	Somewhat more likely	Much more likely
5.0 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?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Excellent	Very good	Good	Fair	Poor
5.1 In general would you say your health is	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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 <u>initially</u> 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
- ☐ Spouse
- ☐ Other Family Relative
- ☐ Friend
- ☐ Co-worker
- ☐ Stranger
- ☐ GP:
- ☐ Other: ☐

14. 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

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 ± 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

Letter accompanying 3 month questionnaire

ACS RESPONSE TIME INTERVENTION TRIAL

School of Nursing & Midwifery,
Trinity College Dublin,
24 D'Olier Street,
Dublin 2

Dear

I hope you have been keeping well since your discharge from hospital.

When you enrolled in our research study about heart symptoms, I explained to you that I would be sending you a questionnaire in three months. If you can complete the questionnaire then that would be wonderful and much appreciated. I have enclosed a pre-paid envelope with my return address.

If not don't worry I will be phoning you shortly to see how you are getting on and if you prefer, we can complete it over the phone at that stage. Please fill out as many questions as you can before the phone call and we will finish it during our chat.

If you have any questions about the study or the questionnaire then please give me a call on 085 8200925. If you leave your name and telephone number, I will phone you back.

Thank you so much for your participation. It is much appreciated.

Yours sincerely

_____
Frances O'Brien
Research Nurse

Letter accompanying the 12 month questionnaire

ACS RESPONSE TIME INTERVENTION TRIAL
School of Nursing & Midwifery,
Trinity College Dublin,
24 D'Olier Street,
Dublin 2

Dear

I hope you have been keeping well since we were last in touch.

It is now one year since you enrolled in the research study about heart symptoms. Thank you so much for your participation to date. I now enclose the final questionnaire along with a stamped addressed envelope in the hope that you will kindly fill it in and return it to me.

I will be phoning you shortly to see how you are getting on.

If you have any questions about the study or the questionnaire then please give me a call on 085 8200925, leaving your name and telephone number and I will phone you back.

Your contribution over the past year has been invaluable and is much appreciated. I wish you all the best.

With kind regards.

_____
Frances O'Brien
Research Nurse

ACS RESPONSE TIME INTERVENTION TRIAL

Study ID ☐ **3 month** ☐ **12 month**

Have you attended A& E since we last spoke for cardiac related symptoms? ☐ Yes ☐ No

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.	☐	☐
b.	Most heart attacks occur in people over age 65.	☐	☐
c.	Hospitals have treatments that can reduce the damage of a heart attack.	☐	☐
d.	The location and size of a heart attack can vary depending on which blood vessel in the heart is blocked.	☐	☐
e.	Most patients benefit from taking two puffs of GTN spray immediately if they experience heart attack symptoms.	☐	☐

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)	☐	☐
2.	Arm pain or shoulder pain	☐	☐
3.	Arm paralysis (unable to move arm)	☐	☐
4.	Back pain	☐	☐
5.	Chest pain/pressure/tightness	☐	☐
6.	Chest discomfort (heaviness, burning, tenderness)	☐	☐
7.	Cough	☐	☐
8.	Dizziness, light-headedness	☐	☐
9.	Headache	☐	☐
10.	Heartburn/indigestion/stomach problem	☐	☐
11.	Jaw pain	☐	☐
12.	Loss of consciousness/fainting	☐	☐
13.	Nausea/vomiting	☐	☐
14.	Neck pain	☐	☐
15.	Numbness/tingling in arm or hand	☐	☐
16.	Pale, ashen, loss/change of colour	☐	☐
17.	Palpitations/rapid heart rate	☐	☐
18.	Shortness of breath/difficulty breathing	☐	☐
19.	Slurred speech	☐	☐
20.	Sweating	☐	☐
21.	Weakness/fatigue	☐	☐

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?	☐ 1	☐ 2	☐ 3	☐ 4
3.2 How sure are you that you could recognise the signs and symptoms of a heart attack in yourself?	☐ 1	☐ 2	☐ 3	☐ 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?	☐ 1	☐ 2	☐ 3	☐ 4
3.4 How sure are you that you could get help for someone if you thought they were having a heart attack?	☐ 1	☐ 2	☐ 3	☐ 4
3.5 How sure are you that you could get help for yourself if you thought you were having a heart attack?	☐ 1	☐ 2	☐ 3	☐ 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.	☐ 1	☐ 2	☐ 3	☐ 4
4.1 Most people who have heart attacks have crushing, severe chest pain.	☐ 1	☐ 2	☐ 3	☐ 4
4.3 Women rarely have heart attacks	☐ 1	☐ 2	☐ 3	☐ 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.	☐ 1	☐ 2	☐ 3	☐ 4

