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Evaluating the feasibility and effectiveness of a web based cardiac rehabilitation programme for those with angina in primary care

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EVALUATING THE FEASIBILITY AND EFFECTIVENESS OF A WEB BASED

CARDIAC REHABILITATION PROGRAMME FOR THOSE WITH ANGINA IN

PRIMARY CARE

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Dissemination as a Result of Work in this Thesis

A piece work resulting from this thesis is the following Cochrane review; the full version of this review is currently being carried out.

Devi, R., Igbinedion, E., Powell, J., Singh, S., and Rees, K. (2011) Internet Based Interventions for the Secondary Prevention of Coronary Heart Disease (Protocol). *Cochrane Database of Systematic Reviews*

Findings from this thesis were presented as platform presentations at the following conferences:

- Is a Novel Web Based Cardiac Rehabilitation Programme effective for Patients with Angina? Pilot Data. Digital Healthcare (Warwick, Oct 2010).

- Is a Novel Web Based Cardiac Rehabilitation Programme effective for Patients with Angina? Pilot Data. British Association of Cardiac Rehabilitation (Liverpool, Oct 2010).

- Is a Novel Web Based Cardiac Rehabilitation Programme effective for Patients with Angina? Pilot Data. TeleMed & eHealth '09 (London, Nov 2009).

- Online Study of CArdiac Rehabilitation – The OSCAR Trial. NHS Confederation, Delivering Better Health Services (Birmingham, June 2009).

Findings from this thesis were presented as poster presentations at the following conferences:

- The Effectiveness of a Web Based Cardiac Rehabilitation Programme - Pilot Data. British Association of Cardiac Rehabilitation (Birmingham, Oct 2009).

- Monitoring Physical Activity using a 'Sensewear Physical Activity Monitor' in Individuals with angina. Does age or gender influence activity? British Association of Cardiac Rehabilitation (Birmingham, Oct 2009).

- Monitoring Physical Activity in Individuals with Angina Managed in Primary Care. Royal College of General Practice, Annual Faculty Research Meeting (Warwick, June 2009).

- Study Protocol to Investigate the Effectiveness of a New Internet Based Cardiac Rehabilitation Programme. Online Study of CArdiac Rehabilitation – The OSCAR Trial. UK Society of Behavioural Medicine (Exeter, Jan 2009).

The following prizes were awarded as a result of work presented in this thesis:

- Awarded best poster prize at the British Association of Cardiac Rehabilitation Conference, October 2009.

- £500 prize awarded at the annual 'New Universities Applied Research Competition' where the RCT pilot data was presented in a platform presentation. This was held at the University of Gloucestershire in May 2011.

Abbreviations

AMP - Angina Management Programme

ANOVA - Analysis of Variance

AP - Angina Plan

BACR - British Association for Cardiac Rehabilitation

BHF - British Heart Foundation

BMI – Body Mass Index

CABG - Coronary Artery Bypass Grafting

CAD - Coronary Artery Disease

CHD - Coronary Heart Disease

CONSORT - Consolidated Standards of Reporting Trials

CR - Cardiac Rehabilitation

DBP - Diastolic Blood Pressure

DDMA - Daily Duration of Moderate Activity

DDSA - Daily Duration of Sedentary Activity

DDVA - Daily Duration of Vigorous Activity

DDVVA - Daily Duration of Very Vigorous Activity

DH – Department of Health

DINE - Dietary Instrument for Nutritional Evaluation

EE - Energy Expenditure

HADS - Hospital Anxiety and Depression scale

HR-QOL - Health related quality of life

ISRCTN - International Standard Randomised Controlled Trial Number

Register

MET - Metabolic Equivalent Test

MI - Myocardial Infarction

NACR - National Audit of Cardiac Rehabilitation

NHS - National Health Service

NICE - National Institute for Health and Clinical Excellence

PA - Physical Activity

PASE - Physical Activity Scale for the Elderly

PCI - Percutaneous Coronary Intervention

PTCA - Percutaneous Transluminal Coronary Angioplasty

QOL – Quality of Life

RCT - Randomised Control Trial

SAQ - Seattle Angina Questionnaire

SBP - Systolic Blood Pressure

SIGN - Scottish Intercollegiate Guidelines Network

SPSS - Statistical Package for Social Scientists

WHO - World Health Organisation

Abstract

In the UK angina affects 2 million people (BHF, 2010b) and unfortunately secondary prevention interventions such as Cardiac Rehabilitation (CR) are not widely available for this population (NACR, 2011). This doctoral research project examined the effectiveness and feasibility of an alternative intervention for this population; CR delivered via the internet. The programme was interactive and comprised personalised goal setting orientated around exercise, diet, emotions, and smoking with support available through an online email link or synchronised chat room. A randomised controlled trial (RCT) and semi-structured interviews were used to evaluate the intervention. Primary care patients with angina were randomised to either an intervention group (n=48) or to a control group that did not receive any intervention other than treatment as usual (n=47). Outcome measures were taken at baseline, 6 week and 6 month follow ups. The primary outcome measure was daily steps (measured objectively using Sensewear Pro 3® accelerometer technology). Secondary outcome measures included daily energy expenditure (EE), daily duration of sedentary activity (DDSA), daily duration of moderate activity (DDMA), daily duration of vigorous activity (DDVA), weight, diastolic blood pressure (DBP), systolic blood pressure (SBP), body fat %, fat intake, fibre intake, anxiety, depression, self-efficacy, and health related quality of life (HRQOL). At the 6 week follow up the intervention group had greater improvements than the control group in daily steps, daily EE, DDSA, DDMA, weight, self-efficacy, emotional quality of life and frequency of angina symptoms. In addition, at the 6 month follow up there were significantly greater improvements in anxiety, and frequency of angina symptoms among the intervention group compared to the control group. Semi-structured

interviews were also conducted with a subsample of intervention group participants at the 6 week follow up (n=16). Themes resulting from these interviews indicated a high level of programme acceptability and feasibility; 'self reported improvements' and 'programme facilitators'. However, the theme labelled 'programme barriers' illustrated intervention related challenges which should be taken into account when delivering the programme.

Overall the study demonstrated that a new web based CR programme was effective at improving lifestyle related cardiac risk factors for a primary care angina population in both the short-term (significantly improved daily steps, DDSA, DDMA, weight, self-efficacy, emotional QOL and frequency of angina) and medium-term (significantly improved anxiety, and frequency of angina). These findings on the whole suggest that the programme could be offered to a primary care angina population who are not routinely included within conventional CR. However, there is a need to consider the factors described to affect engagement of the programme; family and work commitments, bad weather, older age, receiving the programme late in angina diagnosis and levels of self-motivation.

CHAPTER 1

THESIS INTRODUCTION

The purpose of this doctoral research project was to evaluate a new internet-based CR programme. Specifically I assessed the programme's effectiveness to improve lifestyle related cardiac risk factors and programme feasibility amongst an angina population in primary care. The aim of this chapter is to outline the research rationale. Initially Coronary Heart Disease (CHD) and angina will be defined and the need to investigate secondary prevention strategies for this population described. Following this, CHD risk factors and Cardiac Rehabilitation (CR) will be outlined. The current availability of CR for those with angina will be illustrated using national audited data. This will demonstrate the importance of investigating ways of increasing CR availability and uptake for this population. The potential for web-based interventions will then be described. Advantages of using the internet for both intervention users and healthcare providers will be outlined to demonstrate reasons why an internet-based alternative to conventional CR should be investigated. The chapter will then be summarised with a brief description of the current research project. An outline of each chapter contained in this thesis will follow, in order to familiarise the reader with the thesis layout and structure.

1.1. _Coronary Heart Disease Prevalence_

CHD can be referred to as Coronary Artery Disease (CAD) and is a condition where plaque accumulates inside the arteries (National Heart Lung and Blood Institute 2011). The United States National Library of Medicine states:

"CAD happens when the arteries that supply blood to heart muscle become hardened and narrowed. This is due to the build up of cholesterol and other material, called plaque, on their inner walls. This build up is called atherosclerosis. As it grows, less blood can flow through the arteries. As a result, the heart muscle can't get the blood or oxygen it needs. This can lead to chest pain (angina) or a heart attack. Most heart attacks happen when a blood clot suddenly cuts off the hearts' blood supply, causing permanent heart damage" (MedlinePlus 2012).

The World Health Organisation (WHO) outline that blocked arteries prevent blood flowing to the heart or brain cause heart attacks and strokes (WHO 2012) and is the highest cause of death globally (WHO 2011). The WHO estimated that in 2008 17.3 million people died from CAD of which 7.3 million were due to CHD (WHO 2011). This is also the case in the UK where CHD is the most common cause of death. The British Heart Foundation (BHF) report that in 2009 1 in 5 male deaths and 1 in 8 female deaths resulted from the disease, in turn causing approximately 82,000 deaths (BHF 2010a). In addition, there is currently an estimated 2.7 million people living with the condition (BHF 2010b). Consequently, the cost of the disease to the National Health Service (NHS) is high; Liu et al (2002) reported the total annual cost of CHD during 1999 was £7.06 billion in the UK.

1.2. Angina and Prevalence

Chronic stable angina pectoris is a symptom of CHD and is pain or discomfort in the chest, upper abdomen, back, arm(s), shoulders, neck, jaw, and/or teeth (Stewart, Inglis and Hawkes 2006). It has been described as:

'a clinical syndrome characterized by discomfort in the chest, jaw, shoulder, back, or arms, typically elicited by exertion or emotional stress and relieved by rest or nitroglycerin' (Fox et al. 2006).

Angina pain is caused by a decreased supply of blood to the heart (Miller, Keane and O'Toole 1992). Narrowed coronary arteries cause this restricted flow of oxygenated blood which in turn results in angina pain (Klabunde 1998). Physically demanding tasks or periods of strong emotion create a high demand for oxygen, which puts strain on narrowed arteries and thus causes angina pain (Miller, Keane and O'Toole 1992). The pain can be reduced with rest or sublingual nitroglycerin (Anderson, Anderson and Glanze 1994). If the pain is not relieved, unmet oxygen demand further increase making the chance of myocardial infarction (MI) more likely (Miller, Keane and O'Toole 1992).

Angina affects 2 million people in the UK, with approximately 28,000 new cases of angina every year (BHF 2010b). The potential for disease progression in this population is high. Buckley et al (2009) followed 1785 newly diagnosed angina patients for a 5 year period and reported 9% underwent coronary artery bypass grafting (CABG), 6% underwent percutaneous transluminal coronary angioplasty (PTCA), 5% died from CHD and 10% died from other causes. This study effectively illustrated the resulting clinical burden of angina, which has resulting cost implications. The healthcare cost of angina in the year 2000 was calculated at £669 million, which accounted for 1.3% of total NHS expenditure (Stewart et al. 2003). Hospital activity was the main cost in terms of both hospital bed utilisation and the cost of revascularisation procedures such as angiograms, percutaneous coronary

interventions (PCI) and CABG. However, calculations by Stewart et al (2003) excluded costs incurred by electrocardiogram procedures, practice nurse visits, accident and emergency visits not leading to hospital admissions, or indirect cost such as loss of employment; indicating the real cost of angina is likely to be even higher than reported. The high prevalence of angina and the inevitable resulting cost suggests the need to employ effective strategies to reduce the risk of disease progression in this population. McCallum et al (2001) illustrate the need for secondary prevention strategies for those with angina in a UK based study. Forty participants admitted to hospital with angina were assessed for CHD risk factors and at hospital discharge 65% had elevated blood cholesterol (>5.2 mmol/l), 5% had hypertension, 20% were smokers, and 80% overweight with a body mass index (BMI) >25 kg/m. In addition, 45% did no exercise and 15% reported some degree of stress related symptoms. Consequently, McCallum et al (2001) demonstrated that there is a need to address both lifestyle (smoking, cholesterol, exercise, stress, BMI) and medication (cholesterol, blood pressure and diabetes mellitus) related factors to reduce CHD risk.

1.3. *Coronary Heart Disease Risk Factors*

Behavioural risk factors of CHD such as cigarette smoking, physical inactivity and unhealthy diets are lifestyle related (WHO 2007). Adopting favourable lifestyle behaviours such as not smoking, healthy eating, regular physical activity, maintaining a healthy weight, moderate drinking, controlled blood pressure, and managing stress help to prevent the disease from worsening (Ford et al. 2007, Joshipura et al. 2001, Lam et al. 2002). Other authors in a systematic review report that reducing dietary fat lowers the incidence of both cardiovascular events and cardiac related mortality (Lee

Hooper et al. 2001). Physical Activity (PA) is additionally important for those with CHD as regular PA reduces the risk of MI and sudden cardiac death by approximately 45% and 30% respectively (Batty 2002). Undertaking higher intensity PA such as running is associated with greater benefits. Williams (2010) examined running distance and CHD risk and reported those running >9km per day had significantly lower angina and nonfatal/fatal CHD risk at a 7 year follow up. These findings are consistent with an earlier review which reported PA and cardio-respiratory fitness are inversely related to CHD risk in older adults (Batty 2002). Additionally, the importance of QOL in CHD has been demonstrated by Westin et al (2005) and Ho et al (2005). Westin et al (2005) studied mortality after a cardiac event and found QOL to be related to death after a cardiac event. Furthermore, this has been shown by Ho et al (2005) who demonstrated QOL predicts mortality after cardiac surgery. It is useful to examine the direction of change for the relationship between QOL and mortality. Zhang et al (2010) retrospectively examined QOL (measured using the Short-Form 36) and mortality in 1785 cardiac patients attending a cardiology prevention clinic. At the end of the 5 year follow up there had been 54 deaths within the sample. Participants were split into groups; groups were based on those scoring either above or below the median physical and mental health score. Participants with a lower quality of physical health (n=879) had a higher rate of mortality at the 5 year follow up than those with a higher quality of physical health (n=879) ($p<0.001$). Whereas there was no difference in mortality between those with a high quality of mental health (877) and those with a low quality of mental health (881), ($p=0.56$). This study therefore showed that a high quality of physical health although not necessarily mental health has a protective effect against rate of long term mortality.

Overall this demonstrates that improved lifestyle related factors decrease CHD severity, and thus the risk of recurrent CHD events.

1.4. *Cardiac Rehabilitation*

CR is a well established secondary prevention intervention. The WHO defines CR as:

"the sum of activity required to ensure patients the best possible physical, mental and social conditions so that they may, by their efforts, resume as normal a place as possible in the life of the community" (WHO 1993).

As the term suggests it is a supportive and restorative programme for those suffering from CHD. The development of CR has origins in early work by Hellerstein, Wenger and Zohman who in the 1950s and 1960s showed that progressive regular exercise after an MI is beneficial for both physiological and psychological recovery (Certo 1985). This effectively outlined that regular exercise after a cardiac event (MI or cardiac surgery) re-establishes and enhances patients' health status (Hellerstein 1968). This pioneering research formed the foundation of CR, which is now an internationally established intervention for those with CHD.

NICE outline the components of comprehensive CR (NICE 2008). Patients receiving comprehensive CR are provided with a tailored exercise programme and with health education/information, advice on lifestyle (diet, weight management, PA, exercise, smoking cessation, and alcohol consumption), psychological/social support, and cultural/vocational support. The programme also addresses the needs of the patients' family/carer. Patients are encouraged to attend all components of the programme,

though they are not excluded if they do not attend all components (NICE 2008). The overall aim of CR is to reduce the risk of subsequent cardiac events and enable patients to return to normal active life, for instance employment or retirement (Department of Health 2000). Therefore the aim is to support those with CHD to be healthier and reduce the likelihood of the disease deteriorating and suffering further acute events. There is also a large emphasis on helping patients become active self-managers of their condition (NICE 2008). This is achieved through lifestyle management (exercise, diet, weight management, and smoking cessation), education (correcting CHD misconceptions), and psychological management (anxiety/depression, illness beliefs) (SIGN 2002). Research evidence demonstrates benefits of the programme include reduced overall and cardiovascular mortality, reduced hospital admissions, increased PA, improved exercise time and exercise tolerance, improved anxiety and depression, and increased quality of life (QOL) (Eshah and Bond 2009, Heran et al. 2011, Kennedy et al. 2003, Yohannes et al. 2010). Therefore CR effectively lowers CHD risk and reduces the burden of CHD.

1.5. *Cardiac Rehabilitation for those with Angina*

Given the well established evidence supporting CR it appears to be appropriate for those with angina. NICE indicate that those with stable angina should be offered the programme (NICE 2008). However, currently in the UK the focus of CR is predominately with MI or revascularisation patients. The National Audit of Cardiac Rehabilitation (NACR) annual report in 2011 revealed that angina patients constituted only 4% of referrals to rehabilitation during 2009-2010 in the UK (NACR 2011). In addition, 18% of programmes reported a policy of not accepting patients with angina

to CR (NACR 2011). This demonstrated that overall the angina population are not able to reap the health benefits available from CR. Possible reasons for this have been investigated. Challenges facing CR services are inadequate funding and space within services, thus there is little room for growth within existing services (Brodie, Bethell and Breen 2006). Consequently, the focus of CR continues to be with predominately post MI or post cardiac surgery patients. This highlights the need to consider and investigate alternative ways of delivering CR in order to widen and increase access to services. These alternative strategies could then be utilised to accommodate those with angina.

1.6. *Overview of Web-based Interventions for health behaviour change*

The internet could be considered as a route to delivering CR. Researchers are becoming increasingly interested in exploring the use of the internet to deliver health behaviour change interventions. A term used to refer to this concept is e-health. One of the most cited definitions of e-health has been offered by Eysenbach (Oh et al. 2005):

"e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology"(Eysenbach 2001).

Research evidence provides support for these interventions. Wantland et al (2004) conducted a meta-analysis on behavioural outcomes from web-based interventions and chronic disease populations and reported positive effects in 16 out of 17 studies. These effects included increased exercise time, improved knowledge of nutritional status, greater awareness of asthma treatment, increased participation in healthcare, slower health decline, improved body shape perception, and 18 month weight loss maintenance in comparison to non-internet-based interventions. In addition, Wantland et al (2004) reported that individually tailored materials resulted in higher intervention use in terms of longer duration of website use and higher number of website visits. Furthermore, the use of chat room facilities was reported to increase social support. In addition, a Cochrane review conducted by Murray et al (2005) systematically reviewed the effectiveness of internet interventions for those with chronic disease. The review included 24 studies and reported internet interventions have a significant positive impact on users' knowledge, social support, health behaviours, clinical outcomes, and self-efficacy (Murray et al. 2005). A recent systematic review and meta-analysis assessed the effectiveness of web-based interventions in promoting health behaviour change (Webb et al. 2010). This review included 85 studies, which indicated significant health-related behaviour effects. An interesting finding by Webb et al (2010) showed that interventions incorporating more behaviour change techniques had larger effects compared to interventions that incorporated fewer techniques (p<0.001). Specifically behaviour effects were greatest for interventions with stress management, communication, modelling, relapse prevention/coping planning, facilitating social comparison, goal-setting, action planning and performance feedback strategies. In contrast, the following techniques had small or no significant behaviour effects: follow up prompts, self-monitoring of

behavioural outcome, emotional control training, and information about others approval. Overall, Webb et al (2010) reported that interventions employing more techniques had larger effects on behaviour than interventions using fewer techniques. In addition, theory based programmes were associated with increased effect sizes, in particular the theory of planned behaviour. Moreover, the effectiveness of interventions was enhanced with the use of communication components (Webb et al. 2010).

1.7. _Advantages to using Internet Delivered Interventions_

There are important benefits of utilising the internet, these are summarised in table 1 and then further explained.

Table 1: A summary of the benefits of internet interventions to both intervention users and providers

Advantages for Users	Advantages for healthcare providers
• 24/7 availability and no requirement to travel to 'intervention location' (Griffiths et al. 2006). • Web-based communication strategies can be used to contact healthcare professionals and peers for on-going support (Cassell, Jackson and Cheuvront 1998). • Possible to remain anonymous.	• Reach large geographically dispersed populations (Cassell, Jackson and Cheuvront 1998, Eysenbach 2001, Griffiths et al. 2006). • Cost effective (Murray 2008). • Possible to maintain contact with users through web-based communication channels (Griffiths et al. 2006, Murray 2008). • Interventions can be vibrant and interactive, incorporating features such as audio/video clips, graphics, chat rooms, web-conferencing, and discussion forums (Murray 2008). • Store large volumes of information easily (Murray 2008). • Intervention content can be updated easily as new research evidence becomes available (Dijkstra and De Vries 1999, Murray 2008). • Increasing choice and access to services as 'traditional' barriers are reduced such as unavailability of skilled professionals and long waiting lists (Ritterband and Tate 2009). • Providing self-directive interventions subtlety shifts the responsibility of self-care from healthcare providers to the individual, thus stimulating independence.

Advantages to intervention users include the benefit of 'availability'; an online intervention is available 24/7 and therefore can be accessed at a day and time that suits the user. Related to this is the concept that users can control "intervention dose" increasing use when they need it more and less if symptoms are well controlled

(Murray 2008). Users overcome the inconvenience and expense involved in travelling to 'intervention locations' (Griffiths et al. 2006). Additionally, the user can gain on-going support through the use of e-mail, discussion forums, web-conferencing, and online chat facilities (Cassell, Jackson and Cheuvront 1998). These communication channels can be useful to those feeling isolated or in need of emotional/social support (Griffiths et al. 2006, Murray 2008). Furthermore, it is possible for individuals to remain anonymous, this is especially useful to those seeking sensitive health information or those avoiding stigma.

Advantages to healthcare providers include the ability to reach large portions of the population as for many the internet is a regular part of daily life. Internet usage statistics reported that approximately 73% of UK households in 2011 had access to the internet (Dutton and Blank 2011). There is also evidence of internet usage growing as the percentage of Britons who had never used the internet decreased from 28% in 2009 to 23% in 2011 (Dutton and Blank 2011). In addition, the report outlined that the retired population accessing the internet increased from 34% in 2009 to 37% in 2011 (Dutton and Blank 2011). Effectively this illustrates a web-based intervention could be offered to over one third of older adults; a group likely to be in need. Further, healthcare professionals benefit from increased efficiency with the possibility of reaching large geographically dispersed populations without time/location restrictions (Cassell, Jackson and Cheuvront 1998, Eysenbach 2001, Griffiths et al. 2006). Additionally, interventions are potentially cost effective, as the main costs of online interventions are associated with intervention development (Murray 2008). Murray (2008) provides an illustration of this in a recent review. 'DownYourDrink' is an online intervention for heavy drinkers and after the initial programme development cost the total maintenance cost was £250 per month to a

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company maintaining the server with no additional marginal costs per user (Murray 2008). In addition, it is possible to create vibrant and interactive interventions with the use of features such as audio/video clips, graphics, chat rooms, web-conferencing and discussion forums. These features are likely to capture a higher level of interest and comprehensibility from users (Murray 2008). Further, healthcare providers can maintain contact with users through e-mail, instant chat or discussion forums (Griffiths et al. 2006, Murray 2008). Web-based interventions also have potential to store large volumes of information, which can be delivered in stages so participants are not overwhelmed with vast volumes of information (Murray 2008). Furthermore intervention content can be updated easily as new research evidence becomes available, enabling information to be kept accurate and current (Dijkstra and De Vries 1999, Murray 2008).

Importantly online interventions are largely self-directive and thus have potential to stimulate independence. It is possible to subtly shift the responsibility of self-care from the healthcare provider to the individual. This inevitably enables the individual to take/gain greater control over self-managing their own health. Through this health professionals can become more efficient providers of care. Further, web-based interventions have potential to reduce the variability of CR. For instance the NACR report outlined that CR changes over time in terms of programme content and level of comprehensiveness (NACR 2011). This is likely to be due to varying levels of funding and staff availability. A web-based programme could help to reduce this variability as intervention content could be standardised and would not rely heavily on physical resources. Consequently, interventions delivered online reduce 'traditional' barriers such as unavailability of skilled professionals and long waiting lists

(Ritterband and Tate 2009). Therefore, due to both the behaviour change potential and advantages of web-based interventions the internet should be considered as a viable option and a resource to help those with angina reduce their CHD risk.

1.8. The Current Research Project

In summary, given that CR is not widely available for those with angina an internet-based programme could offer an innovative alternative. This could help widen access and choice of CR for this group who are currently poorly represented within current service provision. This would enable service capacity to be increased. Consequently, there is a strong case to assess the effectiveness, acceptability, and feasibility of an online version of CR for those with angina. Professor Sally Singh at University Hospitals of Leicester NHS Trust and other health professionals around the UK designed and developed a new web-based CR programme. The primary purpose of this PhD project was to evaluate the programme in two ways. Firstly, to evaluate the programme's level of effectiveness to improve lifestyle behaviour related cardiac risk factors and secondly, to explore patients' views regarding the programmes' level of acceptability and feasibility. This was carried out amongst a primary care angina population.

The study is presented within 6 chapters, from chapter 2 to 8. Chapter 2 provides a narrative literature review on existing research investigating CR, secondary prevention strategies for those with angina, and internet-based interventions. The purpose of chapter 2 is to provide a research rationale for the current study. An additional objective is to explain the current gap in research and describe the

importance of undertaking the current study. Chapter 3 describes the new web-based CR programme, outlining the content through providing visual illustrations of the intervention. Chapter 4 begins with an explanation of why both quantitative and qualitative research methods were considered necessary. Details of the two specific research methods are then provided. The quantitative method section will outline details of the randomised controlled trial (RCT) design employed to study the effectiveness of the web-based CR programme. The qualitative method section will describe the semi-structured interview study design that was used to explore the feasibility and acceptability of the programme. Chapter 5 presents and discusses the short-term effectiveness of the online CR programme. Chapter 6 outlines and discusses the medium-term effectiveness of the web-based CR programme. Chapter 7 outlines the qualitative findings, presenting participants' views regarding the acceptability and feasibility of the programme. A discussion of these findings then follows on from this. The final chapter is chapter 8. This is the final discussion which describes the overall study findings, contributions this study has made to the research literature, study strengths and limitations, broader challenges of web-based interventions, study implications, and future recommendations. The chapter will then be summarised with a conclusion of the thesis.

CHAPTER 2

LITERATURE REVIEW

This chapter is divided into three sections. These sections are on the subjects of CR, secondary prevention of angina and internet-based interventions.

The CR section begins with describing the service and the commonly researched outcomes of the programme. Research evidence illustrating the survival, cardio-respiratory fitness, PA, and psychological benefits of the programme will then be outlined. Following this, methodological issues with research in this area are presented. CR within the UK healthcare system and the challenge of programme uptake are then outlined. The final part of this section will describe research investigating alternative home-based CR programmes.

The second section will outline research investigating secondary prevention interventions specifically for angina populations.

The third and final part will focus on web-based intervention research outlining CHD studies first. There are currently a limited number of online CHD intervention studies available. Consequently, studies recruiting other populations will be examined to provide a more widespread account of the literature.

The chapter concludes with a summary and implications of the literature reviewed. Overall the literature review is narrative and describes the most relevant and recent research. Studies recruiting those with heart failure will be purposely excluded, as this is a different population with varying self-management needs.

Various combinations of the following terms were used to search for the literature contained in this chapter, coronary heart disease, heart disease, cardiac risk, angina, rehabilitation, cardiac rehabilitation, hospital based rehabilitation, secondary prevention strategies, home-based secondary prevention strategies, home-based rehabilitation, home-based interventions, lifestyle management interventions, cardiac risk factors, cardiac related risk, physical activity, daily activity, activity levels, smoking, diet, internet-based interventions, online interventions, web-based interventions, and internet delivered secondary prevention strategies. The following databases were used to search for literature: Medline, Embase, PsycINFO, Cinahl, ISI Web of Science, Science Direct, and PubMed.

2.1 *Cardiac Rehabilitation Programme Outline*

Lifestyle related risk factors are targeted in CR. NICE commissioning guidelines report that CR provides physical, psychological and social help to those with CHD to gain/regain the best possible functioning (NICE 2008). These guidelines report that comprehensive CR comprises health, education/information, advice on lifestyle (diet, weight management, physical activity, exercise, smoking cessation, and alcohol consumption), and psychological/social support. Cultural/vocational and family needs are also addressed (NICE 2008). In addition, advice regarding pharmaceutical drug therapy is offered (NICE 2007a). Traditionally CR is provided in hospitals and delivered across 4 distinct stages and is initiated after a CHD related hospital admission. The Scottish Intercollegiate Guidelines Network (SIGN) provides a more comprehensive description of these stages; these are outlined in figure 1.

Figure 1: The 4 stages of CR as described in the SIGN national clinical guidelines (SIGN 2002).

Stage 1 – In-patient Stay

> After hospital admission resulting from CHD (such as an MI, cardiac surgery, angioplasty) the patient receives 'in-patient care'. Each patient undergoes a cardiac risk factor assessment and a medical evaluation. In this stage efforts are made to provide reassurance, correct any cardiac misconceptions, and alleviate levels of depression and anxiety in both the patient and their significant others.

Stage 2 – Immediate Discharge Period

> This stage occurs immediately after hospital discharge. Support is provided through home visits or telephone contact as this is a period where patients often feel anxious or insecure (SIGN 2002). Additionally, the patient may be offered a self-help guide, such as the 'Heart Manual'. This manual is paper-based, offering the patient information, and advice regarding recovery (the Heart Manual is described in full in section 2.7).

Stage 3 – Rehabilitation Phase

> This stage begins once the patient is physically ready to exercise. The length of time it takes for patients to feel physically ready to exercise will vary depending on the nature of the original hospital admission (MI, cardiac surgery, angioplasty, heart failure).
>
> This stage comprises exercise training, education regarding cardiac risk factors and psychological support (SIGN 2002). Each patient receives a tailored exercise programme from a physiotherapist, one which compliments their functional capabilities. This exercise programme is carried out on gym/exercise equipment provided at the hospital. Educational sessions are run by a variety of health professionals who teach individuals about CHD and effective self-management strategies. Specifically issues such as CHD misconceptions, PA, smoking, weight management, diet, blood pressure, lipids, glucose, psychological issues, occupational factors, and sexual dysfunction are covered.
>
> Traditionally this stage is group-based and is recommended twice per week for 8 weeks.

Stage 4 – Long Term Maintenance

> Patients are placed on a CHD register at their local GP practice and subsequently managed in primary care. This will involve a CHD annual check-up.

Figure 1 illustrates that CR is offered in 4 distinct stages. However, recent commissioning guidelines emphasise that the programme does not have to be an exclusively hospital stage-based therapy (NICE 2008):

"Cardiac rehabilitation services are no longer exclusively hospital-based; emphasis is placed on helping patients become active self-managers of their condition and this can involve hospital, home and community-based cardiac rehabilitation programmes, all of which are effective. Collaboration between primary and secondary care services is vital in order to achieve the best cardiac rehabilitation outcomes" (NICE 2008).

Therefore, comprehensive CR is not confined to the traditional stage-based model shown in figure 1. Instead the programme can be delivered in the community or through home-based programmes and therefore mixed models of provision can be considered (NICE 2008). Hence, CR can involve combining both primary and secondary care services. Community-based programmes can be offered via local sports and leisure centres or via home-based programmes. An example of a home-based programme is 'The Heart Manual' which can be offered alone or alongside traditional hospital-based programmes. Even though these non-traditional CR programmes should be offered to patients, NICE states that they should not be used to replace hospital-based programmes (NICE 2008).

Overall CR should be offered to those suffering an MI, or to those who have undergone coronary revascularisation (CABG, and PCI) and should be available to

those admitted to hospital with other signs of CHD such as those with stable angina and heart failure (NICE 2008). In addition, commissioning guidelines state that service providers should systematically identify and engage those eligible for CR and actively promote the service (NICE 2008). There is an additional need to ensure that the service is equally accessible to all after an MI, particularly those less likely to access the service (ethnic minority groups, older patients, lower socioeconomic groups, women, those living in rural areas, and those with transport problems) (NICE 2008). Additionally, service providers should telephone/mail patients to improve uptake, efforts should be made to address patient preferences for single-sex classes or mixed classes and for differing cultural needs and physical capabilities (NICE 2008). Furthermore, the British Association for Cardiac Rehabilitation (BACR) recommend that a multidisciplinary approach to CR should be used and consist of a cardiac specialist nurse, physiotherapist, dietician, occupational therapist, administrator, and a GP with a special interest in CHD or a cardiologist (BACR 2007).

2.2 *Outcomes of Cardiac Rehabilitation*

Various outcome measures indicate the value of CR in terms of reducing CHD risk. The desired outcomes of CR are improvements in baseline CHD risk factors measured immediately after the programme and at longer term follow ups. Typically benefits are measured in terms of survival rates, physiological factors, lifestyle and behavioural factors, and psychological factors. These outcomes and examples of how each is measured are outlined in table 2.

Table 2: Typical CR Outcomes and Examples of Instruments Used

CR Outcome	Indicators of effectiveness	Instruments Used
Survival	All cause and cardiac related mortality.	Patient death rates following CR indicate the programmes' effectiveness to improve all cause and cardiac related mortality.
	Recurrent MI or need of revascularisation.	Data with regards to subsequent MI or need of further cardiac surgery (CABG, PCI) after taking part in CR shows the effectiveness of the programme to prevent future cardiac events.
	Hospital readmissions.	Reduced hospital readmission after CR provides an indication of how effective the programme is at reducing this.
Lifestyle and Behavioural	PA	Increased day to day PA after CR indicates the programme's effectiveness to positively influence level of PA. PA questionnaires are most commonly used to measure this. An example is the seven-day recall activity questionnaire (Blair et al. 1985). This tool calculates the number of hours spent per day in sleep and in light, moderate, hard, and very hard activity. Each activity type has a MET (metabolic equivalent test) level equivalence and from this activity intensity can be determined. From this the total kilocalories per kilogram of body weight expended per day can be calculated to show the total number of calories expended per day.

Yohannes et al (2010) used this measure and showed CR increased level of PA.

The Godin Leisure-Time Exercise Questionnaire (Godin, G. & Shephard, R.J. 1985) could also be used. This questionnaire assesses PA over a 7 day period and asks how many times per week the participant did strenuous activity (e.g. running, jogging, hockey, football, soccer), moderate activity (e.g. fast walking, baseball, tennis), and mild activity (yoga, fishing, golf) for a period of more than 15 minutes. Jolly et al (2007) used this measure to assess the benefits of hospital-based CR compared with home-based CR.

An alternative measure that could be used is the International Physical Activity Questionnaire (IPAQ) (Craig et al. 2003). This measure assesses the frequency and duration of activity over the previous 7 days. There are 2 versions of the IPAQ; a short and a long version. The short version measures walking, moderate/vigorous activities, and time spent sitting per week. The long version measures time spent in occupational, transportation, household, leisure-related activities, and total time spent sitting per week (Craig et al. 2003). Total weekly PA is estimated by calculating duration of activity X frequency per week X MET intensity; this calculation is summed across each activity domain to produce a weighted estimate of total PA. This measure has been utilised by Maddison et al (2011) to assess the PA benefit of a mobile phone delivered exercise-based CR programme compared with usual CR.

However a contentious issue is that self-report questionnaires can be potentially unreliable due to the risk of participants responding with inaccurate recall and overestimation of PA. Measuring PA using objective measures is more robust and combat issues of self-report bias inherent within questionnaire measures. Pedometers are

		objective measures; these are waist worn instruments that generate step counts measured from walking activity. Even though pedometers are practical in terms of cost and feasibility of data collection/management they do not capture time spent being physically active during non-walking activities (e.g. cycling, swimming, weight training) (Tudor-Locke and Myers 2001). Nor can pedometers provide any information regarding the speed of walking which is a very important when considering the intensity of activity (Tudor-Locke and Myers 2001). In contrast accelometers are more comprehensive as they detect various elements of PA such as step count and the intensity and duration of PA. For instance, the Bodymedia® SenseWear Pro3 Armband is a multi sensor body monitor, which is worn on the right tricep and uses physiological signals such as skin temperature, dissipated heat from the body (heat flux), galvanic skin response and movement to generate PA recordings such as step count, energy expenditure (EE), and duration of time spent whilst active at different intensity levels. However currently to date these accelometers have not yet been used within CR research.
	Cardio-respiratory fitness	An improvement in cardio-respiratory fitness following CR indicates the effectiveness of the programme to improve exercise tolerance levels. This is measured typically in terms of exercise capacity/tolerance on gym type equipment such as a treadmill or stationary bike. In the literature peak oxygen consumption (VO2 peak), or maximal exercise duration on treadmill graded exercise test or bicycle ergometer have been used within CR research (Choo, Burke and Pyo Hong 2007, Egger et al. 2008). The Incremental Shuttle Walking Test (ISWT) can be considered to assess cardio-respiratory fitness, this test is described in Singh et al (1992). This test involves walking up and down a 10 meter course separated by 2 cones;

| | | the distance from one cone to the other is called a shuttle. The speed of walking is dictated by an audio bleep signal. At each beep sound the participant should have reached the cone and be walking towards the second cone placed 10 meters away. Throughout the test the expected speed of walking progressively increases, and therefore the beep sounds are gradually sounded closer together, indicating that the participant needs to walk faster in order to complete the shuttle. The original test has 10 levels, and there are 12 levels in the modified protocol, with each level lasting for 1 minute. The test is ended when the participant becomes too breathless to maintain the required speed or when the participant is unable to reach the cone before the bleep. Jolly et al (2007) used this measure to assess the effectiveness of hospital-based CR compared with home-based CR.

The six-minute walk test (6MWT) (Guyatt et al. 1985) could also be used to assess cardio-respiratory fitness. The test is conducted indoors walking on a flat course, and records total distance walked within 6 minutes. At the end of the 6 minutes the participant is instructed to stop and total distance walked is measured (to the nearest meter or foot). Instructors giving participants encouragement such as comments such as 'you're doing well', 'keep up the good work' improves performance. The validity and reliability of this test has been established in a CR population (Hamilton and Haennel 2000). |
|---|---|---|
| | Diet | Improvements in diet following CR indicate the effectiveness of the programme. Diet can be measured using questionnaire or food diary type measures. |
| | Smoking | Rates of smoking cessation during CR show programme effectiveness. |

	Weight	
Physiological	Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)	Improvements in physiological measures indicate improvements in the physiological state of patients. Standard instruments are used to measure these outcomes.
Psychological	Anxiety and Depression	Anxiety and depression can be measured in order to assess the impact of CR to improve psychological health. A frequently used measure is the Hospital Anxiety and Depression scale (HADS); this was developed by Zigmond and Snaith (1983). Various CR researchers have used this measure to assess anxiety and depression (Dalal et al. 2007, Egger et al. 2008, Jolly et al. 2007, Yohannes et al. 2010, Yonezawa et al. 2009). Depression could also be measured using the Beck Depression Inventory (Beck, Steer and Carbin 1988). This questionnaire measures the intensity (scale is 0 to 3) of 21 symptoms and attitudes (mood, pessimism, sense of failure, lack of satisfaction, guilt feelings, sense of punishment, self-dislike, self-accusation, suicidal wishes, crying, irritability, social withdrawal, indecisiveness, distortion of body image, work inhibition, sleep disturbance, fatigability, loss of appetite, weight loss, somatic preoccupation and loss of libido). Bettencourt et al (2005) and Sharif et al (2012) used this measure to assess the value of CR in impacting level of depression.

	Health related quality of life (HR-QOL)	A commonly reported psychological outcome is HR-QOL. A commonly used measure is the MacNew questionnaire which measures HR-QOL on emotional, physical, and social subscales (Hofer et al. 2004).
		The Seattle Angina Questionnaire (SAQ) is specific to angina and measures QOL in terms of physical limitations, angina stability, angina frequency, treatment satisfaction and disease perception (Spertus et al. 1995). This questionnaire has been used in angina specific studies (Lewin et al. 2002, Zetta et al. 2009).
		Another measure that could be used to assess HR-QOL is the Short Form (SF-36). This measures three aspects of health: functional status, wellbeing, and overall evaluation of health (Ware Jr and Sherbourne 1992). There are 4 scales that form 'functional status' (physical functioning, social functioning, role limitations attributed to physical problems, role limitations attributed to emotional problems), three scales form 'wellbeing' (mental health, energy and fatigue and pain) and one scale measures overall health (general health perception). Brown (2003) describe that this measure is appropriate for use within CR.

2.3 Effectiveness of Cardiac Rehabilitation

This section will examine the effectiveness of CR to improve rates of survival, cardio-respiratory fitness, PA and psychological well-being. The evidence used in this section will be for traditional CR provided in hospitals or community centres. CR can also be delivered via home-based programmes; evidence for home-based programmes will be outlined further in this chapter in section 2.7.

2.3.1 Survival

The survival benefit of CR has been studied extensively. The earliest meta-analyses assessing the survival benefit of CR were conducted by Oldridge et al (1988) and O'Connor et al (1989). The meta-analysis carried out by Oldridge et al (1988) contained 10 CR trials (2145 control participants, 2202 rehabilitation participants) and assessed the benefits upon all-cause death, cardiovascular mortality, and recurrent MI. Seven trials evaluated programmes which were exercise focused with some risk factor management, and 3 trials evaluated programmes focused on risk factor management with some exercise/exercise advice. The range of time in which participants were recruited ranged from hospital admission to 36 months after MI. The duration of rehabilitation ranged from 6 weeks to 48 months and trial follow-up ranged from 24 to 60 months. Compared with the control group the rate of all-cause death (OR: 0.76, 95% CI: -0.63 to 0.92, p=0.004) and cardiovascular death (OR: 0.75, 95% CI: 0.62 to 0.93, p=0.006) was significantly lower in the rehabilitation group. There was no significance difference in rate of nonfatal re-infarction (OR: 1.15, 95% CI: 0.93-1.42, p=0.175). Oldridge et al (1988) thus report the benefit of CR upon all-cause death and cardiovascular death, although not for nonfatal recurrent MI. However, caution should be taken when interpreting findings as the data in this meta-analysis was based

on predominately male samples with a maximum age of 71 years. Thus, it is difficult to generalise these findings to females or older populations. Another meta-analysis carried out during the same time period by O'Connor et al (1989) contained 22 CR trials (2244 control participants, 2310 rehabilitation participants). Considering both these reviews were conducted within the same time period there is a large difference in terms of number of studies included. This difference is due to the way in which authors have counted a large trial carried out by the WHO. The trial was carried out across 24 centres. Oldridge et al (1988) included 13 of these trials of which 12 were grouped together and the thirtieth trial was counted as one as it was published separately. O'Connor et al (1989) in contrast included 14 trials and counted each one individually. O'Connor et al (1989) explain that the reason for doing this was because the method of randomisation varied between sites, and for this reason each trial was counted separately. In terms of included studies both reviews overlapped and included 7 of the same trials. O'Connor et al (1989) describe that the range of time in which participants were recruited to trials ranged from 5 days after hospital admission to over 3 years. All programmes had a structured exercise component alongside either a formal or informal non-exercise component. The non-exercise component ranged from advice given by project staff to an organised multidisciplinary intervention. At 3 years the odds ratios (p-value not reported) were significantly lower in the rehabilitation group compared to the comparison group for total mortality (OR=0.80, 95% CI: 0.66-0.96), cardiovascular mortality (OR: 0.78, 95% CI: 0.63-0.96) and fatal re-infarction (OR: 0.75, CI: 0.59- 0.95). Whereas for non-fatal re-infarction there were no significant differences between the two groups after 1 year (OR: 1.09, 95% CI: 0.76-1.57), 2 years (OR: 1.10, 95% CI: 0.82-1.47) or at a 3 year (OR: 1.09, 95% CI: 0.88-1.34) follow up. Therefore both meta-analyses

carried out by O'Connor et al (1989) and Oldridge et al (1988) demonstrated those taking part in CR benefit from a decreased risk of total mortality, cardiovascular mortality, and fatal re-infarction throughout at least 3 years. Similar to Oldridge et al (1988), O'Connor et al (1989) reported no significant benefit of CR for non-fatal re-infarction between groups at 1, 2, or 3 year follow up.

While both meta-analyses are useful and have been widely cited there are a number of issues that should be considered. One is the issue of heterogeneity, even though all studies included an exercise component, the interventions varied. Some studies were multi-factorial and others focused primarily on physical exercise as the sole intervention (O'Connor et al 1989). Another issue raised by the authors is information on individual patients was not always available; therefore confirmation that randomisation was successful was generally not possible (O'Connor et al 1989). There is also a need to be aware of publication bias, and the predominately male sample limits the ability to generalise the findings to females. Another important issue is the need to be cautious when applying these findings to modern day practice. These findings were based on very early research and early CR programmes and thus whether the findings can be generalised and applied to current CR practice is questionable.