	Strongly agree	Agree	Disagree	Strongly disagree
4.5 I would be embarrassed to go to the hospital if I thought I was having a heart attack but I wasn't.	☐ 1	☐ 2	☐ 3	☐ 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.	☐ 1	☐ 2	☐ 3	☐ 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.	☐ 1	☐ 2	☐ 3	☐ 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.	☐ 1	☐ 2	☐ 3	☐ 4
4.9 If I thought I was having a heart attack, I would go to the hospital right away.	☐ 1	☐ 2	☐ 3	☐ 4

	Much less likely	Somewhat less likely	About the same	Somewhat more likely	Much more likely
5.0 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?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Excellent	Very good	Good	Fair	Poor
5.1 In general would you say your health is	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

CARDIAC REHABILITATION QUESTIONS

Were you offered a place on a cardiac rehabilitation programme?

☐ Yes ☐ No

If your answer to the above question is yes, please complete any of the following that are true for you:

a) Date of commencement of programme Date ☐

☐ b) I am waiting to commence a program

☐ c) I am currently attending a cardiac rehabilitation programme

☐ d) I have completed a cardiac rehabilitation programme

☐ e) I was offered a commencement date, but did not attend

☐ f) I started a cardiac rehabilitation programme, but dropped out before it was completed

Please return the questionnaires in the enclosed stamped addressed envelopes.
Thank you for taking the time to complete the questionnaires.

Appendix 7: Consort checklist for this RCT

Section/Topic	Aspects included	Section or page
Title	Identification as a randomised trial in the title.	Title page
Abstract	Structure summary of trial design, methods, results and conclusions.	Pages iv and v
Introduction		
Background & objectives.	Background and explanation of rationale. Specific objectives & hypotheses.	1.5 2.10
Methods		
Trial design.	Description of trial design.	3.3, 3.4
Sample size.	How sample was determined.	4.4.4
	Setting and location where data were collected.	4.4.1
Participants.	Eligibility criteria.	4.4.3
Intervention	Sufficient detail of the intervention to allow replication.	3.10, 4.2
outcomes.	Completed pre-defined outcome measures including method of analysis.	4.5, 4.11
Randomisation sequence generation	Method used to generate random sequence allocation and type of randomisation.	4.8.1
	Who generated the randomisation sequence and enrolled and assigned participants to their group?	4.8.1
Allocation concealment	Steps taken to conceal allocation sequence until assignment.	4.8.1
Blinding	Who was blinded after assignment to intervention?	
Statistical methods	Statistical methods used to compare groups for outcomes and all analyses.	4.8.1 4.11
Results		
Participant flow diagram	Flow diagram of participants by group, through each stage, including losses and exclusions after randomisation, together with reasons.	Figure 5
Recruitment	Dates defining the periods of recruitment and follow-up.	4.8.1, 4.8.3, Figure 4
Baseline data	A table showing baseline demographic and clinical characteristics for each group.	Tables 4 & 5
Numbers analysed and outcomes.	Number of participants included in each analysis with results for each primary & secondary outcome.	Tables 8-18
Discussion		
Interpretation	Interpretation, consistent with the trial results.	6.2-6.7
Limitations	Trial limitations including source of potential bias.	6.8
Generalisability	Generalisability of the trial findings.	6.3-6.7
Other information		
Protocol	The inclusion of the full trial protocol.	Appendix 3
Funding	Source of funding acknowledged.	Page iii

Appendix 8: Ethical Approval Letters

Mater Misericordiae University Hospital
SISTERS OF MERCY
Eccles Street, Dublin 7, Ireland.

Ospidéal Ollscoille Mater Misericordiae
SIÚRACHA NA TRÓCAIRE
Sráid Eccles, Baile Átha Cliath 7, Éire.

Not for prescription purposes

Tel: +353 1 8032000
Fax: +353 1 8032404
Email: mmh@mater.ie
Web: www.mater.ie

Dr Declan Sugrue
Consultant Cardiologist
Mater Misericordiae University Hospital
Eccles Street
Dublin 7

05th 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 19th October 2007 clarifying the points addressed in my letter to you of 25th 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 25th 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.

St. Vincent's Healthcare GROUP LIMITED

UCD DUBLIN

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 5th September 2007.

Following review of your clarifications outlined in your covering letter dated 12th 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:	29th June 2007
Final Approval Date:	6th September 2007
From:	Ethics (Medical Research) Committee - Beaumont Hospital, Beaumont, Dublin 9

Documents Reviewed

Document and Date	Date Reviewed	Approved
Application 07/46, Signed T. Gumbrielle, 20/7/07	6/9/07	Yes
GP Letter, Version 1, 20/7/07	6/9/07	Yes
Flow Chart of Experimental Protocol, Version 2, 20/7/07	6/9/07	Yes
Patient Information Leaflet Version 2, 20/7/07	6/9/07	Yes
Consent Form, Version 2, 20/7/07	6/9/07	Yes
Detail of Participants, Version 2, 20/7/07	6/9/07	Yes
Background Beaumont Version 1	6/9/07	Yes
Eligibility Checklist Beaumont Version 1	6/9/07	Yes
Socio-Demographic Information Beaumont Version 1	6/9/07	Yes
Clinical History Beaumont Version 1	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

Professor Kieran Murphy
ERC/IRB – Convenor's Signature
Approval # 1, dated 6th September 2007

THIS NOTEPAPER MUST NOT BE USED FOR PRESENTATION OR PUBLICATION

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

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

TALLAGHT, DUBLIN 24, IRELAND
TELEPHONE +353 1 4142000

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

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 questionnaires (the research nurse will help you with this). These will be repeated twice over the next two years, by post and/or telephone. The questionnaires 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 nurse. To help in the filling out of the questionnaires 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 beliefs and understanding of heart disease**: you will be asked to fill out these questions before you are discharged with the help of the research nurse. They will also be filled out at 3 and 12 months. At these times, the questionnaires will be posted to you and you will be asked to send them back in the paid envelope given to you. If you prefer the research assistant can 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 nurse **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.

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 on your ward and the research nurse 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 Frances O'Brien. Frances can be contacted by telephone at 085 8200925 or by email at obrienfa@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

Title of study: **ACS Response-Time Intervention Trial**

Researchers: Dr.Gabrielle McKee, Professor Debra Moser, Dr.Sharon O'Donnell, Ms.Frances O'Brien & Ms.Mary Mooney.

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.

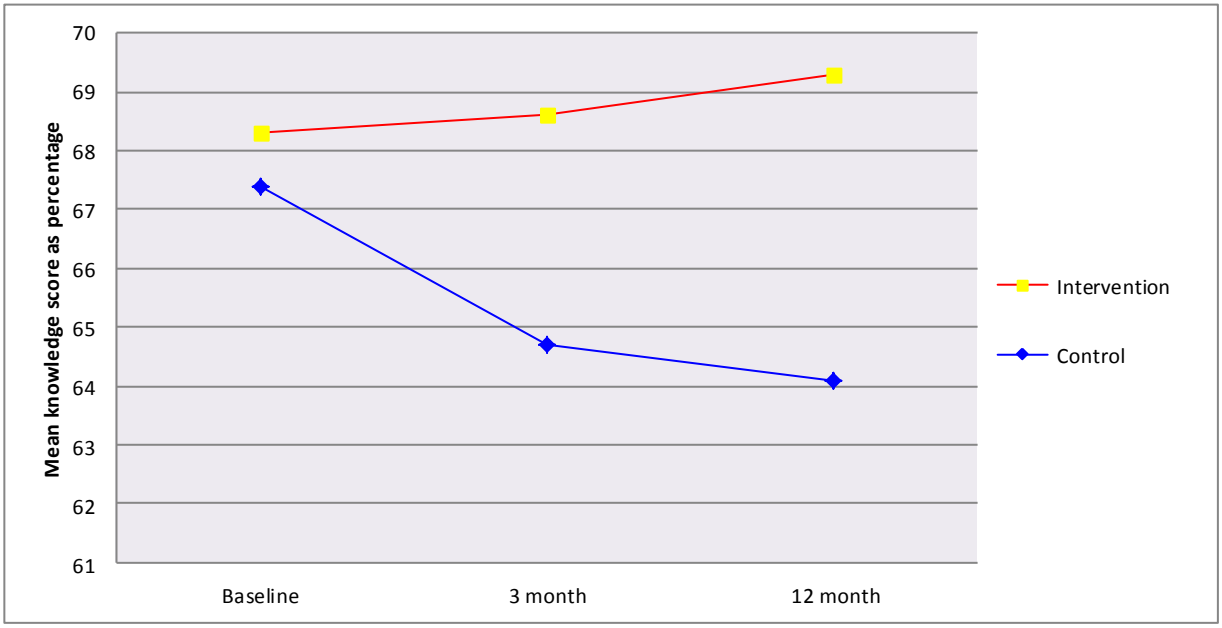
RESEARCHERS SIGNATURE:…… Date:……

Appendix 11: Unadjusted knowledge, attitude and belief scores

The effect of the educational intervention on knowledge about ACS (unadjusted)