More recently a Cochrane review carried out by Jolliffe et al (2001) assessed 32 trials and demonstrated exercise based CR reduced total mortality by 27% (OR: 0.73, 95% CI: 0.54–0.98) and comprehensive CR reduced total mortality by 13% (OR: 0.87, 95% CI: 0.71- 1.05). Furthermore, cardiac mortality was reduced by 31% (OR: 0.69, 95% CI: 0.51-0.94) and 26% (OR: 0.74, 95% CI: 0.57- 0.96) in exercise only CR and

comprehensive CR respectively. This finding indicated better survival benefits resulting from exercise only CR in comparison to comprehensive rehabilitation. Additionally, this review reported that neither exercise only nor comprehensive rehabilitation had any effect on recurrence of non-fatal MI. However, the populations studied were predominantly male, middle aged, low risk, and mainly MI patients. Consequently other cardiac groups (post revascularisation and angina patients), women, and elderly populations were underrepresented. In addition, the majority of studies were under-powered and methodology reporting in most trials was inadequate. Heran et al (2011) recently extended and updated the review carried out by Jolliffe et al (2001). Heran et al (2011) included 47 studies of which 30 were part of the original review, and thus an additional 17 trials were included. Seventeen studies trialled exercise only CR, 29 studies evaluated comprehensive CR and 1 trialled both. Patients with MI alone were recruited in 30 trials; the remaining trials recruited either exclusively CABG or PTCA or both groups. Heran et al (2011) reported in the medium to longer term (i.e. 12 or more months follow up) exercise-based CR reduced overall mortality (RR: 0.87, 95% CI: 0.75-0.99), cardiovascular mortality (RR: 0.74, 95% CI: 0.63-0.87). This mortality benefit did not differ between both the exercise only and comprehensive programmes (with exercise, educational and psychological components). This was in contrast to the original review which reported a higher mortality effect in the exercise only CR group (Jolliffe et al. 2001). The risk of hospital admissions in the shorter term (<12 months follow up) after undergoing exercise-based CR was also reduced (RR: 0.69, 95% CI: 0.51-0.93). Although consistent with Jolliffe et al (2001) this review found no differences between exercise based CR and usual care groups in the risk of recurrent MI or revascularisation at follow up longer than 12 months. The pooled risk ratios for total MI, CABG, and

PTCA were 0.97 (95% CI: 0.82- 1.15), 0.93 (95% CI: 0.68-1.27) and 0.89 (95% CI: 0.66-1.19) respectively. Despite the inclusion of more recent trials the population studied in this review was still predominantly male, middle aged and low risk, and thus similar to the original review. In addition, Heran et al (2011) report that the method of randomisation, allocation concealment, and blinding of outcome assessments were rarely described. Incomplete data in terms of reasons for drop-out were also rarely reported. In addition, losses to follow up were relatively high across trials, with one third of trials reporting a >20% loss to follow up. There is also a need to be aware of the issue of heterogeneity as inevitably there were differences across studies in terms of criteria for patient selection, geographical location, specific intervention details, time of enrolment after MI, and length of study follow up. Therefore there is a need to be careful when interpreting and applying findings of reviews.

2.3.2 *Cardio-respiratory Fitness and Physical Activity*

Given that CR contains a large focus on exercise it offers a means to increasing PA and cardio-respiratory fitness. Both entities largely depend on one another, physical fitness is a physiological outcome of regular PA and to a certain extent physical fitness is required to carry out PA (Jolliffe and Taylor 1998). PA has been described as:

'Any body movement produced by the skeletal muscles that result in a substantial increase over the resting energy expenditure' (Jolliffe and Taylor 1998).

in contrast physical fitness is:

'A set of attributes which people can have, or achieve that relates to the ability to perform physical activity' (Caspersen, Powell and Christenson 1985).

The effectiveness of CR to improve both cardio-respiratory fitness and PA levels will be outlined below starting with PA.

2.3.3 *Physical Activity*

A systematic review carried out by Jolliffe and Taylor (1998) examined the effectiveness of CR to increase PA in 10 studies of which 4 were carried out in the USA, 2 in Sweden, 2 in Finland, and 1 each in the Netherlands and the UK. In all studies the control group received no formal exercise training. The PA outcomes in studies were described as level of PA, walking distance, exercise habits, leisure time exertion, habitual exercise, leisure time PA, participation in moderate and heavy exercise, PA performance, PA level, and habitual PA. All studies measured PA subjectively; 7 used questionnaires, 1 used structured interview, 1 used both questionnaire and interview, and 1 used an activity diary assessment. The review provided no other details regarding the specific instruments used. The review reported significantly increased PA among those receiving CR compared to controls in 20% of trials. These PA benefits were immediately after CR and were not maintained in the long term; hence illustrating CR has a limited effect on increasing PA. Jolliffe et al (1998) report the methodological quality of the studies was low and had a median score of 2 out of a possible score of 5. However, this review was carried out over 10 years ago and therefore may not be generalised to current practices. More recently a systematic review assessed the value of psychoeducational CR to affect PA (Aldcroft et al. 2011). Psychoeducational CR is information based

and employs cognitive behavioural strategies to promote behaviour change. This review included 6 RCTs and 1 quasiexperimental trial although no information regarding location of the included studies was provided. Similar to Jolliffe et al (1998) PA was measured using mainly self-reported questionnaires, with the exception of 1 study utilising a pedometer and another measuring time spent exercising at a prescribed heart rate. Aldcroft et al (2011) reported that PA outcomes were available in 6 out of 7 trials representing data for 209 patients and reported that psychoeducational CR is more effective at increasing PA in the medium-term (6-12 months) than exercise and/or risk factor education alone. Interestingly Aldcroft et al (2011) reported strategies such as goal-setting, problem solving, self-monitoring and role modelling were influential in this change. These findings are consistent with an observational study carried out in the UK (Yohannes et al. 2010). Yohannes et al (2010) examined the effectiveness of hospital-based CR to improve PA and will be described as it was UK based and not included in the previously outlined review by Aldcroft et al (2011). Yohannes et al (2010) reported a sample of 105 MI, CABG and PCI patients taking part in a 6 week CR programme significantly increased EE from baseline to a 6 week follow up (+226.76 kcal, $p<0.05$), a 6 month follow up (+176.1 kcal, $p<0.05$) and at a 12 month follow up (+139.34 kcal, $p<0.05$). However this study measured PA using a self-report measure and did not include a control group, therefore whether these PA improvements were significantly different from those not undergoing rehabilitation is unknown.

Overall findings from Jolliffe et al (1998), Aldcroft et al (2011), and Yohannes et al (2010) indicate that CR is effective at improving PA. However, there is a need to acknowledge that few studies utilised objective measures of PA. All studies included

in the review carried out by Jolliffe et al (1998) measured PA subjectively and similarly self-reported questionnaires were the main outcome measure in studies included in the review by Aldcroft et al (2011). Consequently the majority of evidence is limited to self-reported measures of PA which can be prone to bias and recall issues (Jolliffe and Taylor 1998). To some extent the findings are questionable and should be interpreted with caution. Even though this is the case it is interesting to know how PA effects are achieved. A narrative review carried out by Ferrier et al (2011) studied explanations for PA effects and examined 23 studies of which diagnosis included those with heart failure, CHD, MI, CABG, and PCI. Fourteen studies were CR based and 9 were not. Of the 14 CR studies 10 measured PA using self-report measures and 4 used objective measures, however the review did not provide any details of the specific instruments used in studies. The PA outcomes were frequency of PA per week, duration of PA, intensity of PA, adherence to PA, daily PA, exercise maintenance, PA intensity compliance, adherence to PA goals, daily PA diary, daily step count, and readiness for exercise in terms of the transtheoretical model of behaviour change. The behavioural change techniques most frequently associated with positive PA outcomes were self-monitoring of PA, self goal-setting, identifying barriers, and developing plans for relapse prevention. The authors reported that self-regulatory techniques create empowerment and perceived control among participants and as a result have longer lasting PA effects.

2.3.4 *Cardio-respiratory Fitness*

A narrative review carried out by Eshah and Bond (2009) examined studies carried out from 2001-2006 and reported the impact of CR upon cardio-respiratory fitness. The review included 13 studies of which 11 reported significantly improved exercise

capacity and exercise tolerance following CR. This shows encouraging findings that CR is effective at increasing exercise capacity and exercise tolerance. However, Eshah and Bond (2009) only provide a narrative account of the study effects and do not report the way that exercise capacity or exercise tolerance was measured. In addition, population details and the location of where studies were carried out were not provided. To date this is the only review that has assessed the effects of CR on cardio-respiratory fitness.

As a result of the somewhat limited findings of Eshah and Bond (2009) and the lack of other reviews in this area other CR studies measuring exercise tolerance will be described to provide more research evidence. Studies carried out by Kennedy et al (2003) Simms et al (2007) and Egger et al (2008) reported an increase in exercise tolerance after CR. These studies were not included in the review conducted by Eshah and Bond (2008) and will therefore be described in more detail. Kennedy et al (2003) carried out a retrospective study of 126 women with MI, CABG, angioplasty, valve surgery, CAD who had undertaken a 14-week CR programme based in Canada. This programme consisted of 7 weeks of formal supervised exercise training and 7 weeks of unsupervised exercise and lifestyle modification. Exercise time and tolerance were assessed using incremental exercise tolerance testing on the treadmill both before and after CR. Kennedy et al (2003) reported significantly improved exercise tolerance time, from an average of 6.6 minutes at baseline which improved to 8 minutes at post rehabilitation, this represented a 21% increase in exercise tolerance (p<0.05). However the female only sample limits the generalisability of these findings. A further observational study carried out in USA by Simms et al (2007) comprised 103 MI, cardiac surgery and heart failure patients and measured exercise

tolerance using a treadmill walking test at both pre and post CR. Simms et al (2007) reported a significant increase in exercise time by 2 minutes 8 seconds (p<0.0001) and physiologic capacity by 0.9 METs at post CR (p<0.0001). Egger et al (2008) reported evidence consistent with these findings. This study examined exercise capacity amongst 114 participants referred to CR after PTCA, CABG, cardiac valve reconstruction, or replacement, aortic dissection, aortic composite graft, MI and those with reported chest pains. Exercise capacity was tested in watts on a bicycle ergometer. At baseline the mean watts achieved was 127 watts which significantly increased to 144 watts after CR (p<0.001). However, these findings may be questionable as all participants were grouped together in the analysis despite participants receiving various forms of CR; 45 received a long-term programme, 43 received a 12 week programme for seniors and 26 received a short-term programme lasting 4-6 weeks.

Even though the studies of Kennedy et al (2003), Simms et al (2007) and Egger et al (2008) demonstrated that CR resulted in increased cardio-respiratory fitness there is a need to consider that these findings are limited. None of the effects were compared to a control group and exercise capacity was tested at post rehabilitation with no longer term follow up. Nonetheless these studies do demonstrate the value of hospital-based CR in terms of improving cardio-respiratory fitness. In contrast, there is less evidence illustrating PA effects. Even though physical fitness is a physiological outcome of regular PA (Batty 2002) there is a danger in assuming increased exercise tolerance on gym based equipment corresponds with increased daily living PA. The measure of day to day PA would provide a clearer illustration of changed PA. This therefore

illustrates a need for more evidence investigating the effectiveness of CR to improve day to day PA in order to strengthen the evidence base.

2.3.5   *Psychological Benefits*

The following section will describe the research evidence demonstrating the value of CR to improve QOL, and levels of anxiety and depression. The previously described Cochrane review conducted by Jolliffe et al (2001) reported the impact of CR on QOL. The review included 32 trials of which 11 trials reported QOL outcomes. Jolliffe et al (2001) reported that 18 different instruments were used to measure QOL of which 4 used self-report measures that were not validated, and 2 used a disease specific scale (Quality of Life after Myocardial Infarction Questionnaire). Specific details of the other questionnaires were not provided. The QOL findings were not presented in a quantitative way due to both the small number of trials available and variations in QOL measures used. Thus QOL data was reported qualitatively and the overall summary was that QOL effects were small and variable. There were small or no changes in trials evaluating exercise only CR and similarly small benefits in the 7 trials evaluating comprehensive CR. Heran et al (2011) extended and updated this review of which 10 of the included trials measured and reported impact upon QOL. A range of outcome measures were used, 2 used the Nottingham Health Profile, 1 used the Medical Outcomes Study, 2 used Quality of Life after Myocardial Infarction, 1 used Angina Pectoris Quality of Life Questionnaire, 1 used Karolinska Questionnaire, and 3 used Short Form 36 questionnaire. There was also a range in terms of duration of follow up, the shortest follow up was 6 months, and the longest was 5 years. Similar to Jolliffe et al (2001) QOL findings were reported qualitatively as there was heterogeneity between trials in outcome measures used and in the way that QOL was

reported. Overall Heran et al (2011) reported significantly higher QOL in those receiving exercise based CR compared to controls at follow up in 7 out of 10 trials.

Other research has examined the impact of CR upon anxiety and depression. A CR study carried out in Japan compared those who dropped out of CR (n=37) with those who continued with CR (n=72) among 109 acute MI patients (Yonezawa et al. 2009). Anxiety and depression levels were measured using the HADS at hospital discharge and at a 3 and 6 month follow up. Yonezawa et al (2009) reported no significant anxiety or depression benefits. However, scores on the HADS were below the classification for mild depression and mild anxiety throughout the study period and for this reason the non-significant effects are unsurprising. However, this study was conducted in Japan and comprised a 5 month duration CR programme and therefore generalisation to UK may be questionable. Other studies previously described by Egger et al (2008) and Yohannes et al (2010) also assessed the impact of hospital based CR on anxiety and depression. Both studies employed the HADS measure. Egger et al (2008) demonstrated decreased anxiety and depression after CR. The depression score lowered from 4.0 at baseline to 2.7 at post intervention (p<0.001), and anxiety score before the programme was 5.4 and 4.1 after the programme (p<0.001). This is encouraging given that the baseline levels of both anxiety and depression were not high enough to be classified as mildly depressed or mildly anxious. This was in contrast to the findings of Yonezawa et al (2009). An additional study reporting the effectiveness of CR to reduce anxiety and depression has been carried out by Yohannes et al (2010) amongst a post CABG, MI and PCI population. Yohannes et al (2010) reported significantly improved anxiety at a 6 week follow up (baseline score 7.87, 6 week follow up score 5.71, p<0.05), at a 6 month follow up (6

month follow up score 6.35, p<0.05) and at a 12 month follow up (12 month follow up score 6.51, p<0.05). Similarly, the depression score significantly improved from baseline (baseline score 7.35) to a 6 week follow up (6 week follow up score 5.51, p<0.05), to a 6 month follow up (6 month follow up score 5.27, p<0.05), and to a 12 month follow up (12 month follow up score 5.73, p<0.05). In terms of the influence of hospital based CR on anxiety and depression both Egger et al (2008) and Yohannes et al (2010) demonstrated improved anxiety and depression immediately after CR. Yohannes et al (2010) also demonstrated this at a long term follow- up (6 and 12 months). This is encouraging as it indicates CR has psychological benefits. However, the findings of both Yohannes et al (2010) and Egger et al (2008) may be somewhat limited with the absence of a control group comparison.

Furthermore, psychological effects of CR have been examined using qualitative methodology. Qualitative methodology offers the advantage of capturing participants' in-depths views and perspectives. Jones et al (2009) conducted 3 focus groups amongst 16 participants who attended hospital-based rehabilitation and reported that participants gained motivation and support from others in the group-based setting (Jones et al. 2009). Participants' exercise fears were relieved as a result of exercising under supervision (Jones et al. 2009). There were also feelings of improved health and increased confidence in their health. This study is useful as it provides an in-depth exploration of patients' perspectives on their own gained benefits of CR.

2.4 Methodological Considerations

Overall this evidence provides support to the positive benefits of CR on survival rates, PA, cardio-respiratory fitness, and psychological health. However, a recent UK based multi-centre RCT contradicts the abovementioned evidence and advocates the value of CR is debateable. This study reported no significant differences between post MI patients referred to rehabilitation (n=903) and controls (n=910) in mortality at a 1 year, 2 years, or 7-9 years follow up. In addition, no significant rehabilitation effect was present for morbidity, HR-QOL, rates of smoking, alcohol consumption, or diet. Interestingly, significantly fewer patients in the CR group compared to controls reported >100 kcal of daily PA at the 1 year follow up, this was measured using a self-report measure of leisure time PA. Authors suggest the absence of significant lifestyle improvements indicated that rehabilitation added little to patients' knowledge and motivation levels (West, Jones and Henderson 2011). The negative outcomes reported in this trial provoke controversy, as it contradicts earlier work. West et al (2011) speculate that the benefits of rehabilitation may have declined as medicine has advanced and suggest that the public are now more aware of the importance of lifestyle factors, thus control group participants adopt similar behaviours as those receiving CR. As a result, West et al (2011) suggest that more intensive rehabilitation programmes may be required.

Further, there is a need to be aware of study quality and methodological issues (Taylor et al. 2004). CR is an internationally recognised intervention and therefore research is conducted on an international level. Consequently the degree to which research can be generalised to UK populations might be questionable due to

differences in service provision across countries. Similarly, CR programmes have inevitable variations in content, length, and intensity. Furthermore, there is a need to be aware of differences across studies in outcome measures used, such as variations in questionnaires and methods. There is also a need to consider the influence of selection bias when qualitative methods are used to explore the psychological benefits of CR. Participants who volunteer to be interviewed and share their feedback/views/experiences are more likely to have a positive story to tell. As these participants are volunteering to share their views it is possible that they were more actively engaged and enthusiastic than those who do not volunteer to be interviewed. Participants may also be reluctant to appear ungrateful by expressing negative feedback to service providers or researchers. For these reasons qualitative research can be biased when used in this context. These methodological considerations are issues inherent in most intervention based research and are not specific to CR based research. However, an issue which is specific to CR is the populations included in studies. Whilst it is understood that CR is an intervention for those with CHD the focus is mainly on MI and cardiac surgery patients and as a result lower risk populations such as those with stable angina are underrepresented.

2.5 *Cardiac Rehabilitation in Practice*

To contextualise this thesis the UK CR targets will now be outlined. CR is considered an essential part of contemporary CHD care in the UK. The National Service Framework for CHD was a 10 year plan and was instigated in March 2000 in the UK (Department of Health 2000). The NSF stated that more than 85% of people discharged from hospital with a primary diagnosis of AMI or after coronary revascularisation should be offered CR. However, uptake rates fall considerably short

of this. The NACR report outlined 42% of MI, CABG and angioplasty patients participated in CR from 2009-2010 (NACR 2011). This illustrates a large discrepancy between national targets and what is currently being achieved. A further issue is from 2009-2010 only 4 % of angina patients used the programme and 18% of CR providers reported a policy of not accepting those with angina (NACR 2011). This is against NICE guidelines which state that CR should be available to include those with stable angina (NICE 2008). Additionally NICE (2007a) state that CR should be equally accessible and relevant to all patients after an MI and particularly for those less likely to access the service. This includes individuals from ethnic minority groups, older people, lower socioeconomic groups, women, those from rural communities, and those with co-morbidities. There is a need to examine reasons for why CR targets are currently not being met.

2.6 _Why are targets not being met?_

The reasons why CR targets are not being achieved are categorised as service, referral, patient, and psychological related reasons; each reason will now be explained.

2.6.1 _Service Related Reasons_

Brodie et al (2006) studied a random selection of 28 CR centres across England and reported a 37% fall short of staff numbers and only 57% of programmes had adequate premises. Poor record keeping systems, lack of tailoring and inadequate exercise sessions were also reported. In addition, 79% of programmes offered less exercise than is recommended in the CR SIGN guidelines. O'Driscoll et al (2007) interviewed

11 CR staff and reported a lack of professional training, confused roles, and poor communication between primary and secondary care. Furthermore, staff expressed decreased enthusiasm with growing workloads (O'Driscoll, Shave and Cushion 2007) and reported that the possibility of including other cardiac patient groups within rehabilitation to be low without additional funding (O'Driscoll, Shave and Cushion 2007). A similar UK based study reported comparable findings. Tod et al (2002) explored views of 15 CR staff and reported CR services lacked clear strategy, funding, planning, and adequately trained staff. Similar to O'Driscoll et al (2007), Tod et al (2002) reported CR staff felt overwhelmed by existing workloads and were concerned with expanding services without additional resources. Therefore, in terms of service related factors it appears that there is a need for increased investment to raise service capacity and staff levels.

2.6.2   *Referral Related Reasons*

Cortes et al (2006) reviewed factors predicting referral across 10 studies published from 1999-2004. Five of these studies were based in the USA, 2 were based in Australia and 3 in Canada. This review illustrated inequalities in referral to CR. Age was negatively associated with being referred and factors predicting referral were ability to speak English, male gender, Caucasian background, higher education level, urban area residence, having suffered an MI, being a smoker, the presence of hypertension, and hypercholesterolemia (Cortes and Arthur 2006). In addition, Korenfeld et al (2009) reported that distance to travel to CR and patients' financial concerns to be common reasons for under-referral. Furthermore, UK based studies report inequalities in the referral of CR. Raine et al (2004) examined referral patterns in 94 UK hospitals and discovered hypertensive males were more likely than

hypertensive females to be referred to CR. Additionally, hypertensive women were less likely to be referred than normotensive women although this difference did not exist among male patients. This demonstrates biases in patterns of CR referral, indicating referral inequalities as individuals with certain characteristics are more likely to be referred than others. Yalfani et al (2006) extended these findings by investigating perceptions of referrers in 23 CR programmes across England and revealed reasons given for low referral levels comprised funding limitations, shortage of trained staff and poor physical ability of patients.

2.6.3   *Patient Related Reasons*

An early review carried out by Cooper et al (2002) reviewed 15 studies and reported CR non-attendees were likely to be older and to have a lower income. Correspondingly, a later review carried out by Jackson et al (2005) showed high socioeconomic status, high education, being diabetic, being hypercholesterolaemia and having PTCA treatment were predictors of on-going participation in CR. In contrast, those with lack of insurance cover, female gender, old age, obesity, disease severity, and the presence of disease co-morbidites were less likely to take part in CR (Jackson et al. 2005). Additionally, Suaya et al (2007) reported older individuals, women, non-whites, those with co-morbidities were significantly less likely to take part while CABG procedures, higher income, higher education level, shorter distance to travel predicted higher CR use. Health issues preventing exercise for example arthritis and continuing cardiac problems have also been reported for reasons of non-adherence to CR in a qualitative study (Jones et al. 2007).

Common findings are that female gender and older age predict CR non-attendance (Cooper et al. 2002, Jackson et al. 2005, Suaya et al. 2007). One speculation is that women are more likely than men to have a home-centred life with responsibilities and CR may disrupt this. In addition, a predominately male group may be off putting for women (Yohannes et al. 2007). Furthermore, it may be the case that women are under pressure to return to their house, work, and family responsibilities (Tod, Lacey and McNeill 2002). However, research showing age to be related to CR attendance is mixed. Cooper et al (2002), Jackson et al (2005), and Suaya et al (2007) reported that older individuals were less likely to take part in CR while Yohannes et al (2007) reported that younger age predicted early CR drop out. Yohannes et al (2007) state younger age groups may have more commitments than older age groups which prevents CR uptake. However interestingly the differences in CR uptake and adherence between gender and age groups were not present in a recent study. A study carried out in Ireland by Kerins et al (2011) employed a mixed methods design to examine reasons for not attending or not completing phase III CR. Participants' who had enrolled onto CR but did not attend or did not complete were asked for their underlying reasons via telephone. Kerins et al (2011) also examined factors associated with non-attendance and non-completion. Of the 267 patients enrolled onto CR, 70% (187) completed the programme, 11% (n=29) did not attend and 19% (n=51) started but did not complete the programme. No significant associations of age, gender, family history, cholesterol, hypertension, obesity, physical inactivity, stress, excess alcohol, or depression with completion or attendance were found (Kerins, McKee and Bennett 2011). However non-attendees and non-completers were significantly more likely to be unskilled manual workers (p=0.01) or smokers (p=0.001). The authors state that this could be due to financial considerations,

particularly loss of earnings. When participants were asked why they did not complete the programme the most common reason reported was due to illness. Whereas the most common reason reported for not attending the programme was due to a lack of interest. A convenience subsample of participants were then asked to take part in semi-structured interviews (n=7, of which 3 were non-attendees and 4 were non-completers) to further explore the reasons for non-attendance/non-completion. Semi-structured interviews revealed that participants were dissatisfied with the programme's exercise component. Participants either found the exercise too easy/too hard, difficult due to co-morbidities or experienced difficulties with the equipment. Participants also had difficulties related to CR access (traffic, time taken to reach the hospital, parking and programme timings), employment commitments, stress (health and family related), or depression. There were also misconceptions; participants misunderstood that the entire programmes was based on exercise alone and held the view that CR was not applicable to them. While this study is revealing there is a need to consider the small sample size for the qualitative part of the study; Kerins et al (2011) interviewed only 7 participants. It is also important to consider that 10% of those who did not attend and 7% of those who did not complete were un-contactable. While some missing data is inevitable, the reasons for non-attendance/non-completion may have differed between those who took part in the study and those who were un-contactable. Other limitations acknowledged by the authors include the study being a non-causal study design, conducted on one site only, and that the CHD risk factor information was either self report or taken from patient notes. Another important limitation acknowledged by the authors is up to 10 months had elapsed from non-attendance/non-completion to interviewing and therefore there may have been poor patient recollection.

Other research has revealed factors contributing to poor CR uptake is the ability to travel to CR (Jackson et al. 2005, Jones et al. 2007, O'Driscoll, Shave and Cushion 2007, Suaya et al. 2007, Tod, Lacey and McNeill 2002).

2.6.4   *Psychological Related Reasons*

Cooper et al (2002) reviewed 15 studies and reported non-attendees were more likely to deny the severity of their illness, less likely to believe that they could influence their illness and less likely to believe that their physician recommended CR. Tod et al (2002) also report a lack of understanding and the belief that symptoms are not severe contribute to the lack of uptake. On-going participation in CR is also associated with high levels of self-efficacy and social support (Jackson et al. 2005). Additionally, French et al (2006) reviewed 8 studies and reported those who understand their condition and view it as controllable with severe consequences are more likely to attend CR. High levels of anxiety, the belief that CHD has minor consequences, and negative views towards rehabilitation also predicted early drop out of CR (Yohannes et al. 2007). A further finding is that the group setting of CR can be perceived as socially stressful and there is fear around re-visiting the hospital as patients associate the hospital with the acute event and are thus reluctant to revisit the hospital (Tod, Lacey and McNeill 2002).

The above section illustrates multiple reasons for CR non-attendance; service, referral, patient, and psychological factors all contribute to low CR uptake. However there is a need to consider methodological issues with the studies outlined. When

questioning patients about CR services they are likely to respond with socially acceptable/desirable answers as they will hesitate to express negative opinions to service providers. There is an additional need to consider that researchers and clinicians all define CR attendance differently. In the study carried out by Kerins et al (2011) patients were deemed as a 'non-attendee' if they did not attend on the first day, and 'non-completers' were those attending less than 60% of the programme. Not all studies reveal how they defined these terms and it is likely that each author defines these terms differently. Consequently it is difficult to compare adherence, attendance and completion rates across studies.

Nevertheless given the issues described with CR uptake and adherence there is a need to provide alternative ways of delivering CR. Likewise the NACR report suggests CR programmes and delivery methods should be redesigned in order accommodate barriers associated with CR uptake/adherence (NACR 2009). Home-based CR programmes are an alternative and address service related challenges associated with conventional programmes such as inadequate funding, lack of staff, inadequate space, and high levels of existing workloads. Additionally, patients' practical related issues such as difficulties with travel, family obligations, and employment commitments are addressed with home-based programmes.

2.7 *Home-based Cardiac Rehabilitation*

Home-based CR has been defined as:

'a structured programme with clear objectives for the participants, including monitoring, follow up visits, letters or telephone calls from staff or at least self-monitoring diaries' (Taylor et al. 2010).

'The Heart Manual' is a well known and established home-based CR programme. It was developed by Lewin at the University of York in the UK and takes a cognitive-behavioural framework towards CR (Lewin 1998). The manual was designed to modify and correct inaccurate cardiac beliefs. The duration of the programme is 6 weeks and consists of a written manual, a work-book and 2 audio tapes. The programme is guided by a facilitator, who discusses cardiac misconceptions and outlines the coping strategies the patient should adopt. The manual contains a walking based exercise programme, risk factor/medication advice, relaxation/stress management, patient testimonies, advice regarding symptoms and patient quizzes. There is also help available on how the patient's significant others can help with recovery. The manual also contains answers to frequently asked questions and information is provided in a way to correct misconceptions. A specially trained facilitator would introduce the manual to the patient, and then maintain contact throughout the programme to check progress. The initial meeting would take place before hospital discharge and the facilitator would motivate patients and their partner.

2.7.1 *UK Based Heart Manual Studies*

Various reports have revealed that those receiving the Heart Manual show improvements in cardiac risk factors comparable to those receiving hospital-based CR. The original study evaluating the heart manual was published in The Lancet (Lewin et al. 1992). This study utilised an RCT study design, randomising 176 post MI participants to the heart manual (n=88) or to a standard care control condition (n=88). Standard care comprised an information based informal counselling package. Patients were allocated to study groups 3 days after an MI and then introduced to

either the heart manual or to the control condition by a facilitator at hospital discharge. Anxiety/depression and QOL were measured using the HADS, and the 30-item General Health Questionnaire respectively at a 6 week, 6 month, and at a 1 year follow up. Utilisation of healthcare services was also assessed at a 6 and 12 month follow up. Lewin et al (1992) reported a significant treatment effect for anxiety at 6 weeks (95% CI: 0.1-2.6, p=0.04) and at a 1 year follow up (95% CI: 0.2-3.7, p=0.03). There was also a significant intervention effect upon depression at a 6 week (95% CI: 0.1-2.0, p=0.04) and at a 6 month follow up (95% CI: -0.1- 2.8, p=0.06). Significant intervention effects upon general health were also detected at a 6 week (95% CI: 1.4-5.6, p=0.001), 6 month (95% CI: 0.3-5.9, p=0.03) and at a 1 year (95% CI: 0.9-6.7, p=0.01) follow up. In addition, Lewin et al (1992) demonstrated that participants who were psychologically distressed at baseline (patients scoring in the clinically anxious or clinically depressed HADS range) made significant improvements in comparison to the control group in anxiety at the 6 week (95% CI: 0.1-3.7, p=0.04), 6 month (95% CI: 1-4.5, p=0.003) and at the 1 year follow up (95% CI: 2.2-6.3, p=0.0005). These participants also made significant improvements upon depression in comparison to the control group at the 6 week (95% CI: 0.3- 3.1, p=0.03), 6 month (95% CI: 0.1-3.7, p=0.04) and at the 1 year follow up (95% CI: 0.2-3.8, p=0.02). In addition, the psychologically distressed participants also demonstrated significant intervention effects upon general health at the 6 week (95% CI: 2.1-8.7, p=0.002), 6 month (95% CI: 1.2- 9.6, p=0.01) and at the 1 year follow up (95% CI: 2.6-11.0, p=0.002). Participants receiving the heart manual also demonstrated fewer GP consultations in comparison to the control group at the 6 month follow up (heart manual = 6, control =7, p<0.0001) and at the 12 month follow up (heart manual = 3, control = 5, p<0.05). There were also significantly more control participants admitted to hospital compared

to those in the heart manual group at the 6 month follow up (control = 18 vs heart manual = 6, p=0.02). This early study of the heart manual demonstrated very promising findings and indicated promising potential for home-based rehabilitation using the heart manual. Since this early study there has been a vast amount of subsequent research evaluating the heart manual.

Jolly et al (2007) and Dalal et al (2007) are the most recent UK based evaluations of the heart manual. Jolly et al (2007) illustrated that outcomes in those allocated to the heart manual are comparable to those offered centre-based CR. This was demonstrated using a large RCT recruiting 525 MI, PTCA and CABG patients. Home based CR was comparable to centre-based as there was no clinical or statistically significant differences at a 6, 12 and 24 month follow up in smoking cessation, blood pressure, total and high-density lipoprotein cholesterol, exercise capacity (measured using the Incremental shuttle walking test), anxiety, depression, diet, self-reported PA (measured using a modified Godin questionnaire), cardiac symptoms, and QOL. However this study did not measure exercise capacity at baseline as it was unsafe as participants were recruited shortly after the cardiac event. Exercise capacity declined throughout the study from the 6 month follow up through to the 24 month follow up in both groups with no differences between groups. Even though this was the case the change from baseline is unknown and therefore the true exercise capacity effect is not known. Further, the PA finding will be examined closely as this was the primary outcome measure in the present study. The PA score in the home-based group at baseline, 6, 12, and 24 month follow up was 6.21, 6.96, 7.11, and 6.81 respectively. In contrast the PA score in the hospital-based group at baseline, 6, 12, and 24 month follow up was 6.04, 6.99, 6.83, and 6.69 respectively.

There were no significant differences between groups in PA at any point of follow up. Both groups increased PA scores from baseline to 6 months, however only the home-based CR group sustained a further increase at the 12 month follow up, demonstrating that the home-based group had better sustained PA at 12 months which was not maintained in the centre based group. In addition, this trial contained an embedded qualitative study carried out by Jones et al (2009). This was a qualitative study comprising 2 focus groups among home-based group participants and demonstrated that the Heart Manual increased patients' knowledge and understanding. Relaxation skills also improved as a result of the relaxation audio tapes, and confidence to exercise was reported to increase. Importantly users felt reassured that the programme was available when required and felt in control of their own rehabilitation programme. Consequently, patients using the Heart Manual described it as a lifestyle change (Jones et al. 2009). This 'lifestyle change' element was reflected within PA changes reported within the trial.

Further, Dalal et al (2007) evaluated the Heart Manual and consistent with Jolly et al (2007) reported no differences in outcome measures between hospital-based rehabilitation and the Heart Manual among a post MI population. Dalal et al (2007) randomised 104 to either the Heart Manual or to hospital-based rehabilitation and reported no difference in change between groups in depression, anxiety, QOL, and cholesterol levels at the 9 month follow up. An additional component of this study examined whether patient choice affected clinical outcomes. This was assessed using a preference based randomisation arm. Participants in this arm were offered a choice of either home-based or hospital-based rehabilitation with 54 choosing hospital-based and 72 choosing home-based. No differences in outcomes between the preference

based groups were reported demonstrating patient choice does not affect the impact upon clinical outcomes (Dalal et al. 2007). An integrated qualitative study examined factors influencing patients' choice. Wingham et al (2006) interviewed 10 participants expressing a preference for home-based and 7 for hospital-based rehabilitation. The hospital-based group emphasised wanting supervision while exercising and the company of others within a group setting and expressed a lack of self discipline. Conversely, the home-based group believed the programme should fit within their current lives without fitting their lives around the programme, were self disciplined, disliked the hospital group based setting, and had practical concerns. Interestingly, Wingham et al (2006) demonstrated that participants felt it was important to make their own decision with regards to rehabilitation choice and interpreted this in light of 'locus of control'. Those who chose the home-based programme believed they had control to influence cardiac risk factors, while the hospital-based group attributed control to the CR professionals.

2.7.2 Home-based Cardiac Rehabilitation Reviews

Various reviews consolidate the evidence of home-based CR (Blair et al. 2011, Clark et al. 2010, Ferrier et al. 2011, Jolly et al. 2006, Taylor et al. 2010). Jolly et al (2006) compared home-based CR with both usual care and with supervised centre-based programmes. This review included 21 studies. Home-based programmes were compared with control groups in 18 studies, compared with conventional rehabilitation in 6 studies and compared with both in 3 studies. The home-based programmes were a mixture of comprehensive programmes (n=9, of which 1 was the Heart Manual), exercise only (n=5) or predominantly psychological/educational

programmes (n=4). In contrast to usual care the home-based group improved SBP, smoking cessation, exercise capacity, total cholesterol, anxiety, and depression. In comparison to centre based CR there were no significant differences in exercise capacity, SBP, and total cholesterol with the home-based group. However, Jolly et al (2006) acknowledge that this review was limited by the small sample sizes, poor adherence reporting, variety of measures used, duration of follow up, and had limited data on mortality rates. Nonetheless, Jolly et al (2006) demonstrated home-based programmes bring more favourable changes compared to a control group and have comparable outcomes to centre-based supervised programmes.

A later Cochrane review conducted by Taylor et al (2010) compared home-based programmes with centre-based rehabilitation in 12 trials. Dalal et al (2010) report the short version of the same review in the British Medical Journal. Of the 12 included studies 6 had already been included in the previous review conducted by Jolly et al (2006). Consistent with Jolly et al (2006) this review illustrated home-based and hospital/centre based CR programmes are equally effective in low risk MI and revascularisation patients. There were no differences in terms of mortality, cardiac events, exercise capacity, SBP, DBP, total cholesterol, portion of smokers at follow up or HR-QOL outcomes among those receiving home-based or centre based CR in the short-term (3-12 months) or longer term (up to 24 months). Taylor et al (2010) therefore illustrate that patients can be offered a choice of either home or hospital-based rehabilitation as there were no differences found between the two programmes.

Blair et al (2011) extended these findings and reviewed community and home-based CR and focused on issues for remote and rural populations. This review was not limited to RCT studies and thus comprised studies employing other methodologies and qualitative studies. Blair et al (2011) included 22 studies, of which 8 compared home-based with hospital-based CR and the remaining studies compared home-based rehabilitation with a control group. There is overlap with previous reviews, 7 of the studies were included in the review carried out by Jolly et al (2006) and 6 were included in the review by Taylor et al (2010). Similar to previous findings Blair et al (2011) reported little difference between hospital and home-based CR in terms of mortality, cardiovascular events, blood pressure, smoking habit, prevalence of angina, anxiety, depression, and QOL. This review extended previous reviews as it reported that home-based programmes may be better at maintaining greater levels of PA than hospital-based programmes. Blair et al (2011) illustrate this with the findings from Jones et al (2009) study who suggested that home-based rehabilitation can be seen as 'more of a lifestyle change rather than treatment', further patients feel like they are the ones in control during home rehabilitation whereas in hospital-based others are in control (Jones et al. 2009). Consequently, consistent with Taylor et al (2010), Blair et al (2011) suggest home-based programmes may be offered as an alternative to hospital-based programmes as both are equally effective at improving clinical and psychological outcomes. Limitations of this review acknowledged by Blair et al (2011) was the inconsistency between studies in terms of the content of 'home' or 'community base CR' and lack of detail regarding what constituted usual or standard care. Additionally studies may not be directly comparable due to differences in severity and CHD risk levels of samples recruited.

An additional review relevant to the studies discussed here has been carried out by Clark et al (2010). This review examined the effectiveness of CHD secondary prevention interventions which had a predominant home-based content and included 36 trials, of which were paper-based (n=16), telephone-based (n=12), involved home visits (n=5) or were electronic (n=2), 1 trial did not describe the mode of delivery. Twenty trials compared the home-based programme with usual care while 9 compared home-based programmes with CR. Clark et al (2010) reported that compared with usual care home-based interventions significantly improved QOL, SBP, smoking cessation, total cholesterol and depression. This review contains considerable overlap with Jolly et al (2006) as Clark et al (2010) included 14 of the same trials and included 10 of the same trials as Blair et al (2011). In addition, 8 of the studies included overlap with the studies included in the review carried out by Taylor et al (2010).

Despite the overlap in terms of studies included, the outlined reviews demonstrate strong evidence indicating that home-based programmes are comparable to hospital-based and are more favourable than usual care control groups. There have been other recent studies carried out demonstrating the benefits of home-based CR which have not yet been included in any reviews. These will be described in the following section.

2.7.3 *Recent Home-based Cardiac Rehabilitation Studies*

A Canadian study carried out by Blanchard et al (2010) recruited 280 MI (34%), CABG (17%) and PCI (32%) participants to a 12 week home-based programme. The programme comprised risk factor assessment, a cardiopulmonary stress test, action

planning, a tailored PA action plan and contact with a clinical mentor (face to face and telephone). The study reported moderate-vigorous PA (measured using a modified version of Godin Leisure-Time Exercise questionnaire) to significantly increase from 88.5 minutes per week to 191.1 minutes per week at post intervention. However, these findings are limited by the absence of a control group and the self-reported PA data. In addition, the programme was comprehensive lasting 3 months and thus findings may not be generalisable to shorter programmes. Furthermore, Smith et al (2011) conducted a study that contributes significant value to the home-based CR literature as it assessed exercise capacity changes over a longer term follow up of 6 years. This study compared hospital-based CR with telephone monitored home-based exercise training on exercise capacity and habitual PA measured by a cycle ergometer and the Physical Activity Scale for the Elderly (PASE) respectively. Participants were an older CABG population with an average age of 70 years; 74 randomised to the hospital-based CR programme group and 70 to the home-based programme. Smith et al (2011) reported significant between-group differences in the primary outcome measure of exercise capacity, mean peak Vo_2 in the home group (1621 ± 472 ml/min, n=48) was significantly greater than the hospital group (1418 ± 373 ml/min, n=60, p=0.01) at the 6 year follow up. The home based group also had higher levels of habitual PA than the hospital based group at the 6 year follow up. Scores on the PASE ranged from 0 to 360, with lower scores indicating lower levels of PA and higher scores indicating higher levels of PA. At the 6 year follow up the PASE score was significantly higher in the home based group (166.7) than in the hospital based group (139.7), the difference between groups was significant, p<0.01. This supports findings reported by Blair et al (2011) who reported that home-based programmes may be better at maintaining greater levels of PA as home-based CR can

be viewed as more of a lifestyle change. However similar to Blanchard et al (2010) these findings may not be generalised to UK based programmes as the programme duration was 6 months, considerably longer than programmes in the UK.

The evidence for using home-based CR as a substitute for centre based CR has been extended by Furber et al (2010) in an RCT carried out in Australia. The unique feature of this study was those who could not or chose not to attend CR were recruited and thus were a sample for which home-based CR is intended for. The programme was a 6 week telephone-based programme involving behavioural counselling, goal-setting and self-monitoring of daily pedometer measured step count. The control group were sent PA brochures by mail. There were 215 patients recruited and consisted of CABG, PCI, MI, and acute coronary syndrome patients. Data on PA was collected at baseline, at post intervention and at a 6 month follow up using a self report measure; The Active Australian Questionnaire. At post intervention there was an increase in duration of PA per week in the intervention group (94.7minutes, SD=213.9) compared to the control group (31.2 minutes, SD=193.5), the difference between groups was statistically significant, $p < 0.05$. In addition the duration of time spent walking per week increased in the intervention group (80.1minutes, SD=176.1) compared to the control group (22.0 minutes, SD=154.0), $p < 0.05$, at the post intervention follow up. There were also improvements detected at the 6 month follow up. The intervention group increased duration of PA per week (+86.4minutes, SD=225.3) compared to the control group (+9.4 minutes, SD=218.5), $p < 0.05$ level. There was also an increase in duration of time spent walking at the 6 month follow up in the intervention group (+62.5 minutes, SD=172.3) compared to a decrease in the control group (-13.7 minutes, SD=167.3), $p < 0.05$ level. However, even though a

pedometer was used as part of the intervention the PA outcome measure was self-reported PA and therefore somewhat limits the findings. Nonetheless a unique feature of this study is it examined those who do not attend CR and demonstrated positive PA trends among those who home-based CR is intended for.

Ferrier et al (2011) reviewed the behaviour change techniques used in home-based CR interventions to increase PA. Ferrier et al (2011) reported follow up prompts, general encouragement, goal-setting, and self-monitoring techniques used within home-based rehabilitation are associated with increased PA. The home-based programme evaluated by Furber et al (2010) incorporated goal-setting and self-monitoring of daily PA, further the programme evaluated by Blanchard et al (2010) comprised goal-setting. Therefore Furber et al (2010) and Blanchard et al (2010) provide support for the findings of Ferrier et al (2011).

Even though these findings are encouraging the evidence demonstrating the influence of home-based CR upon PA is limited by the lack of objectively measured PA in studies. There is also difficultly in measuring programme adherence to home-based programmes and thus adherence rate is often unknown. An additional issue with the literature is a lack of consensus regarding what constitutes home-based CR programmes. Consequently, there is an inevitable range in the comprehensiveness and style of home-based rehabilitation in the literature. Furthermore, in general, low risk populations have been studied and therefore it is difficult to conclude that home-based rehabilitation is as effective as centre-based programmes for a wide range of CHD patients. Nonetheless the evidence supporting home-based rehabilitation is strong. There are many practical advantages for patients. Home-based programmes

are accessible and convenient which is important for those with work and family commitments. Further, partners and family members can be involved in offering support to the patient (Jones et al. 2007). In addition, the programme can be incorporated into everyday routine (Wingham et al. 2006), which is helpful for sustaining any behavioural changes to translate into lifestyle changes.