Knowledge scores across time by group (unadjusted)

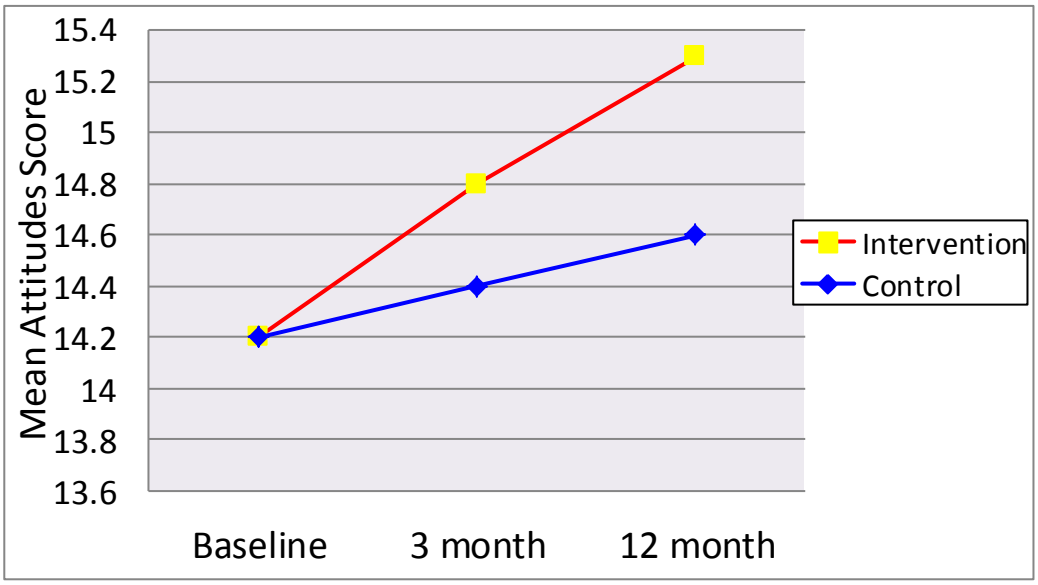
Knowledge (%) N=1136	Control (n=551) Mean ± SD (CI)	Intervention (n=585) Mean ± SD (CI)	*P* value
Baseline	67.4 ± 13.8 (66.3-68.6)	68.3 ± 14.5 (67.1-69.5)	
3 months	64.7 ± 11.0 (63.8-65.6)	68.6 ± 10.8 (67.7-69.5)	<0.001
12 months	64.1 ± 11.8 (63.1-65.1)	69.3 ± 10.8 (68.5-70.2)	



The effect of the educational intervention on attitude scores about ACS (unadjusted)

Attitude scores across time by group (unadjusted)

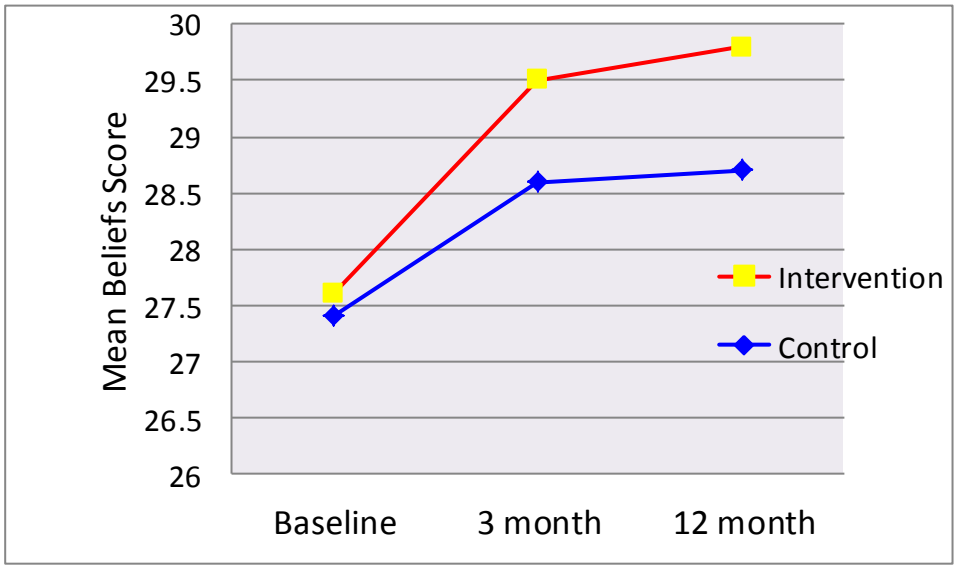
Attitudes	Control (n=551) Mean ± SD (CI)	Intervention (n=585) Mean ± SD (CI)	*P* value
Baseline	14.2 ± 2.9 (13.9-14.4)	14.2 ± 2.8 (14.0-14.5)	
3 months	14.4 ± 2.8 (14.1-14.6)	14.8 ± 2.5 (14.6-15.0)	0.002
12 months	14.6 ± 2.7 (14.4-14.8)	15.3 ± 2.4 (15.1-15.5)	



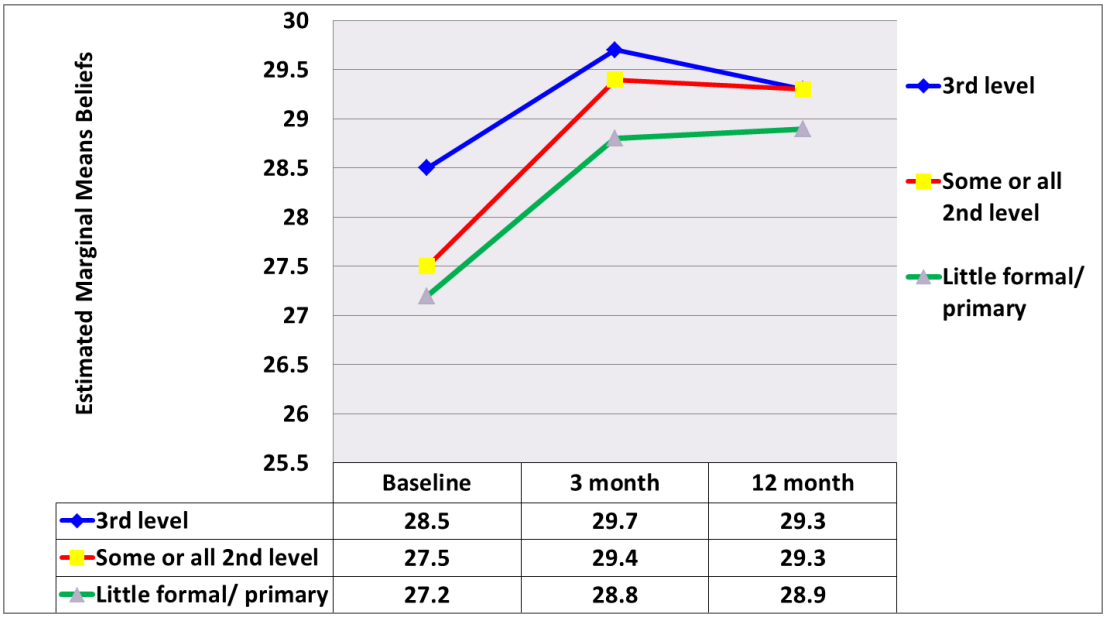
The effect of the educational intervention on belief scores about ACS (unadjusted)

Belief scores across time by group (unadjusted)

Beliefs	Control (n=551) Mean ± SD (CI)	Intervention (n=585) Mean ± SD (CI)	*P* value
Baseline	27.4 ± 3.2 (27.1-27.7)	27.6 ± 3.2 (27.3-27.8)	
3 months	28.6 ± 3.5 (28.3-28.9)	29.5 ± 3.6 (29.2-29.8)	<0.001
12 months	28.7 ± 3.5 (28.5-29.0)	29.8 ± 3.6 (29.5-30.1)	