A further advantage is home-based CR programmes allow service providers to offer patients an alternative to traditional rehabilitation and therefore service capacity is increased. However, the current evidence available does not represent those with angina and instead focuses mainly on other CHD populations (MI, CABG, and PCI). Researchers have recognised this and investigated other secondary prevention strategies for this group, this evidence will be described in the following section.

2.8 *Angina and Secondary Prevention Interventions*

In the UK there are 2 million people with angina and an estimated 28,000 new cases every year (BHF 2010b). As outlined earlier CR services are not widely available for this population (NACR 2011). This is a serious challenge given the high prevalence of angina. Research evidence shows those with angina benefit from secondary prevention interventions. A systematic review and meta-analysis examining psychoeducational interventions delivered via a trained professional for those with stable angina was carried out by McGillion et al (2008a), this included 7 trials representing 949 participants. Four studies were carried out in the UK (Bundy et al. 1994, Gallacher et al. 1997, Lewin et al. 1995, Lewin et al. 2002) 1 conducted in USA, 1 in Canada and 1 in China. The maximum follow up time for the studies was 6 months and control groups comprised usual medical and/or nursing care.

The combined results of 5 trials reported psychoeducational interventions reduced medication use by a mean of 3.69 times per week (p<0.001), which was a positive short-term effect, indicating a reduction in symptoms. Two studies used the disease specific SAQ and demonstrated significant improvements in the physical limitations (p<0.001) and disease perception (p=0.042) subscales, although these were short-term improvements. Three trials reported psychological well-being effects and across these trials 4 measures were used (Centre for Epidemiologic Studies Depression Scale, Spielbeger State-Trait Personality Inventory, Derogatis Stress Profile and the HADS). The authors reported a pooled estimate of effect on psychological well being was not possible due to the heterogeneity of the measures. Overall McGillion et al (2008a) reported that the majority of trials lacked detail regarding allocation concealment, outcome assessment, reliability and validity of symptom related measures, standardised intervention delivery, and experimental controls. Nonetheless the review does provide evidence that psychoeducational interventions delivered via a trained professional improves angina symptoms, and HR-QOL (physical limitations and disease perceptions) in those with angina (McGillion et al. 2008a). A more recent narrative review reported 'exercise is not enough' and interventions for those with angina should address cognitive aspects of CHD. Furze et al (2010) outlined 2 examples of interventions which take such a cognitive behavioural approach; the Angina Management Programme (AMP) and the Angina Plan (AP). Both of these interventions were developed in the UK by Professor Robert Lewin at York University. Trials evaluating both the AMP (Lewin et al. 1995) and the AP (Lewin et al. 2002) were included in the previously outlined review by McGillion et al (2008a).

The AMP is an 8 week hospital-based programme carried out twice per week (Lewin et al. 1995) and comprises exercise, stress management, behavioural change, education, and relaxation components. Stress management is targeted using relaxation and negative or incorrect CHD beliefs are challenged. Lewin et al (1995) evaluated the programme, randomising 39 to the AMP group and 38 to a waiting list control group. Participants were instructed to keep a diary recording frequency, severity, duration of angina symptoms and use of medication. Exercise tolerance was measured on a treadmill. At post intervention the AMP group significantly improved compared to the control group in terms of reported episodes of angina ($p<0.001$), reported severity of angina ($p<0.05$), medication use ($p<0.001$), disability ($p<0.001$), and exercise tolerance ($p<0.001$). At the 4 month follow up there remained significant improvements within the intervention group in terms of angina episodes ($p<0.001$), angina severity ($p<0.01$), angina duration ($p<0.001$), medication use ($p<0.001$), disability ($p<0.001$), and exercise tolerance ($p<0.001$) from baseline. Additionally, at the 1 year follow up episodes of angina, medication use and disability remained significant ($p<0.001$). However there was no control group comparison at the 4 month and 1 year follow up. Furthermore, there was no 1 year follow up for the exercise tolerance measure available due to limited resources. Nevertheless this study demonstrated the AMP which is a group-based intervention provided in a hospital setting induced significant improvements in angina symptoms, medication use and exercise tolerance.

The AP has been described and evaluated by Lewin et al (2002), Zetta et al (2009) and Furze et al (2012). In the UK it is the most commonly delivered programme for those with angina and has been recommended by the SIGN as an evidence based

programme for the management of Angina (NACR 2011). Similar to the AMP the AP takes a cognitive behavioural approach, although the AMP is group-based and the AP is individualised and carried out independently with the help of a trained facilitator. The AP is followed over a period of 12 weeks, and essentially is a home 'work-book' based intervention. An AP trained nurse initiates the intervention with a consultation where cardiac misconceptions are corrected, individual risk assessed, risk reduction advice given, goals are set, and stress management/other psychological issues discussed. The nurse facilitator then contacts the patient during the intervention to encourage patients and to discuss progress with goals.

To date the AP has been evaluated in 3 RCTs, of which all were carried out in the UK (Furze et al. 2012, Lewin et al. 2002, Zetta et al. 2009). Trials conducted by Lewin et al (2002) and Furze et al (2012) recruited newly diagnosed angina patients in primary care. In contrast Zetta et al (2009) recruited secondary care patients hospitalised with angina. Lewin et al (2002) compared groups receiving the AP (n=68) with those receiving a nurse led educational session (n=74). At a 6 month follow up the AP group demonstrated greater improvements in anxiety (p=0.05) and depression (p=0.01) (measured using the HADS), in angina episodes per week (p=0.016) and medication use per week (p=0.018) (measured using an angina diary) compared to the educational control group. The trial assessed HR-QOL using the SAQ and reported significant improvements in the physical limitations subscale among the AP group compared to the control group (p<0.001). Furthermore, 31.5% of the AP group versus 16.2% of the control group changed their diet (p<0.001) and 23.3% of the AP group versus 1.6% in the control group increased their daily walking (p<0.001). In this study the favourable impact upon walking was reliant upon subjective reporting.

Similar to Lewin et al (2002) the trial conducted by Furze et al (2012) recruited newly diagnosed primary care angina patients, although a unique feature of this study was Furze et al (2012) assessed the value of the programme delivered by lay-facilitators. The study involved training 6 lay facilitators (4 women and 2 men) with experience of heart disease to deliver the AP. Participants were then randomised to the lay-facilitated AP group (n=70) or to routine care (n=72). At the 3 month follow up the AP group significantly improved anxiety (p=0.001) (measured using the HADS), QOL (p=0.01) (measured using the EQ-5D) and self-reported PA (p=0.01) in comparison to the control group. At a further 6 month follow up there were significant differences between groups in waist/hip ratio (p=0.05), anxiety score (p=0.03), depression score (p=0.05), and QOL (p=0.008) favouring the AP group.

In contrast to previous AP studies Zetta et al (2009) evaluated the programme within a secondary care setting, randomising 218 patients hospitalised angina patients to either the AP or to standard care. Standard care constituted a nurse providing risk factor reduction guidance during hospital admission. At a 6 month follow up the AP participants significantly improved their knowledge and misconceptions (p<0.00), BMI (p=0.005), social and leisure activities (a subscale on the Cardiovasular Limitations And Symptoms Profile questionnaire) (p=0.04), level of physical limitations (a subscale on the SAQ) (p=0.02), and health perceptions (a subscale on the SF-36) (p=0.03) compared to the control group. Additionally, in terms of motivation to change the AP participants were significantly more likely than the control participants to move from the 'non-active' stage to the 'active' stage (p=0.02). In contrast to previous trials evaluating the AP this study reported no significant anxiety or depression effects (measured using the HADS) resulting from the AP.

Overall the evidence reporting the use of AP within primary or secondary care is encouraging. The evidence reports significantly favourable anxiety, depression, QOL, physical limitations, knowledge and misconceptions, social and leisure activities, health perceptions, angina symptoms, medication use, diet, PA, waist/hip ratio, and BMI improvements resulting from the AP. However the significant anxiety and depression benefit was not observed within a secondary care setting (Zetta et al. 2009). A speculation is whilst the AP significantly improved anxiety and depression in the primary care samples the programme may not be adequate at improving anxiety or depression for patients hospitalised with angina. However, it is not possible to examine baseline values of anxiety or depression of the samples recruited in Lewin et al (2002) and Furze et al (2012) as these studies report change values only and not baseline levels. Further the PA effects were not objectively measured. Lewin et al (2002) and Furze et al (2012) used self-report measures and Zetta et al (2009) measured motivation to change instead of an actual quantifiable measure of PA. Therefore the effectiveness of the AP to increase PA requires further investigation using an objective and comprehensive measure.

Alternative interventions for those with angina have been evaluated in the UK. These studies were included in McGillion et al's review. Bundy et al (1994) evaluated a weekly group-based stress management programme lasting 7 weeks targeting cognitive/anger control, stress levels, risk factor assessment, and lifestyle change/maintenance components. The study randomised 29 primary care stable angina patients to either the stress management programme (n=14) or routine care (n=15). At the 8 week follow up (post intervention) there were significant differences between groups in exercise tolerance (p<0.05) (performance measured in watts)

duration of angina (p<0.05) (measured using a daily diary) and medication use (p<0.005) (measured using a daily diary) favouring the experimental group. However, non-significant intervention effects were reported for heart rate, blood pressure, angina frequency and anxiety, though the very small sample size in this study limits the extent to which findings can be generalised. Gallacher et al (1997) also assessed the effectiveness of a group-based stress management intervention among those with angina. This study randomised primary care male patients to either a stress management intervention (n=227) or to a no treatment control group (n=225) and at a 6 month follow up reported significantly reduced stress (p<0.005), frequency of chest pain when at rest (p<0.02) in the intervention group compared to the control group. Overall, both Bundy et al (1994) and Gallacher et al (1997) illustrate group-based stress management interventions are feasible and effective for angina populations. However given that both studies were carried out over 15 years ago the extent to which these findings might be applied or valid to current practice is questionable.

A more recent study of a group-based intervention has been reported by McGillion et al (2008b) and was not included in the review carried out by McGillion et al (2008a). The programme comprised a manual and nurse-facilitated group-based sessions held twice per week over 6 weeks, both elements addressed angina risk factor reduction and self-management strategies. The trial randomised community-based angina patients to an intervention group (n=66) or to a waiting list control group (n=64). At a 3 month follow up there were significant intervention effects for self-efficacy (p=0.004), physical functioning (p<0.001) and general health (p=0.001) (both

subscales of the SF-36 QOL measure), angina frequency (p=0.02) and angina stability (p=0.001) (both subscales on the SAQ) compared to usual care.

Overall the evidence described demonstrates the effectiveness of various self-management programmes reducing the risk of CHD among those with angina. The studies conducted by Lewin et al (1995), Bundy et al (1994), Gallacher et al (1997) and McGillion et al (2008b) demonstrate the effectiveness of group-based interventions. In contrast, Lewin et al (2002), Zetta et al (2009) and Furze et al (2012) report the effectiveness of the AP, a home-based nurse facilitated programme. Of these interventions the AP appears to have the most impact, Furze et al (2012) reported that over 900 professionals have been trained to deliver the AP and in turn over 20,000 have received the programme (Furze et al. 2012). This is encouraging as it indicates growth in terms of providing secondary prevention for this population, although there are over 2 million people living with angina in the UK (BHF 2010b) and therefore a large portion of those with angina are still not receiving self-management interventions. Consequently there is a need to investigate other ways interventions could be provided for this population. One option might be to offer patients web-based CR. Offering an interactive internet-based programme could help to provide both an alternative and flexible option for those unable to attend hospital-based programmes (Blair et al. 2011). In addition, an intervention delivered via the internet which is carried out at home would have less reliance on resources. Moreover the NHS stress the need to offer patients a choice in the mode of rehabilitation delivery (Department of Health 2006), a web-based option of rehabilitation would help to create this choice.

2.9 Internet Interventions

The growth of the internet offers great potential as an alternative route for delivering CR. It is fitting with current contemporary lifestyle as the internet is a part of daily life for a large portion of the population. Web-based interventions are appropriate for CHD secondary prevention given that CHD is associated with behavioural (e.g. PA and diet) and cognitive (stress and coping) factors (Kuhl, Sears and Conti 2006). The possibility of an online CR programme has been endorsed by CR experts. Vandelanotte et al (2010) conducted a study in Australia which obtained opinions from CR experts regarding issues important to the development of an internet based CR intervention. Participants were recruited via an email invitations sent out to CR professionals attending the 2007 Australian Cardiovascular Health and Rehabilitation Association (ACRA) conference. CR professionals known by the research team were also invited. Recruited participants included CR co-ordinators and managers (n=17), CR nurses (n=13), physicians (n=3), allied health workers (n=5) and cardiac researchers (n=6). Overall, experts perceived that an internet-based CR programme is both a feasible and valuable alternative to face-to-face programmes. CR experts felt a web-based version of CR should be consistent with traditional programmes in terms of information provided and interactions between CR managers and patients. Experts also expressed that tailoring and goal-setting are important behavioural techniques that should be incorporated into programmes.

The potential of web-based interventions for users has also been described. A study carried out in Australia by Neubeck et al (2011) recruited participants from an urban-based teaching hospital in Sydney, Australia, and investigated computer literacy, consumer need and perceived usefulness of the internet. The study was a 2-stage

mixed methods study design (employed both survey and focus group designs). Those participating in the survey part (n=66) were patients eligible for CR but had not yet received the programme. Whereas the focus group participants (2 focus groups, each with 5 participants) were a purposive sample of participants who had already taken part in CR. The study demonstrated the possibility of web-based interventions for this population as 70% of participants had internet access via a home computer, 60% were confident in performing internet related tasks such as opening links, 62% showed confidence in navigating websites, 72% were confident in completing forms, and 65% displayed confidence in viewing online videos. Focus group data revealed participants felt the availability of an online programme would help overcome the shock of diagnosis as information could be accessed if and whenever required. Furthermore, they discussed how a web-based programme could help to reinforce information given during CR educational sessions. Therefore, Neubeck et al (2011) indicate potential for web-based interventions for those with CHD. A similar study was carried out by Kerr et al (2008) who examined usability of an internet-based intervention for those with CHD. This study was UK based, and patients with CHD were recruited by advertisement in local press and in patient group newsletters. Participants were also recruited from CR exercise classes. This intervention was called 'CHESS Living with Heart Disease' which provides information, emotional/social support, self-assessment/monitoring tools and behaviour change support. The acronym 'CHESS' stood for 'Comprehensive Health Enhancement and Social Support'. The usability of the programme was tested over 3 weeks with a panel of CHD patients (4 men and 1 woman aged 41-84 years). Throughout the 3 week period participants kept individual diaries recording comments and feedback related to using the programme. Overall participants made positive comments about

the information content. However, participants were critical of the presentation, ease of navigation, understanding of the different programme sections and ease of finding the information. Overall research conducted by Vandelotte et al (2010), Neubeck et al (2011) and Kerr et al (2008) demonstrate the potential of web-based interventions among this population. The following section will examine the current evidence available investigating the effectiveness of web-based programmes for those with CHD.

2.10   *Are Web-based Health Interventions Effective for those with CHD?*

To date Kuhl et al (2006), and Neubeck et al (2009) have reviewed cardiac related web-based intervention studies. Kuhl et al (2006) provide an overview of internet-based studies for patients with CHD and examined the potential for web-based interventions to improve behavioural, psychosocial, educational factors and for interventions to be cost effective (Kuhl, Sears and Conti 2006). Overall Kuhl, Sears and Conti (2006) reported the use of online interventions as reasonable in improving patient outcomes. A later conducted meta-analysis assessed the effectiveness of telehealth in CHD management and reported intervention groups benefited from lower all cause mortality ($p=0.12$), total cholesterol ($p<0.001$), SBP ($p<0.001$), BMI ($p=0.06$) and rates of smoking ($p=0.04$) than control groups (Neubeck et al. 2009). Further, 5 out of 7 trials measuring PA reported significantly improved PA at follow up indicating strong evidence of the possibility to influence cardiac risk factors using technology based interventions. However only 2 out of the 11 included studies investigated internet-based interventions, the remainder were telephone-based and therefore the review does not provide an exclusively internet-based intervention perspective. I am currently conducting a Cochrane review which aims to examine the

effectiveness of specifically web-based interventions in the secondary prevention of CHD. As this review is not yet available individual studies found as a result of this review will now be outlined. An overview of studies is provided in table 3.

Table 3: Overview of web-based studies for those with CHD

First Author (Year), Country of origin, and Study Design	Participants	Web-based Intervention	Control Group	Outcome Measures	Duration of follow up	Findings
Kukafka et al (2002), USA, RCT.	94 participants recruited via physicians and media advertisements. CHD characteristics of participants were not described.	1 month duration 'MI-Heart'; a tailored information programme designed to improve MI symptom recognition, (number of participants assigned to intervention group not described).	Non-tailored web-based information intervention or a paper-based information intervention, (number of participants assigned groups not described).	Self-efficacy to label and respond to symptoms and self-efficacy of emotional control over symptoms.	1 & 3 months	Improved self-efficacy for all groups at 1 month follow up, and sustained significant increase in all 3 self-efficacy outcomes at 3 months in only the web-based group.
Lindsay et al (2008) Lindsay et al (2009), UK, RCT.	Recruited 108 from primary care. CHD characteristics of participants were not described.	9 month programme comprising CHD risk factor information and discussion forum. Discussions among participants were stimulated and moderated by researchers (first 6 months only).	Control group content unclear.	Exercise frequency (self-report), alcohol consumption, cigarette smoking, diet and healthcare utilisation (GP or other healthcare visits).	6 and 9 months.	The intervention group ate less bad foods (chips, sweets, crisps, fried foods, ready meals and cakes/biscuits) significantly less often compared to the controls at the 6 months follow up (Lindsay et al 2008). This was not sustained during the programme's un-moderated phase (Lindsay et al 2009). However at 9 months the experimental group had significantly more healthcare visits compared with the control,

						There were no other significant benefits of the programme observed at both the 6 month and 9 month follow ups.
Southard et al (2003), USA, RCT.	Recruited 104 participants, from both primary and secondary care (MI, heart failure, CABG, angioplasty, diabetes, transient ischemic attack, peripheral vascular disease, pacemaker and implanted coronary defibrillator).	6 month programme comprising interactive risk factor information, blood pressure and exercise monitoring, and communication with healthcare professionals. (n=53).	Usual care (n=51) (usual care content not described).	QOL, functional status, diet, depression, weight, blood pressure, and low-density lipoprotein.	6 months	Web-based programme resulted in significantly fewer cardiovascular events (15.7% vs. 4.1%, p=0.05) (net cost saving of $965 per patient), greater weight loss (p=0.003) compared to usual care at the 6 month follow up. Reported no significant differences between groups in blood pressure, lipid levels, depression scores, self-reported exercise minutes and dietary habits.
Zutz et al (2007), Canada, observational pilot study.	Recruited 15 participants referred to hospital-based CR (MI, angioplasty, or CABG patients.	12 week programme includes weekly education, monitoring risk factors (exercising heart rate, blood pressure, weight, glucose levels) and one-to-one chats with healthcare professionals (n=8).	Observational waiting list control group (n=7).	Exercise capacity (treadmill exercise stress test), fasting serum lipids, blood pressure, BMI, waist circumference, PA (self-report questionnaire), general self-efficacy, and exercise specific self-efficacy.	3 months.	Outcome measures were not compared to the control group. Participants were reported to significantly improve HDL-C, triglycerides, total cholesterol: HDL-C ratio, exercise capacity (METs), weekly PA, and exercise specific self-efficacy at follow up (p<0.05). No significant change in any other risk factors or lifestyle variables was reported.

Further to the studies outlined in table 3 there are other studies currently being conducted. A recent study protocol describes a study investigating the value of a web-based intervention designed to facilitate better information exchange between patients and healthcare providers and to promote effective disease management (Shah et al. 2011). This study is being carried out in the USA, and is recruiting participants from a tertiary-care healthcare system based in a suburban setting and intends to compare this intervention with both a telephone-based version and with usual care in terms of risk factor modification, process of care and cost of disease management. In addition, Cockayne et al (2011) describe a randomised, double blind, placebo control trial currently being carried out in Australia. The target population are older adults, aged 45-75 with self-reported CVD history or with significant risk factors, and also with depressive symptoms. Participants are being recruited alongside another large-scale longitudinal study where participants are randomly selected from a national health insurance database (Medicare Australia). The trial aims to determine the benefits of an internet-based intervention for depression among a population with depressive symptoms who have CVD or are at risk of developing CVD. The trial will measure the intervention's effect on cognitive function and adherence to treatment for CVD. Additionally, Brennan et al (2001) describe an internet-based information and support system for home recovery after CABG being carried out in USA, unfortunately the authors do not provide detailed information regarding participant recruitment. Even though evaluation of this programme is currently ongoing the authors report from one representative week there were 12 patients accessing the programme 451 times, an average of 64 times per day, demonstrating a high level of programme use. The findings of the studies described by Shah et al (2011), Cockayne

et al (2011), and Bernnan et al (2001) are not yet available and therefore are unable to contribute to our understanding of web-based interventions for this population.

In terms of available evidence there are currently only 4 studies reporting the value of web-based interventions for those with CHD (outlined in table 3). Even though the evidence is in its infancy the findings are nonetheless encouraging. There appears to be potential for web-based interventions to improve self-efficacy (Kukafka et al. 2002), reduce cost (Southard, Southard and Nuckolls 2003), reduce weight (Southard, Southard and Nuckolls 2003), and improve diet (Lindsay et al. 2008) in CHD populations. Zutz et al (2007) also report improved HDL-C, triglycerides, total cholesterol, HDL-C ratio, exercise capacity (treadmill exercise test), self-reported weekly PA and exercise specific self-efficacy. It should be acknowledged that while Lindsay et al (2008) report significantly improved diet there was no evidence of the sample increasing intake of 'healthier foods', instead only reported a reduction in eating 'bad foods'.

In terms of intervention comprehensiveness the programme evaluated by Kukafka et al (2002) was information based and the main feature of the intervention evaluated by Lindsay et al (2008) was the 'moderated discussion forum'. In contrast, both Zutz et al and Southard et al evaluated comprehensive interventions, which lasted 12 weeks and 6 months respectively. Components of these interventions appeared to mirror traditional CR in terms of the interventions comprising educational materials, monitoring of behaviours, and communication with cardiac professionals. However, the PA benefits reported from Zutz et al (2007) is limited to self-reported PA and even more restricted with the extremely small sample size and the absence of a

control group comparison. It is additionally important to consider none of the previous studies recruited an exclusively angina population. Currently available studies have recruited MI, heart failure, CABG, angioplasty, diabetic, transient ischemic attack, peripheral vascular disease, pacemaker and implanted coronary defibrillator population participants, angioplasty or CABG (Southard, Southard and Nuckolls 2003, Zutz et al. 2007). The studies carried out by Lindsay et al (2008) and Kukafa et al (2002) did not provide details regarding participants' CHD characteristics. Given the current high prevalence of angina in the UK and that secondary prevention programmes are not widely accessible for this population there is a need to examine the effectiveness of a web-based alternative for this population. Moreover, it would be useful to qualitatively explore experiences of those with CHD using a web-based intervention, this would generate an in-depth insight into their views regarding feasibility and acceptability of using an online tool to target cardiac risk factors. As the evidence of CHD internet interventions is severely limited in terms of quantity and quality it would be useful to examine the value of web-based interventions in non-CHD populations. This will enable a more widespread understanding of the value of web-based interventions.

2.11 Web-based Interventions and Lifestyle Related Factors

Previous studies have successfully demonstrated internet-based programmes can improve PA, diet, and smoking; behavioural factors that significantly affect CHD risk. The following section will briefly describe this research placing greater emphasis on the literature reporting PA improvements given that PA was the main outcome measure within the RCT employed in this study.

2.11.1 Web-based Interventions and Physical Activity

To date 5 reviews have consolidated research evidence investigating the effectiveness of web-based interventions to improve PA (Ciccolo, Lewis and Marcus 2008, Marcus, Ciccolo and Sciamanna 2009, van den Berg, Schoones and Vliet Vlieland 2007, Vandelanotte et al. 2007) . These reviews were published in a 3 year time period thus there is overlap in terms of studies included. The most comprehensive are the reviews carried out by Van den Berg et al and Vandelanotte et al, of which both were systematic reviews and published in 2007. Vandelanotte et al (2007) examined both RCT and quasi experimental design studies and reviewed 15 studies. In contrast Van den Berg et al (2007) included only RCT studies, and therefore is the most methodologically robust review including 10 studies. Both reviews included 9 of the same studies. In terms of study effectiveness 8 out of 15 studies in Vandelanotte's review reported positive changes in PA. Vandelanotte et al (2007) calculated the overall mean effect size for 5 of these studies, which was 0.44 (range 0.13 to 0.67). Vandelanotte et al (2007) detected a decrease in intervention effectiveness as time to follow up increased. Six out of 10 studies reporting short-term outcomes (follow up $\leq$ 3 months) were effective (60%), 4 out of 8 studies reporting medium-term outcomes (follow up 4-6 months) were effective (50%), and 2 out of 5 studies reporting long term outcomes (follow up >6 months) were effective (40%). The review did not report the effect size at each follow up and only reported the percentage of studies that had positive outcomes. Vandelanotte et al (2007) also examined intervention effects and the level of communication between intervention providers and intervention users. Interventions incorporating more than 5 communications with users were more effective. One out of 6 (17%) interventions with between 1-5 patient communications reported positive outcomes, while 7 out of 9 (78%) interventions with more than 5

communications were effectiveness. In addition, Vandelanotte et al (2007) also report that interventions shorter than 3 months had more potential than longer interventions. In 8 studies the intervention duration was ≤3 months of which 5 (63%) reported positive outcomes. Three interventions were between 3-6 months duration, of which 1 (33%) demonstrated positive results, and finally 2 out of 4 (50%) interventions longer than 6 months detected improved PA. Even though Vandelanotte et al did not calculate the size of the effects the findings demonstrate a general trend for shorter interventions to be more effective than longer interventions. This has also been found in other home-based and group-based PA interventions (van, Laurant and Wensing 2002). Van, Laurant and Wensing (2002) reviewed the effectiveness of PA interventions amongst a group of older adults (mean age 68 years) and interventions <1 year demonstrated higher levels of participation in comparison to interventions ≥ 1 year. Taken together the findings of Vandelanotte et al (2007) and Van, Laurant and Wensing (2002) it appears that engaging and retaining participants in longer interventions is difficult. It is possible that this inverse relationship between participation rate and intervention duration could be due to declining interest, motivation, enjoyment, time, or perceived benefits as the intervention continues (van, Laurant and Wensing 2002). It is also possible that there may have been a bias in the timing of follow-ups. Shorter interventions generally measure outcomes at shorter follow ups and for this reason may appear more effective than longer interventions. It is also reasonable to speculate that intervention features can impact engagement and retention of participants. Vandelanotte et al (2007) attempted to evaluate whether there was a difference in outcomes of interventions that provided PA information only versus those that used behavioural modification techniques (e.g. goal setting, reinforcement, social support, assessment, and feedback). Unfortunately there was a

wide variation in intervention methods and multiple behavioural techniques used and therefore it was not possible to classify the studies into distinct categories.

Vandelanotte et al (2007) also report interventions carried out entirely online with no face-to-face contact were as effective as those with some face-to-face contact. This demonstrated if face to face contact is not necessary then the reach of interventions could be greatly extended. Consequently, Vandelanotte et al (2007) concluded that research on website delivered PA interventions is still at an early stage but there appears to be potential of web-based interventions to improving PA. Unsurprisingly, Van den Berg et al (2007) reported similar findings and reported that online interventions are more effective at increasing PA than waiting list groups. However, Van den Berg et al (2007) emphasised that studies lacked methodological quality and stressed the need for longer follow up periods and the need to measure PA objectively. Other narrative reviews have been carried out by Ciccolo et al (2008) and Marcus et al (2009), Ciccolo et al examined 6 studies of which 2 overlapped with the included studies in both Van den Berg et al (2007) and Vandelanotte et al (2007). Ciccolo et al (2008) reported that web-based interventions produce significant improvements in PA although not necessarily different from traditional interventions. Marcus et al (2009) reviewed 7 studies of which 2 were included in Van den Berg et al (2007), 4 in Vandelanotte et al (2007) and 2 in Ciccolo et al (2008). Similar to previous reviews Marcus et al (2009) reported that internet interventions favourably affect PA over time, although recommend future studies to be adequately powered, comprise larger sample sizes, have longer follow ups and have adequate comparison groups. In summary, reviews indicate potential for web-based interventions to have a favourable impact upon PA. However, PA effects should be viewed tentatively due to

the benefits being short-term, small and methodological challenges including the need to examine PA objectively (Marcus, Ciccolo and Sciamanna 2009, van den Berg, Schoones and Vliet Vlieland 2007, Vandelanotte et al. 2007).

Other more recent studies not included in the aforementioned reviews will be examined to provide an up to date account of the literature. A large RCT carried out in the Netherlands investigated the short-term effectiveness of a tailored internet intervention targeting fat intake, PA and smoking cessation compared to a waiting list control group (Oenema et al. 2008). The study recruited 2159 participants via an online research panel and were randomised to the internet intervention group (n=1080) or a waiting list control group (n=1079). Participants not reaching the PA guideline (30 minutes of moderate level PA 5 times per week) were significantly more likely to meet this guideline after 4 weeks of intervention use. Similar positive findings have been reported from an RCT randomising 156 healthy and ethnically diverse women to an interactive website combined with 10 weekly e-mail and individual PA feedback (n=85) or to a wait-list control group (n=71) (Dunton and Robertson 2008). Data was collected at baseline, and at 1, 2 and 3 months after the intervention. Dunton and Robertson (2008) reported significantly more favourable changes in walking (p=0.035) and moderate-to-vigorous (p=0.045) among the intervention group in comparison to the control group at the 3 month follow up, although these effects were not present until the 3 month follow up. Dunton and Robertson (2008) speculate extended exposure to internet-based interventions may be necessary to impact behaviour. This contradicted Vandelanotte et al (2007) who reported interventions lasting longer than 3 months were less effective as engaging and retaining participants were difficult. A further web-based study evaluated a 12

week programme involving weekly e-mails and reported significantly increased PA at a post intervention follow up (Liebreich et al. 2009). Liebreich et al (2009) randomised a type 2 diabetic sample to either a control group which received generic diabetes and PA information (n=24) or to a web-based intervention group (n=25). At the post intervention follow up the intervention group significantly increased weekly duration of moderate-vigorous activity compared to the control group. An additional RCT reporting the benefits of an online intervention have been outlined by Webber et al (2008). This study randomised 66 women to either a minimal (n=33) or enhanced (n=33) 16 week weight loss programme. Initially all participants received a motivational face-to-face goal-setting session before receiving the study website. The 'enhanced' group received additional weekly chats with a moderator trained in motivational interviewing. At a post intervention follow up Webber et al (2008) reported EE to increase in both groups, the difference between groups was not significant (p=0.79). Further support for web-based interventions to affect PA has been reported by Sternfeld et al (2009) who described the effectiveness of a 16 week e-mail programme which offered tailored goal-setting and tips and educational information on increasing PA. This RCT study recruited 787 healthcare organisation employees, 351 were randomised to the intervention group and 436 to a control group. Sternfeld et al (2009) reported significantly increased moderate PA (p=0.03), and walking (p=0.003) compared to the control group at post intervention, these effects remained 4 months after the intervention ended. However, the content of the control group was not well described in this study.

Oenema et al (2008), Dunton et al (2008), Liebreich et al (2009), Webber et al (2008), and Sternfeld et al (2009) report PA improvements resulting from web-based interventions. However, a serious limitation with these studies is PA was measured

subjectively. As outlined by Van den Berg et al (2007) there is a need to incorporate objective measures of PA within web-based studies. Subjective measures rely on the co-operation and honesty of participants and there is a risk of participants responding with inaccurate recall and overestimation of PA. Wanner et al (2009) demonstrated the importance of measuring PA objectively in a study comparing an online intervention with a non-tailored website. In this study PA was assessed using both self-report and accelerometer measures. Self-reported PA indicated increased duration of moderate and vigorous PA at both a 6 week follow up (p=0.001) and a 13 month follow up (p<0.001) in all participants with no significant differences between groups. In contrast, there was no increase in PA over time in either groups detected with the objective measure and therefore contradicted the subjectively measured PA. This illustrated the importance of measuring PA using accurate and objective measures. Nevertheless, overall both past reviews and recent studies indicate the potential of web-based interventions to increase levels of PA.

2.11.2 *Web-based Interventions and Diet*

Studies carried out by Oenema et al (2008), Webber et al (2008), and Sternfeld et al (2009) described in the previous section also assessed the impact of the intervention to favourably influence diet. Oenema et al (2008) reported at a 1 month follow up the intervention group demonstrated significantly lower self-reported saturated fat intake (p<0.01). In addition, Webber et al (2008) demonstrated significantly decreased calories consumed at a post intervention follow up in both groups receiving a web-based weight loss programme. The group receiving additional weekly motivational chat sessions reduced calorie intake (-253 kcal) to a lesser extent than those without this extra feature (-488kcal per day), although the difference between groups was not

significant (p=0.31). Further Sternfeld et al (2009) evaluated a web-based programme comprising a 16 week e-mail programme aimed at improving diet. Sternfeld et al (2009) reported significant improvements relative to the control group at post-intervention in saturated fat (p=0.01), trans fats (p=0.02) and consumption of fruits and vegetables (p=0.03). These benefits were still significant in comparison to the control group at a 4 month follow up. Furthermore, a study carried out by Moore et al (2008) reported similar positive findings. Moore et al (2008) evaluated an internet-based intervention which provided dietary advice designed to control hypertension. This intervention lasted 12 months and published weekly articles about healthy nutrition and promoting weight loss, participants were sent weekly e-mails notifying participants that a new article had been published on the website. The programme was offered as a free benefit to all US based employees and thereby recruited 2834. Moore et al (2008) reported increased intake of fruit (p=0.03), vegetables (p=0.002) and reduced grain products (p=0.04) at post intervention. However, this study was limited in a number of ways, there was no control comparison group and even though a large sample was recruited there was only data available for 181 participants at the 12 month follow up. However, there was a high level of external validity as there was no individual contact with participants, which reflects how an entirely web-based intervention would be implemented.

2.11.3 Web-based Interventions and Smoking

Civlijak et al (2010) recently reviewed the literature examining the effectiveness of web-based interventions in smoking cessation. Civlijak et al (2010) carried out a Cochrane review including 20 trials, of which 10 compared an internet intervention to a non internet-based intervention or to a no intervention control. Of these, 6 studies

recruited adults, 1 young adults and 3 adolescents. The remaining 10 trials were all carried out in adult populations and compared different variations of internet sites. The review reported tailored and interactive web-based programmes were more effective than static sites. However, this finding was not consistently found in all trials exploring this factor. In addition, the review reported higher abstinence among more frequent users of the programmes. Moreover there may be additional benefits when internet interventions were used alongside other interventions such as nicotine replacement therapy or other pharmacotherapy.

The aforementioned studies outlined the effectiveness of web-based programmes to favourably influence PA, diet, weight loss and smoking, thus illustrating the potential of web-based interventions to reduce CHD related risk factors. Even though these studies were not conducted in cardiac populations they demonstrate the potential of web-based interventions to modify behaviours related to CHD risk.

2.11.4 *Literature Review: Summary and Implications*

It is clear that CR is an intervention which effectively improves rate of survival, cardio-respiratory fitness, level of PA, and psychological health in those with CHD. However in the UK only 42% of MI, CABG and angioplasty patients and only 4% of those with angina attended CR during 2009-2010 (NACR 2011). Reasons for this are multi-factorial including service, referral, patient, and psychological related reasons. Research demonstrates home-based alternatives to CR are equally effective as hospital-based programmes in reducing cardiac risk factors and are more effective than control groups. Other research has demonstrated the effectiveness of other secondary prevention programmes for those with angina, however currently these

programmes are not widely used within practice. Currently there are approximately 2 million people in the UK living with angina with 28,000 new cases every year (BHF 2010b). This indicates this population should be given more focus than is currently the case. Providing an intervention via the internet for this population might be a suitable alternative in being able to reach this population. There is some evidence demonstrating the potential of web delivered interventions in broader CHD populations, although there are only a small number of studies available. Other web-based intervention studies carried out in non-CHD populations have demonstrated potential to improve PA, diet, and smoking behaviours. The evidence therefore indicates web-based interventions have potential to improve cardiac related risk factors.

Therefore the purpose of the present study was to examine the effectiveness and explore the acceptability/feasibility of a web-based, self directed CR programme for a low risk angina group in primary care. An angina population was employed for the reasons described previously; the high prevalence and subsequent cost of angina, lack of current CR service provision for this population and due to a lack of angina representation within the CR and web-based intervention research literature. It was envisaged that a web-based version of CR would create both choice and opportunity and thereby increase service capacity for this population.

Additionally, this study will utilise new technology to measure PA objectively and comprehensively. Research evidence demonstrates potential for internet interventions to effectively improve PA, although there is a need to rigorously assess PA using

objective measures. Sophisticated accelerometers are now commercially available (Sensewear Pro 3®) which objectively assess the duration and intensity of PA.

The next chapter will provide a description of the web-based CR programme evaluated in this study.

CHAPTER 3

A NEW WEB-BASED CARDIAC REHABILITATION PROGRAMME

The literature review provided in chapter 2 outlined the potential for a web-based alternative to CR. As a result Professor Sally Singh at University Hospitals of Leicester NHS Trust and other health professionals around the UK designed and developed an online CR programme, which was evaluated in this PhD project. Prior to outlining the methods used to evaluate the intervention it is necessary to describe the programme content. Therefore, the primary aim of this chapter was to describe this new internet-based CR programme.

3.1. *Activate Your Heart: Web-based Cardiac Rehabilitation*

'ActivateYourHeart' is the name of the programme and can be accessed on the World Wide Web at www.activateyourheart.org.uk. The programme is designed to be carried out at home, hence it is a self directed programme. Prior to beginning the programme users are required to register. The registration process comprises questions relating to demographic characteristics and cardiac risk factors. Users provided details regarding gender, age, ethnicity, employment status, height, weight and lifestyle details regarding exercise, diet, and smoking. Participants were also asked to rate their level of self confidence and stress on a scale of 1-10. In addition, participants answered questions related to their CHD medical history, other co-morbidities, current medications and family history of CHD. The participant then created a unique username and password which was needed to access the full programme. Illustrations of the registration process are provided in figures 2 to 4.

Figure 2: Registration form example 1

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Figure 3: Registration form example 2

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Figure 4: Registration form example 3

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3.2 Stage-based

The whole programme consists of 4 distinct stages which are designed to complete within 6 weeks. After registration the user is welcomed to the programme (figure 5) and then enters the first stage (figure 6). The 'welcome home page' appears each time the user logs into the programme (figure 7). The user completes an 'end of stage quiz' each time a stage has been completed.

Figure 5: Programme welcome page at stage 1

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Figure 6: Personal Plan at Stage 1

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Figure 7: Programme welcome page every time the user logs into the programme

3.3 *Personal Plan and Tailored Goal-setting*

At the beginning of each stage a personal plan is set for every user. This personal plan comprises 4 tailored goals. Each goal is orientated around exercise, diet, anxiety/emotions, and smoking. Goals set in this personal plan are tailored to the individual user and are based on how questions are answered in both the registration form and the end of stage quizzes. In the example illustrated on figure 8 the user has been set a goal to exercise to 30 minutes 5 times per week, increase fruit and vegetable intake and to practice relaxation techniques. The goal regarding smoking was not relevant for this user and he/she was not a smoker. Another example is illustrated in figure 9, here the user has entered stage 3 and is achieving the exercise, anxiety/emotions goal and now needs to consider reducing alcohol intake and to seek smoking cessation advice.

Figure 8: Personal plan and goal-setting at stage 1

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Figure 9: Patient's goal-setting at stage 3

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3.4 <u>Secondary Prevention Advice</u>

The programme contains advice and guidance regarding managing CHD symptoms and lifestyle associated factors. This advice and guidance is tailored at each stage of the programme and aims to aid users achieve the goals set in their personal plan. Specifically advice regarding exercise, diet, sex, driving, returning to work, hobbies, holidays, benefits, smoking and anxiety/emotions is provided. Users obtain this advice by clicking on the heading of each section. Figure 10 illustrates a snapshot of the dietary advice available at stage 1 and figure 11 illustrates a snapshot of the exercise advice provided at stage 3.

Figure 10: Diet advice available at stage 1

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Figure 11: Example of exercise advice provided at stage 3

3.5 *Progress along the Programme*

Progress along the programme is not automatic and depends on 2 requirements from the user. The first requirement is the user must achieve the number of exercise minutes set in their personal plan. This is assessed using the programme's online exercise diary where the daily number of exercise minutes are recorded. Once the user has achieved the exercise requirement they are then able to move onto the subsequent stage. However prior to moving to the next stage the user must complete an end of stage self assesmsent quiz. This quiz re-assesses the user's cardiac risk profile which determines the personal plan goals for the subsequent stage. An example of the exercise diary and the end of stage quiz are illustrated in figure 12 and figures 13-14 respectively.

Figure 12: Online exercise diary

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Figure 13: Example of self assessment quiz

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Figure 14: Example of self assessment quiz

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3.6 <u>Advice and Support available</u>

The user is able to contact a cardiac nurse for advice and support by using an online e-mail link or by joining a synchronised chat room held every Wednesday evening. An example of the online e-mail link is illustrated in figure 15.

3.7 <u>General information</u>

The programme contains general information about CHD. This information explains the physiology of the heart (example in figure 16) and describes CHD diagnoses, for instance the signs and symptoms of angina (example in figure 17). There is information regarding different hospital procedures and different treatments of CHD. An additional section is labelled 'why me' which comprises information regarding the cause of heart disease and provides information about factors which contribute towards CHD. Information about risk factors such as blood pressure, cholesterol, diet, exercise, alcohol, smoking, stress, family history and diabetes is provided. Figure 18 illustrates an example of the exercise related information available.

Figure 16: Example of the heart physiology explained

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Figure 17: Example of CHD diagnosis available

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Figure 18: Example of risk factor information available: exercise

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3.8 Chapter Summary

The overall programme features described here formed the basis of 'activateyourheart', the following chapter will outline the methodology and specific methods used in this PhD thesis to evaluate the programme.

CHAPTER 4

METHODOLOGY

At the outset this chapter outlines the research approach and the overall study design adopted in this thesis. This is followed by a justification of why both quantitative and qualitative research methods were considered necessary. Detailed and specific methods of each study will follow on from this.

4.1. *Broad Study Design*

The aims of this PhD research study were to:

1. Examine the short-term effectiveness of the new web-based CR programme at improving lifestyle related cardiac risk factors.

2. Examine the medium-term effectiveness of the new web-based CR programme at improving lifestyle related cardiac risk factors.

3. Explore participants' experiences of using the programme and their views regarding the programmes' level of acceptability and feasibility.

Both quantitative and qualitative methods were utilised to achieve these aims. An RCT study design was used to achieve both the first and second aim and semi-structured interviews used to achieve the third aim. Thus pragmatism was the philosophical position adopted; a practical approach selecting methods that best addressed each aim (Creswell and Clark 2010). A visual representation of the overall study design is illustrated in figure 19; visually illustrating the interaction, timings and

mix of both quantitative and qualitative methods. Creswell and Clark (2010) describe

this design as an embedded mixed methods design.

Figure 19: Visual representation of the Study Design adopted in this thesis, an Embedded Mixed Methods Design
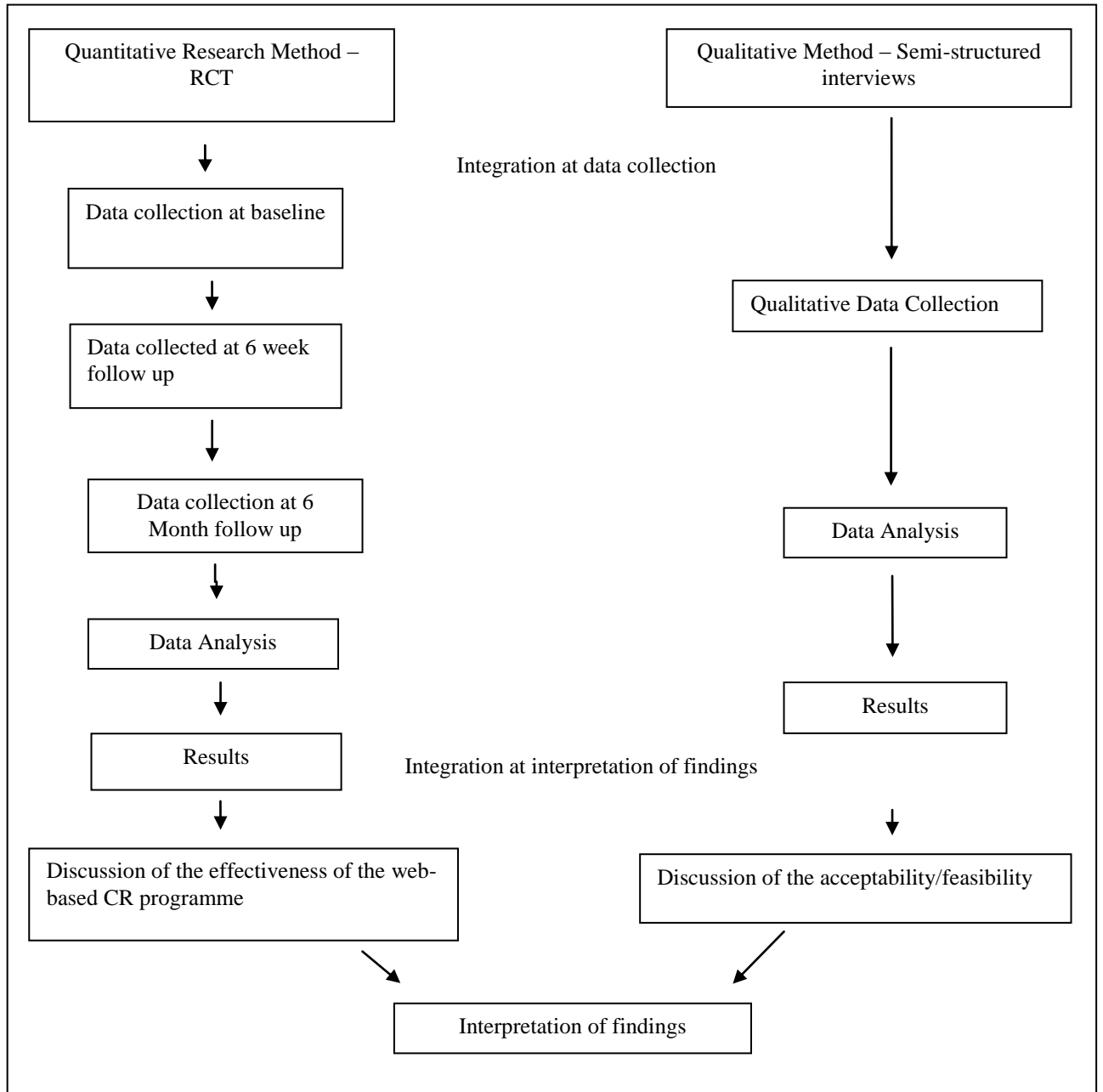
An RCT design and semi-structured interviews were the two specific methods

employed. The semi-structured interviews were conducted alongside the main

predominate study; the RCT. An RCT design was considered appropriate to measure the effectiveness of the web-based CR programme to improve lifestyle related cardiac risk factors. This was for the reason that randomly allocating participants to the study groups controlled for bias (Sibbald and Roland 1998). Random allocation ensured groups were comparable in every way apart from the experimental manipulation (Simon 2001). Thus, any significant differences between groups in study outcomes were then attributed to the intervention. Semi-structured interviews were used in addition, to the RCT; this was to explore acceptability and feasibility of the online CR programme. Semi-structured interviews allowed the researcher to conduct interviews which had both structure and flexibility. The interview content was structured to discuss feasibility and acceptability while remaining flexible to explore any new information revealed during the interviews.

4.2. *Justification of using Mixed Methods*

A combination of quantitative and qualitative methods was used. The research aim comprised two distinct elements; (i) to evaluate the effectiveness and (ii) evaluate the feasibility of the web-based CR programme. Both quantitative and qualitative approaches were required to adequately address both of these elements; since each method offered a valuable and distinct contribution to the study. Employing a quantitative research design allowed the study to gain an understanding of cause and effect, capability to control extraneous variables while having the potential to generalise findings to larger target populations. Utilising an additional qualitative design allowed an in-depth exploration of the thoughts and experiences of those using the rehabilitation programme. Furthermore, the use of a qualitative study alongside a

quantitative study was valuable as qualitative findings could help to explain, strengthen and interpret the quantitative findings. Additionally, the use of both an RCT and semi-structured interviews enhanced the ability and potential for implementing this web-based CR programme in practical settings. Understanding the effectiveness was important as there was a need to assess if the intervention 'worked' while also determining the acceptability and feasibility of this programme for those with CHD in practice.

As outlined it was necessary to employ both an RCT and a semi-structured interview study design. A more thorough and comprehensive understanding was particularly important as the web-based CR programme is a complex multi-component intervention with multi-disciplinary stages targeting multiple health behaviours. Therefore, a comprehensive and holistic approach adopting both quantitative and qualitative research methods was required to evaluate the programme.

4.3. *Quantitative Research Method*

4.3.1 *Study Design*

An RCT design was employed. Individuals with stable angina were recruited from Primary Care and randomised to either:

1. An experimental group – Participants in this group received the web-based CR programme.

2. A Control group – Participants in this group received usual care.

The experimental group and the control group were not denied any primary care services. The sole difference was the experimental group took part in the web-based CR programme and the control group did not. It was considered a breach of study design if a participant was offered conventional CR or any other secondary prevention intervention during the course of the study. If this did occur the participant was excluded from the study. It was not possible to blind the researcher as there was only one researcher carrying out the study field work i.e. data collection. The outcome measures were assessed at baseline, 6 weeks after baseline (6 week follow up) and then 6 months after that (6 month follow up).

4.3.2 *Recruitment of GP practices to the Study*

For feasibility reasons GP practices in and around the Coventry and Warwickshire area were targeted. First and foremost contact was made with the practice managers, if an interest was expressed in the study more information was sent via e-mail, fax or

post. If the GPs showed an interest in the study then a meeting was arranged. In this meeting the study purpose was explained in detail and the specific involvement required from the practice was discussed. If the practice agreed to take part then patient searches to identify eligible participants were organised.

4.3.3 *Participants*

The inclusion and exclusion criterion presented in table 4 were applied to participant recruitment.

Table 4: Inclusion and Exclusion Criteria applied to participant recruitment

Inclusion Criteria -	Exclusion Criteria -
Stable angina.	Severely anxious.
Percutaneous Transluminal Coronary Angioplasty (PTCA).	Severely depressed.
	Unstable angina.
Read/speak fluent English.	Significant cardiac arrhythmia.
Regular access to the internet.	Co-mordities prevent physical activity.
No prior CR within the previous year.	History of previous MI.
	CR in the previous year.

Those who were severely anxious or depressed were excluded for ethical reasons. It was uncertain whether this web-based CR programme would be suitable for those with significant levels of anxiety or depression as managing the clinical

anxiety/depression could be considered a priority. In addition, those with unstable angina or significant cardiac arrhythmia had to be excluded for similar reasons. Both of these groups are routinely excluded from CR in practice due to concerns with safety of exercising. As this was a new home-based, predominately independent programme, it was unethical and inappropriate to include vulnerable higher risk patients. Furthermore, those with co-morbidities preventing PA were excluded as this would affect the ability to follow the rehabilitation programme. Those who received CR within the previous year had to be excluded as the study aimed to examine effectiveness of a non-conventional rehabilitation programme, thus the influence of recent traditional rehabilitation would have contaminated the findings.

4.3.4 *How the inclusion and exclusion criterion was applied*

Each GP practice was given the participant inclusion and exclusion criteria (table 4). It was then the task of the GP practice to select patients from their CHD register that met these criteria. The member of staff responsible for selecting patients varied from practice to practice; most commonly this task was carried out by the practice nurse or the practice manager. All practices had patient details stored electronically, there were subtle differences between practices in the type of system/database used. All practices began the task with selecting all those who had stable angina (eliminating anyone with unstable angina) and all those who had been treated with PTCA. Once a list of stable angina and PTCA patients was generated a process of elimination was carried out regarding other exclusion criteria. This process varied from practice to practice. Some practices preferred to go through the stable angina and PTCA list manually, using each patient's record and their own personal knowledge of the

patient's medical history to make a judgement. Or alternatively other practices preferred to carry out this process electronically, using search codes corresponding to the exclusion criteria to reach a list of eligible patients. Severely anxious or severely depressed patients were excluded by eliminating those who had a history of being prescribed medication for either anxiety or depression. Patients with a past history of suffering with significant cardiac arrhythmia, or previous MI were also excluded, and details of either of these 2 conditions were contained within patient records. As discussions were carried out with GP practice staff it became apparent that some of the eligibility criteria was not documented in GP records. The criteria of excluding anyone with co-morbidities preventing PA, having received conventional CR in the last year, being unable to read/speak English and not having regular access to the internet were not documented within patient records. For this reason it was decided that the researcher should conduct an initial screening process before the consent procedure. It also became apparent that the criteria of excluding those with 'co-morbidities that prevented PA' was vague and not clearly defined. It was later agreed that if patients were able to walk outdoors they then were considered as fulfilling this criteria.

4.3.5 _Procedure_

Each GP practice notified the researcher when a list of eligible patients was produced. The researcher then provided the practice with the required number of study invitation packs, each pack contained an invitation letter (appendix no.1), a patient information sheet (appendix no.2), a reply sheet (appendix no.3), and a stamped addressed envelope. Invitation packs were sent to prospective patients from the practice, and each GP practice was reimbursed for postage costs. The invitation letter instructed

patients to read the patient information sheet and to post the reply slip in the stamped addressed envelope provided. All reply slips were then received at the research centre at Coventry University where I was based. Individuals indicating an interest in the study were contacted and further suitability to the study was verified. The criterion of having co-morbidities preventing PA, receiving conventional CR in the previous year, reading/speaking fluent English, and having regular access to the internet could not be determined from GP records. Therefore the researcher conducted an initial screening process via telephone on those who expressed an interest in the study. Once suitability was checked a home visit was arranged on a day and at a time convenient to the individual. During the initial home visit the researcher carried out the consent procedure. The consenting procedure began by introducing myself and describing the study details contained in the patient information sheet which had already been received in the initial postal invitation. The study's aims/objectives, study procedure and the expected involvement of participants was described. The prospective participant then had the opportunity to ask the researcher any questions related to the project. If the patient was satisfied with the study information they then consented by signing the study consent form (consent sheet example in appendix 4). The initial baseline assessment then followed during the same home visit. The baseline assessment involved measuring primary and secondary outcome measures. Details regarding the primary and secondary outcome measures are outlined in section 4.3.7 and 4.3.8 respectively. The physical measures were taken during the home visit (measuring weight, and height, blood pressure and body fat %). PA was measured using an accelerometer, which had to be worn for 7 days. Before the monitor could be worn the researcher had to calibrate each accelerometer to the individual participant. This involved entering gender, age, height, weight, dexterity and smoking

information into the software programme (InnerView Research Software version 6.1, Bodymedia) (figure 21). Each participant was instructed to wear the device daily for 12 daytime hours per day. The way that the monitor should be worn was demonstrated and each participant practiced putting it on the correct way (upper right arm with elastic, Velcro strap) and taking it off. Other outcome measures were assessed using questionnaires (fat intake, fibre intake, anxiety, depression, self-efficacy, and HR-QOL). The accelerometer and the questionnaires were left with each participant and another home visit was arranged so that the researcher could collect both these items. Participant randomisation was carried out during the period of time between the initial home visit and the visit to collect the accelerometer and questionnaires. The process of randomisation is described in section 4.3.6. Each participant was told which group they were in during the second home visit.

Those in the web-based CR group received a face to face introductory session. If convenient this session was either carried out during the second home visit or it was arranged at a time more suitable for the patient. The session involved outlining the programme content and describing the website components. Each participant created their own unique username and password, which allowed individual access to the intervention website. The researcher explained the purpose of different sections/website pages and described each stage of the programme. In addition, the researcher demonstrated how to use each interactive component of the programme such as the exercise diary, discussion chat room and the online self assessment quizzes. Furthermore, participants were shown a short CD ROM animated description of the programme features. Each participant was instructed to visit the website regularly and to complete the exercise diary daily. In contrast, participants in

the control group continued as usual. Study outcome measures were then repeated at the 6 week and 6 month follow up. As outlined in section 4.3.3 it was considered a breach of study design if a participant was offered conventional CR or any other secondary prevention intervention during the course of the study. If this did occur the participant was excluded from the study. For this reason at each follow up, the participant was asked about any changes to their medical status, this included asking whether they may have been offered any alternative treatments or being involved in any alternative interventions.

4.3.6   *Randomisation*

Participants were allocated to the web-based CR group or to the control group using a block randomisation technique. This was carried out using randomisation software and prepared by a statistical advisor employed in the University department at the time. This software randomly allocated participant numbers to either the intervention or the control group. These participant numbers and group allocation details were kept in sealed envelopes which were numbered to ensure they were used in sequence.

4.3.7   *Primary Outcome Measure*

Daily average step count was the chosen primary outcome measure, this was measured using Sensewear Pro 3® accelerometer technology. This was chosen as the primary outcome measure as it corresponded with the intervention's walking based exercise programme. While other measures of PA such as duration of sedentary intensity activity or duration of moderate intensity activity are also important, these

were not available during the study design stage. The software supporting the accelerometer device developed throughout the period of the study, and during data collection a newer version of the software made it possible to assess the duration of time participants spent being active at a sedentary or moderate intensity level. These measures of PA (duration of sedentary activity, duration of moderate activity) were then included as secondary outcome measures.

The Bodymedia® SenseWear Pro3 Armband is a multi-sensor body monitor, which is worn on the tricep of the right arm. This monitor has a continuous recording of physiological signals from the body such as skin temperature, dissipated heat from the body (heat flux), galvanic skin response and movement. The monitor and physiological sensors are shown in figure 20.

Figure 20: The Sensewear Pro 3 monitor

1 Accelerometer (inside) – tracks movement and provides information about body position (lying down).

2 Heart beat receiver board (inside)

3 Skin temperature sensor - measures the surface temperature of the skin

4 Galvanic skin response sensors – these sensors measure the electrical conductivity of the skin as the electrical conductivity of the skin changes in response to sweat and emotional stimuli.

5 Heat Flux Sensor – measures the amount of heat which is dissipated from the body.

Physiological data is collected from the sensors labelled in figure 20. The physiological signals from the multiple sensors and the in-built algorithms apply formula to estimate different elements of PA. The armband's multiple sensors and advanced algorithms recognise many basic activities such as weight-lifting, walking, running, biking and resting and consequently produces an output of daily average step count, overall EE, and daily duration of sedentary (< 3 MET) activity (DDSA), daily duration of moderate (3-6 MET) activity (DDMA), daily duration of vigorous (6-9 MET) activity (DDVA) and daily duration of very vigorous (>9 MET) activity (DDVVA). Before the monitor could be worn each device had to be configured to each participant. This involved entering gender, age, height, weight, dexterity and smoking history information into the software programme (InnerView Research Software version 6.1, Bodymedia) (figure 21). Participants wore the monitor on the upper right arm fastened with an elastic fabric belt. Each participant was instructed to wear the device for 7 consecutive days for 12 daytime hours per day.

Figure 21: Monitor configuration

All participants wore the armband at baseline, at the 6 week follow up and at the 6 month follow up and it was worn during their usual daily routine. The device has no display, this ensured participants were blinded to their own activity levels. Reliability and accuracy of this device has been established in healthy and unhealthy individuals (Dwyer et al. 2009, Jakicic et al. 2004). Participants were instructed to remove the armband when showering, bathing, and swimming as the monitor was not waterproof. The armband turned on automatically when worn and automatically switched off when removed. The data was saved into an internal memory contained in the monitor, which was then downloaded to a PC. An example of the data output is shown in figure 22.

Figure 22: Example of data output
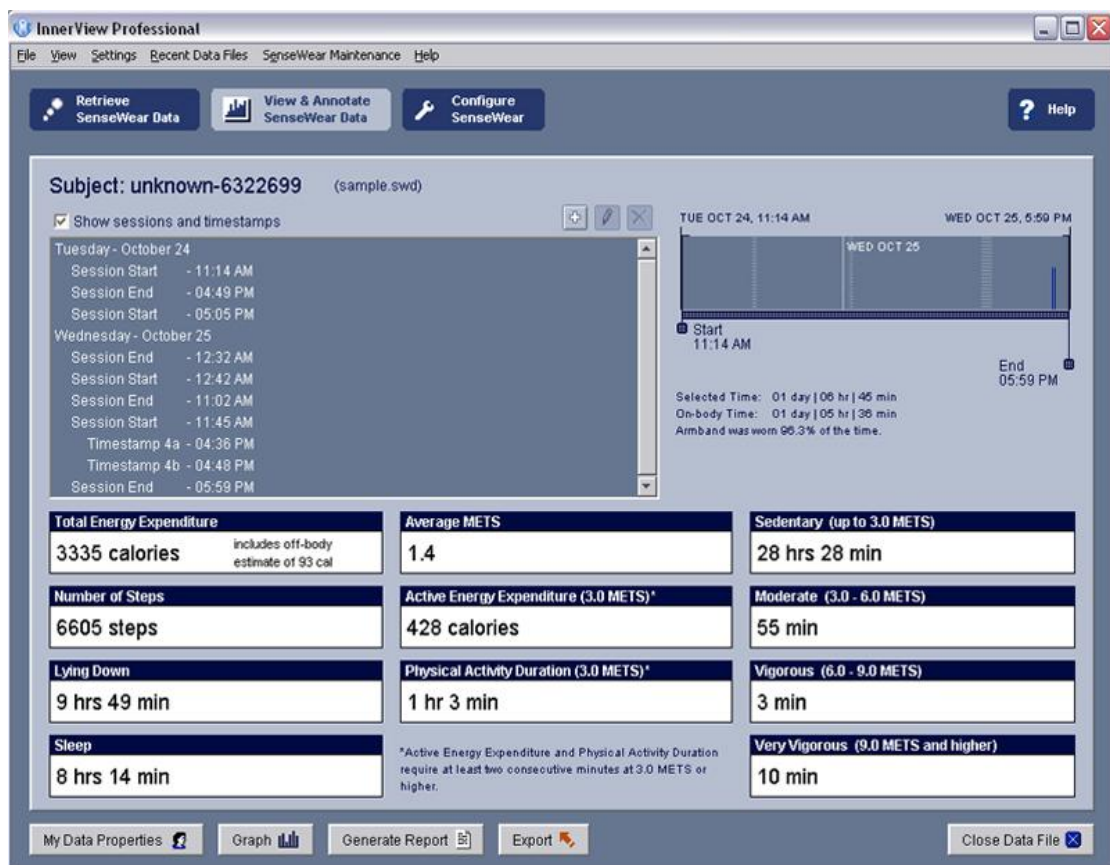
4.3.8 *Secondary Outcome Measures*

Other secondary outcome measures related to CHD were taken to evaluate the web-based CR programme. These are outlined in table 5.

Table 5: Secondary Outcome Measures

Outcome measure	Measure used	Measure characteristics and Procedure
Overall EE		
DDSA	Sensewear Pro 3® accelerometer	Measure described previously in primary outcome measure section.
DDMA		
DDVA		
DDVVA		
Weight (Kgs)	Seca 761 Mechanical Personal Scales	Measured to the nearest kilogram. Each participant wore indoor clothing with no shoes when measuring weight.
Blood pressure (BP)	OMRON upper arm BP.	Participants sat back with feet flat, the strap was then placed around the patients' left arm and blood pressure assessed. Data was expressed as DBP (mmHg) and SBP (mmHg).
Body Fat %	Bodystat 1500 - bio-impedance analyser.	Patients were required to lay down flat with 2 electrodes placed on 1 hand and on 1 foot. Data was expressed as body fat %.

Fat and Fibre Intake	Dietary Instrument for Nutritional Evaluation (DINE) (Roe et al. 1994).	A validated measure to assess total fat and fibre intake (Roe et al. 1994). This measure contained 19 groups of foods, all representing fat, and fibre in a typical UK diet. This measure involved participants choosing the frequency of food groups consumed from multiple choice answers. Each group of foods were assigned a score proportional to the fat or fibre content. The individual scores were then added together to produce total scores for dietary fat and dietary fibre. Participants scoring ≤30 represented a low fat, 30-40 medium fat score, and ≥40 high fat score. On the fibre subscale participants scoring ≤30 were classified as low fibre intake, 30-40 medium fibre score, and ≥40 high fibre sore.
Anxiety and Depression	HADS (Zigmond and Snaith 1983).	This is a validated measure of anxiety and depression (Bjelland et al. 2002). The measure consisted of 14 items; each item rated on a 4-point likert scale ranging from 0-3. Participants were scored as follows: mild depression (score 8-10), moderate depression (score 11-14) and severe depression (≥15). The same mild, moderate and severe score ranges were for the anxiety subscale (Zigmond and Snaith 1983).
Self-efficacy	The General Self-Efficacy Scale (Schwarzer and Fuchs 1996).	10 item questionnaire, with each response scored on a 4-point scale. The developers acknowledge it is a general scale (Schwarzer, and Jerusalem 1995), therefore suggest additional items can be added to cover the content of an intervention. In this study 5 items related to self-efficacy of exercise (3items), knowledge of heart disease (1 item), eating a healthy diet (1 item) were added. The final score of all items was used to describe the overall self-efficacy of

		participants, higher scores reflected greater self-efficacy.
HR-QOL	MacNew Heart Disease Questionnaire (Hofer et al. 2004).	This measure evaluates how physical, emotional and social functioning are affected by CHD. The questionnaire consists of 27 questions, which divide into emotional, physical, and social subscales. Each item is based on a 7 point scoring, with lower scores corresponding to impaired QOL. This has been reported to be both a valid and reliable measure and is sensitive to changes in HR-QOL following interventions (Hofer et al. 2004).
	SAQ (Spertus et al 1995).	This questionnaire comprises 19 questions that constitute 5 subscales; physical limitations, angina stability, angina frequency, treatment satisfaction and disease perception. The questions examined these scales over the past month. Lower scores indicated poorer health status and higher scores indicated better health. As the scale developers suggest no summary score is generated and therefore each subscale was examined separately. This measure has undergone validity and reliability testing (Spertus et al. 1995).

Participants also completed an information sheet, which asked questions regarding date of birth, ethnicity, number of years since angina diagnosis, angina treatment received, smoking status and employment status. The accelerometer device and the questionnaires were left with participants and collected after approximately 1 week. Thus, allowing participants adequate time to complete the questionnaires and to wear the accelerometer device for 7 days, 12 hours per day.

4.3.9   *Trial Registration*

This trial was registered with the International Standard Randomised Controlled Trial Number Register (ISRCTN). The registration number is ISRCTN90110503 and the web-link is http://www.controlled-trials.com/ISRCTN90110503. In the registered protocol the primary outcome measure was described as PA. As the project progressed specifically daily average step count was used as the primary outcome measure and the additional PA elements categorised as secondary outcome measures.

4.3.10   *Ethical Considerations*

Ethical approval for the study protocol and all study documents was sought and granted by 2 ethics committees;

1.   National Research Ethics Service (NRES) - ref: 08/H1210/84. A copy of the formal letter to notify ethical approval can be found in appendix 5 and Research and Development approval in appendix 6.

2. Coventry University – A copy of the e-mail to notify ethical approval can be found in appendix 7.

4.3.11   *Sample Size Calculation*

The sample size calculation was based on detecting a significant change in the number of steps walked by participants using the web based CR programme. Using the findings of Tudor-Locke et al (2004a), our sample size calculation was based on detecting a difference in means of 3501 steps walked between the intervention and control group. This would require 24 participants in each group (with 90% power, and 0.05 significance). We recruited more than this to allow for drop-out and to allow for the detection of differences between secondary measures.

4.3.12   *Data Management and Analysis*

All data was downloaded and inputted into Statistical Package for Social Scientists (SPSS). All data collected was kept confidential and secure, it was also anonymously coded in data analysis and in the report write up. First and foremost the primary outcome measure was analysed. Analysis of the secondary outcome measures followed this. All data was analysed using SPSS and the significance level was set at the conventional level of $p < 0.05$. Advice from the department of mathematics and statistics at both Coventry University and the University of Warwick was sought prior to and during data analysis.

4.3.13 *Parametric Tests Assumptions*

Prior to data analysis parametric test assumptions were checked; data type, distribution of the data, homogeneity of variance and independence.   These parametric test assumptions will now be outlined:

1.   Data type - All data was considered to be interval scale data; PA data, physiological measures and questionnaire measures.   Variables measured using questionnaires scales (anxiety, depression, fat and fibre intake, self-efficacy, social QOL, physical QOL, and emotional QOL, SAQ subscales) were considered as interval data.   It is acknowledged that treating questionnaire data as interval level data is a controversial issue.   One side of this debate reports that likert scale data is 'rank order' data and equal intervals between the values cannot be presumed and therefore non-parametric statistics should be used (Jamieson 2004).   The other side of the debate recognises single likert scale items represent ordinal data.   However when scores from multiple likert scale responses are collectively summed together and a total subscale score is used then it is reasonable and acceptable to analyse the data on an interval scale (Carifio and Perla 2007).   Other authors also state a collection of likert items produce interval data and reports it is acceptable to use parametric techniques with likert scales (Cohen, Manion and Morrison 2000).

2. Distribution of data - The distribution of scores for each outcome variable was examined visually plotting scores on frequency histograms. The distribution of data for each outcome variable was checked in both groups and at each stage of the study i.e. the data was split by group and at baseline, then again at the 6 week and the 6 month follow. This split was carried out for the reason

that in the analysis both groups and follow ups would be compared and it was therefore necessary to check the distribution of data this way. When data was found to be non-normal, the data was analysed non-parametrically.

3. Homogeneity of Variance - This assumption states that when comparing groups the variance of the outcome variable should be the same in each group. When the homogeneity of variance assumption was violated then the non-parametric equivalent was used.

4. Independence - Data collected was from independent participants. The behaviour of one participant did not influence the behaviour of another. However, 2 participants in the intervention group were husband and wife and did the intervention together; this was the only case where there was not independence. However both of these participants carried out the outcome measures independently. Within-subject factors in this study were completely non-independent as this was a repeated measures design.

4.3.14 *Statistical Analysis*

Information regarding participant enrolment, group allocation, participant retention and numbers in analysis were outlined in a flow chart according to CONSORT (Consolidated Standards of Reporting Trials) guidelines (Schulz, Altman and Moher 2010). Trial data was then analysed, data analysis was split up into 4 sections:

4.3.15 *Participants Recruitment and Baseline Characteristics*

Both groups' demographic characteristics and baseline outcome measures were compared at baseline using Pearsons chi-square test (categorical variables),

independent samples t-tests (continuous, normally distributed data) and Mann Whitney U tests (continuous data non normally distributed). Fisher's Exact test was used when chi-square test assumptions were violated. 'Trial completers' and 'trial dropouts' characteristics and baseline outcome measures were also compared.

Data was presented in table format, describing continuous normally distributed data using means and standard deviations. Numerical data not normally distributed was summarised using median and inter-quartile range values. Categorical variables were described using percentages.

4.3.16 *Short-term Effectiveness of Web-based Cardiac Rehabilitation*

The short-term effectiveness of the web-based CR programme was assessed by examining change from baseline to 6 week follow up in each outcome variable (6 week follow up score/value minus baseline score/value). The change value in the intervention and control group was compared using an independent sample t-test or Mann-Whitney U test when data was non-normally distributed. Where a significant difference was detected this was illustrated graphically. The change in daily steps was reported first as this was the primary outcome measure, all secondary outcome variables followed on from this; PA variables, physiological, diet, psychological and HR-QOL. Within group differences between baseline and 6 week follow up were also examined using paired t-tests or Wilcoxon signed-rank test when data was non-normally distributed. All within group differences were outlined in a table format. All participants completing both baseline and 6 week follow ups with valid/complete data were included in data analysis.

4.3.17   *Medium-term Effectiveness of Web-based Cardiac Rehabilitation*

Medium-term effectiveness of the web-based CR programme was ascertained using mixed design Analysis of Variance (ANOVA). This test incorporated both between and within subject variables simultaneously. Therefore, both baseline to 6 month follow up and 6 week to 6 month follow up changes could be compared between groups concurrently within one statistical test. Participants with complete data; baseline, 6 week, and 6 month follow up data were assessed. The group X outcome variable interaction analysis was examined and reported. This was of primary interest as the group interaction analysis determined whether there were any significant favourable effects of the web-based CR programme in comparison to treatment as usual. Further, the ANOVA contrasts analyses were reported as this provided specific baseline to 6 month change and 6 week to 6 month change analysis. Only participants with complete data sets were included in the ANOVA analysis, i.e. participants with baseline, 6 week, and 6 month follow up data.

In cases where scores/values were not normally distributed medium-term effectiveness was assessed by examining change. Baseline to 6 month follow up change and 6 week to 6 month follow up change in outcome measures were calculated. Change from baseline to the 6 month follow up was calculated by subtracting the 6 month follow up value from the baseline value. Change from the 6 week to the 6 month follow up was calculated by subtracting the 6 month follow up value from the 6 week follow up value. The distribution of the change scores were examined visually using frequency histograms. Depending on the distribution of change scores an independent samples t-test (normally distributed data) or a Mann Whitey U test (non-normally distributed data) was utilised to assess the difference between groups.

All statistical analysis findings utilised the 2-tailed statistic. Two tailed findings were reported in order to keep an open mind regarding the direction of change; therefore 2 tailed findings were reported.

4.3.18 Responders vs Non-responders

Further analyses were carried out in order to examine whether those who benefited most from the programme were characteristically any different from those who did not. Evidently this analysis was carried out on participants in the web-based intervention group only. The level of change in each individual outcome variable was assessed and participants demonstrating clinically meaningful changes were identified. Outcome measures with a pre-established threshold for a clinically important change have already been quantified for the following outcome variables; fat and fibre intake (Roe et al 1994), anxiety and depression (HADS, Puhan et al. 2008), emotional QOL, physical QOL and social QOL (Hofer et al. 2004), SAQ variables, and weight change (Wing et al. 2011). The questionnaire used to measure self efficacy (The General Self-Efficacy Scale, Schwarzer and Fuchs 1996) does not have guidelines available regarding the score change required for a meaningful change. For this reason it was decided to define ≥10% improvement in baseline self-efficacy score as a favourable change. This was also the case for the PA variables, and therefore ≥10% improvement in baseline PA was the threshold set for a favourable change in PA. For other physiological variables a significant favourable change was defined as a ≥5% reduction in SBP, DBP or bodyfat percentage. Following this, the next step was to determine which participants had demonstrated consistently favourable changes on multiple outcome measures. A frequency count

was carried out; counting the number of times a participant had demonstrated a favourable change on at least 6 outcome variables. These participants were then classified as a 'responder' and participants who did not meet this threshold were categorised as a 'non-responder'. Comparisons were then carried out between responders and non-responders in terms of participants' demographic characteristics (age, gender, employment, number of years since angina diagnosis, angina treatment, previous experience of CR) and baseline outcome measures (PA, physiological, diet, psychological, and HR-QOL outcomes). Depending on the distribution of data continuous variables were compared using independent samples t-tests or Mann Whitney U tests, and categorical variables were compared using chi-square tests. This analysis enabled the possibility to examine whether 'responders' could be identified in any way different to 'non-responders'.

4.3.19 *Consideration of Multiplicity of Statistical Testing*

Statistical analysis was performed on the primary and secondary outcome variables which altogether comprised 22 outcome measures; daily step count, daily EE, DDSA, DDMA, DDVA, weight, SBP, DBP, body fat %, fat intake, fibre intake, anxiety, depression, self-efficacy, emotional QOL, physical QOL, social QOL, physical limitation, angina stability, angina frequency, treatment satisfaction and disease perception. A large number and a variety of secondary outcome measures were used to optimise the evaluation and therefore the potential impact of the web-based CR programme. However, a potential disadvantage is the issue of 'multiplicity'; increasing the risk of obtaining statistical significance when a large number of statistical tests are carried out (Bland and Altman 1995). Variables were measured at

3 time points with statistical tests comparing each time point to baseline. Inevitably a large number of statistical tests were carried out and therefore suggests a need to consider the issue of 'multiplicity'. Using a Bonferroni adjustment to account for multiple testing has been suggested. However, a strict Bonferroni adjustment would have been too conservative when outcomes were related as they were in this trial (Brown and Russell 1997). Furthermore, Bender and Lange (2001) state the Bonferroni method is not appropriate when the number of tests is large as was the case in this study. Bender et al (2001) reports the Bonferroni corrections should only be used in cases whether the number of tests is small (less than 5) and where the correlations among the test statistics are low.

4.3.20 *Intention to Treat Analysis*

Data were analysed on an intention-to-treat basis. Inevitably with health promotion studies there are participants randomised to the intervention that completed the study outcome measures but do not actively take part in or complete the intervention. As long as there was data available participants were included in data analysis according to the group first assigned at randomisation regardless of intervention compliance or adherence.

4.4 Qualitative Research Method

4.4.1   Study Aim

The aim was to explore participants' views regarding the web-based CR programmes' level of acceptability and feasibility.

4.4.2   Study Design

A semi-structured interview design was used. The interview focus was structured to discuss acceptability and feasibility of the web-based CR programme whilst remaining flexible to explore any new information revealed during the interviews.

4.4.3   Participant Recruitment

Participants were recruited from the intervention group in the RCT study using a maximum variation sampling strategy. Thus, participants with a range of demographic characteristics (age, sex, gender, length of time since diagnosis) were recruited. Participant recruitment was sequential alongside the RCT and was conducted over an approximately 15 month period.

4.4.4   Procedure

Interviews took place in participants' homes and were carried out alongside the 6 week follow up of the main RCT study. Interviews were recorded on a digital recorder for 2 reasons. Firstly, so a complete verbatim transcription of the interviews

could be produced. The second reason was so the interviewer could fully concentrate on the interviewees' responses without having to write notes. The interviews involved asking participants questions from the interview schedule, listening to responses and being involved in the discussions of their reflections of the programme. Participants were anonymous as they were assigned a number to their transcription and this was used in writing the study findings.

4.4.5 *Content of Interviews*

A flexible emergent design was used in developing the interview schedule. This involved developing the interview schedule alongside data collection. Each time a new discussion topic was brought up in an interview that had not been anticipated previously was added to the interview schedule. This 'new item' was then asked in the subsequent interviews. Data collection continued until data saturation was reached whereby no additional information was obtained from the last participant. A copy of the final interview schedule is provided in Table 6. The interview began by asking participants to describe their current angina condition. This was to ease the participant into the interview and thus make them feel comfortable at speaking about their condition. Participants were also asked questions regarding their lifestyle since using the programme, perceptions regarding intervention content, usability of specific intervention features, and the general practicability and feasibility of the web-based CR programme. There was a conscious effort to remain neutral, non-judgemental, approachable, and friendly when conducting the interviews.

Table 6: The Interview Schedule

Interview Schedule

1. To begin with could you please describe your current angina condition?

2. What were your initial thoughts and feelings regarding this web-based programme?

3. How was your overall experience of using the programme?

4. Generally, how did you feel about being given this programme to do?

5. Have you noticed any changes in yourself related to using the web-based programmme?
   a. If yes, what are these changes? How did the website encourage you to make these changes?

   b. If no why do you think this is?

6. Did the programme challenge you in a way that you have not previously thought about?
7. Did the programme influence your awareness in anyway?

8. How did you feel about goal-setting?
   a. Exercise goal-setting
   b. Diet goal-setting etc
9. To what extent did you accept the programme and why?
10. Were there any enjoyable parts of the programme? (and why?)

11. Were there any useful parts of the rehabilitation programme? (and why)

12. How was the information and advice offered on the website?

13. Did you find the programme easy to use?

14. What did you think about the length of the programme?

15. How was the timing of the programme? In terms of the stage of your angina condition.

16. What do you think about the support available on the programme? In terms of the e-mail link and chat room?

17. How did you find the programme being online and delivered via the internet?

18. How did the programme fit in with your lifestyle?

19. Were there any difficulties/drawbacks to using the programme?

20. What are the overall benefits to using the program?

21. What are your views about using the programme being carried out via the internet?

22. Can you recommend any improvements to the programme?

23. What are your self-management plans for the future?

24. Any other comments?

4.4.6   Data Analysis

Thematic analysis (TA) was the approach used to analyse the data. Overall, the aim of this study guided the data analysis process. Data was analysed and subsequently presented in data analysis whenever a participant spoke about something in relation to the acceptability and feasibility of the programme. The following section will describe and outline the data analysis process that was carried out. The thematic analysis framework outlined by Braun and Clark (2006) was used as a point of reference and as a guide for data analysis. Data analysis was carried out over 5 stages; details of each stage are described below.

4.4.7   Stage 1 – Familiarisation with the data

I conducted and transcribed each interview. Once all interviews had been transcribed each interview was listened to again alongside the transcript in order to ensure the transcript was accurate and thorough. Carrying out these tasks enabled familiarisation with the content of the data. In addition interviewing participants meant I was able to listen to participants' accounts first hand. There was further familiarisation of the data when interviews were transcribed and when each transcript was checked. Thus altogether each interview was listened to 3 times before the data was coded. This

contributed to the data analysis process as it enabled the researcher to be familiar with the general trend and content of each interview before generating codes from the interviews.

4.4.8   *Stage 2 – Generating initial codes*

Each transcript was examined individually to generate coded segments of data. Codes were generated by reading each transcript and coding data identified to relate to the research question. Each segment of data relevant to the research question was coded, thus each code represented a piece of data. Each transcript was coded individually, and therefore each transcript had different codes assigned to different segments of data within the transcript. This was carried out electronically on each individual Microsoft word document, the number of codes within each transcript ranged from 6 to 48. An example of a coded transcript is provided in appendix 8.

4.4.9   *Stage 3 – Coded Data was Placed into Categories*

The coded data segments were then grouped to form categories. All data across transcripts assigned common, or similar codes were grouped and therefore data with similar extracts were placed together. When all similar coded pieces of data were grouped these then formed a 'category'. There were 48 categories altogether. A few examples are 'easy to use', 'motivation', 'support on the programme', 'created awareness' and 'source of information'. These examples can be viewed in appendix 9.

4.4.10 Stage 4 Grouping Categories to form Sub themes

The 48 categories were then grouped together further. Categories with similar trends or were strongly related were merged to form sub-themes. For example, 3 different categories were no day or time restriction, no need to travel, and easy to use were grouped together as a sub-theme and given a title of 'practical aspects of the programme'. An additional example is the categories self-motivation, positivity, and taking it seriously were grouped to form a sub-theme and were labelled 'personality requirements'. The process of grouping categories into sub themes was a dynamic and fluctuating one in the sense that deciding which categories were related to other categories changed frequently until final sub themes were decided on. In the process of creating sub themes brief descriptions were written in order to conceptualise and formulate what each sub theme meant and what was understood by each category placed within that subtheme. These brief descriptors were mainly for the use of the researcher to formulate what was meant by each and to conceptualise meanings. This contained some interpretative analysis, assessing and analysing meaning underlying participant quotes. Overall 10 subthemes were generated in this way.

4.4.11 Stage 5 Sub-themes into Themes

In this stage sub-themes and brief descriptors of each sub-theme were reviewed. All the sub-themes were checked to see whether they related to one another or if themes were similar. If themes were considered too broad they were split. Small sub-themes with similar descriptions were grouped together to form a theme. In contrast, large and broad sub-themes containing many categories were subdivided. There were 3 final themes. Each theme was defined and described considering in terms of how the

theme fitted into the boarder overall study aim. For each theme data extracts/quotes that illustrated the theme were used to support the interpretive decisions made in generating the final themes.

4.5. *Chapter Summary*

This chapter has outlined the overall approach used to address the overarching research aim. Detailed accounts of both quantitative and qualitative methods employed in this thesis were then described. The following chapters will present findings from the RCT trial, outlining the intervention's short-term effectiveness (chapter 5) and then medium-term effectiveness (chapter 6). Following this will be an outline of the qualitative study findings (chapter 7).

CHAPTER 5

PARTICIPANT RECRUITMENT AND SHORT-TERM EFFECTS OF

THE WEB-BASED CARDIAC REHABILITATION PROGRAMME

The main focus of this chapter was to report participant recruitment, flow of participants through the study and the short-term effectiveness of the online CR programme. To begin with a brief method of the study will be described. This is followed by a description of study recruitment and flow of participants through the trial. Challenges experienced with data collection are then explained. This is followed by outlining participant characteristics and outcome measures in both groups at baseline. Participant characteristics and baseline outcome measures of trial completers and trial drop-outs will also be outlined. The short-term effects of the web-based CR programme are then reported. The primary outcome measure will be analysed at the outset and secondary outcome measures analysis will follow. Secondary outcome measures will be divided into PA, physiological, diet, psychological and HR-QOL variables. After between group differences have been examined the chapter then outlines within group differences (baseline to 6 week follow up) in each group, these are presented in table format. A discussion of the intervention's short-term effectiveness will conclude the chapter.

5.1 *Summary of Method*

The specific details of the method used are outlined in chapter 4 section 4.3. Altogether there were 95 participants recruited to the study, of which 94 completed baseline measures, these participants were then randomised to either the intervention

group (n=48), or the control group (n=46). Full details of how participants were recruited are outlined in chapter 4, section 4.3.2. This chapter reports on the short-term effectiveness of the intervention and its influence on study outcome measures. Full details of the primary and secondary outcome measures are provided in chapter 4, section 4.3.6, and section 4.3.7 respectively. Initially participant characteristics and baseline outcome measures between trial groups were compared. 'Trial completers' and 'trial dropouts' were then also compared. Short-term benefits of the programme were examined by calculating baseline to 6 week follow up change in each outcome measure (6 week follow up score/value minus baseline score/value). Full details of the statistical tests used to analyse short-term effectiveness can be found in chapter 4, section 4.3.15.

5.2 *Participants*

Recruitment of GP practices was staggered over approximately 16 months to allow for a gradual increase in participants. Altogether 9 GP practices took part. The overall recruitment rate into the RCT was 95/612 (16%), with 48 and 47 in the intervention and control group respectively. One control group participant withdrew during baseline measurement stage, thus 46 remained in the control group. Altogether 94 participants completed baseline measures, 84 at 6 week follow up (11% attrition) and 73 at 6 month follow up (22% attrition). At the 6 week follow up attrition was 15% and 7% in the intervention and control group respectively. At the 6 month follow up attrition was 25% in the web-based CR group and 20% in the control group. Participant flow is illustrated in figure 23.