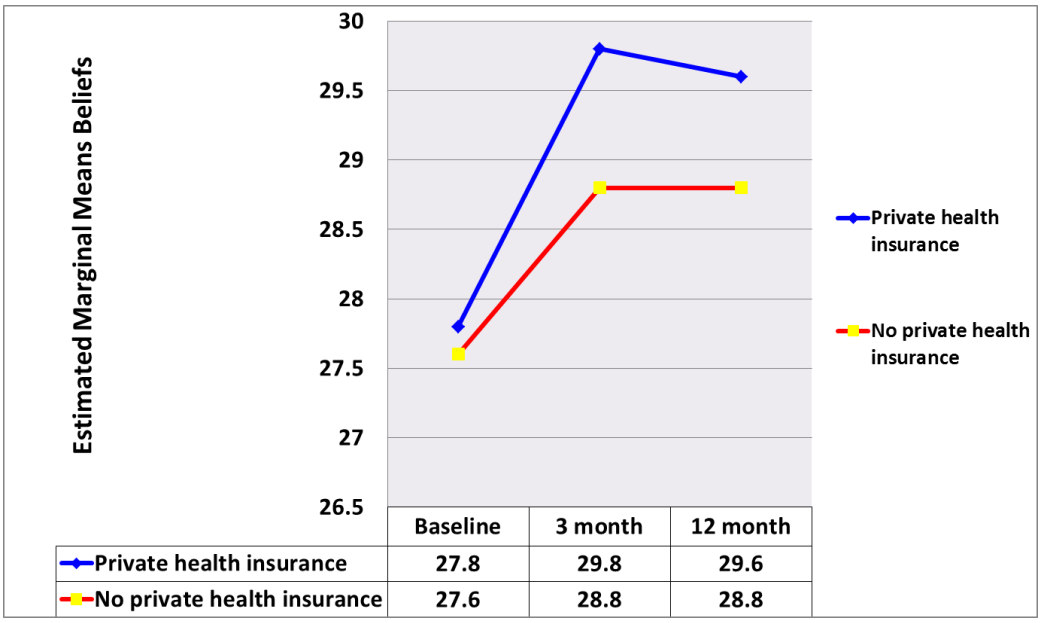


Appendix 12: The effect of education and health insurance on beliefs



	Baseline	3 month	12 month
3rd level	28.5	29.7	29.3
Some or all 2nd level	27.5	29.4	29.3
Little formal/ primary	27.2	28.8	28.9

Figure 13: The effect of education level on the change in belief scores over time



	Baseline	3 month	12 month
Private health insurance	27.8	29.8	29.6
No private health insurance	27.6	28.8	28.8

Figure 14: The effect of health insurance on the change in belief scores over time

Appendix 13: Study dissemination

Peer reviewed publications

O'Brien F., O'Donnell S., McKee G., Mooney M. & Moser D. (2013) Knowledge, attitudes, and beliefs about acute coronary syndrome in patients diagnosed with ACS: an Irish cross-sectional study. *European Journal of Cardiovascular Nursing* **12**(2), 201-208.

O'Brien F., McKee G., Mooney M., O'Donnell S. & Moser D. (2014) Improving knowledge, attitudes and beliefs about acute coronary syndrome through an individualized educational intervention: A randomized controlled trial. *Patient Education & Counseling* **96**, 179-197.

Conferences

O'Brien F., Mooney M., O'Donnell S., McKee G. & Moser D. (2012) Irish patients' perceptions of their risk for a heart attack in the future following the diagnosis of acute coronary syndrome. British Cardiovascular Society Annual Conference, Manchester. May 28–30. Heart, 98(1), A69. (doi:10.1136/heartjnl-2012-301877b.123).

O'Brien F., McKee G., O' Donnell S., Mooney M. & Moser D. (2011) Improving ACS patients' knowledge, attitudes and beliefs about ACS. European Society of Cardiology Congress, Paris. August 27-31. European Heart Journal, Book of Abstracts, 1(Suppl. 1), 2337.

O'Brien F., O' Donnell S., McKee G., Mooney M. & Moser D. (2011) The effectiveness of an educational intervention on ACS patients' knowledge, attitudes and beliefs about heart disease: a randomised controlled trial. 12th Annual Interdisciplinary Research Conference. School of Nursing and Midwifery, Trinity College Dublin. November 9th-10th Book of Abstracts, pg.82.

O'Brien F., Mooney M., O' Donnell S., McKee G. & Moser D. (2011) Knowledge of ACS symptoms: an Irish population survey. 11th Annual Spring meeting on Cardiovascular Nursing. Brussels, Belgium. April 1-2. European Journal of Cardiovascular Nursing, Book of Abstracts, 10(Suppl. 1), 35.

O'Brien F., Mooney M., O' Donnell S., McKee G. & Moser D. (2011) Knowledge of symptoms of acute coronary syndrome in an Irish population. 4th Annual Multidisciplinary Research, Clinical Audit & Quality Improvement Seminar. St. James's Hospital, Dublin, May 19th.