Figure 23: Participant flow through the trial –
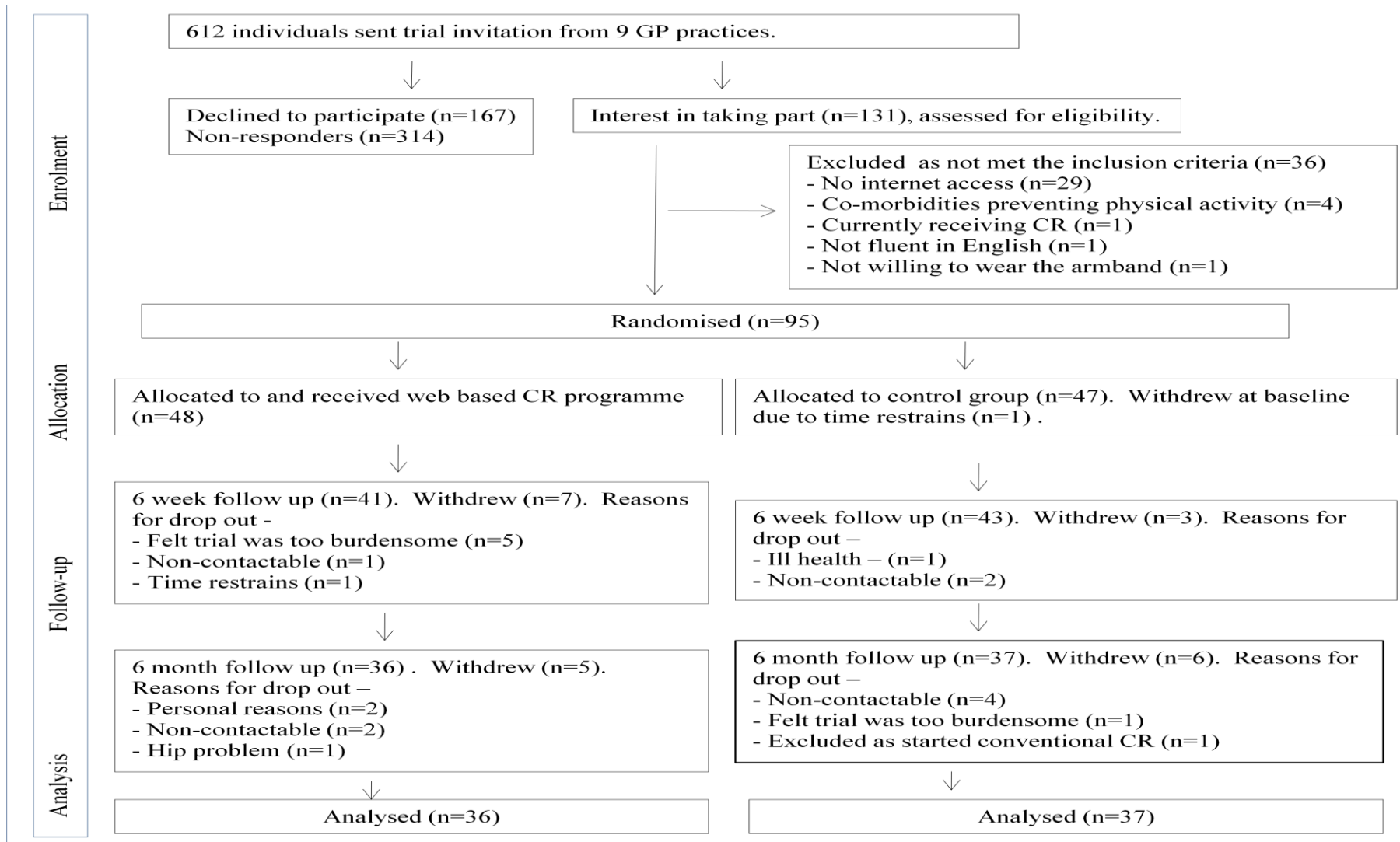
5.3 *Missing Data*

During the trial it became apparent that participants were not adhering to wearing the accelerometer for the required time period; 7 days, 12 hours per day. As this issue was noticed the importance of wearing the monitor for the required time period was emphasised to each participant. However, inevitably not all participants adhered to this. The majority of participants did wear the monitor for 7 days, although the number of hours varied considerably; ranging from 4 hours to 18 hours. It was important to utilise and retain the maximum number of participants' data as possible. Therefore, it was decided to use 2 week days (12 hours per day) of data for each participant. Prior research reports this is a sufficient length of monitoring time for chronic disease populations as there is less day to day variability (Tudor-Locke and Myers 2001). It was decided to only use weekday data as previous research indicates a difference in activity levels performed on weekdays and weekend days (Tudor-Locke et al. 2004b). Only using participants who wore the monitor for 12 hours on the same days at baseline, 6 week, and 6 month follow up was not realistic and would have severely restricted usability of the data. For this reason random weekdays were selected. A list of random digits numbered 1-5 was generated using this website http://www.random.org/integers/. Each digit represented a week day; Monday-Friday. For instance 1 represented Monday, 2 represented Tuesday and so on. This list was used sequentially to select which days to use for each participant. If the monitor was worn for less than 12 hours the next random digit/day was selected until a 12 hour day was selected. This process was repeated for PA data at baseline, 6 week and 6 month follow up. Participants who did not wear the monitor for 12 hours on any days had to be excluded. Further there were sporadic occasions where the armband generated a faulty reading; these participants also had to be excluded.

In addition, there was missing data among the self-report measures, as occasionally participants returned measures with individual items that had been missed. There was also missing data due to participant withdrawal. Depending on the point at which the participant withdrew no further data was available for these participants.

There is no data presented for DDVVA throughout the whole study as this level of activity was only detected twice and therefore was not considered meaningful to carry out any analysis. In the web-based CR group there was only 1 participant active at this level for 1.5 minutes and 2 minutes at baseline and 6 week follow up respectively, and none detected at the 6 month follow up in the web-based CR group. There was no DDVVA detected in the control group at baseline, 6 week follow up, or at the 6 month follow up.

5.4 *Demographic Characteristics and Baseline Measures*

There were no statistically significant differences between the intervention and control group in demographic characteristics (table 7) or baseline measures (table 8).

Table 7: Demographic Characteristics of participants, values are numbers (percentages) unless stated otherwise

Demographic Characteristic	Intervention Group (n=48)	Control Group (n=46)
Age (years)[a]	66.27 (8.35)	66.20 (10.06)
Male Gender	34 (71%)	36 (78%)
Female Gender	14 (29%)	10 (22%)
Employment	Retired - 29 (60%) Full-time - 13 (27%) Part-time - 4 (8%) Unemployed – 2 (4%)	Retired - 21 (46%) Full-time -18 (39%) Part-time - 7 (15%)
Ethnicity	White British - 44 (92%) Other – 4 (8%)	White British - 42 (91%) Other – 4 (9%)
Years since diagnosis	7.98 (4.53)	9.44 (5.81)
Angina Treatment	Medication only - 19 (44%) Stent(s) - 15 (35%) CABG - 9 (21%)	Medication only - 16 (37%) Stent(s) - 21 (49%) CABG - 6 (14%)
Previous CR	No – 34 (76%) Yes – 11 (24%)	No - 35 (81%) Yes - 8 (19%)
Current Smoking Status	No – 46 (96%) Yes – 2 (4%)	No – 40 (87%) Yes – 6 (13%)

[a] Values are mean (SD)

Table 8: Baseline Outcomes of participants, values are mean (SD) unless stated otherwise

Baseline Outcome Measures	n[a]	Intervention Group	n[b]	Control Group
PA				
Daily Steps[c]	35	6716 (3060)	40	6624 (3189)
Daily EE (Kcal)	35	1902.47 (392.32)	40	2055.05 (431.80)
DDSA (minutes)[d]	35	675.00 (45.00)	40	663.25 (103.25)
DDMA (minutes)[d]	35	43.50 (43.00)	40	55.50 (96.25)
DDVA (minutes)[d]	35	0.00 (1.00)	40	0.5 (1.38)
Physiological Measures				
Weight (kgs)	48	81.65 (13.63)	46	80.35 (14.59)
Body Fat (%)	48	37.79 (10.34)	46	36.05 (8.37)
SBP (mmHg)	48	134.00 (16.56)	46	137.43 (15.99)
DBP (mmHg)	48	72.94 (10.08)	46	72.09 (10.66)
Diet				
Fat Score	44	37.18 (8.21)	43	41.05 (12.23)
Fibre Score	46	36.26 (9.34)	43	35.33 (11.51)
Psychological				
Anxiety Score	40	5.53(3.80)	42	5.93 (3.67)
Depression Score[d]	46	2.50 (4.25)	46	2.50 (4.00)
Self-efficacy Score	45	49.89 (6.73)	42	49.62 (7.42)
MacNew QOL				
Emotional QOL Score[d]	46	6.00 (1.39)	44	5.93 (1.66)
Physical QOL Score[d]	45	6.50 (0.96)	45	6.50 (1.33)
Social QOL Score[d]	46	6.54 (0.88)	44	6.42 (1.23)
Seattle Angina Questionnaire[e]				
Physical Limitation Score	37	64.19 (21.55)	42	63.49 (25.40)
Angina Stability Score[d]	33	42.86 (57.14)	37	42.86 (57.14)
Angina Frequency Score	33	43.56 (31.58)	41	44.51 (32.36)
Treatment Satisfaction Score[d]	43	100.00 (0.00)	41	42.86 (28.57)
Disease Perception Score[d]	44	83.33 (33.33)	43	83.33 (41.67)

[a]Number of participants in the intervention group with complete baseline data.
[b]Number of participants in the control group with complete baseline data.
[c]Primary Outcome Measure
[d]Values were not normally distributed therefore median (inter-quartile range) values reported.
[e]Higher Scores on this questionnaire represent better functioning.

5.5 Trial Adherence

The following tables outline the demographic characteristics (table 9) and baseline

measures (table 10) in trial completers and trial drop outs.

Table 9: Demographic Characteristics of trial completers and drop outs, values are numbers (percentages) unless stated otherwise

Demographic Characteristic	Trial Completers (n=73)	Trial Drop-Outs (n=21)
Age (years)[a]	65.67 (8.96)	68.19 (9.84)
Male Gender	52 (71%)	18 (86%)
Female Gender	21 (29%)	3 (14%)
Employment	Retired - 37 (51%) Full-time - 25 (34%) Part-time - 10 (14%) Unemployed – 1 (1%)	Retired - 13 (62%) Full-time - 6 (28%) Part-time - 1 (5%) Unemployed – 1 (5%)
Ethnicity	White British 68 (93%) Other – 5 (7%)	White British 18 (86%) Other – 3 (14%)
Years since diagnosis[a]	8.90 (5.36)	8.00 (4.81)
Angina Treatment	Medication only - 26 (39%) Stent(s) - 29 (43%) CABG - 12 (18%)	Medication only - 9 (47%) Stent(s) - 7 (37%) CABG - 3 (16%)
Previous CR	No – 52 (75%) Yes – 17 (25%)	No – 17 (89%) Yes – 2 (11%)
Current Smoking Status	No – 66 (90%) Yes – 7 (10%	No – 20 (95%) Yes – 1 (5%)

[a] Values are mean (SD)

Table 10: Baseline Outcomes of trial completers and drop outs, values are Mean (SD) unless stated otherwise

Baseline Outcome Measures	n[a]	Completers	n[b]	Dropouts
PA				
Daily Steps[c]	65	6726 (3135)	10	6285 (3063)
Daily EE (Kcal)	65	1983.99 (416.52)	10	1982.90 (451.67)
DDSA (minutes)[d]	65	668.50 (72.00)	10	668.25 (80.25)
DDMA (minutes)[d]	65	51.50 (70.00)	10	51.50 (79.00)
DDVA (minutes)[d]	65	0.00 (1.00)	10	0.75 (1.75)
Physiological Measures				
Weight (kgs)	73	81.18 (14.67)	21	80.43 (11.94)
Body Fat (%)	73	37.55 (9.59)	21	34.83 (8.68)
SBP (mmHg)	73	132.95 (16.28)	21	145.19 (12.53)*
DBP (mmHg)	73	71.88 (10.42)	21	74.76 (9.90)
Diet				
Fat Score	69	38.57 (9.52)	18	41.11 (13.83)
Fibre Score	69	35.58 (10.76)	20	36.60 (9.22)
Psychological				
Anxiety Score[d]	72	5.00 (5.00)	10	5.50 (9.50)
Depression Scores[d]	72	2.50 (4.00)	20	2.50 (3.75)
Self-efficacy Score[d]	68	48.97 (7.08)	19	52.58 (6.27)*
MacNew QOL				
Emotional QOL Score[d]	69	5.93 (1.39)	21	6.14 (1.82)
Physical QOL Score[d]	69	6.50 (1.25)	21	6.42 (1.00)
Social QOL Score[d]	69	6.46 (1.12)	21	6.62 (0.92)
Seattle Angina Questionnaire[e]				
Physical Limitation Score	69	64.01 (23.77)	10	62.50 (22.91)
Angina Stability Score[d]	63	42.86 (57.14)	7	42.86 (57.14)
Angina Frequency Score	64	47.85 (31.15)	10	20.00 (25.82)*
Treatment Satisfaction Score[d]	66	100.00 (0.00)	18	100.00 (60.71)
Disease Perception Score[d]	68	83.33 (24.08)	19	83.33 (33.33)

[a]Number of participants in the intervention group with complete baseline data.
[b]Number of participants in the control group with complete baseline data.
[c]Primary Outcome Measure.
[d]Values were not normally distributed therefore median (inter-quartile range) values reported.
[e]Higher Scores on this questionnaire represent better functioning.
*Difference between groups statistically significant ($p < 0.05$).

Trial completers had significantly lower SBP compared to those who dropped out, p=0.001. In addition, frequency of angina symptoms were significantly higher among drop-outs compared to study completers (p=0.01). Further, those dropping out of the trial had significantly higher self-efficacy than those who remained in the study, p=0.05. There were no other significant differences between groups in participant characteristics or baseline outcome measures.

5.6 *Short-term Intervention Effects*

Table 11 outlines outcome measure values detected at baseline and at the 6 week follow up in both groups. The change in outcome measures in each group is also shown.

Table 11: Outcome Measures at Baseline and 6 week follow up, values are means (SD) unless stated otherwise

Outcome Measures	n[b]	Intervention Group			n[c]	Control Group			p-Value[d]
		Baseline	6 week follow up	Change		Baseline	6 week follow up	Change	
PA									
Daily Steps[a]	35	6716 (3060)	7212 (3188)	+497 (2171)	40	6624 (3189)	5763 (2533)	-861(2534)	p=0.02
Daily EE (Kcal)	35	1902.47 (392.32)	1946.41 (351.79)	+43.94 271.90)	40	2055.05 (431.80)	1922.04 (306.47)	-133.01 (302.01)	p=0.01
DDSA (minutes)[f]	35	675.00 (45.00)	671.50 (55.50)	-7.79[e] (40.14)	40	663.25 (103.25)	672.25 (61.75)	+23.23[e] (62.78)	p=0.01
DDMA (minutes)[f]	35	43.50 (43.00)	48.50 (50.00)	+6.31[e] (34.37)	40	55.50 (96.25)	47.75 (61.38)	-22.29[e] (61.34)	p=0.01
DDVA (minutes)[f]	35	0.00 (1.00)	0.50 (1.00)	+0.03[e] (4.05)	40	0.50 (1.38)	0.00 (0.50)	-0.94[e] (3.40)	p=0.27
Physiological Measures									
Weight (kgs)	41	82.80 (13.49)	82.24 (13.30)	-0.56 (2.00)	42	79.52 (14.36)	79.93 (14.74)	+0.41 (1.71)	p=0.02
Body Fat (%)	39	38.78 (10.80)	38.36 (11.52)	-0.42 (7.67)	41	36.34 (8.01)	37.01 (7.07)	+0.67 (6.39)	p=0.49
SBP (mmHg)	40	131.35 (15.34)	130.80 (14.70)	-0.55 (12.03)	42	137.55 (16.51)	128.55 (14.88)	-9.00 (12.77)	p=0.00
DBP (mmHg)	39	72.92 (9.95)	69.00 (9.57)	-3.92 (8.75)	42	72.52 (10.73)	68.52 (9.16)	-4.00 (8.27)	p=0.97

	n				n				
Diet									
Fat Score	33	38.76 (8.46)	35.55 (9.18)	-3.21 (7.98)	32	40.88 (11.63)	39.38 (10.38)	-1.50 (11.89)	*p*=0.50
Fibre Score	35	36.40 (9.84)	36.51 (8.77)	+0.11 (6.88)	33	35.09 (12.46)	33.79 (12.24)	-1.30 (12.14)	*p*=0.55
Psychological									
Anxiety Score	36	5.61 (3.57)	4.14 (3.50)	-1.47 (3.19)	39	5.51 (3.42)	4.87 (3.73)	-0.64 (2.27)	*p*=0.20
Depression Scores[f]	37	3.00 (4.00)	2.00 (2.00)	-0.43[e] (2.15)	42	2.00 (3.00)	2.00 (4.25)	+0.01[e] (2.30)	*p*=0.30
Self-efficacy Score	37	49.03 (6.55)	51.70 (6.37)	+2.68 (5.92)	39	49.79 (7.56)	49.92 (7.76)	+0.13 (3.49)	*p*=0.03
MacNew QOL									
Emotional QOL Score[f]	36	5.89 (1.21)	6.25 (1.04)	+0.31[e] (0.67)	40	5.96 (1.45)	6.32 (1.21)	+0.04[e] (0.44)	*p*=0.04
Physical QOL Score[f]	33	6.50 (0.71)	6.50 (0.92)	+0.04[e] (0.69)	41	6.50 (1.42)	6.58 (1.33)	+0.11[e] (0.57)	*p*=0.62
Social QOL Score[f]	34	6.54 (0.85)	6.73 (0.50)	+0.21[e] (0.66)	40	6.54 (1.17)	6.62 (1.19)	+0.73[e] (0.57)	*p*=0.34
Seattle Angina Questionnaire[g]									
Physical Limitations Score	37	64.19 (21.55)	62.16 (25.43)	-2.03 (19.20)	42	63.49 (25.40)	63.69 (27.03)	+0.20 (15.19)	*p*=0.57

Angina Stability Score[f]	33	42.86 (57.14)	33.33 (66.67)	-9.74[e] (39.81)	37	42.86 (57.14)	33.33 (66.67)	-9.97[e] (33.63)	*p*=0.98
Angina Frequency Score	33	43.56 (31.58)	53.79 (30.70)	+10.23 (26.78)	41	44.51 (32.36)	32.93 (28.74)	-11.59 (29.63)	*p*=0.00
Treatment Satisfaction Score[f]	35	100.00 (0.00)	100.00 (0.00)	+4.04[e] (23.38)	36	100.00 (28.57)	100.00 (22.22)	-1.90[e] (30.52)	*p*=0.36
Disease Perception Score[f]	36	83.33 (33.33)	80.00 (40.00)	+0.97[e] (20.15)	40	83.33 (39.58)	80.00 (40.00)	-2.13[e] (17.54)	*p*=0.48

[a]Primary Outcome Measure.
[b]Number of participants in the intervention group with complete baseline and 6 week follow up data.
[c]Number of participants in the control group with complete baseline and 6 week follow up data.
[d]Independent Samples t test comparing change scores.
[e]The change values were normally distributed and therefore mean value reported.
[f]Baseline and 6 week follow up values were not normally distributed therefore median (inter-quartile range) values reported.
[g]Higher Scores on this questionnaire represent better functioning.

5.7 Primary Outcome Measure

At the 6 week follow up the intervention group increased daily steps walked by 497 (2171) steps, while the control group decreased daily steps walked by 861 (2533). This represented a 13% decrease in the control group and 7% increase in the web-based CR group. This is illustrated in both figure 24 and figure 25. The difference between groups was significant (*p=0.02*).

Figure 24: Daily Steps Walked at Baseline and 6 Week Follow up in the Intervention and Control Group
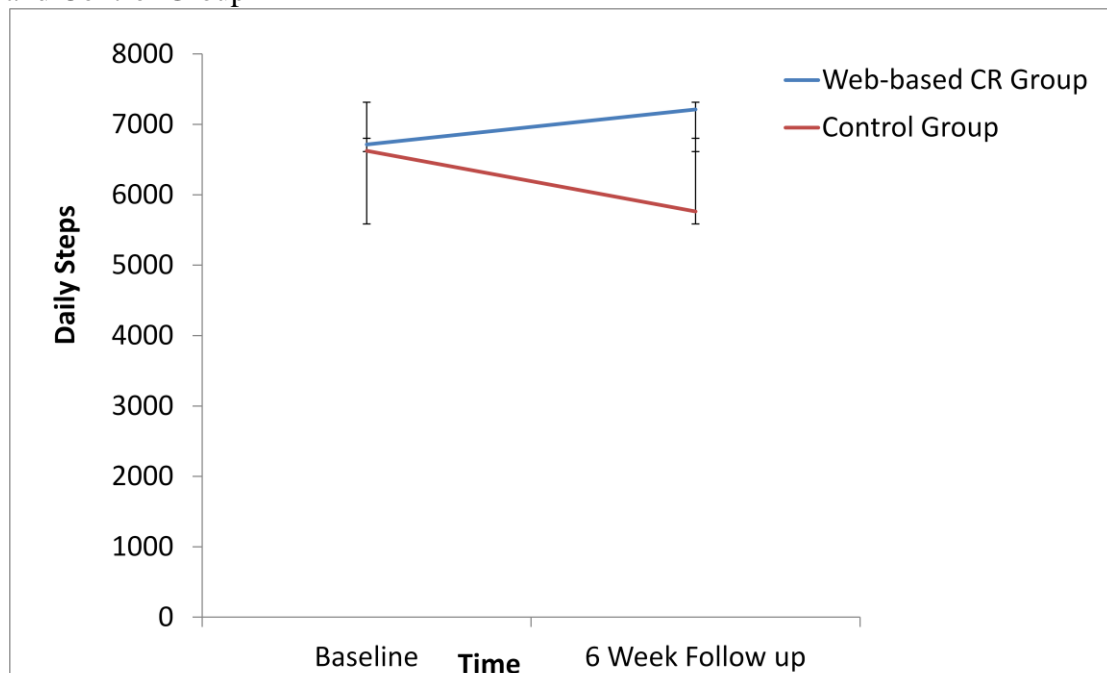
Figure 25: Baseline to 6 Week Follow up Change in Daily Step Count
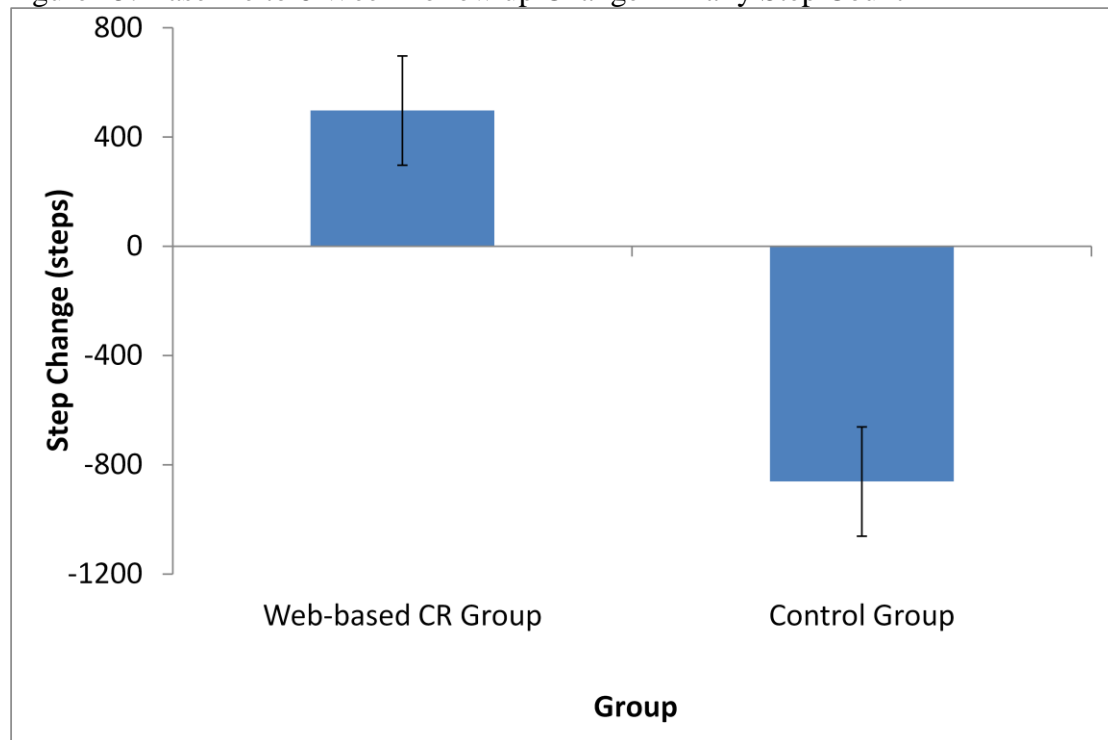
5.8 *Secondary Outcome Measures*

5.8.1. *Physical Activity Changes*

EE increased in the intervention group by 43.94 (271.90) kcal, while it declined in the control group by -133.01 (302.01) kcal, the difference between groups was significant *(p=0.01)*. This is illustrated in figure 26.

Figure 26: Baseline to 6 Week Follow up Change in Daily EE
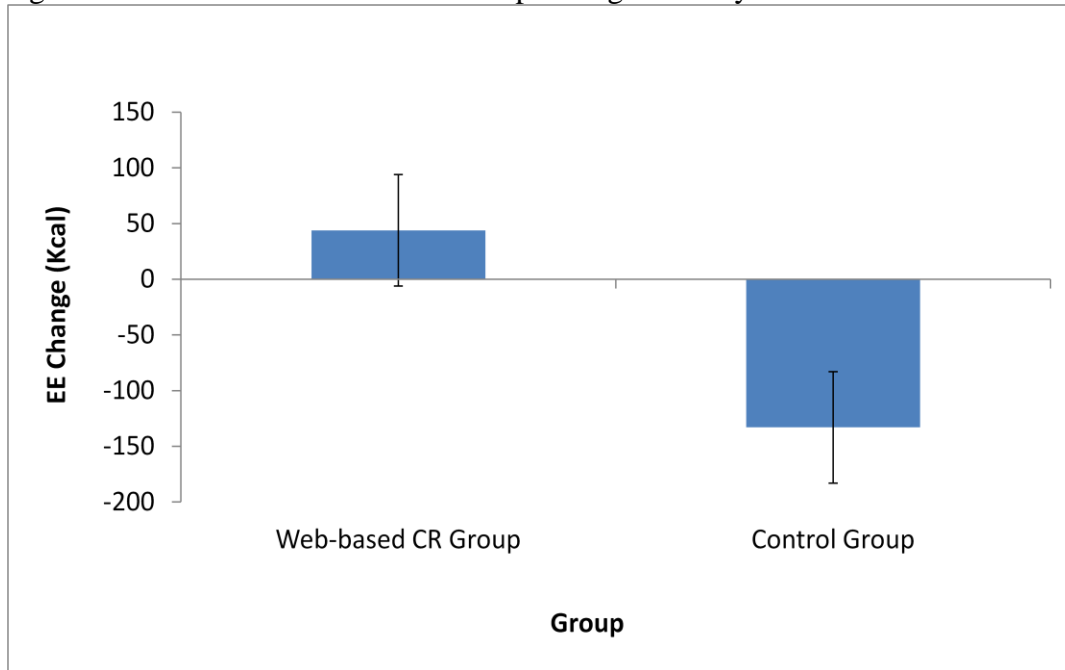
DDSA decreased in the intervention group by 7.79 (40.14) minutes, and increased in the control group by 23.23 (62.78) minutes, the difference between groups was significant *(p=0.01)*. This finding is illustrated in figure 27.

Figure 27: Baseline to 6 Week Follow up Change in DDSA
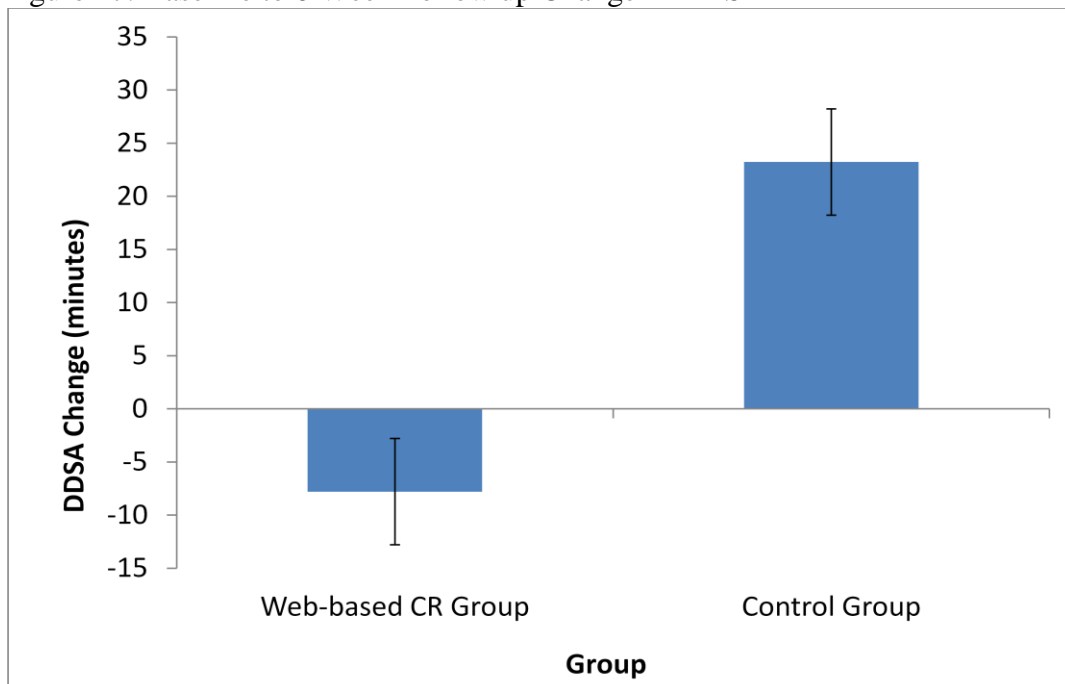
DDMA increased in the intervention group by 6.31 (34.37) minutes while the control group decreased by 22.29 (61.34) minutes, the difference between groups was significant *(p=0.01)*. This is illustrated in figure 28.

Figure 28: Baseline to 6 Week Follow up Change in DDMA
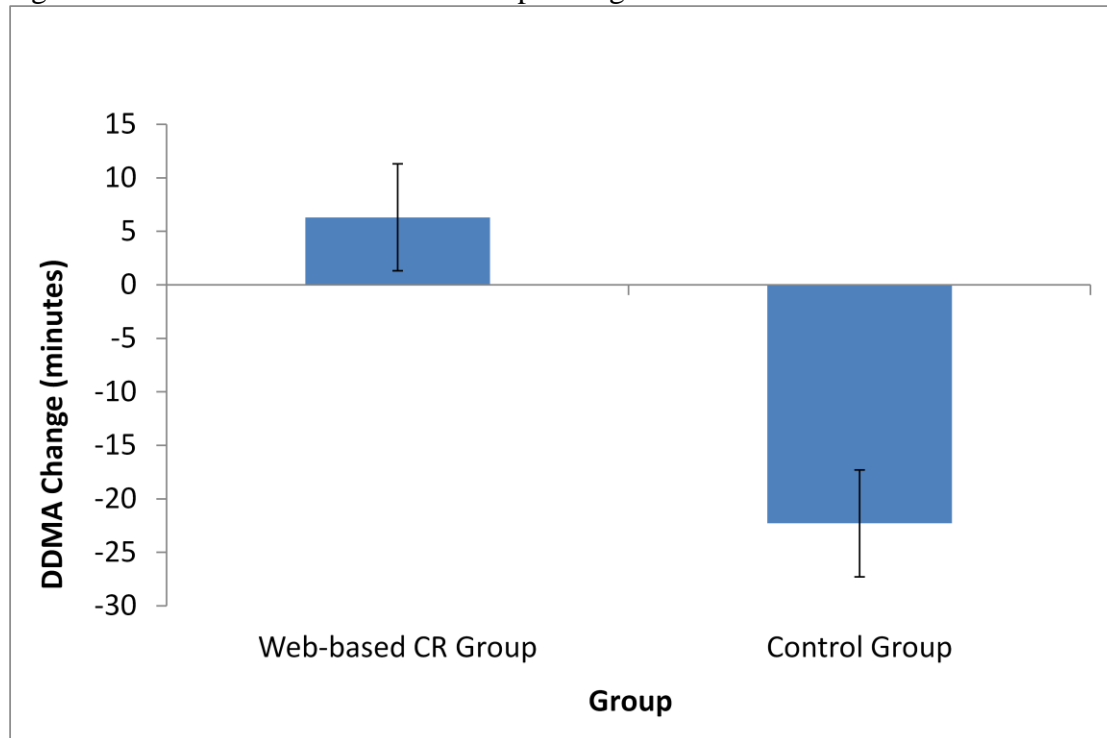
There was no significant difference between groups in DDVA change *(p=0.27)*.

5.8.2. *Physiological Impact*

In terms of weight there was a decrease among the web-based CR group of 0.56 (2.00) kgs and an increase of 0.41 (1.71) kgs in the control group, the difference between groups was significant *(p=0.02)*. This is shown in figure 29.

Figure 29: Baseline to 6 Week Follow up Change in weight
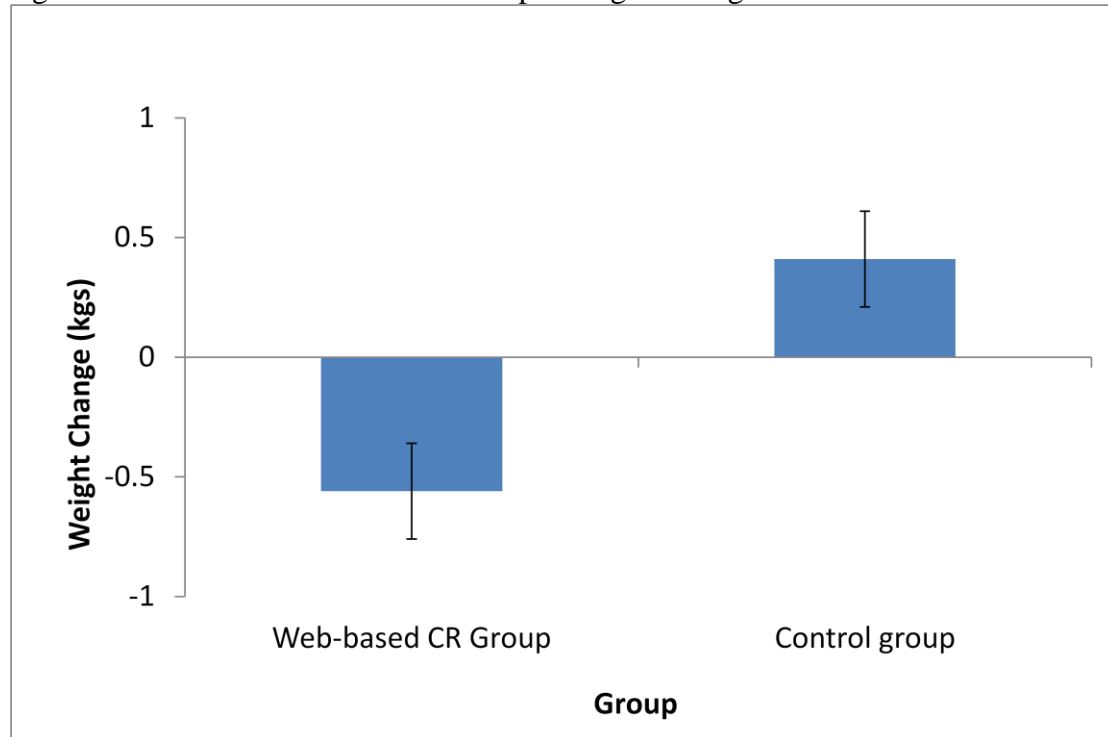
Unexpectedly, there was a significantly greater reduction in SBP in the control group. The control group reduced SBP by 9.00 (12.77) mmHg, and the intervention group reduced SBP by 0.55 (12.03) mmHg, *(p=0.00)*. There were no significant differences between groups in body fat % change *(p=0.49)* or DBP *(p=0.97)* observed.

5.8.3. *Diet Impact*
There were no significant differences between groups with regard to fat intake change *(p=0.50)* or fibre intake change *(p=0.55)*.

5.8.4. *Psychological Impact*
There were no significant differences between groups in anxiety change *(p=0.20)* or depression change *(p=0.30)*.   The intervention influence upon self-efficacy was

significant with a score increase of 2.68 (5.92) in the web-based CR group and a change of +0.13 (3.49) in the control group *(p=0.03)*, figure 30 illustrates this.

Figure 30: Baseline to 6 Week Follow up Change in self-efficacy score
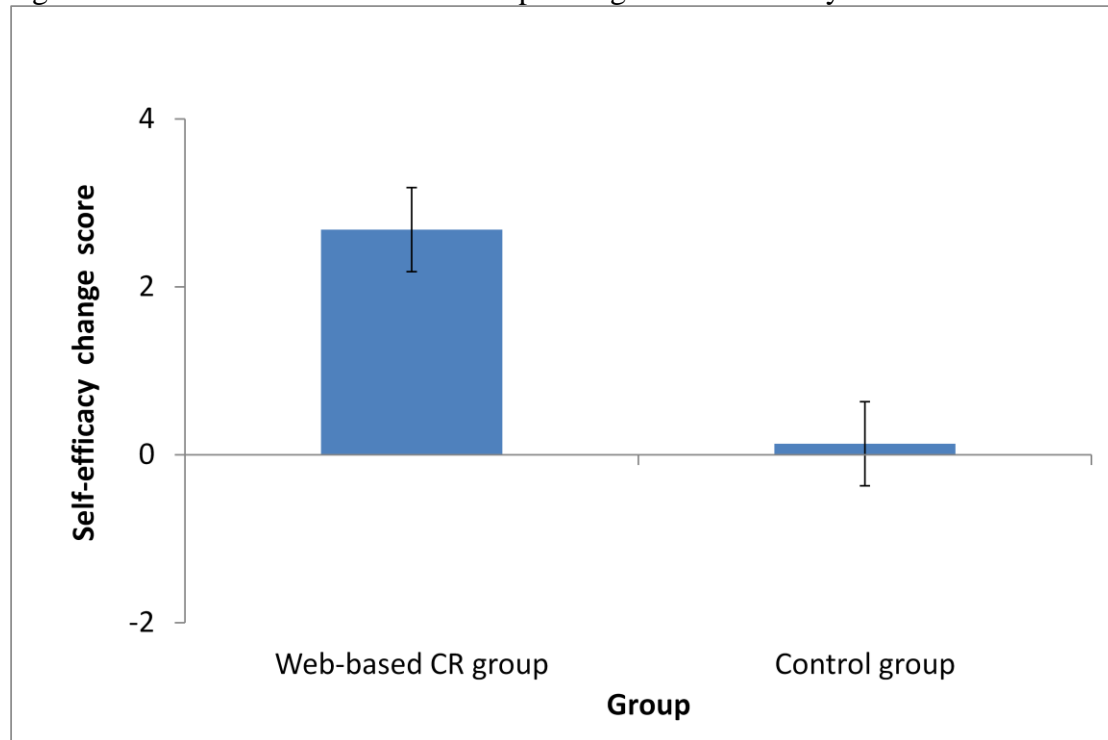
5.8.5. *MacNew Quality of Life Subscales*

At the 6 week follow up the intervention group significantly increased emotional QOL score by 0.31 (0.67) while the change score was +0.04 (0.44) in the control group *(p=0.04)*. This is shown in figure 31.

Figure 31: Baseline to 6 Week Follow up Change in emotional QOL score
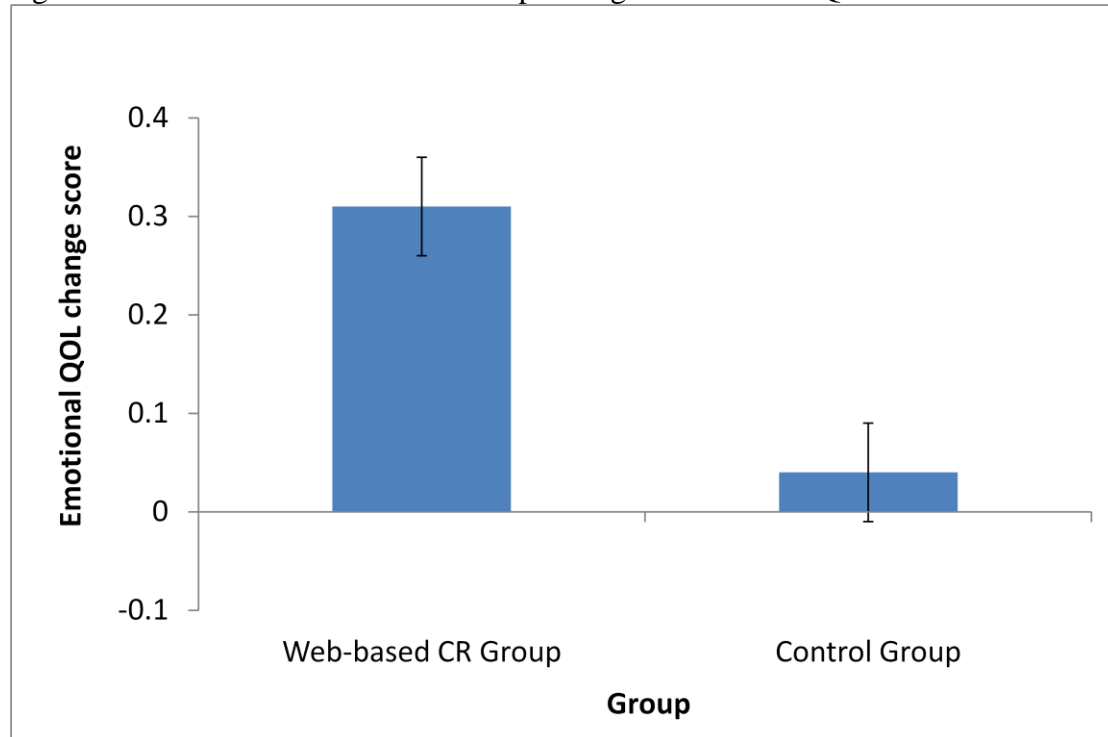
There were no significant differences between groups in change scores on the physical or social QOL subscales, *(p=0.62)* and *(p=0.34)* respectively.

5.8.6. *Seattle Angina Questionnaire Subscales*

There were no significant differences between groups in the 6 week follow up change on the physical limitation subscale *(p=0.57)*, angina stability subscale *(p=0.98)*, treatment satisfaction subscale *(p=0.36)* or disease perception subscale *(p=0.48)*. However, the intervention group did show significantly higher, more favourable, change on the angina frequency subscale. There was an increase in score of 10.23 (26.78) in the intervention group and a decrease of 11.59 (29.63) in the control group, *(p=0.00)*. This is illustrated in figure 32.

Figure 32: Baseline to 6 Week Follow up Change in angina frequency scores (higher scores represent better functioning)
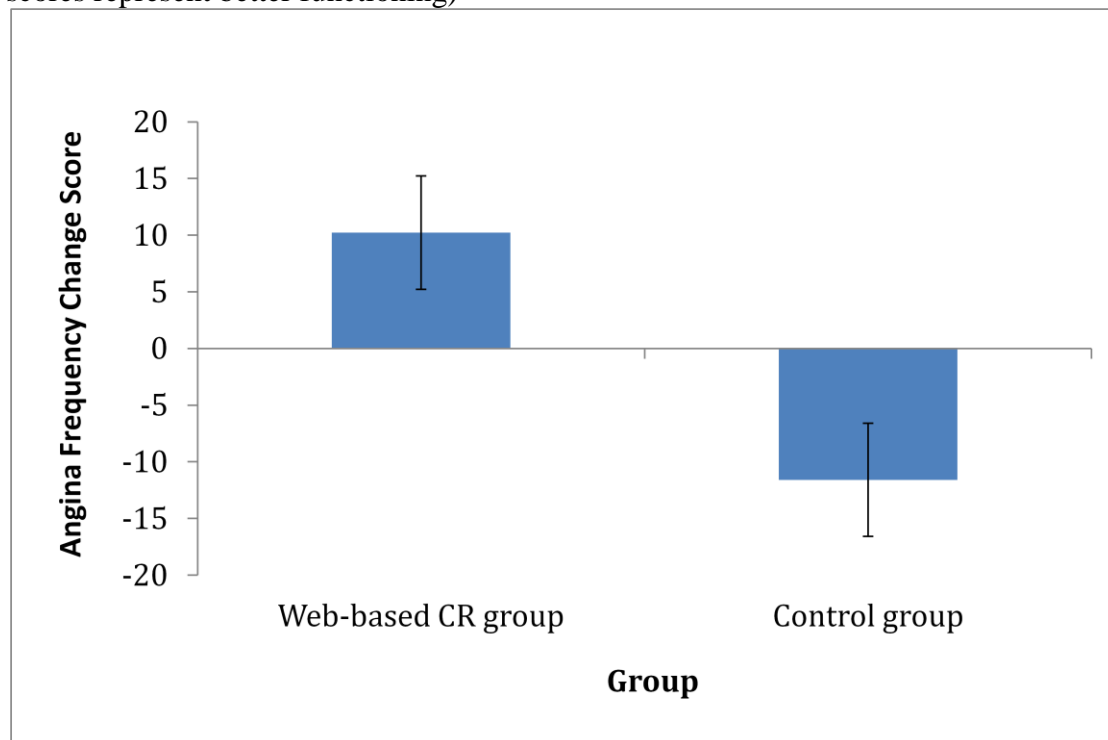
5.9. *Intervention Usage and Adherence*

Out of the 48 intervention group participants 19 (40%) completed the intervention, 12 (25%) completed up to stage 3, and 17 (35%) did not progress past stage 3. The mean number of logins to the programme was 18.68 (13.13, range 1-51), an average of 3 logins per week per participant.

5.10.   *Within Group Differences*

Within group differences in the intervention and control group are outlined in table 12

and table 13 respectively.

Table 12: Within-group differences in outcomes: Intervention Group, values are means (SD) unless stated otherwise

Outcome Measure	n[b]	Baseline	6 Week Follow Up	p-Value
PA				
Daily Steps[a]	35	6716 (3060)	7212 (3188)	p=0.19[c]
Daily EE (Kcal)	35	1902.47 (392.32)	1946.41 (351.79)	p=0.35[c]
DDSA (minutes)[f]	35	675.00 (45.00)	671.50 (55.50)	p=0.08[d]
DDMA (minutes)[f]	35	43.50 (43.00)	48.50 (50.00)	p=0.05[d]
DDVA (minutes)[f]	35	0.00 (1.00)	0.50 (1.00)	p=0.94[d]
Physiological Measures				
Weight (kgs)	41	82.80 (13.49)	82.24 (13.30)	p=0.08[c]
Body Fat (%)	39	38.78 (10.80)	38.36 (11.52)	p=0.74[c]
SBP (mmHg)	40	131.35 (15.34)	130.80 (14.70)	p=0.77[c]
DBP (mmHg)	39	72.92 (9.95)	69.00 (9.57)	p=0.01[c]
Diet				
Fat Score	33	38.76 (8.46)	35.55 (9.18)	p=0.03[c]
Fibre Score	35	36.40 (9.84)	36.51 (8.77)	p=0.92[c]
Psychological				
Anxiety Score	36	5.61 (3.57)	4.14 (3.50)	p=0.01[c]
Depression Scores[f]	37	3.00 (4.00)	2.00 (2.00)	p=0.05[d]
Self-efficacy Score	37	49.03 (6.55)	51.70 (6.37)	p=0.01[c]
MacNew QOL				
Emotional QOL Score[f]	36	5.89 (1.21)	6.25 (1.04)	p=0.00[d]
Physical QOL Score[f]	33	6.50 (0.71)	6.50 (0.92)	p=0.90[d]
Social QOL Score[f]	34	6.54 (0.85)	6.73 (0.50)	p=0.01[d]
Seattle Angina Questionnaire[e]				
Physical Limitation Score	37	64.19 (21.55)	62.16 (25.43)	p=0.53[c]
Angina Stability Score[f]	33	42.86 (57.14)	33.33 (66.67)	p=0.84[d]
Angina Frequency Score	33	43.56 (31.58)	53.79 (30.70)	p=0.04[c]
Treatment Satisfaction Score[f]	35	100.00 (0.00)	100.00 (0.00)	p=0.17[d]
Disease Perception Score[f]	36	83.33 (33.33)	80.00 (40.00)	p=0.72[d]

[a]Primary Outcome Measure
[b]Number of participants with complete baseline and 6 week follow up data.
[c]Paired t-test
[d]Wilcoxon signed rank test
[e]Higher Scores on this questionnaire represent better functioning.
[f]Baseline and 6 week follow up values were not normally distributed therefore median (inter-quartile range) values reported.

As illustrated in table 12, at the 6 weeks follow up there were significant within-group improvements detected in the intervention group for DDMA, DBP, fat intake, anxiety, depression, self-efficacy, emotional QOL, social QOL, and angina frequency; indicating more favourable within group changes to psychological variables. In contrast, there were non-significant within-group changes in daily steps, daily EE, DDSA, DDVA, weight, body fat %, SBP, fibre intake, physical QOL, physical limitations, angina stability, treatment satisfaction and disease perception scores.

Table 13: Within-group differences in outcomes: Control Group, values are means (SD) unless stated otherwise

Outcome Measure	n[b]	Baseline	6 Week Follow Up	p-Value
PA				
Daily Steps[a]	40	6624 (3189)	5763 (2533)	p=0.04[c]
Daily EE (Kcal)	40	2055.05 (431.80)	1922.04 (306.47)	p=0.01[c]
DDSA (minutes)[f]	40	663.25 (103.25)	672.25 (61.75)	p=0.03[d]
DDMA (minutes)[f]	40	55.50 (96.25)	47.75 (61.38)	p=0.03[d]
DDVA (minutes)[f]	40	0.50 (1.38)	0.00 (0.50)	p=0.12[d]
Physiological Measures				
Weight (kgs)	42	79.52 (14.36)	79.93 (14.74)	p=0.13[c]
Body Fat (%)	41	36.34 (8.01)	37.01 (7.07)	p=0.50[c]
SBP (mmHg)	42	137.55 (16.51)	128.55 (14.88)	p=0.00[c]
DBP (mmHg)	42	72.52 (10.73)	68.52 (9.16)	p=0.00[c]
Diet				
Fat Score	32	40.88 (11.63)	39.38 (10.38)	p=0.48[c]
Fibre Score	33	35.09 (12.46)	33.79 (12.24)	p=0.54[c]
Psychological				
Anxiety Score	39	5.51 (3.42)	4.87 (3.73)	p=0.09[c]
Depression Scores[f]	42	2.00 (3.00)	2.00 (4.25)	p=0.82[d]
Self-efficacy Score	39	49.79 (7.56)	49.92 (7.76)	p=0.82[c]
MacNew QOL				
Emotional QOL Score[f]	40	5.96 (1.45)	6.32 (1.21)	p=0.66[d]
Physical QOL Score[f]	41	6.50 (1.42)	6.58 (1.33)	p=0.41[d]
Social QOL Score[f]	40	6.54 (1.17)	6.62 (1.19)	p=0.56[d]
Seattle Angina Questionnaire[e]				
Physical Limitation Score	42	63.49 (25.40)	63.69 (27.03)	p=0.93[c]
Angina Stability Score[f]	37	42.86 (57.14)	33.33 (66.67)	p=0.03[d]
Angina Frequency Score	41	44.51 (32.36)	32.93 (28.74)	p=0.02[c]
Treatment Satisfaction Score[f]	36	100.00 (28.57)	100.00 (22.22)	p=0.67[d]
Disease Perception Score[f]	40	83.33 (39.58)	80.00 (40.00)	p=0.38[d]

[a]Primary Outcome Measure

[b]Number of participants with complete baseline and 6 week follow up data.

[c]Paired t-test

[d]Wilcoxon signed rank test

[e]Higher Scores on this questionnaire represent better functioning.

[f]Baseline and 6 week follow up values were not normally distributed therefore median (inter-quartile range) values reported.

As illustrated in table 13, there were significantly within-group differences at the 6 week follow up detected in the control group for daily step count, daily EE, DDSA, DDMA, angina stability, and angina frequency; these changes represented a worsening of activity and symptoms. There were also significantly lower levels of both SBP and DBP at the 6 week follow up. In contrast, there were non-significant changes in DDVA, weight, body fat %, fat and fibre intake, anxiety, depression, self-efficacy, emotional QOL, physical QOL, social QOL, physical limitations, treatment satisfaction, and disease perception.

5:11 Responders Vs Non-responders

The level of success at the 6 week follow up amongst participants in the web-based CR group was examined. Table 14 displays the number of participants who did and did not demonstrate favourable changes in each individual outcome measure at the 6 week follow up. The criteria used to define a 'favourable change' is described in chapter 4, section 4.3.18.

Table 14: Participants Demonstrating Favourable changes in Each Outcome Measure

Outcome Measures	Participants (n)	
	Unfavourable Change	Favourable Change
Physiological Measures		
Weight (kgs)	40	1
Body Fat (%)	26	13
SBP (mmHg)	27	13
DBP (mmHg)	27	13
Physical Activity		
Daily steps	22	13
Daily EE	22	13
DDSA	22	13
DDMA	22	13
Diet		
Fat intake	12	21
Fibre intake	16	19
Psychological characteristics		
Anxiety Score	20	16
Depression Score	26	11
Self-efficacy	23	14
Health related quality of life		
Emotional QOL score	24	12
Physical QOL score	27	6
Social QOL score	28	6
Physical Limitations score	30	7
Angina Stability score	26	7
Angina Frequency Score	26	7
Treatment Satisfaction Score	29	6
Disease Perception	25	11

Participants who made favourable changes consistently in 6 or more outcome measures were grouped together and labelled 'responders' (n=14) and the remaining participants who did not make favourable changes on 6 or more outcome measures were grouped together and labelled 'non-responders' (n=33). There were non-significant differences between responders and non-responders in the following participant characteristics: gender (p=0.42), age (p=0.16), and number of years since angina diagnosis (p=0.68). There were also non-significant differences between participants in the following baseline outcome variables; daily average steps walked (p=0.33), daily average EE (p=0.76), DDSA (p=0.21), DDMA (p= 0.22), weight (p=0.14), bodyfat percentage (p=0.86), SBP (p=0.80), DBP (p=0.51), fat intake (p=0.94), fibre intake (p=0.51), anxiety (p=0.70), depression (p=0.91), self-efficacy (p=0.67), emotional QOL (p=0.93), physical QOL (p=0.14), social QOL (p=0.98), physical limitations (=0.14), angina stability (p=0.41), angina frequency (p=0.59), treatment satisfaction (p=0.23), and disease perception (p=0.20).

There were however significant differences detected between groups in terms of employment status (p=0.05). There were a higher proportion of responders who were either employed part time and unemployed in comparison to the non-responders. There were also more non-responders compared to responders employed full time. Both groups comprised similar portions of retired patients. These differences between groups are illustrated in figure 33 and figure 34.

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Figure 33: The Employment Status of Responders
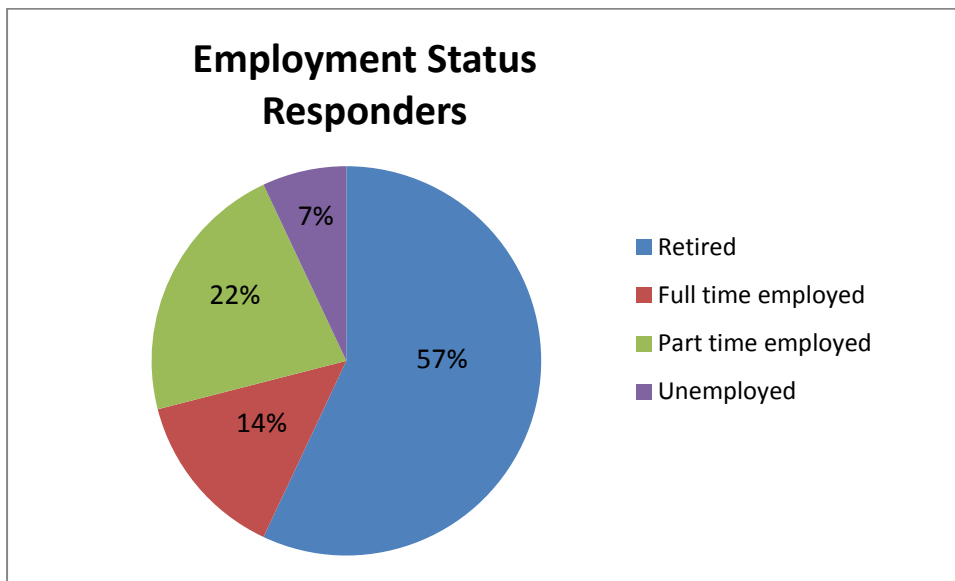
Figure 34: The Employment Status of Non-responders
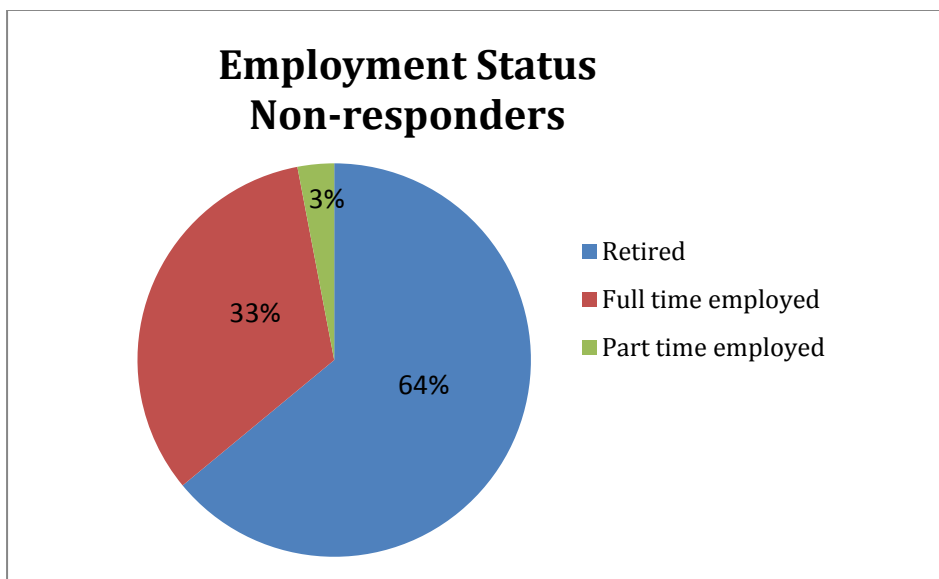
There was also a significant difference between responders and non-responders in terms of previous treatment received (p=0.04). There were a higher proportion of responders who had not received treatment before, and likewise there were proportionally more non-responders than responders who had previously received a

surgical treatment (stent and CABG).   These differences between groups are

illustrated in figure 35 and figure 36.

Figure 35: Treatment History Amongst Responders
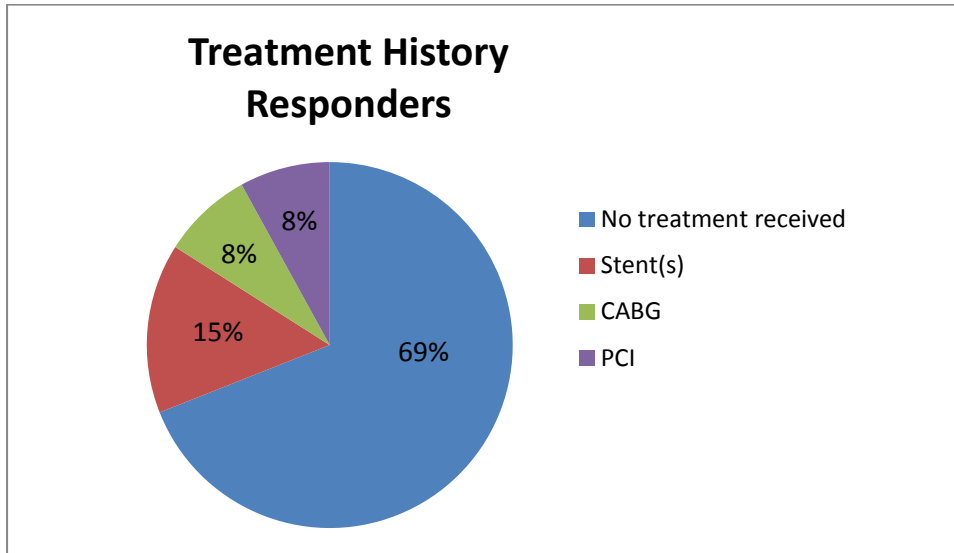
Figure 36: Treatment History Amongst Non Responders
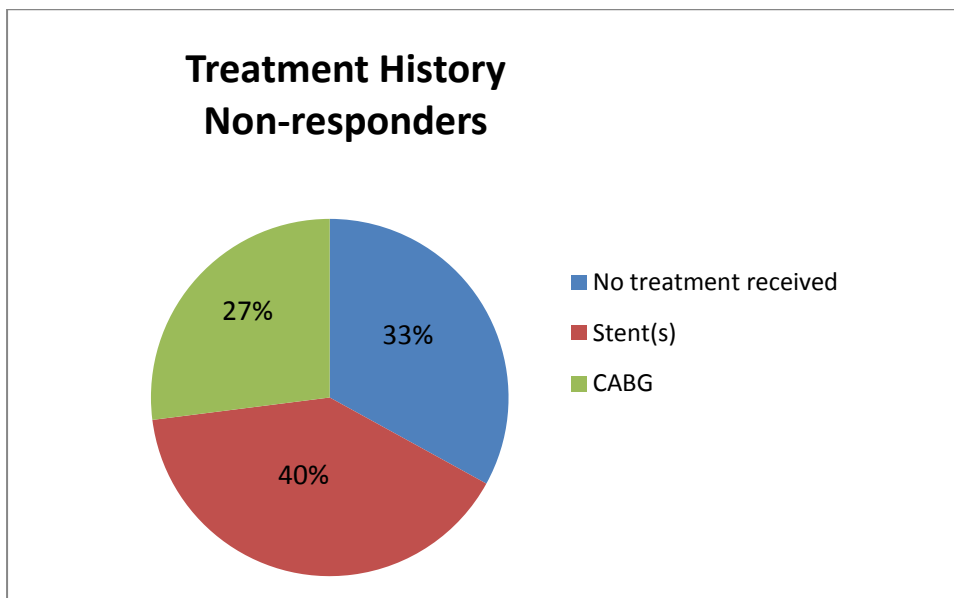
There was also a greater proportion of responders that had no prior experience of CR

in comparison to non-responders.   This difference between groups approached

statistical significance, (p=0.06). These differences between groups are illustrated in figure 37 and figure 38.

Figure 37: Cardiac Rehabilitation History amongst Responders
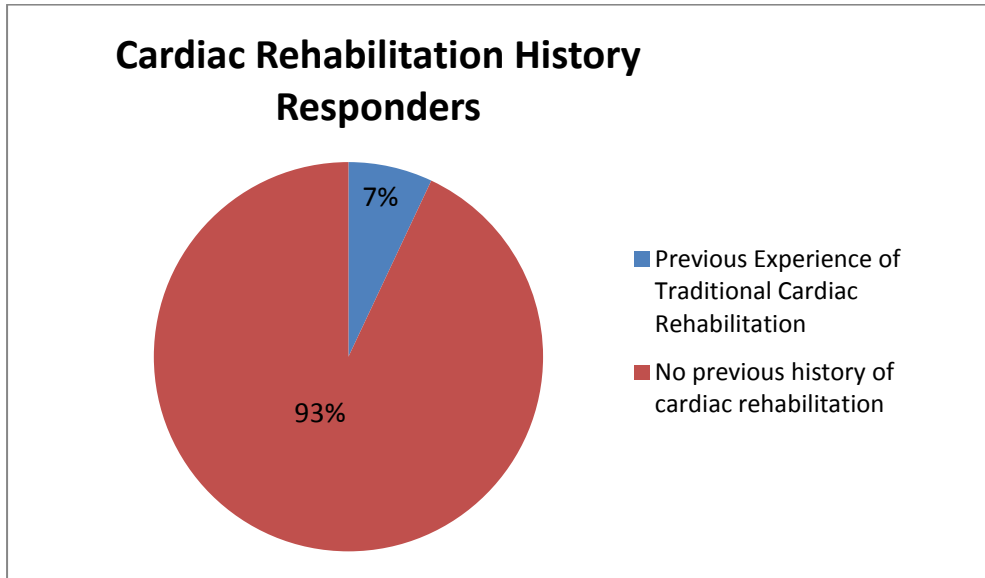
Figure 38: Cardiac Rehabilitation History amongst Non-responders
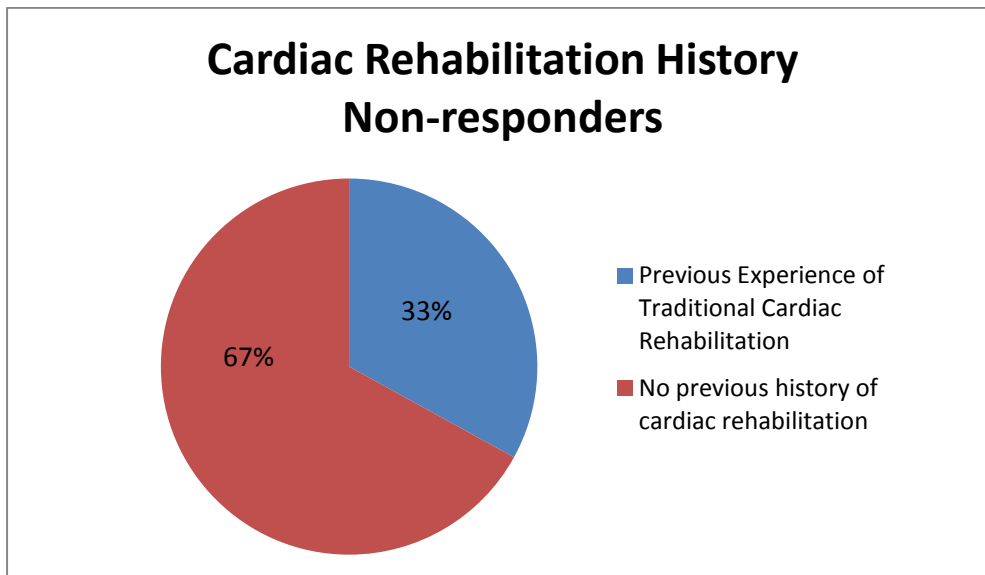
5.12 Discussion of the Web-based CR Programme's Short-term Effects

This is the first UK based study reporting the outcomes of an RCT exploring the use of the internet to deliver a package of secondary prevention for those with angina managed in primary care. This study has contributed to and progressed knowledge in 3 broad research areas which are PA monitoring, angina and secondary prevention interventions, and web-based interventions. There are very few trials evaluating the impact upon PA of CR programmes, none of which have used modern accelerometer technology. Previous research examining secondary prevention interventions for those with angina have comprised either group-based (for example the AMP) or individualised nurse facilitated paper-based programmes (for example the AP). This study progressed this literature as it investigated a contemporary and innovative alternative for this population; web-based CR. Moreover, the current research literature on internet interventions for those with CHD have not included those with angina or measured impact on PA objectively.

5.12.1 Study Findings

At a 6 week follow up there were significantly more favourable changes among the intervention group in daily steps, daily EE, DDSA, DDMA, weight, self-efficacy, emotional QOL (measured using the MacNew), and angina frequency (measured using the SAQ) compared to the control group. However, no significant short-term intervention benefits upon DDVA, body fat %, SBP, DBP, fat intake, fibre intake, anxiety, depression, physical QOL and social QOL were detected. Nor were there any significantly favourable changes detected on 4 of the SAQ subscales; physical limitations, angina stability, treatment satisfaction, and disease perception. These

findings will now be interpreted, discussed and related to past research. The way that these findings link with the qualitative component in this thesis, possible reasons as to what caused the outcomes, study strengths/limitations, challenges with web-based interventions, broad study implications and recommendations for future research are outlined in the overall discussion, chapter 8.

5.12.2 Clinical Significance of the Results

As described there were statistically significant short term intervention effects upon the following outcome variables; PA variables, weight, self-efficacy, emotional QOL and frequency of angina. Even though statistically significant differences were detected it is important to consider whether these changes were clinically meaningful. Unfortunately there are currently no guidelines available regarding the level of change in PA required for a clinically meaningful change. This is also the case for the self-efficacy finding. The scale used to measure self efficacy was the General Self-Efficacy Scale (Schwarzer and Fuchs 1996), and the level of change required for a meaningful improvement is yet to be established.

In terms of the weight loss change, previous research indicates that a 5% weight loss in overweight/obese individuals is associated with improved cardiovascular disease risk factors at 1 year (Wing et al. 2011). In the present study, the average baseline BMI in the web-based intervention group was 29.06 (therefore classified as overweight) and the average baseline weight was 82.80kgs. The statistically significant mean reduction in weight at the 6 week follow up was -0.56kgs (SD=2.00) p=0.02, which was equivalent to a 0.68% decrease in baseline weight. This indicated that the reduction in weight was not clinically meaningful. Similarly the statistically

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significant change in emotional QOL was also not clinically meaningful. The average score change in emotional QOL was +0.31 (SD=0.67), p=0.04. This was below the pre-defined score change required for a clinically meaningful change (+0.50) (Oldridge et al. 2002). In contrast, the change in the angina frequency score did represent a clinically meaningful change. The change in score was +10.23 (SD=26.78) p=0.00, which met the score change (+10) required for a clinically significant change (Spertus et al. 1995).

5.12.3 *Comparison with Previous Research*

The observed favourable impact upon overall PA is important and encouraging given that regular PA is associated with reduced risk of MI and sudden cardiac death risk by approximately 45% and 30% respectively (Batty 2002). The objective measure of PA added strength to this finding, in contrast to the majority of previous CR studies. The review carried out by Jolliffe et al (1998) reported CR is limited in improving PA, although many of the studies were deemed to be of low methodological quality and unlike the present study assessed PA using mainly subjective measures. The findings are however, in agreement with more recent research. A recent review reported psychoeducational CR results in significantly favourable PA benefits (Aldcroft et al. 2011). As previously indicated by Aldcroft et al (2011) the favourable change in PA may have been facilitated by the 'goal-setting' and 'self-monitoring' aspects of the website. More details on how 'goal-setting' and 'self-monitoring' may have influenced PA are provided in the final discussion (chapter 8 section 8.4). Further, Yohannes et al (2010) in a UK study reported hospital-based CR is effective at improving PA at post intervention. The change in daily EE detected by Yohannes et al (2010) was +226.76 kcal, considerably higher than the daily EE change observed in

the current study, +43.94 kcal. However, the baseline value reported by Yohannes et al (2010) was considerably lower than in the present study (1767.48 kcal vs 1902.47 kcal), which may explain the differing size of change. However, unlike the present study Yohannes et al (2010) did not compare outcomes with a control group or measure PA objectively, instead daily EE was calculated using a 7-day recall activity questionnaire.

The PA gains are comparable to past studies of home-based CR programmes (Blanchard et al. 2010, Furber et al. 2010). Both Blanchard et al (2010) and Furber et al (2010) reported significantly improved PA at post intervention. However, it is not possible to compare the size of change. Furber et al (2010) reported the change in time spent engaging in leisure PA, whereas the present study examined change in time spent during different intensities of PA (e.g. sedentary, moderate and vigorous). Similarly, Blanchard et al (2010) reported the change in the number/percentage of those undertaking <150 or ≥150 minutes of moderate to vigorous level activity. Therefore, due to these differences the data in the current study could not be directly compared with previous reports. However, similar to this study the home-based CR programme in Blanchard et al's study incorporated 'action planning' (comparable to goal-setting in this study) and Furber et al's programme included a 'self-monitoring' of PA component. This study therefore, adds support to previous findings and importantly progresses from past research as unlike Blanchard et al (2010) and Furber et al (2010) the present study measured PA objectively. In terms of intervention duration both the present study and Furber et al (2010) report significantly improved PA immediately after a 6 week home-based intervention, this is encouraging considering the relatively short time frame. In contrast, Blanchard et al (2010)

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reported PA benefits immediately after a 12 week programme, which is considerably longer.

The short-term gains in PA support Furze et al (2012), which demonstrated significantly increased self-reported PA among those receiving the AP in comparison to a control group. The participants were newly diagnosed patients, a stage when motivation levels may be higher, in contrast to those with a longer established diagnosis of angina recruited in the present study. This is encouraging as it indicates the current online intervention produced comparable findings with Furze et al (2012) in a group with possibly lower motivation levels. In addition, the AP is facilitated by a nurse; the online CR programme was not 'facilitated' in the same way and thus potentially has less reliance on resources. Moreover, the web-based delivery of the programme extends prior studies as it offers a more innovative and contemporary approach to rehabilitation for this population. However, direct comparisons of the size of PA change are not possible as Furze et al (2012) reported the change in the number/percentage of participants meeting the national recommended levels of PA. The current study did not examine PA data in this way.

Prior to this study there have been 3 reports evaluating the affect of internet interventions on PA in broad CHD populations (Lindsay et al. 2008, Southard, Southard and Nuckolls 2003, Zutz et al. 2007). However, unlike the present study, previous reports have relied on self-report measures and samples recruited did not include those with angina. Both Lindsay et al (2008) and Southard et al (2003) failed to detect a significant post intervention impact upon PA. However, the present findings are consistent with Zutz et al (2007). Similar to the current online

programme, the intervention evaluated by Zutz et al also comprised 'communication with cardiac professionals', and 'exercise monitoring' components. Unfortunately, the magnitude of PA change cannot be easily compared, as Zutz et al (2007) studied EE during leisure time PA while the current study examined total daily EE. Additionally, a direct comparison is difficult as the present study measured PA objectively, whereas Zutz et al (2007) used self report measures. Further, there was no control group within Zutz et al (2007). However, the intervention evaluated by Zutz et al (2007) was of 12 weeks duration, considerably longer than the intervention described in this thesis. It is encouraging that the present study detected significantly favourable PA benefits in a shorter time frame.

The findings are also consistent with internet-based intervention research carried out in non-CHD populations. This study adds supports to past reviews which reported that web-based interventions favourably influence PA (Ciccolo, Lewis and Marcus 2008, Marcus, Ciccolo and Sciamanna 2009, van den Berg, Schoones and Vliet Vlieland 2007, Vandelanotte et al. 2007). Studies carried out by Oenema et al (2008), Liebreich et al (2009), Webber et al (2008), and Sternfeld et al (2009) also report an important beneficial impact upon PA at a post intervention follow up. Even though past studies examined PA using self report measures and recruited non-CHD populations it is useful to compare the magnitude of change detected in PA. Sternfeld et al (2009) studied a 16 week web-based intervention and reported at post intervention follow up the experimental group displayed a daily average increase in moderate and vigorous level activity of 4.00 and 1.79 minutes respectively. Further, Liebreich et al (2009) examined a 12 week online intervention and reported at post intervention the experimental group reported a daily average increase of 5 minutes in

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moderate to vigorous activity levels. Even though the present study did not detect a change in vigorous level activity there was an average increase of 6.31 minutes in moderate level activity. Thus, the size of change in moderate level activity in the present study was higher than the change reported in both Sternfeld et al (2009) and Liebreich et al (2009). This is encouraging considering the comparatively shorter intervention duration in the present study. Unfortunately it is not possible to compare the magnitude of PA change with reports by Oenema et al (2008) or Webber et al (2008). Oenema et al (2008) reported the change in percentage of participants adhering to the national PA guidelines following a 1 month online intervention. Further, Webber et al (2008) examined EE during leisure time PA while the current study examined total daily EE. The present study did not examine PA data this way and therefore direct comparisons are not possible. However, a positive aspect of the current study is that it extends findings reported by Oenema et al (2008), Liebreich et al (2009), Webber et al (2008), and Sternfeld et al (2009) with the use of an objective and comprehensive measure of PA.

The findings revealed that there was virtually no DDVA carried out by participants in both groups at either baseline or post intervention follow up. The average age of participants was 66.27 years in the intervention group and 66.20 years in the control group. Previous work carried out among a non-disease population reported this age group to engage in accelerometer measured moderate-vigorous level activity (Evenson, Buchner and Morland 2012). Given the similar age group reasons for the current sample not engaging in vigorous level activity is unclear. Perhaps this activity is not reasonable within this chronic disease population. It would be important for future research to compare daily PA levels of those with angina with a healthy

population in order to define the PA levels of this population and thereby investigate whether the lack of DDVA is population specific. An alternative explanation could be that participants in this study learned from previous experience that vigorous activity induced an angina attack and therefore this level of activity should be avoided. Or alternatively participants avoided vigorous activity as they believed that they should be careful and only participate in gentle activities. Evidence for this has been demonstrated by Furze et al (2001). Furze et al (2001) carried out semi-structured interviews with 20 individuals diagnosed with angina and explored their beliefs about angina. Participants were recruited from 2 cardiology outpatient clinics in the UK, and had been diagnosed with angina by their GP which was also confirmed by a cardiologist. The average length of time of angina diagnosis was 23 months (range 6-108) and all participants were of Caucasian and English origin. An interesting theme resulting from the qualitative data was 'avoidance', 14 of the participants believed that people with angina should avoid angina pain by 'taking it easy', 'slowing down' and 'resting'. Participants also held the view that it was fatal to continue an activity whilst experiencing angina pain. This has also been found more recently by Lin et al (2012) in a study carried out in Taiwan. Lin et al (2012) examined heart disease misconceptions held by a broad range of cardiac patients and other chronic illness of which the most common was hypertension and diabetes mellitus. Cardiac beliefs and misconceptions were assessed using the pilot York Cardiac Beliefs Questionnaire (Furze et al. 2003). Participants were discovered to hold similar misconceptions and agreed with statements such as 'people with heart disease should take life easy' and 'it is important to avoid anything that might bring on angina or chest pain'. Given the research evidence outlined it is possible that participants in the current study may have also held similar beliefs and did not carry

out vigorous activity as they believed it could induce an angina attack and therefore avoided this activity.

In terms of physiological measures there was a significant reduction in weight in the web-based CR group. Even though the actual reduction in weight in the web-based group was modest (-0.56kgs), it is encouraging given that higher levels of body weight increases the risk of CHD (Willett et al. 1995). Similarly, Southard et al (2003) also reported significant weight loss in a CHD population receiving a comprehensive web-based intervention. However, the drop in weight reported by Southard et al (2003) was -3.68lbs, and therefore detected a larger decline than in the present study. In terms of other physiological changes there were no significant short-term improvements observed for body fat %, or DBP. The non-significant difference between groups in body fat % change may be unsurprising given that 6 weeks duration was perhaps too short to detect significant changes in body fat %. Surprisingly, the control group reduced SBP significantly more than the intervention group. This was unexpected and the same pattern was not observed for DBP. There is no plausible explanation for this finding.

There were no significant short-term changes in diet reported after the intervention. The intervention group's baseline scores indicated a medium level of both fat and fibre intake. Thus, baseline dietary scores indicated potential room for improvement. This is comparable to Southard et al (2003) who reported no significant change in diet at a post intervention follow up of a web-based programme delivered to a CHD population. Given that both the current online CR programme and the intervention evaluated by Southard et al (2003) comprised similar intervention components it may

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be reasonable to assume that the intervention was not sufficient to induce dietary changes. Another possibility is that participants may not have placed great importance on their diet. A recent study illustrated CR patients make dietary changes if they perceive their diet to be the cause of their cardiac condition. White et al (2011) conducted a qualitative study, interviewing post MI patients completing hospital-based CR and reported participants made dietary changes if they perceived their diet to be the cause of their CHD. It is possible that in the current study participants may not have identified diet as the cause of their condition and therefore did not take action to change this. Future intervention development could perhaps place more emphasis on the importance of diet in CHD and improve the dietary component of the programme. In contrast to the current findings, Lindsay et al (2008) report significantly lowered intake of unhealthy foods compared to a control group in a CHD population receiving a web-based programme. The discrepancy in findings could be attributable to differences between interventions. The intervention evaluated by Lindsay et al (2008) lasted 9 months and the main focus was a moderated discussion forum where participants communicated with both peers and study researchers. Therefore, it is plausible that the differing findings may be due to the substantial contrasts in intervention style. The current lack of impact on diet also disagrees with previous web-based studies carried out in non-CHD populations reporting diet improvements at post intervention (Moore et al. 2008, Oenema et al. 2008, Sternfeld et al. 2009, Webber, Tate and Bowling 2008). Here the difference in findings could be attributed to the difference in populations studied. The reasons why different populations might make a difference is unclear and more research is required to investigate this further.

In terms of the psychological outcomes there were no significant improvements in anxiety or depression. Baseline scores were below the HADS threshold for mild anxiety and mild depression, and thus could explain the lack of meaningful change. This contradicts studies of hospital-based CR. Both Egger et al (2008) and Yohannes et al (2010) demonstrated significantly lowered anxiety and depression immediately after hospital-based CR, although baseline anxiety and depression scores were higher in Yohannes et al (2010) than in the current sample, the baseline anxiety and depression score was 7.87, and 7.35 respectively. This was comparatively higher than the baseline scores in the current study, which were 5.61 and 3.00 for anxiety and depression respectively. The difference in populations recruited may explain this, Yohannes et al (2010) recruited post MI, CABG and PCI patients, and thus it is plausible that they were more anxious and depressed at baseline than the stable angina patients recruited in the current study. Differences in baseline scores cannot explain the contrast between the findings of the current study and Egger et al (2008). Similar to the present study baseline scores reported by Egger et al (2008) were low, 5.4 for anxiety and 4.00 for depression, although significant effects were still detected. Reasons for the discrepancy in findings are unclear. Unlike the present study, findings reported by Egger et al (2008) and Yohannes et al (2010) were limited with the absence of a control group. The current findings also contrast previous reviews that report compared with usual care home-based CR leads to improvements in anxiety and depression (Clark et al. 2010, Jolly et al. 2006). It is difficult to compare the size of change in anxiety and depression with the review reported by Jolly et al (2006) and Clark et al (2010) due to varied lengths of follow ups in studies included. In addition, the current non-significant change in anxiety contradicts a recent evaluation of the AP carried out by Furze et al (2012), who reported significantly

improved anxiety at post intervention compared to the control group. Furze et al (2012) recruited a newly diagnosed angina population, which, may have been more anxious than the sample with longer established angina diagnosis recruited in this study. Unfortunately a direct comparison of baseline anxiety scores is not possible as Furze et al (2012) did not report baseline values.

The significant increase in self-efficacy is also promising considering that low self-efficacy among CHD populations is associated with poor health (Sarkar, Ali and Whooley 2007) and predictive of all cause mortality and hospitalisation (Sarkar, Ali and Whooley 2009). In addition, it is reasonable to suppose that increased self-efficacy contributed to the significant impact upon PA. Previous research supports this speculation as Lapier et al (2009) found self-efficacy and level of physical function to be positively correlated in a hospitalised CHD population. The significant impact upon self-efficacy is consistent with other web-based CHD population studies (Kukafka et al. 2002, Zutz et al. 2007). Zutz et al (2007) reported self-efficacy improvements immediately following a comprehensive web-based intervention. However, Zutz et al (2007) findings were limited with the absence of a control group. In addition, Kukafka et al (2002) reported significantly improved self-efficacy following the use of a tailored web-based CHD intervention, where self-efficacy was measured in terms of being able to respond appropriately to MI symptoms. Unfortunately, it is not possible to directly compare the size of self-efficacy change with previous reports due to differences in outcome measures used. Nevertheless the consistency in findings of web-based interventions improving self-efficacy in those with CHD is encouraging. Further, this study was able to extend previous research as to date those with angina have not yet been included in web-based intervention

studies. Overall, these findings support the conclusions of Murray et al (2005) who reviewed the effectiveness of internet interventions for those with chronic disease and reported that online interventions stimulate improvements in self-efficacy.

In terms of HR-QOL, there were significantly favourable post intervention improvements in emotional QOL (a subscale on the MacNew questionnaire) and frequency of angina (a subscale on the SAQ) in the intervention group compared to the control group. However, the change in emotional QOL score was not clinically meaningful, the change in score was +0.31, which is below the threshold for a clinically meaningful change (Oldridge et al. 2002). Nonetheless, the finding is consistent with previous reviews reporting significantly improved QOL following centre based CR (Heran et al. 2011, Jolliffe et al. 2001). It is difficult to compare the size of change in this study with reports of Jolliffe et al (2001) and Heran et al (2011) due to differences in questionnaires used to measure QOL. In addition, Furze et al (2012) detected significantly improved QOL measured using the EQ-5D at post intervention of the AP. In terms of the SAQ subscales, McGillion et al (2008a) reported significant short-term improvements in the physical limitations and the disease perception subscales following psychoeducational interventions for those with stable angina. The magnitude of improvement on these subscales was higher than in the current study. McGillion et al (2008a) reported the change in disease perception score was 4.46, and 8.00 on the physical limitations subscale. Whereas the change in scores on the disease perception and physical limitation subscales in the current study were in comparison much smaller, 0.97 and -2.03 respectively. The contrasting findings could be due to differences in intervention style. Five of the trials (out of 7) reviewed by McGillion et al (2008a) tested group-based interventions, this could

account for some differences in findings. Previous qualitative research has demonstrated those taking part in group-based rehabilitation gain motivation and support from others (Jones et al. 2009). This may help to explain some of the differences in findings between the current study and McGillion et al (2008a).

There were no significant benefits of the intervention detected for physical QOL or social QOL (subscales on the MacNew questionnaire). Nor were there any significant improvements detected on 4 SAQ subscales; physical limitations, angina stability, treatment satisfaction, and disease perception. Baseline scores obtained on these subscales may help to explain the non-significant findings. The maximum score available on the MacNew subscales is 7. Participants in both study groups scored towards the maximum at baseline on the physical QOL (median score was 6.50) and social QOL (median score was 6.54) subscales. Similarly, the maximum score on the SAQ subscales is 100, the baseline score obtained on the disease perception subscale was 83.33 in both groups, and thus near the upper limit. This was also the case for the treatment satisfaction subscale, where participants in both groups scored 100 at baseline. Therefore it is likely that baseline scores for these variables (physical QOL, social QOL, disease perception, and treatment satisfaction) suffered from a 'ceiling effect', which occurs when a large portion of participants score towards the upper limit (Hessling, Traxel and Schmidt 2011). However, baseline scores on the SAQ physical limitations and SAQ angina stability were at approximately mid-point, and no significant benefits were observed for these variables. Reasons as to why there were no significant improvements on SAQ physical limitations and angina stability subscales are unknown.

There is a need to consider why there was a worsening of PA and angina symptoms in the control group. The control group demonstrated unfavourable changes in daily average step count, daily average EE, DDSA, DDMA and frequency of angina symptoms. This decline in PA may be accounted for by the influence of 'measurement reactivity', where 'measurement results in changes in the people being measured' (French and Sutton 2010). It is possible that 'measurement reactivity' was similar across both groups at baseline but there was a stronger influence in the intervention group at follow up. Participants in the control group may not have been influenced by 'measurement reactivity' in the same way as the intervention group at follow up due to the different demands being put on participants. The intervention group were aware that they were being assessed to determine whether the intervention had made a difference to their PA levels. For this reason it is likely that 'measurement reactivity' was an issue at follow up for the intervention group and not in the control group. This could explain why there was a decline in activity in the control group at the 6 week follow up. There is also a need to consider why there was a worsening of angina symptoms in the control group. This is somewhat surprising given that the sample were a group of stable angina patients. It could be possible that this group did not receive any intervention and thus without careful advice their symptoms got worse.

5.12.4 _Intervention adherence_

In this study exposure to the web-based programme was defined as number of website logins, on average participants logged into the programme 3 times per week, indicating high user acceptance. This supports a previous review reporting tailored web-based interventions result in higher number of website visits (Wantland et al

2004). This is also consistent with past web-based CHD studies which report significant benefits with similar levels of intervention usage (Southard et al (2003) and Zutz et al (2007). The average website login per week was 2 and 4 times per week in Southard et al (2003) and Zutz et al (2007) respectively; similar to the average number of logins in the current study.

It is also promising that the study attracted segments of the older and retired population. The intervention group participants were on average 66.27 years old and 60% were retired, similarly in the control group the average age was 66.20 years and 46% were retired. The low study dropout rate is also promising, study attrition was only 11% overall and adds strength to the findings reported.

5.12.5 *Trial Adherence*

It is interesting to discuss the comparison of trial completers and trial drop-outs. Broadly the baseline characteristics were similar except for a couple of differences. Trial completers indicated significantly better health in terms of frequency of angina symptoms as those who dropped out of the trial scored significantly lower on the SAQ angina frequency subscale (higher scores represent better functioning). It is possible that those suffering from a higher frequency of angina symptoms had a resulting higher level of disease morbidity and were therefore less motivated to complete the trial. However, this is debateable considering the observed lower SBP and higher level of self-efficacy in trial drop outs compared to those who remained in the study. This is difficult to explain, especially since the higher level of self-efficacy is somewhat contradictory of the higher level of angina symptoms.

5.12.6 *Responders vs Non-responders*

There were non-significant differences between responders and non-responders in all baseline outcome measures. There were, however, some statistically significant differences in participant demographic characteristics. However these analyses were not powered to detect differences, and therefore should be treated as exploratory analyses.

Responders differed from non-responders in terms of employment status and history of treatment received. There were a greater proportion of responders employed part-time or unemployed in comparison to the non-responders. On the other hand there were comparatively more non-responders employed full time. This finding is in some ways consistent with Kerins et al (2011) who reported employment commitments are often barriers described for not taking part in CR (Kerins et al 2011). Perhaps participants with fewer work commitments had more time to use the intervention and therefore demonstrated greater improvements. However if this was the case an expectation is that a greater proportion of retired participants would also be successful participants, benefitting from the programme. This was however, not the case. There were similar portions of retired participants amongst both responders and non-responders. It is also interesting to compare this finding with Van Dixhoorn et al (1990) who evaluated 156 patients who underwent a 5 week daily exercise training programme after recovery from acute MI. Van Dixhoorn et al (1990) reported that those who benefited most from the exercise programme were more likely to be employed prior to the MI. In contrast, the current study comprised similar portions of employment (regardless of part time or full time) amongst both responders and non-

responders. It is possible that the difference in study findings could be due to the differences in samples studied.

There were also differences between responders and non-responders in terms of the type of angina treatment previously received. More responders had not had surgical treatment and a comparatively larger proportion of non-responders had a history of surgical treatments (stent and CABG). It is possible that participants who had not yet had any surgical treatment were more motivated and anxious about preventing the need for future surgical treatments, and for this reason made more effort. Whereas those who had already received treatment felt that they had been 'treated' and therefore felt they did not need to change their lifestyle. This has been indicated in prior research. Peterson et al (2010) carried out semi-structured interviews amongst 61 post-angioplasty patients, of which 52% had successfully changed 2 or more health behaviours and 48% had been unsuccessful at behaviour change. Peterson et al (2010) reported that unsuccessful behaviour change was related to patients holding the belief that the angioplasty treatment 'cured' the heart disease.

The final interesting finding detected from these analyses was there were a greater number of responders compared to non-responders who had no prior experience of CR. This difference between groups approached statistical significance (p=0.06). A speculation is perhaps those who have never received CR were more motivated by the novelty of the new programme. In contrast, those who have previously taken part in rehabilitation were not overly motivated or enthusiastic by the programme. These participants may hold the view that they do not need to repeat rehabilitation and therefore did not benefit from the programme.

The current findings are interesting and indicate that participants employed part time or those unemployed, those without prior surgical treatment and those who have not yet received CR are more likely to benefit from the web-based CR programme. There is a need for future research to carry out a larger scale study to investigate this further. There is also a need for future research to establish a criterion for defining a 'successful' participant. For the purposes of this exploratory analyses 'successful participants' were defined as participants reaching a clinically important change on 6 or more outcome measures. This stringent criterion was considered reasonable as this exploratory analyses was intended to capture participants who benefited most from the programme. Future research should consider establishing a standardised pre-defined criterion from which participants can be categorised as a responder or a non-responder. Future research should also be powered to detect differences between responders and non-responders. It might also be useful to include other outcome measures which previous research indicates to also be important in predicting success in rehabilitation. Previous studies have reported that the patients' personality and external support (Bergman and Berterö 2001), and the level of optimism (Shepperd, Maroto and Pbert 1996) are important outcomes for predicting success in CR.

5.13 *Chapter Summary*

This study was the first in the UK to describe the short-term effectiveness of an online secondary prevention intervention for those with angina. Overall, this chapter outlined encouraging short-term intervention benefits. Specifically, there were significant short-term intervention benefits detected in daily step count, daily EE, DDSA, DDMA, weight, self-efficacy, emotional QOL and angina frequency. These findings are promising and fit with guidelines advocating the need for alternative CR

delivery modes (NICE, 2008). Other points for discussion regarding how the effects may have been achieved, overall strengths/ limitations to the study, broad challenges of web-based interventions, study implications, and recommendations for future research are described in chapter 8, the overall discussion.

CHAPTER 6

MEDIUM-TERM EFFECTS OF THE WEB-BASED CARDIAC

REHABILITATION PROGRAMME

The primary aim of this chapter is to report the medium-term effectiveness of the online CR programme. Initially a brief method will be outlined. This will be followed by presenting the medium-term effectiveness analysis. The primary outcome measure will be presented first and the secondary outcome measures analysis will follow. A discussion of the medium-term effects will be outlined at the end of the chapter.

6.1 *Summary of Method*

The specific details of the study method are outlined in chapter 4 section 4.3. Altogether there were 73 participants completing the 6 month follow up (22% attrition). More details of participant recruitment and flow through the study are provided in figure 23. Full details of the primary and secondary outcome measures and the statistical tests used to analyse the medium-term effectiveness of the programme are provided in chapter 4, sections 4.36-4.3.7, and section 4.3.16 respectively.

6.2 *Results*

Table 14 outlines the outcome measures observed at baseline, the 6 week and the 6 month follow up in both groups and the significance level.

Table 15: Outcome Measures at Baseline, 6 week follow up and 6 month follow up, values are means (SD) unless stated otherwise

Outcome Measures	n[b]	Intervention Group			n[c]	Control Group			p-Value
		Baseline	*6 week follow up*	*6 month follow up*		*Baseline*	*6 week follow up*	*6 month follow up*	
PA									
Daily Steps[a]	29	6983 (3191)	7177 (3345)	7107 (3773)	34	6487 (3208)	5871 (2664)	5671 (3596)	$p=0.19^{\pm}$ $p=0.83^{\neq}$
Daily EE (Kcal)	29	1945.24 (392.50)	1977.03 (365.47)	1952.91 (306.94)	34	2030.13 (446.07)	1916.41 (326.48)	1927.88 (435.87)	$p=0.14^{\pm}$ $p=0.57^{\neq}$
DDSA (minutes)[d]	29	676.50 (44.75)	670.00 (58.00)	684.00 (52.00)	34	664.25 (107.50)	666.25 (72.13)	675.00 (41.63)	$p=0.16^{\pm}$ $p=0.76^{\neq}$
DDMA (minutes)[d]	29	43.50 (43.00)	49.00 (52.50)	36.00 (52.25)	34	54.50 (100.13)	53.75 (71.75)	44.00 (41.63)	$p=0.24^{\pm}$ $p=0.79^{\neq}$
DDVA (minutes)[d]	29	0.00 (0.75)	0.50 (1.00)	0.50 (1.00)	34	0.00 (1.13)	0.00 (1.00)	0.00 (0.50)	$p=0.26^{\pm}$ $p=0.62^{\neq}$
Physiological Measures									
Weight (kgs)	36	83.17 (13.81)	82.53 (13.59)	82.97 (13.30)	36	78.75 (15.31)	79.14 (15.72)	79.64 (15.79)	$p=0.13^{\pm}$ $p=0.93^{\neq}$
Body Fat (%)	34	38.52 (11.28)	38.77 (11.84)	38.48 (9.25)	35	36.95 (8.11)	36.84 (7.58)	36.49 (8.00)	$p=0.83^{\pm}$ $p=0.98^{\neq}$
SBP (mmHg)	35	129.89 (15.65)	129.57 (15.02)	128.83 (14.47)	36	135.64 (16.62)	126.25 (13.55)	131.15 (19.43)	$p=0.33^{\pm}$ $p=0.14^{\neq}$

	N				N				p-value
DBP (mmHg)	34	72.91 (9.61)	69.03 (9.30)	71.44 (10.27)	36	71.58 (11.23)	67.50 (9.35)	70.25 (13.13)	$p=0.95^{\pm}$ $p=0.90^{\neq}$
Diet									
Fat Score	25	38.16 (8.57)	34.16 (7.61)	34.68 (9.29)	19	38.11 (9.57)	37.74 (9.13)	35.95 (7.55)	$p=0.47^{\pm}$ $p=0.31^{\neq}$
Fibre Score	29	35.90 (10.54)	35.76 (9.28)	34.07 (11.30)	26	34.19 (12.52)	33.19 (12.27)	28.88 (11.86)	$p=0.26^{\pm}$ $p=0.27^{\neq}$
Psychological									
Anxiety Score	33	5.73 (3.63)	4.03 (3.57)	3.85 (3.36)	34	5.29 (3.11)	4.68 (3.76)	4.79 (3.51)	$p=0.04^{\pm*}$ $p=0.58^{\neq}$
Depression Score[d]	32	3.00 (3.75)	2.00 (2.00)	2.00 (3.75)	35	2.00 (3.00)	2.00 (4.00)	2.00 (4.00)	$p=0.15^{\pm}$ $p=0.72^{\neq}$
Self-efficacy Score	29	48.24 (6.69)	51.66 (6.22)	50.55 (7.73)	30	49.27 (7.87)	49.87 (8.16)	51.07 (7.51)	$p=0.72^{\pm}$ $p=0.07^{\neq}$
MacNew QOL									
Emotional QOL Score[d]	31	5.86 (1.29)	6.21 (0.93)	6.29 (0.86)	33	5.93 (1.68)	6.29 (1.36)	5.86 (1.07)	$p=0.06^{\pm}$ $p=0.62^{\neq}$
Physical QOL Score[d]	29	6.50 (0.96)	6.50 (1.04)	6.42 (1.21)	33	6.50 (1.42)	6.50 (1.33)	6.33 (1.67)	$p=0.21^{\pm}$ $p=0.24^{\neq}$
Social QOL Score[d]	29	6.46 (1.12)	6.69 (0.69)	6.69 (0.65)	32	6.42 (1.17)	6.62 (1.21)	6.46 (1.21)	$p=0.24^{\pm}$ $p=0.21^{\neq}$

Seattle Angina Questionnaire[e]									
Physical Limitation Score	32	64.84 (22.05)	63.28 (25.80)	63.10 (24.91)	35	64.76 (24.39)	65.14 (26.83)	61.36 (25.69)	p=0.71[±] p=0.58[≠]
Angina Stability Score[d]	28	42.86 (42.86)	33.33 (66.67)	66.67 (66.67)	30	50.00 (57.14)	33.33 (66.67)	50.00 (70.83)	p=0.73[±] p=0.03[≠]
Angina Frequency Score	29	49.60 (28.83)	61.21 (24.63)	54.48 (27.07)	34	47.79 (32.78)	32.35 (27.20)	37.06 (28.13)	p=0.03[±**] p=0.29[≠]
Treatment Satisfaction Score[d]	31	100.00 (0.00)	100.00 (0.00)	83.33 (50.00)	30	100.00 (28.57)	100.00 (27.78)	66.67 (50.00)	p=0.72[±] p=0.24[≠]
Disease Perception Score[d]	31	83.33 (41.67)	80.00 (40.00)	66.67 (55.56)	33	83.33 (41.67)	80.00 (45.00)	66.67 (44.44)	p=0.58[±] p=0.82[≠]

[a]Primary Outcome Measure.

[b]Number of participants in the intervention group with complete baseline, 6 week and 6 month follow up data.

[c]Number of participants in the control group with complete baseline, 6 week and 6 month follow up data.

[d]Values were not normally distributed therefore median (inter-quartile range) values reported.

[e]Higher Scores on this questionnaire represent better functioning.

[±] Significance of baseline to 6 month follow up change between groups.

[≠] Significance of 6 week to 6 month follow up change between groups.

[*]Significant at p<0.05 level

[**]Significant at the p<0.01 level

6.3 Primary Outcome Measure

In the control group the daily number of steps walked decreased throughout the study, the baseline value of steps was 6487 (3208), this declined at the 6 week follow up to 5871 (2664) and then further declined at the 6 month follow up to 5671 (3596). In contrast, the daily average number of steps walked at baseline in the intervention group was 6983 (3191), this increased to 7177 (3345) at the 6 week follow up, and was then relatively maintained at 7107 (3773) at the 6 month follow up. Even though this was the case the difference in daily step change between the two groups over time was not significant (p=0.28). Contrasts analyses showed baseline to the 6 month follow up and the 6 week to the 6 month follow up change between groups were not significant, p=0.19 and p=0.83 respectively.

6.4 Secondary Outcome Measures

6.4.1 Daily EE

The difference in daily EE change between the two groups over time was not significant (p=0.10). The corresponding contrast tests showed baseline to 6 month follow up and 6 week to 6 month follow up change in EE between groups was not significant, p=0.14, p=0.57 respectively.

6.4.2 DDSA

The distribution of DDSA values were skewed in both groups at baseline, 6 week follow up and at 6 month follow up. For this reason change over time in each group was calculated and compared between groups. The change scores were also not normally distributed and therefore a Mann Whitney U test was used to compare

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change score in both groups. The median change in sedentary activity from baseline to the 6 month follow up was +9.75 in the control group and +4.50 in the intervention group. The difference between groups was not significant, U=391.50, p=0.16.

The median change in sedentary activity from the 6 week to the 6 month follow up was +8.00 minutes in the control group and +6.00 minutes in the intervention group, the difference between groups was not significant, U=487.50, p=0.76.

6.4.3   *DDMA*

The distribution of DDMA values were skewed in both groups at baseline, 6 week follow up and at the 6 month follow up. Consequently, change over time was calculated, and groups compared. Change scores were also not normally distributed. The median change in moderate level activity was -16.50minutes in the control group and -10.00minutes in the intervention group. The difference between groups was not significant, U=423.50, p=0.24.

The median change in moderate level activity from the 6 week to the 6 month follow up was -7.75 minutes in the control group and -7.00 in the intervention group. The difference between groups was not significant, U=490.00, p=0.79.

6.4.4 DDVA

The distribution of daily DDVA values were skewed in both groups at baseline, 6 week follow up and at the 6 month follow up. Thus, change over time was calculated and compared between groups. The mean change from baseline to the 6 month follow up in DDVA was -0.87 (2.90) minutes in the control group and 0.05 (3.58) minutes in the intervention group. The difference between groups was not significant, p=0.26. The mean change from the 6 week to the 6 month follow up in DDVA was -0.40 (1.78) and -0.12 (2.71) minutes in the control group and the intervention group respectively. The difference between groups was not significant, p=0.62.

6.4.5 Weight

The difference in weight change between groups was not significant (p=0.15). The corresponding contrasts tests were also not significant, for weight change from baseline to the 6 month follow up between groups (p=0.13) and from the 6 week to the 6 month follow up change between groups (p=0.93).

6.4.6 Body Fat Percentage

The difference in body fat % change between groups was not significant (p=0.97). Correspondingly, baseline to the 6 month follow up change in body fat % between groups was not significant (p=0.83), and the 6 week to the 6 month follow up change in body fat % was also not significant, p=0.98.

6.4.7   *SBP*

The difference in change in SBP over time between groups was significant (p=0.03). However, post-hoc analysis revealed baseline to the 6 month follow up change between groups was not significant, (p=0.33) and the 6 week to the 6 month follow up change between groups was similarly not significant (p=0.14).

6.4.8   *DBP*

The difference in DBP change between groups was not significant (p=0.99). Post-hoc test analysis showed baseline to the 6 month change between groups was not significant (p=0.95) and the 6 week to the 6 month follow up change in DBP between groups was also not significant (p=0.90).

6.4.9   *Fat Intake*

The difference between groups in fat intake change was not significant (p=0.21). The corresponding contrasts tests showed baseline to the 6 month follow up difference in change between groups was not significant (p=0.47) and the 6 week to the 6 month follow up difference in change between groups was similarly not significant (p=0.31).

6.4.10   *Fibre Intake*

The difference between groups in fibre intake change was not significant (p=0.34). Correspondingly, baseline to the 6 month follow up change between groups was not significant (p=0.26). Similarly, the 6 week to the 6 month follow up change between groups was not significant (p=0.27).

6.4.11   Anxiety

The difference in anxiety change between the two groups over time approached significance (p=0.07). The corresponding contrast tests showed baseline to the 6 month follow up difference in change between groups was significant (p=0.04). This finding indicates the decrease in anxiety from baseline to the 6 month follow up was significantly larger in the intervention group compared to the control group. This is shown in figure 35.

Figure 39: Anxiety Score at Baseline and 6 Month Follow up in the Control and Web-based CR group
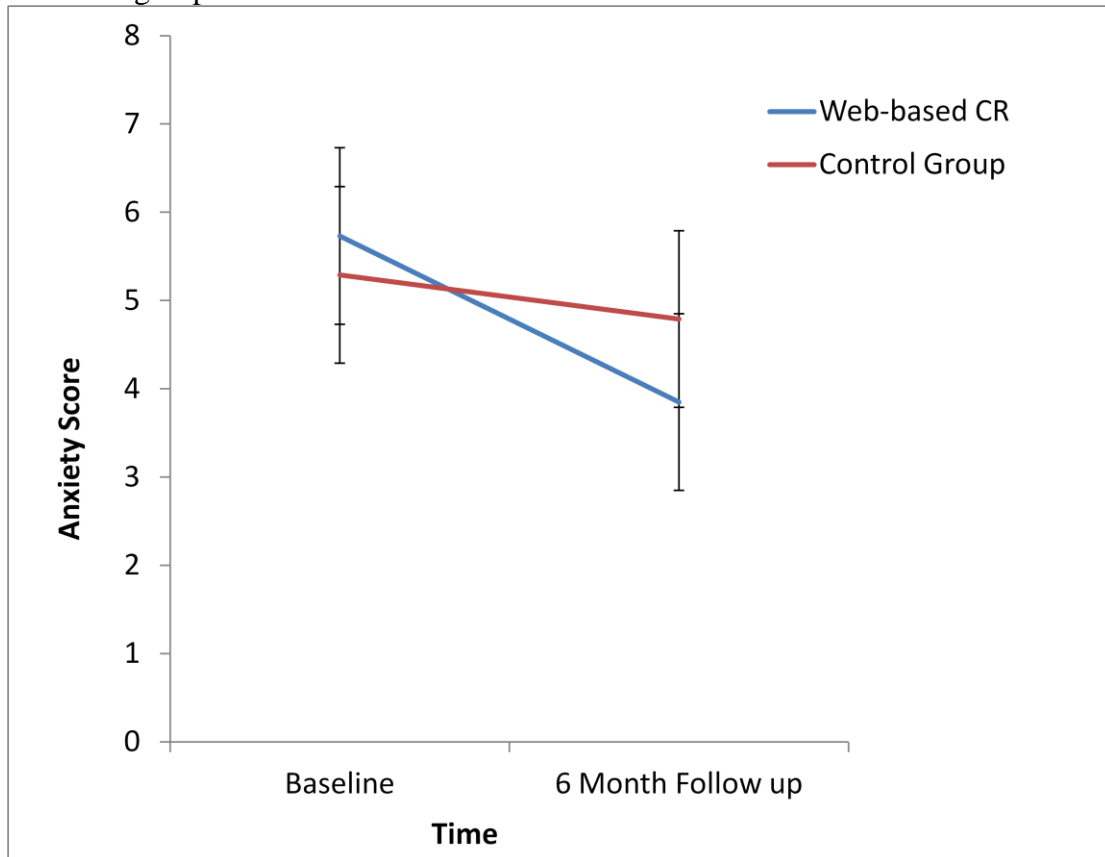
In contrast, the difference in change from the 6 week to the 6 month follow up between groups was not significant (p=0.58).

6.4.12 *Depression*

Depression scores were not normally distributed in both groups at baseline, at the 6 week follow up, and at the 6 month follow up. For this reason change over time was calculated in each group and then compared. The change in depression scores were +0.25 (2.71) in the control group and -0.64 (2.36) in the web-based CR group. The difference between groups was not significant (p=0.15). The mean depression score change from the 6 week to the 6 month follow up was 0.23 (2.03) and 0.06 (1.63) in the control group and the web-based CR group respectively and the difference between groups was not significant (p=0.72).

6.4.13 *Self-Efficacy*

The difference in self-efficacy change between the two groups over time was significant (p=0.04). However, post-hoc analysis showed baseline to the 6 month follow up difference in change between groups was not significant (p=0.72) and the difference in change from the 6 weeks to the 6 month follow up between groups was similarly not significant (p=0.07).

6.4.14 *Emotional QOL*

Scores on the emotional QOL subscale were skewed at baseline, the 6 week follow up, and at the 6 month follow up. For this reason change over time was calculated in both groups and compared. The baseline to the 6 month follow up change in emotional QOL score was -0.05 (0.52) in the control group and +0.25 (0.77) in the intervention group. The difference between groups approached statistical significance (p=0.06). This is illustrated in figure 36.

Figure 40: Baseline to 6 Month Follow up Change in Emotional QOL Sore
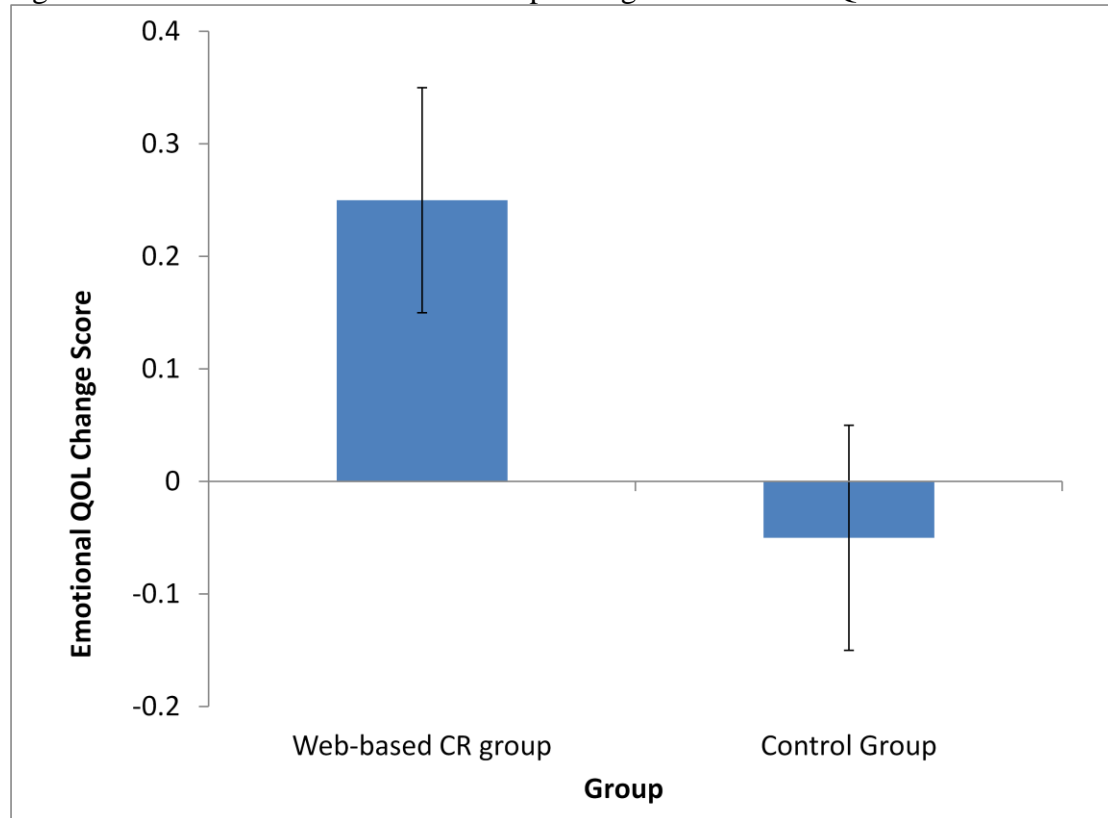
The change from the 6 week follow up to the 6 month follow up in emotional QOL score was -0.13 (0.54) and -0.07 (0.37) in the control and the intervention group respectively. The difference between groups was not significant (p=0.62).

6.4.15   *Physical QOL*

Scores on the physical QOL subscale were not normally distributed in both groups at baseline, the 6 week follow up and at the 6 month follow up. As a result change over time was calculated in each group and compared. The baseline to the 6 month follow up change in physical QOL score in the control group was -0.18 (0.64) and +0.02 (0.61) in the web-based CR group. The difference between groups was not significant (p=0.21). The mean change from the 6 week to the 6 month follow up in physical

QOL scores was -0.10 (0.52) and -0.06 (0.57) in the control group and web-based CR group respectively, the difference between groups was not significant (p=0.24).

6.4.16 *Social QOL*

Scores on the social QOL subscale were skewed in both groups at baseline, 6 week follow up, and at the 6 month follow up. For this reason change over time was calculated and compared between groups. The baseline to the 6 month change in social QOL score in the control group was -0.10 (0.52), whereas the change score in the intervention group was +0.06 (0.57). The difference between groups was not significant (p=0.24). The 6 week to the 6 month follow up change in social QOL score was -0.18 (0.65) in the control group and +0.02 (0.62) in the web-based CR group. The difference between groups was not significant (p=0.21).

6.4.17 *Physical Limitation*

The difference in physical limitation score change between groups was not significant, p=0.68. Correspondingly, baseline to the 6 month follow up change in the physical limitations score between groups was not significant (p=0.71). Likewise, the 6 week to the 6 month follow up change in the physical limitations score between groups was not significant (p=0.34).

6.4.18 *Angina Stability*

Scores on the angina stability subscale were not normally distributed in both groups at baseline, the 6 week follow up and at the 6 month follow up. Thus, change over time

was calculated in both groups and then compared. The mean change from baseline to the 6 month follow up in angina stability score was -1.75 (42.84) and 3.49 (27.92) in the control group and web-based CR group respectively. The difference between groups was not significant (p=0.58). In addition, the change from the 6 week to the 6 month follow up in angina stability score was +6.11 (37.77) in the control group and +9.52 (36.91) in the intervention group, the difference between groups was not significant (p=0.73).

6.4.19   _Angina Frequency_

Higher scores on this subscale represent better functioning. The difference in change of angina frequency score over time between groups was significant (p=0.001). The contrasts analysis revealed baseline to the 6 month follow up change between groups was significant, p=0.03. This finding indicated the increase of angina frequency from baseline to the 6 month follow up was significantly larger in the control group, whilst the frequency of angina declined in the web-based CR group. This is illustrated in figure 37.

Figure 41: Angina Frequency Score at Baseline and 6 Month Follow up in the Control and Web-based CR group. Higher scores on this questionnaire represent better functioning.
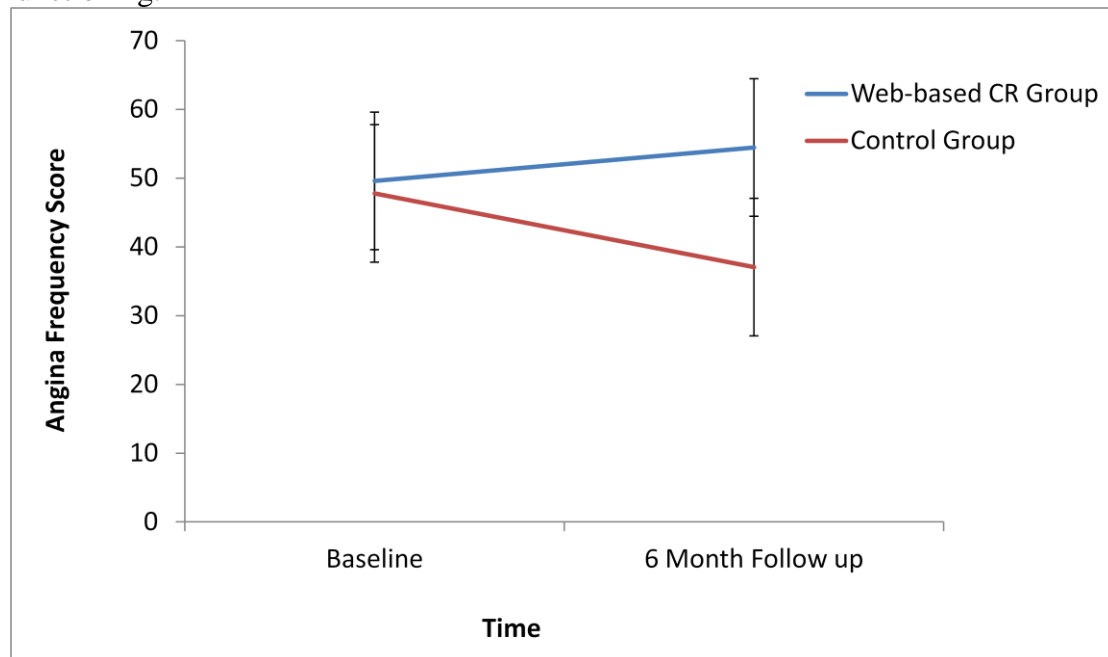
The difference in change from the 6 week to the 6 month follow up in angina frequency score between groups was not significant, (p=0.29).

6.4.20   *Treatment Satisfaction*

Scores on the treatment satisfaction subscale were not normally distributed in either group at baseline, the 6 week follow up and at the 6 month follow up. For this reason change over time was calculated in both groups and then compared. There was a decrease in treatment satisfaction score from baseline to the 6 month follow up in both groups, -17.11 (24.05) in the control group and -19.42 (27.84) in the web-based CR group. The difference between groups was not significant, p=0.72. Similarly, there were decreases in both groups from the 6 week follow up to the 6 month follow up, -12.01 (32.59) in the control group and -21.38 (30.15) in the web-based CR group. The difference between groups was not significant, p=0.20.

6.4.21   *Disease Perception*

Scores on the disease perception subscale were not normally distributed in either group at baseline, the 6 week follow up and at the 6 month follow up. For this reason change over time was calculated in both groups and then compared. Baseline to the 6 month follow up disease perception score decreased in both groups, -17.00 (21.63) in the control group and -13.71 (25.48) in the web-based CR group. The difference between groups was not significant, p=0.58. The change in scores from the 6 week to the 6 month follow up was -13.40 (22.34) in the control group and -14.69 (22.47) in the web-based CR group. The difference between groups was not significant, p=0.82.

6.5 Discussion of the Web-based CR Programme's Medium-term Effects

This section describes and discusses the intervention's medium-term effectiveness. Other points regarding the way these findings link with the qualitative study in this thesis, possible reasons as to what caused the effects, study strengths/limitations, challenges with web-based interventions, broad study implications, and recommendations for future research are outlined in the overall discussion, chapter 8.

6.5.1 Study Findings

Significant medium-term benefits upon anxiety, and angina frequency were detected. An improvement in emotional QOL approached statistical significance. In contrast, there were no significant between group differences for the medium-term change in daily step count, daily EE, DDSA, DDMA, DDVA, weight, body fat %, SBP, DBP, fat intake, fibre intake, depression, self-efficacy, social QOL or physical QOL. There were also no significant between group differences in change on 4 of the SAQ subscales, physical limitations, angina stability, treatment satisfaction, and disease perception. Additionally, no significant between group differences were detected in the 6 week to the 6 month follow up change in any outcome measures.

It should be acknowledged that the significant short-term improvements in daily steps, daily EE, DDSA, DDMA weight, self-efficacy were no longer significant at the 6 month follow up and therefore indicated these benefits were not maintained. There is a need to also outline there were no significant short-term intervention improvements detected in body fat%, SBP, DBP, dietary habits, depression, social/physical QOL and in 4 of the SAQ subscales; physical limitation, angina stability, treatment satisfaction,

and disease perception. Thus, it was unsurprising and unlikely that medium-term benefits would be detected for these outcomes as there were no significant improvements at the short-term follow up.

6.5.2 Clinical Significance of the Results

As previously outlined there were favourable medium term intervention effects upon anxiety and frequency of angina symptoms. Even though the improvement was statistically significant it is important to consider whether the changes were clinically significant. Previous research describes that a reduction in score of 1.50 in HADS measured anxiety is required for a clinically meaningful change in chronic obstructive pulmonary disease (Puhan et al. 2008). The level of change required for a clinically meaningful change in HADS has not yet been established in a CHD population. The average change in anxiety in the intervention group at the 6 month follow up was -1.88 (SD=3.15), p=0.04, and therefore according to Puhan et al (2008) represented a clinically meaningful improvement. In contrast, the improvement in SAQ measured angina frequency did not represent a clinically meaning change. The mean change in angina frequency score was +4.91 (SD=28.46), p=0.03, and thus below the pre-defined score change required for a clinically meaningful change (+10) (Spertus et al. 1995).

6.5.3 *Comparison with Previous Research*

The findings indicate that the intervention did not have a medium-term impact on PA. These findings are similar to an earlier review, which reported PA benefits resulting from CR are limited to immediately after CR and are not sustained at longer term follow ups (Jolliffe and Taylor 1998). However, these findings do contrast a recent

review which reported that psychoeducational CR programmes that employ cognitive behavioural strategies are effective at increasing PA in the medium-term (6-12 months) (Aldcroft et al. 2011). Aldcroft et al (2011) states that favourable changes in PA may have been facilitated by goal-setting, problem solving, self-monitoring and role modelling behavioural change techniques. It is possible that the contrasting findings are due to differences behavioural change techniques adopted. Aldcroft et al (2011) outline 4 effective techniques, of which only 2 were used in the present web-based intervention. Perhaps the inclusion of problem solving and role modelling techniques may have improved the medium term effectiveness of this web-based intervention. The findings are also in contrast with Yohannes et al (2010), a UK based study reporting significantly increased PA from baseline to 6 months following a 6 week hospital-based programme. The 6 month change in daily EE detected by Yohannes et al (2010) was +176.1 kcal, considerably higher than the 6 month change observed in the current study, +7.67 kcal. The baseline value of daily EE reported by Yohannes et al (2010) was 1767.48 kcal, much lower than the baseline level of daily EE reported in the current study, 1945.24 kcal. Thus, baseline levels of daily EE may explain the contrasting levels of daily EE change. Or it is possible there is a difference in treatment effect. However, this is debatable, unlike the current study the findings reported by Yohannes et al (2010) may be limited as the study did not include a control group and calculated daily EE using participants' body weight and a 7-day recall activity questionnaire.

The non-significant benefits upon PA at the 6 month follow up are also in line with past studies of the Heart Manual. Jolly et al (2007) reported increased PA scores from baseline to a 6 month follow up in both home-based and hospital-based rehabilitation

groups, in which PA was measured using a modified version of the Godin Questionnaire. In contrast Furber et al (2010) detected significantly improved PA 6 months following a 6 week telephone home-based programme. This is surprising considering that both the present intervention and the intervention evaluated by Furber et al (2010) both employed similar behaviour change techniques (goal-setting and self-monitoring). It is possible that the difference in findings could be due to differences in participants employed. This study recruited a primary care angina sample with a long history of angina. Whereas the sample recruited in Furber et al (2010) recruited CABG, PCI, MI, and acute coronary syndrome patients. It is possible that the sample recruited in Furber et al (2010) were more motivated than the sample employed in the current study.

Data from the AP indicates significantly increased self-reported daily walking (Lewin et al. 2002) and increased readiness to carry out PA (Zetta et al. 2009) compared to controls at a 6 month follow up. However, comparisons of the size of PA change are not possible due to differences in the way PA data was reported. Lewin et al (2002) assessed the change in the number of participants reporting an increase in daily walking activity, and Zetta et al (2009) assessed motivation to increase PA. It should also be noted the length of the interventions are significantly different, the current intervention lasted 6 weeks and the AP 12 weeks. In addition, as previously noted the AP is facilitated by a nurse and involves an in-depth initial consultation where cardiac misconceptions and individual risk factors are discussed in detail. The nurse then maintains close contact with the patient throughout the intervention period. The current online programme was not facilitated in this way; the contact was initiated by the user and not by the healthcare professional. Further, the difference in findings

could also be due to the subtle differences in participants recruited; the present study recruited a sample with a long established diagnosis of angina, a stage where motivation levels may be low. In contrast, motivation levels may have been higher in previous studies given that Lewin et al (2002) recruited those newly diagnosed with angina and Zetta et al (2009) examined those hospitalised with angina.

There is inconsistency with previous web-based intervention studies carried out among non-CHD populations (Dunton et al 2008, and Sternfeld et al 2009). Dunton et al (2008) report the effectiveness of an online PA intervention compared to a control group at a 3 month follow up. Sternfeld et al (2009) reported significantly increased moderate PA and length of time spent walking compared to a control group 4 months following a 16 week tailored e-mail intervention. Dunton et al (2008) reported an increase of 4.14 minutes of moderate-vigorous level activity per day, while Sternfeld et al (2009) detected an increase of 0.9 minutes of moderate level activity per day. This study is in contrary to previous reports of web-based interventions with non-CHD populations. The difference in populations studied could possibly explain these findings. Both Dunton et al (2008) and Strenfeld et al (2009) recruited healthy individuals free of chronic disease.

Similar to the findings reported in the short-term effectiveness chapter there was practically no DDVA carried out by participants in both groups at either baseline or at the 6 month follow up. The average age of participants was 66.27 years in the intervention group and 66.20 years in the control group. Previous work carried out among a non-disease population reported this age group to engage in accelerometer measured moderate-vigorous level activity (Evenson, Buchner and Morland 2012).

Given the similar age group reasons for the current sample not engaging in vigorous level activity is unclear. A speculation is perhaps this activity is not reasonable within this chronic disease population. It would be useful in future research to compare daily PA levels of those with angina with a healthy population in order to define the PA levels of this population, thereby investigating whether the lack of DDVA is population specific. Another possible explanation for this is participants in this study learned from previous experience that vigorous activity induced an angina attack and therefore this level of activity should be avoided. Or alternatively participants avoided vigorous activity as they believed that instead they should be careful and only participate in gentle activities. This possible explanation is described in detail in the previous chapter 5, section 5.11.

There was a non-significant medium-term benefit upon body weight. This may be considered reasonable given the short-term reduction in weight was modest. Further, there were no significant medium-term improvements observed for other physiological variables; body fat %, SBP or DBP. This is somewhat unsurprising given there were no favourable benefits detected for these outcomes in the short-term. In contrast, Jolly et al (2007) reported significantly increased SBP and DBP among home-based and hospital-based rehabilitation groups at a 6 month follow up. Similarly, Dalal et al (2007) reported increased SBP and DBP in those randomised to and those choosing either hospital-based or home-based rehabilitation at a 9 month follow up. The intervention group in the current study had relatively similar baseline levels of both SBP and DBP as Jolly et al (2007) and Dalal et al (2007), although blood pressure remained stable throughout the study in the current trial. The contrast in findings could be due to differences in samples recruited. Jolly et al (2007) studied

post MI and post coronary revascularisation (PTCA or CABG) patients, while Dalal et al (2007) recruited uncomplicated MI patients.

The current study outlined no significant short-term or medium-term improvements to diet. This contradicts previous findings. Jolly et al (2007) detected significantly improved diet at a 6 month follow up among groups receiving either home-based or hospital-based rehabilitation. As previously outlined Jolly et al (2007) recruited post MI and post coronary revascularisation patients, who may have been more motivated than the primary care angina sample recruited in the current study. In addition, Lewin et al (2002) reported 6 months following the AP participants were significantly more likely than the control group to change their diet. As has already been outlined there were differences between the samples recruited in this study and Lewin et al (2002), in addition, the AP extends over 12 weeks, which is comparatively longer than the current intervention. Supporting a longer term intervention is the study by Sternfeld et al (2009), which demonstrated the effectiveness of a 16 week internet-based intervention at improving diet at a 4 month follow up in a sample of healthcare employees with additional information provided by weekly e-mail. The absence of this 'weekly e-mail' component in the current web-based CR programme could possibly account for some differences in findings. However, it is difficult to understand the additional benefit of weekly e-mails. It appears a longer duration of time may be required to stimulate dietary changes, suggesting a dose response effect or the need to improve the diet advice and support on the website. There is a body of literature indicating a longer time period may be required (Brunner et al. 1997). Brunner et al (1997) conducted a meta-analysis of dietary advice in primary prevention of chronic disease. This review included 17 RCTs of dietary behaviour

interventions of at least 3 months duration and reported favourable changes in diet at a 3–6 month follow up (Brunner et al. 1997).

There was a significantly favourable medium-term benefit in anxiety; this was surprising considering the absence of a short-term anxiety improvement. This finding is consistent with a recent UK based study, which reported significantly improved anxiety 6 months following a 6 week hospital-based CR programme (Yohannes et al. 2010). The change in anxiety score in the present study was -1.88, indicating a comparatively greater decline in anxiety than the change reported by Yohannes et al (2010), -1.52. Improved anxiety amongst those receiving the Heart Manual has also been reported by both Jolly et al (2007) at a 6 month follow up and by Dalal et al (2007) at a 9 month follow up. Jolly et al (2007) reported a decline in HADS assessed anxiety in both home and hospital-based rehabilitation groups, -1.12 and -0.9 respectively. Further, Dalal et al (2007) demonstrated improved HADS assessed anxiety in participants randomised to (-1.00) and those with a preference for (-1.49) for the Heart Manual. Dalal et al (2007) also reported improved anxiety resulting from those randomised to (-0.93) and those choosing (-1.49) hospital-based rehabilitation. It is interesting that a comparatively greater anxiety decline was detected in the present study considering the difference in samples employed in former studies. Medium-term improvements in anxiety have also been reported to result from the AP (Furze et al. 2012, Lewin et al. 2002), although Zetta et al (2009) failed to demonstrate an improvement. Baseline levels of anxiety in Zetta et al's study were below the classification for mild anxiety and could therefore explain the non-significant anxiety findings. However, low baseline levels of anxiety was also the case in the present study and medium-term improvements were still detected. The

comparable findings are also interesting given the current intervention was half the length of the AP, a 12 week programme.

There was no significant benefit upon depression in the medium-term, nor was there a significant depression improvement in the short-term. The findings do not reflect the outcomes reported by Lewin et al (2002) and Furze et al (2012) who reported significantly improved depression after the AP compared to a control group at a 6 month follow up. One possible explanation for the difference in findings is previous samples employed in former studies were more depressed at baseline than the current sample, as both Lewin et al (2002) and Furze et al (2012) recruited those with a new diagnosis of angina. However, a direct comparison of baseline scores with Lewin et al (2002) and Furze et al (2012) is not possible as both reports outlined change scores and do not report baseline scores. Interestingly, Zetta et al (2009) and Yonezawa et al (2009) report no significant improvements upon depression 6 months following the AP and a hospital-based CR programme respectively. Similarly, Jolly et al (2007) outlined unchanged depression scores following either the Heart Manual or hospital-based rehabilitation at a 6 month follow up. Further, Dalal et al (2007) demonstrated no significant differences in depression levels between those randomised to or those allocated choice of either home-based or hospital-based rehabilitation. Baseline levels of depression in this study, Zetta et al (2009), Yonezawa et al (2009), Jolly et al (2007) and Dalal et al (2007) were below the threshold for mild depression. Therefore it is reasonable to postulate this to be the reason for the non-significant change in depression.

The short-term self efficacy benefits were not maintained at the 6 month follow up. This contradicts McGillion et al (2008b) who reported significantly improved self-efficacy 3 months following a group-based 6 week intervention. The differences in intervention style could explain the difference in findings. The current intervention was an individualised approach, whereas the intervention evaluated by McGillion et al was a group-based approach. Previous qualitative research has demonstrated those taking part in group-based rehabilitation gain motivation and support from others (Jones et al. 2009). This could possibly explain some of the differences in findings. Further, Kukafka et al (2002) reported significant self-efficacy improvements compared to a control group in a CHD population using a tailored online intervention at a 3 month follow up. The difference in findings may be attributed to the length of follow up, both McGillion et al (2008b) and Kukafka et al (2002) detected self-efficacy improvements at a 3 month follow up. Whereas, this study comprised a longer follow up of 6 months, it is reasonable to assume perhaps it is more difficult to sustain self-efficacy benefits at longer follow ups.

In terms of HR-QOL the medium-term improvement in emotional QOL, measured using the MacNew, approached statistical significance (p=0.06), suggesting the short-term benefit was relatively sustained. Other literature also reports improved QOL following centre-based CR (Heran et al. 2011, Jolliffe et al. 2001), home-based programmes (Clark et al. 2010) and the AP (Zetta et al. 2009). It is difficult to compare the size of QOL change due to differences in instruments employed in previous research. However, the change in emotional QOL score was not clinically meaningful, the change in score was +0.25, which is below the threshold for a clinically meaningful change (Oldridge et al. 2002). In contrast to this, Dalal et al

(2007) reported clinically significant improvements to emotional QOL following randomisation (and allocated choice) to either the hospital-based or home-based rehabilitation at a 9 month follow up. The changes in scores on the emotional QOL subscale in Dalal et al (2007) were +0.64 and +0.71 in the hospital and home-based randomised groups respectively, and the change in emotional QOL score was +0.69 and +0.46 in the preference based allocations to the home and hospital-based rehabilitation groups respectively. The differences in baseline scores could explain the contrast in findings. In the current study the intervention group scored 5.86 on the emotional QOL subscale, while baseline scores did not exceed 5.22 in any groups in Dalal et al's study. Further, the present study did not detect an improvement to either the physical QOL or social QOL subscales. In contrast, Dalal et al (2007) presented clinically significant improvements to these subscales in all study groups. Again, high baseline scores on these subscales could account for this. As was outlined in the short-term effectiveness discussion (section 5.11) the maximum score available on these subscales is 7, at baseline the median score on the physical QOL subscale was 6.50 in both groups, and the social QOL subscale score was 6.46 and 6.42 in the intervention and control group respectively. It is possible baseline scores on this questionnaire suffered from a 'ceiling effect', which occurs when a large portion of participants score towards the upper limit (Hessling, Traxel and Schmidt 2011). For this reason, it was difficult to improve baseline scores.

The significant short-term intervention improvement to frequency of angina (SAQ subscale) was maintained in the medium-term. Consistent with this, McGillion et al (2008b) also detected a significant improvement on the SAQ angina frequency subscale 3 months following a nurse-facilitated group-based intervention. The change

in angina frequency score was 11.4 in McGillion et al (2008b), considerably higher than the change in the current study, 4.88. It is not possible to compare baseline scores as McGillion et al (2008b) outline change scores only. Nevertheless, the comparable improvement in angina frequency is promising given both the longer follow up and the individualised approach in the current study. However, McGillion et al (2008b) also reported improved angina stability, which was not observed in the current study. Further, both Lewin et al (2002) and Zetta et al (2009) reported significant improvements to the physical limitations subscale 6 months following the AP. Significant improvements were not detected on this subscale in the current study. It is not possible to compare scores with Lewin et al (2002) as the report outlined change values only. However, when comparing the baseline physical limitations score with Zetta et al (2009) AP participants scored 53.67 at baseline, indicating a lower level of physical function at baseline than the current study where the baseline score was 64.84 in the intervention group. Additionally, it is possible that differences in samples employed could account for differing baseline levels. Zetta et al (2009) recruited a secondary care sample, whilst this study examined a primary care sample. Further, there were no significant benefits detected for 4 of the other SAQ subscales; physical limitations, angina stability, treatment satisfaction, and disease perception. These 4 subscales were also not significant at the 6 week follow up and therefore the non-significant medium-term impact is somewhat unsurprising.

6.5.4 *Strategies to Improve the Web-based CR Programme*

Overall some significant medium-term programme effects have been described. This is encouraging and illustrates potential of the online programme to be effective 6 months following intervention use. However it is necessary to acknowledge

significant medium term benefits were lacking for physiological, diet, and some psychological/HR-QOL variables. This may have been due to a lack of maintenance strategy, perhaps more benefits may have been detected if post intervention on-going support was provided. This may be provided through follow up e-mails or telephone calls. Alternatively, there may be a need to modify aspects of the intervention in order to improve medium-term effectiveness. A previous systematic review and meta-analysis carried out by Webb et al (2010) outlined intervention strategies used within web-based interventions associated with larger intervention effects. The strategies outlined to be effective that were not included in the current intervention were modelling, relapse prevention/coping planning, facilitating social comparison and performance feedback techniques. Perhaps inclusion of these techniques in future developments of the current web-based CR programme would enhance effectiveness of the programme. Inclusion of a 'modelling' component could involve providing participants with illustrations of the desired behaviour changes, thus helping users to model their behaviours on the examples provided. A 'relapse prevention/coping planning' technique could be incorporated into the programme through including guidance on ways of returning to positive behaviour change in the event of relapse occurring. Strategies to prevent relapse occurring could also be provided. Further, a 'social comparison' technique could be included with the use of a discussion forum. A discussion forum would provide users with an opportunity to share their experiences with others and thus result in programme users comparing themselves with their peers. In addition, future developments of the programme could incorporate the 'providing performance feedback' technique. This could be done through sending weekly e-mails with a summary of performance progress and progression along the programme. Inclusion of these techniques may lead to

improved programme effectiveness. Therefore, incorporating more maintenance/on-going support strategies and perhaps including other behaviour change techniques into the programme may have strengthened the medium-term effectiveness of the intervention.

6.5.5 *Chapter Summary*

This study was the first in the UK to describe the medium-term effectiveness of an online secondary prevention intervention for those with angina. Overall, this chapter described encouraging medium-term benefits. Specifically, there were significant medium-term intervention improvements detected for DDSA, DDMA, anxiety and angina frequency. The intervention benefit on emotional QOL approached statistical significance. These findings are promising and fitting with guidelines advocating the need of alternative CR delivery modes (NICE 2008). However, there were no significant medium-term improvements detected for daily step count, daily EE, DDVA, physiological variables, diet, and some psychological/HR-QOL variables. Other points for discussion regarding how the effects may have been achieved, overall strengths/ limitations to the study, broad challenges of web-based interventions, study implications, and recommendations for future research are described in chapter 8, the overall discussion.

CHAPTER 7

ACCEPTABILITY AND FEASIBILITY OF THE WEB-BASED

CARDIAC REHABILITATION PROGRAMME

This chapter will outline the findings obtained from the qualitative study, which aimed to explore participants' views regarding the acceptability and feasibility of the web-based programme. Firstly, a brief description of the method used to collect data and the method of analysis will be outlined. Following this the participants will be described and the study findings presented. A discussion of the findings will then conclude the chapter.

7.1 *Summary of Method*

One aim of the overall research project was to examine participants' views regarding the programme's level of acceptability and feasibility. This aim was addressed by conducting semi-structured interviews amongst a sub sample of intervention group participants. This method allowed a more thorough and in-depth examination of participants' experience of using the programme. Participants were recruited from the RCT's intervention group and interviews conducted alongside the 6 week follow up. These interviews were analysed using thematic analysis. Full details of the analysis are described in chapter 4, section 4.46 – 4.4.11.

7.2 Results

Twenty participants from the intervention group were selected by the researcher to take part. Participants were selected with the aim of including a variety of participants, such as those of different age groups, both males and females, employment status, postcode, and length of angina diagnosis. Four participants declined to take part. Altogether 16 trial participants were interviewed; 12 male and 4 female. Data collection was carried out until data saturation was reached. This occurred when there was no more new information or new questions arising from interviews and for this reason data collection was stopped. Participants had a mean age of 66 years (range - 46-80 years) and the mean number of years since angina diagnosis was 8 years (range - 1-21 years). Five participants were treated with medication only, 6 with angioplasty, 3 with CABG, 1 with both angioplasty and CABG, and 1 with PCI balloon treatment. In terms of intervention adherence 10 participants completed the whole intervention, 5 reached up to stage 3 and 1 participant did not progress further than stage 2. For this group of 16 participants the mean number of programme logins was 29, with an average of 5 logins per week over the 6 week intervention period. On average the interview duration was 27 minutes and 44 seconds (range 15 minutes 35 seconds to 50 minutes and 23 seconds).

7.3 Key Themes

Altogether 3 main themes, 'self-reported improvements', 'programme facilitators', and 'programme barriers', were generated from the analysis. The following section will describe and illustrate each theme using quotes contained within the participant transcripts.

7.3.1 Self-reported Improvements

Participants talked about their 'self-improvements' they felt were a result of the programme. One improvement was positive lifestyle changes such as starting to exercise or increasing the amount of exercise. This indicated the programme actively encouraged more exercise. The following quotes support this:

> *"Well I didn't exercise at all the past couple of years, (pause). With this programme I've had to force myself to do the half an hour walk and now I've just started taking Zumba lessons which is an hour. Which I would have never done before"* (Participant 12).

> *"It has encouraged me, I was going swimming once a week but now its encouraged me to go twice a week so I actually now go on a Tuesday and a Thursday. And now I'm hoping that after Christmas I will be able to do a Monday, Tuesday and a Thursday as well"* (participant 2).

> *"I wasn't doing any exercise before, errr I was active yeah but I wasn't doing a lot of exercise at all"* (participant 10).

The programme's requirement to carry out exercise appeared to contribute more structure and routine as participants had to organise their daily lives in order to fit in the requirements of the programme and thus structure and plan their day accordingly:

> *"I thought it would put some discipline back into daily life, if nothing else you know but yes you've got to make time to do the half hour exercise"* (Participant 9).

> *"It gets you into a routine and err I would say generally I've felt a lot better for doing that"* (Participant 13).

> *"I think it's got me into a routine almost ermm as I've said if it was a bit longer it sort of firms up that routine a bit more"* (Participant 13).

Participants also described since carrying out more exercise they felt their energy levels had increased. The following quotes illustrate this:

> *"I feel personally that since I started doing this that I've got a bit more energy than I had before whether its pumping these old leg muscles even more but yeah I do feel as if I've got more energy and willing to do things"* (Participant 10)
>
> *"I seem to have a lot of energy and can keep going a lot longer (pause) and I think that's all down to the programme"* (Participant 10).
>
> Interviewer: *"And you said before that since making these changes you've felt better do you mind explaining a bit more about that?"*
>
> *"Well ermm less lethargic, I feel like I have a bit more energy"* (Participant 13).

Another participant described he felt fitter as he noticed improvements in exercise capacity:

> *"I'll tell you another thing I forgot to tell you, I know I'm fitter than I was I know that because of walking up the caravan site, we borrow a caravan occasionally there is a hill up and I can walk up without being exhausted you know"* (Participant 15).

An additional lifestyle change as a result of the programme was improved diet. Participants appeared to be more conscious of their diet for instance in terms of being more aware of reading food packaging, reducing alcohol, crisps, chocolate and salt intake, and increasing fruit and vegetable intake. Examples of this are provided below:

> *"It has made me read the packets and things like that, that's more than what I was doing before"* (Participant 2).
>
> *"And also the programme has definitely encouraged me to watch my diet and drink less although I'm not a great drinker I do occasionally drink a lot of wine. Ermm spirits I don't drink very much, but as I say the programme has encouraged me to ermm as I say eat and drink less"* (Participant 3).
>
> *"I've cut down on my drink, and I'm trying to stay below 18 units a week. I've changed my diet; I've cut out all crisps and chocolate. I'm eating more fruit and veg"* (Participant 6).

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"I think it was pretty good. there were one or 2 things, I mean salt was one of the main things, I haven't cut it out completely, I've cut it down 90% of what I was having I've cut out" (Participant 13).

Participants also talked about psychological improvements since using the programme. One psychological element apparent in the interviews was increased health related confidence. Examples of this are provided:

"It's as a direct result of the programme that I think I feel more confident about my health you know....I just feel as though my confidence has gone up" (Participant 13).

"I think it's made me feel more confident and… I feel confident that I'm feeling better…… it's made me more self assured" (Participant 13).

In addition, participants reported increased exercise related confidence. Increased confidence to engage in exercise was a consequence of the programme's exercise requirement. Participants indicated that as a result of the increased exercise they were less anxious with regards to exercising:

"And ermm probably a little bit more confident as well. ... I've found that I haven't had a problem when exercising so it's given me more confidence on the bike now" (Participant 13).

"It did give me a bit more confidence to walk faster and that I could do things that were more energetic if I wanted to" (Participant 14).

"Yeah and if I do a little of jog because I can run for a little bit and I'm not frightened so" (Participant 12).

"Doing more exercise, it's made me aware that I can do it, I think before that I was a bit nervous that I couldn't do as much as I've done and now I find that I can actually do more than I've done in 2 or 3 years. So you know it's made me much more positive in err having a go I think before I thought I was going to have a heart attack if I did too much" (Participant 2).

"I was getting pains in my chest all the time I was frightened to push my heart, just in case I had a heart attack or whatever….But it's given me the push……Whereas before I would have just sat at

home and just you know put up with it because I had angina but now I've got a focus" (Participant 12).

It was also apparent that there were increased feelings of motivation as a result of the help and encouragement gained from the programme. The following participant quotes illustrate this increased motivation:

> *"Well it makes you do something positive and up till going on the programme, I must admit I didn't think about it really, but its motivates you to think ohh I've got to get up and do 30 minutes exercise today"* (Participant 1).

> *"Well I think it's just got me self motivated, before I was perhaps idle or lazy (laughs) err and you know walked when I had to err and now I'm walking as much for pleasure"* (Participant 8).

> *"I do need somebody to kick me or whatever, and that does give me the little kick that I need"* (Participant 11).

> *"I think the programme itself has made me, because I agreed to do it then it's made me lose weight…….I think doing this programme has forced me to do it. Whereas I probably wouldn't have done it before on my own without some sort of help like this"* (participant 6).

Participants also talked about their hopes and plans for future activities with regards to exercise, and in terms of losing weight which again demonstrated increased motivation.

Street names have been removed due to the potential to identify participants.

> *"Erm, yeah because like for myself I'd like to jog now, and it's just pushing myself to actually do it. But maybe in the summer when it gets a bit warmer I'll start jogging rather than just walking"* (Participant 12).

> *"That's right, yeah, my next one is when the weather is dry to go up to the island the ▮▮▮▮▮▮▮ island and back. I think that will be a good 2 miles which is a mile there and a mile back I think I've worked it out. So that's my next challenge to do that"* (Participant 2).

> *"If I could get my weight down to 12 stone, that's my ambition apart from playing cricket, if I could get my weight down to 12 stone I*

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wouldn't half be happy, because I'm 13 or whatever it is" (Participant 15).

Furthermore, participants described that since taking action to improve their cardiac risk they felt healthier and happier. This is illustrated by the following comments:

> *"I feel, I know I've lost weight, I can feel I've lost weight, its helped my breathing and I do feel healthier…………..but now I'm losing the weight I do feel a lot healthier. I feel like it's doing me good"* (participant 6).

> *"So doing the programme, you know your programme it tells me I'm doing the right thing for my own health"* (participant 15).

Related to this was increased positivity among participants. Participants felt more positive about life and fears of dying were relieved. It appeared that the extra exercise encouraged participants and gave them more hope for the future. One participant talked about since discovering his ability to exercise his views on the future were more positive:

> *"Before I was perhaps thinking you know at my age I shouldn't be thinking about how to live longer I should be planning to die sort of thing, and think about that side of the world so ermmm but I'm perhaps more on the side that ermm lets do a little bit more exercise and see if we can get on holiday again next year, (laughs) and see another part of the world, God willing. Ermm but yeah you know in that way it's made me feel a little fresher towards the next step of life you know rather than thinking it's all over now"* (Participant 10).

> *"I was fearful that I was going to die any minute, whereas now that the pains have eased hopefully I might live to my 60s which I didn't think I would do before…..I'm more positive about living a longer life and not dying, well hopefully not dying before my kids get into their 20s so whereas before I thought I could be gone now you know"* (Participant 12).

Worrying less was another psychological improvement. Simply having access to information contained in the programme relieved prior worries and concerns:

> *"Whereas with that, I could look at the heart programme and see that it was definitely nothing to worry about and I felt much more calm and confident about it"* (participant 2).

> *"I think my blood pressure has gone right down as well which has helped because I'm not worrying all the time"* (Participant 12).
> Interviewer: "Ok, could you explain how you've felt less worried"?
> *"Just having the information at hand, whereas before I didn't have any information at all, other than having to look for it myself………Its ermm put my mind at ease…..the anxiety of having angina has eased off more. I'm not constantly thinking of it second by second so yeah (pause), it's made me less anxious in that way"* (Participant 12).

> *"I was concerned and I still am to a certain extent that I could have a heart attack and things could get nasty but I feel less bothered about it then I did before. So I think it's eased my mind a little bit you know. And that as a result really of what I've done in the programme"* (Participant 13).

Participants also reported their symptoms while exercising had improved, for example, one participant reported improvements in terms of angina symptoms and found she was able to go for longer walks and rely less on using the angina spray. This indicated less reliance on medication and a general improvement in exercise capacity:

Street names have been removed due to the potential to identify participants.

> *"Now I know that I can push it ermm to a degree and I know that when a pain starts to come on I keep my eye on it, and I think if it doesn't get any worse than that I'm not stopping I just keep going. And if I go down a little bit of a hill it disappears a bit, go back up a hill it comes back on again but it doesn't get any worse and it doesn't cause me any great concern….I know how far I can push myself physically and ermmm I suppose when this pain comes on it's a warning you know but it doesn't get any worse"* (Participant 10).

> *"And I've actually extended my walking now. I can now walk down to the bottom of ████ Street and walk back up. And I only have to*

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take my angina spray on the way back up about ¾ of the way back up. Which is a big improvement for me" (participant 2).

Other participants described improvements in terms of using medication less, and experiencing fewer angina pains:

> *"I have had angina attacks err I haven't taken no note but I think there is probably less than there were when I started the programme. I certainly use the spray less although I still do have to use it from time to time. But it is perhaps less than it was"* (Participant 8).

> *"I still get out of breath if I go for long periods, but its not as intense as it used to be, where I be panicking and I think oh gosh I'm pushing my heart a bit too much I have to slow down….I feel happy (pause), definitely happy, because I'm not getting pains in my chest all the time now"* (Participant 12).

An improvement was reduced blood pressure which participants attributed to worrying less.

> *"I've had 2 or 3 probably little niggly pains but other than that I've been fine. I think my blood pressure has gone right down as well which has helped because I'm not worrying all the time"* (Participant 12).

Participants expressed they felt more in control of their angina after the programme. One participant described that since using the programme she changed the way she dealt with stressful situations. She had begun to examine the causes of her stress levels and now tries to distance herself from these situations:

> *"Whereas before I was told I had angina and I was just left to my own devices. (laughs) And I didn't understand what it was but I do now"* (Participant 12).

"It has made me look at myself a lot more, now I know a lot of mine has been stress related. We have had a lot on, ███████ mum died in July so its been one of those years you know. We've had a lot of problems with other people but I do take a lot of it on myself you know so I'm now learning to try and step back which has (pause) I wouldn't have done it if it hadn't have been for the programme, with the programme explaining it to me" (participant 2).

7.3.2 *Programme Facilitators*

This theme reports the intervention features valued by participants. Participants talked positively about the comprehensiveness of the programme. It was evident that participants valued the volume of information that, in turn, increased their learning and understanding:

> *"I think the information that's on there is extremely comprehensive…there is nothing that I couldn't find out that I wanted to know"* (Participant 13).

> "I*t leads you through everything fairly clearly and it gives you errm a good insight into how the heart works, what the problems are and what they do about it and drugs you take and I think it's extremely comprehensive"* (Participant 13).

> *"Ermm this programme, everything is on there that you need to know"* (Participant 6).

Participants valued the individualised aspect of the programme. They compared the programme with previous experiences of using general websites and expressed their preference for this personally relevant programme. Participants described that it was useful to have everything on one website instead of having to search for information elsewhere.

> *"I've enjoyed using your programme because its connected directly to me………I think sometimes there is too much information unless it's something that is controlled for you, like this heart programme is, then I think that's good…I think some internet is good some is, if*

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its specifically made for you but I think some of it can be quite dangerous really" (Participant 2).
"It's been useful getting that information of there because you wouldn't really know, you'd have to go onto dietary sites or something to try and find it and it's all there all packaged. So again that was very useful" (Participant 13).

Participants spoke positively about the exercise diary and felt it provided motivation and an incentive to be more active. In addition, a completed exercise diary was a requirement to progress on the programme; therefore, participants were obliged to comply with the exercise requirements to complete the programme. One participant explained that he felt a sense of contentment when he had achieved the required number of exercise minutes.

"Up till going on the programme, I must admit I didn't think about it really, but its motivates you to think ohh I've got to get up and do 30 minutes exercise today. (laughs) Because I've got to go up and fill it in. Ermm its motivating" (Participant 1).

"The enjoyable part I see, very basic really is seeing your exercise log come out" (Participant 10).

"Well I'm exercising more than I did, you've got the exercise plan there and you have to record it so you think "I have to do my exercises otherwise I'm not going to get to the next stage to progress" (Participant 12).

"It's good to have a thing to write down and seeing what you're doing…. it's very good that you have this weekly discipline of putting it in what you do…I was much more content when I was doing it and filling it in, doing 30 minutes, good, good, good I'd done 5 for the week and not many weeks did I do 5 but I did 45 minutes ermm some days and err but I did if you count sorting out the shed and that sort of thing you know. No its very good, for the undisciplined person it gives you that discipline, erm which is I think is a very good idea………. you're proving you're doing the exercise and its very important to write it down for me, you know on that weekly thing" (Participant 15).

Participants talked about the 'end of stage quiz', there was a general feeling that participants wanted to do well on the quiz as they experienced satisfaction when they achieved a high score. One participant explained that the quiz made her aware of what she was learning.

> *"One week I got 6/6 right and I was really pleased with myself and the next week I got 4/6 and I'd misread it so I went back and re-read it again"* (Participant 2).

> *"I think I got one wrong out of the whole lot and I thought "woo that was good, that was brilliant!" (laughs) it was like a little exam at the end of it so it showed that I took some of the knowledge in"* (Participant 12).

It appeared being in contact with health professionals led to feeling supported and reassured. One participant described that confidence increased as a result of the health care professional's support available.

> *"Yes I enjoyed the support, I think that's what I would say about you and the programme is that I feel I am supported now"* (Participant 3).

> *"You also as well got an instant call on somebody for advice....if there was something on the programme or you asked something which wasn't understood you can e-mail back and say can you explain this a bit more or am I doing something wrong or have I got this bit right? Rather than waiting 10 days for a doctor's appointment or something because it's perhaps none urgent but it's something just to put your mind at rest"* (Participant 16).

> *"And it does give me confidence, there is somebody at the end of that machine, if there is a problem I can ask"* (Participant 3).

> *"Ermm this programme, everything is on there that you need to know and you've got the back up from the doctors at the hospital if you need it…. Ermm and the backup is there, you can e-mail the consultants with any queries or questions"* (Participant 6).

Participants also viewed the contact with healthcare professionals positively as they felt that they were being attended to. It appeared that participants enjoyed seeing that someone was taking an interest and was concerned about their progress.

> *"It's nice to have contact with a person"* (Participant 4).

> *"So it's nice to have someone to talk to about that. But they were very helpful"* (Participant 15).

> *"I thought well at least somebody is giving me some attention (laughs)"* (Participant 4).

> *"Contact is very important and if people have that contact then there are less walls you know. Errr its always a good thing is contact and speaking to people, its very very good"* (Participant 10).

> *"It's nice to know that somebody is taking an interest"* (Participant 11).

Participants expressed how they enjoyed the chat room and one participant described it to be the best part of the programme. Another participant explained that the chat room was helpful as he is usually the type of person who avoids making GP appointments and the programme provided him with an opportunity to speak to a health care professional without him feeling guilty for wasting GP time.

> *"I did enjoy the chat room as you know. Erm I that extremely helpful… I think the best bit for me was the chat room, I did enjoy that"* (Participant 3).

> *"Ermm and the nurses were very good, and I thought it was a very good idea the Wednesday night thing… I think that's very good for people because if anybody is like me I always think that if I go to the doctors they think that I'm wasting their time"* (Participant 15).

> *"And it's been very good to be able to contact the nurse on a Wednesday and I thought that was a brilliant idea because although I didn't have any particular worries I did ask about my heart beat and they said to see my doctor"* (Participant 15).

The participants also found that the programme was easy to use and follow.

> *"No, it is quite straight forward and it's easy to find your way around and navigate around"* (Participant 1).

> *"Very easy to use, for somebody who is not very good on computers it was very easy"* (Participant 6).

> *"It is simple enough for me to use so it's simple enough for anybody to use that's the way I look at it"* (participant 6).

> *"It's easy to understand, it's very easy to find your way about…there was nothing I found difficult or awkward it was all straight forward so I was pleased and happy with it…I'm not particularly brilliant on a computer, but I didn't have any problems with that"* (Participant 13).

Participants identified other facilitating factors related to practical convenience and the fact that they could access the programme at any time.

> *"Because you can go and sit down at any time of day you can find out what you want to find out"* (Participant 1).

> *"You don't have to do it at any particular time or any particular day. You can please yourself when you do it"* (Participant 10).

> *"It was readily available…..You just log on and it's there"* (Participant 12).

> *"And the other thing I suppose is if you're not quite sure or you think was that right? You can go back and check it. So err there is the availability"* (Participant 13).

> *"I thought it was very good because what it does do is to make it totally accessible, at a time when you want to look at it. You're not, there is no restriction there…It is totally accessible, I mean the laptop is there you can use it whenever you want can't you"* (Participant 13).

> *"I mean it wouldn't make a difference whether I wanted to go onto that site at 9 o'clock in the morning or at midnight so I could go on whenever I like and I think that's the biggest advantage of it if you're going somewhere to a class or if you're getting some information through literature or you're going to a meeting or, it's at a specific time but with that it's at your finger tips whenever you want it"* (Participant 13).

"Errmm the idea I think is excellent, (pause) the fact that you can do it in your own time" (Participant 11).

An element related to convenience was that there is no need to travel as the programme was home-based.

"A lot easier, a lot easier than having time off to go to the hospital, sit around waiting to see the consultant, doctor nurse or whoever" (Participant 6).

"It can be done whenever without having to go and make an appointment to attend somewhere so from that point of view it's ideal" (Participant 8).

"Err there is not a need to go into the hospital or some other place and carry out the exercises I can do it on my own err you know when it suits whether it be first thing in the morning, afternoon or evening" (participant 8).

"You don't have to traipse down to the library to get a specific book or make an appointment to the doctor, or every time you've got a query or question" (Participant 12).

"Well you come home you log on and you use it…You don't have to make appointments to the doctors or ermm get the information elsewhere" (Participant 12).

It appeared that a sense of self-motivation was required in order to complete the programme. This was largely due to the programme being carried out independently and consequently there was a requirement to be self motivated. One participant described that being concerned about his condition gave him additional motivation to carry out the programme.

"I'm the sort of person that will try and keep that up anyway but erm I don't intend to give it up I don't see it as a flash in the pan I see this as what I've got as a possible life threatening problem so why would I give up. I will carry on I mean none of us want to die do we so or I might not die from it, but I might have a heart attack or stroke I mean I don't want that either particularly" (participant 13).

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"I have not sort of sat back and said you know I've got a bad heart I can't do this and I can't do that. And I know people who have done, they've said oh that's it I'll never work again, you know. But if you take that attitude you're not going to win, you're going to sit there, you will get fatter and unhealthier and you're heart is going to get weaker. So you know I've always said I'll teach it a lesson for letting me down (laughs)" (participant 6).

Interviewer: *And so what did you think about doing the internet-based cardiac rehabilitation programme?*

"Yeah, its, you have to stick at it you know. I think you have to dedicate yourself to it……I think you've got to want to do it…ermm on your own there is nobody there to jeer you up" (participant 5).

"Yes, its good for them as long as they're thinking of the angina has made some affect on them, as long as its got them thinking then yeah the programme is fine….you've got to do what it tells you…but yes it would have been, if the person was worried then its good" (Participant 14).

In addition, participants described how they felt a need to take the programme seriously and to be honest when completing the exercise diary. This was mainly due to the fact the programme was carried out independently and therefore required users to be serious and disciplined when using it.

"But its if your that type of person, because it is, because the programme they are relying on, they are relying on you to be honest and do everything correctly and do things religiously and that's the only difference in that and seeing somebody or the doctor at the hospital" (participant 1).

"You've got to take it seriously to benefit from it, or you wouldn't gain anything if you cheated it" (Participant 1).

"There is a temptation to cheat you know but I didn't do that I did what I did" (Participant 15).

In the participants' view those who approached the programme with a positive attitude benefited the most from it.

"I think the vast majority of people who err positively approach the programme would benefit from it" (Participant 8).

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This theme focuses on the difficulties experienced when carrying out the programme and therefore highlights potential intervention barriers. One difficulty described was an inability to commit to the programme due to home and family responsibilities. Home and family commitments are obstacles which need to be considered when negotiating the feasibility of rehabilitation. One participant explained that she could not fully commit herself to the programme as there was a need to constantly look after her husband. She explained that changing her diet was difficult as their meals were dictated by what her husband wanted to eat and therefore it was difficult to cook separate meals. Similarly, the participant explained she could not carry out exercises easily as she had to consider her husband's needs and plan accordingly:

> *"But it's difficult because I'm not in control, everything I do I have to think of him first, so I can't go out in the car and go and walk somewhere nice because I'd be away too long. It's not easy"* (Participant 4).

> *"I've still got to feed him and he's fussy, so short of doing 2 separate meals is no way I can so I probably don't do as well with the low fat as I should do but then we don't have fatty things. He has the cakes and my son as well he's another one because he keeps bringing things that he shouldn't be"* (Participant 4).

Participants also described the difficulty of scheduling exercise to fit in with employment. However, some participants did find it possible to schedule the required exercise for instance one participant talked about the exercise goal of 30 minutes being appropriate for her situation as a single working mum, and another felt that he was able to achieve the 30 minute goal within his working lifestyle:

> *"I'm doing, I'm trying to do half an hour physical, really physical exercise per day. Whether I do it in one burst or 2 or 3 separate burst it just depends when I get the time, and because I'm still working quite a lot it's just fitting it in that's the only, that's the*

hardest part of the programme was actually doing the exercise after you've done a hard day's work" (Participant 6).

"I think exercise as I've already explained takes quite a bit of time up each day….because you sort of do it when you come in at night" (Participant 13).

"If you say you've got to do 1 hour per day, an hour for a single working mum you think where am I gonna fit that hour in my day whereas 30 minutes say if I have a lunch break I can go for a walk for 30 minutes because I only have a hour an hour lunch break, that's achievable" (participant 12).

Weather was also discussed as a barrier to the programme. Participants felt the winter months caused restrictions when engaging in outdoor exercise, and explained how much easier it was to exercise during summer months. These perceptions are illustrated:

"It was the wrong time of the year I mean if it had been another 6 weeks from now, it was all that awful weather so I was trying to walk around in the ice and snow and goodness knows what, and it was cold (laughs)" (Participant 4).

"I do think that it will become more difficult in the winter months as I said a few minutes ago ermm I errm (pause) I think everybody finds it more difficult to go outside and do something when its freezing cold and snowing. When the sun is out and its nice and bright its easy isn't it" (participant 13).

There was also a view that the programme was more suited to a younger age group:

"I think it's like I said before I think sometimes I think it's geared to people who are younger who are middle aged rather than 70s you know" (Participant 4).

A participant explained as he gets older he is more content with his health and therefore focuses on it less:

> *"Well yeah, I don't want to have to start changing my lifestyle to accommodate a programme, I want to maintain what I've been doing for 70 odd years"* (participant 7).
>
> *"And sometimes I think its psychological you know if you've got to push yourself younger yes I think you can get away with it but I think when you get into your 70s you've got to be realistic and sensible, because all the parts are starting to wear a little bit and they're starting to slow down. And if you start putting too much effort onto them then all of a sudden they're going to tell you something"* (participant 7).

These comments may suggest older individuals are more reluctant to make behavioural changes. A participant explained that the programme might be difficult for an older population as this group might not have access to the internet, although it was acknowledged that an increasing number of older people are using the internet and, therefore, this issue may prove a temporary one:

> Interviewer – *"You mentioned before that you are a confident user of the computer so that wasn't an issue that fact that the programme was online"?*
>
> Participant: *No, no no no it might be for some of the older folk undoubtedly there are still some folk who are anti (laughs)......but I think as you go on more and more of the people you'll be dealing with are computer literate err people in their 40s and 50s certainly will be now I think errr I think the 70s and 80s might still be a bit err (laughs) dodgy with err if they've got computers at all some of them* (Participant 8).

Other comments were made regarding the timing of the programme. There was a general consensus that the participants would have benefited more if the programme was received nearer to the time of diagnosis and/or when the stent was fitted. One participant expressed that if he had this programme earlier then his subsequent problems might not have occurred and the stents might not have been necessary. In addition, a participant described that he had been diagnosed approximately 6 years

and thus had established a routine and was aware of how to manage his condition.

These examples are outlined below:

> *"It would have been just what I wanted in the aftermath of having the stent or even before I had the stent from the time I went to the hospital and they'd said I'd got angina"* (Participant 14).

> *"It might be good to catch the people when they just had it done, rather than 3 years later"* (participant 15).

> *"Perhaps a lot of my subsequent problems with stents and things might not have been necessary if I had had a programme at that stage. This is difficult to tell but err we err feel that there is a need for more…there is a need for more physiotherapy immediately after err the op and more encouragement at that point"* (Participant 8).

> *"I thought the programme was probably more useful to people who had had a heart condition attended to more recently as you know I'm 6 years down the line……I'd already got into a routine because I'd been on this for 5 or 6 years now, I'd already got into a routine"* (Participant 16).

7.4 Discussion of the qualitative findings

This study contributed considerably to the main aim of this doctoral research project: evaluating the new web-based CR programme. Utilising a qualitative method ensured participant experiences of using the programme could be explored thoroughly and perceptions of the programme examined in depth. The design of the study was thus a key strength as it allowed a thorough and in-depth exploration of participants' experiences of using the programme. Overall the qualitative data revealed improvements made as a result of using the programme, factors which facilitated programme use, and the challenges facing programme engagement. In this section, the findings will be discussed and related to the previous literature. The limitations and implications specific to this qualitative study will also be described. The way these findings fit with the RCT study will be outlined in chapter eight: the overall discussion.

7.4.1 Study Findings

The first theme outlined was 'self-reported improvements'. This theme illustrated the programme was beneficial with regards to increasing exercise, improving diet, addressing psychological responses to the illness and managing angina symptoms. The exercise related improvements consisted of increased exercise which helped to provide more structure to daily routine, increased energy and improved exercise capacity. There was also evidence of improved dietary habits. The psychological improvements consisted of increased health and exercise related confidence, increased motivation to improve self-management of angina, feeling healthier, feeling more positive, and worrying less. Furthermore, there were improvements in symptoms of

angina, less reliance on medication and improved management of symptoms. This finding was encouraging as it illustrated the intervention's value in terms of improving lifestyle related cardiac risk.

The second theme illustrated the programme components perceived to be helpful. Participants talked positively about specific intervention components; the comprehensiveness of the programme, tailoring aspect, exercise diary, end of stage quiz, contact and support from the cardiac specialists and ease of using the programme. Further, programme feasibility was evident as participants described the convenience of accessibility from home with no time or location restrictions. Programme use was also influenced by psychological aspects; self-motivation and approaching the programme positively. This indicated those who were self motivated and approached the programme positively demonstrated higher levels of programme engagement. Overall this theme illustrated the programme features, home-based convenience, and self-motivation levels were important in actively engaging with the programme.

The third and final theme was labelled as 'programme barriers', this theme illustrated the challenges such as family and work commitments, bad weather, older age, and receiving the programme late in angina diagnosis negatively affected programme use. This theme therefore highlighted the factors that restricted full engagement with the programme.

7.4.2 Comparison with Previous Research

This qualitative study contributed considerably to the research literature on internet interventions for those with CHD. To date two other studies have used qualitative approaches to explore the views of those with CHD using web-based interventions (Kerr et al. 2008, Zutz et al. 2007). Kerr et al (2008) conducted user evaluations of an online programme designed for those with CHD using a focus group method and similar to the present study, Zutz et al (2007) carried out semi-structured interviews alongside a trial evaluating a web-based programme. The findings of both Kerr et al (2008) and Zutz et al (2007) are, however, somewhat limited as neither reports show evidence of an in-depth exploration of how acceptable or feasible a web-based intervention is for a CHD population. Kerr et al (2008) outlined participants' feedback regarding specific recommendations related to the intervention evaluated. The study did not elaborate on how participants felt regarding feasibility or acceptability of the intervention, and instead made intervention development recommendations. Additionally, the qualitative nature of the findings reported by Zutz et al (2007) is debatable. A thorough and in-depth qualitative exploration was not provided even though semi-structured interviews were carried out. In contrast, data was reported numerically, participant ratings for the intervention components were reported in percentages and three participant quotations were used to illustrate positive feedback. Therefore, unlike the present study, neither Kerr et al (2008) nor Zutz et al (2007) provided an in-depth analysis of participants' views regarding the acceptability or feasibility of using an online programme. Consequently, this study has extended the current literature. Furthermore, this is the first study to incorporate a mixed methods design, in which both a quantitative and qualitative study made an equal contribution towards evaluating a web-based programme for those with CHD.

Other non-traditional CR programmes have been evaluated using qualitative methods. Similar to the broad mixed methods design of this study Jones et al (2009) and Wingham et al (2006) conducted a qualitative study alongside an RCT comparing a home-based CR programme (The Heart Manual) with hospital-based CR. Jones et al (2009) conducted two focus groups among those receiving home-based CR and consistent with this study participants reported increased knowledge and understanding of CHD and their confidence to exercise. Similar to the current findings participants in Jones et al (2009) placed value on the availability, convenience, and the comprehensiveness of the home-based programme. This study generated comparable themes. Given that both studies examined the experiences of those taking part in a home-based CR programme the similarities in findings are somewhat unsurprising. In addition, the current findings are consistent with Wingham et al (2006), who qualitatively examined the factors influencing participants' choice of receiving either home-based or hospital-based CR. The study reported those choosing home-based rehabilitation were self-disciplined, similarly, participants in the current study also described levels of self-motivation to be important when engaging with the programme. However, this study progressed from previous research in two ways. Firstly, this study examined an internet-based approach to home-based CR and secondly a different CHD population was examined; a primary care angina population. Whilst Jones et al (2009) examined post MI, PTCA and CABG populations and Wingham et al (2006) examined a post MI population.

In the present study participants described self-motivation as important in being able to fully engage with the programme. Interestingly, this theme was reported by Jones et al's (2007) in a qualitative study which described a lack of self-motivation as a reason for not adhering to home-based CR (The Heart Manual). The similarity

between studies is interesting given the subtle differences in study purpose. The purpose of this study was to explore the experiences of programme users while Jones et al (2007) set out to examine the views of those not adhering to the programme. This consistency in findings further emphasises the importance of self-motivation of those taking part in home-based CR. The high importance of self-motivation is reasonable considering home-based CR is largely self directive, and therefore requires participants to take responsibility of their own behaviour change.

An interesting finding was participants described work and family commitments as difficulties preventing full engagement with the programme. This finding is consistent with the challenges assigned to low uptake of hospital-based CR. Quantitative reports describe these factors as obstacles to taking part in hospital-based CR (Jackson et al. 2005, Kerins, McKee and Bennett 2011). This finding is somewhat surprising when related to home-based programmes as an assumption is that they can be accessed whenever convenient for the user and thus presumably more suited for those with time constraints. This finding also contradicts the descriptions of the programme being convenient and accessible by participants in the current study. Reasons for this contradiction are unclear and more research is required.

When the wider literature is explored it appears that other populations also report work and family commitments as barriers to PA. Casey, De Civita and Dasgupta (2010) carried out focus groups amongst a type 2 diabetic population who had participated in a 24 week supervised exercise programme facilitated by an exercise physiologist. Consistent with the present study Casey et al (2010) describe work and

family responsibilities as barriers that hindered participation in the programme. Weather was also found to be a factor that impacted participation in the intervention, good weather was described as having a positive influence in encouraging exercise behaviours. Other evidence has been provided by Korkiakangas, Alahuhta and Laitinen (2009) who conducted a systematic review that examined exercise barriers in those at risk or already diagnosed with type 2 diabetes. This review included 13 studies and reported that in this population work and home duties, and bad weather were barriers to engaging in PA. Another consistency between the present study and Korkiakangas et al (2009) is levels of self-motivation were reported as a factor affecting exercise. Participants in the present study also perceived levels of motivation as important in being able to actively engage in the programme. Research conducted by Casey et al (2010) and Korkiakangas et al (2009) illustrate that barriers to PA described in the present study were also common issues in type 2 diabetes. It is also interesting that similar issues are reported in non-diseased populations. Buman et al (2010) interviewed 8 men and 9 women with a mean age of 55.76 (SD=6.03) who were physically inactive but free of disease or any disability preventing activity. Participants were recruited from a large university in the USA and reported barriers that took priority over exercising included childcare, work demands, caring for an older parent and studying. Taking together the findings of studies conducted in both diseased and healthy populations it appears that practicalities of life and time management are common issues and barriers to exercising across other populations. This suggests that programme users should be offered advice on how to overcome these barriers prior to taking part in the programme.

Importantly, participants in the present study placed high value on the communicating with healthcare professionals, which was available through the e-mail and chat room facility. This supports previous reviews carried out by Webb et al (2010) and Vandelanotte et al (2007) which reported communication components in online interventions is beneficial. A speculation is the communication with cardiac professionals increased 'perceived sense of support', as participants in the current study expressed the contact from healthcare professionals led to them feeling supported and reassured.

7.4.3 *Study Limitations*

This study had some limitations. Firstly, there is a need to consider that the participants recruited to this study were enthusiastic users of the intervention as they displayed a high level of both intervention use and adherence. Fifteen of 16 participants completed at least 75% of the intervention and logged onto the programme on average 5 times per week. This highlights that the sample recruited were a highly motivated group. In future research it would be useful to interview non-enthusiastic or less motivated participants to examine differences in experiences and perceptions.

There is also a need to consider my role as the researcher within this study. I had prior beliefs that this programme was worthwhile and felt positively about its impact on patients. These beliefs may have influenced the data collection and analysis in terms of the questions asked, how they were asked and how data and findings were

interpreted. Incorporation of strategies, such as, peer review of the data analysis process and keeping a reflective journal would have increased the rigour of the findings.

7.4.4 Clinical Implications

The theme of 'self-reported improvements' suggests that this programme could be offered to patients to help stimulate improvements in their level of cardiac risk. Specifically, the programme could be offered to those who require assistance in improving exercise and dietary habits. The programme could also be offered to those requiring help in managing their angina symptoms. In addition, the psychological improvements reported by participants indicates that the programme may be beneficial to those requiring psychological support. For instance the programme could be offered to those at post treatment stage when anxiety levels are high and confidence levels are low.

The theme 'programme facilitators' revealed the aspects of the programme participants valued; comprehensiveness of the programme, tailoring aspect, exercise diary and the end of stage quiz. Future developments of the programme should continue to comprise these components. Participants also valued communication and contact with healthcare professionals highly, the contact from cardiac specialists created a feeling that someone was interested and concerned about progress being made on the programme. This indicates that CR clinicians should maintain

interaction and communication with patients as participants highlighted this aspect of the programme.

Self-motivation and approaching the programme with a positive mindset were factors described to facilitate higher levels of engagement with the programme. This has considerable clinical implications to consider when recommending or referring this population to a web-based CR programme. Incorporating regular motivational assessments and positive messages in the intervention would help to address this need. In addition, when patients are referred or recommended to the programme it should be introduced positively with the aim to get participants enthusiastic and raise morale before joining the programme. A suggestion is those with particularly low levels of self-motivation could be offered motivational interviewing.

The theme 'programme barriers' also has considerable clinical implications to take into account. Participants had difficulties engaging with the programme due to family and work commitments. There is a need to be aware of this when referring patients with these commitments and responsibilities. These patients may require additional assistance in terms of providing advice and guidance on how to overcome the challenges faced.

In addition, participants expressed that bad weather restricted their ability to carry out outdoor exercise. Thus, the time of year may be a factor to consider when referring patients to the programme, patients may benefit more from the programme if referred

in summer months. There is an additional need to consider the timing of when the programme is offered to patients. The intervention may have higher impact if referred to those with a more recent angina diagnosis.

Further, participants viewed the programme as being more suited to those who are younger. This implied a possibility that older patients might not perceive the programme as entirely relevant for themselves and instead perceive it as more suited to those who are younger. This indicates care should be taken when referring the programme to older age groups. Healthcare professionals should emphasise that the programme is not limited to younger age groups.

7.4.5 *Chapter Summary*

It appears participants benefited from the programme in terms of making positive lifestyle changes, psychological changes and improved angina symptoms. Additionally, certain intervention components such as comprehensive information, personally tailored aspect of the programme, exercise diary, end of stage quiz, ease of using the programme, and the online chat room were spoke about in a positive light. Participants also valued the flexibility and convenience of the programme. Overall these findings suggest the programme could be offered as an alternative option for those unable to commit to tradition rehabilitation. However, there is a need to consider the challenges to programme engagement; family and work commitments, bad weather, older age, and receiving the programme late in angina diagnosis. In addition, the findings suggest self-motivation levels are important in terms of programme engagement. These issues should be considered when referring patients

to the programme.   The way these findings link with the quantitative study in this thesis are described in the final discussion, chapter 8, section 8.3.

CHAPTER 8

OVERALL DISCUSSION AND FUTURE RECOMMENDATIONS

This chapter begins with a summary of how this study contributes to the broader research literature. The overall main findings are then summarised. This is followed by a description of how the quantitative and qualitative findings integrate together. An account of how the observed effects may have been achieved is then provided. This proceeds with an outline of the study strengths and limitations. Broader challenges with web-based interventions are subsequently described. Study implications are described and recommendations for future research are made. A conclusion of the entire thesis will follow on from this.

8.1 What Does This Study Contribute to the Research Literature

The originality of the study ensured a unique contribution was made to the current research literature. This is the first study of web-based interventions for those with CHD to adopt a mixed methods design to explore both intervention effectiveness and feasibility. It is also worth acknowledging in the UK this is the first study to adopt a web-based innovative alterative to CR. Secondly, this study used an objective measure of PA and was therefore less subject to bias. Such an objective measure has not yet been used within CR studies, angina and secondary prevention studies or web-based CHD intervention research. Thirdly, this study recruited an angina population based in primary care; a population seldom included within rehabilitation research or practice and have so far not been included within internet-based intervention studies.

8.2 Summary of Main Findings

The broad study aims were met; examining the effectiveness and feasibility of the new online CR programme. An RCT design was employed to investigate the programme's effectiveness to improve cardiac related risk factors in the short and medium-term. This trial detected significantly favourable intervention benefits compared to a control group at a 6 week follow upon daily steps, daily EE, DDSA, DDMA, weight, self-efficacy, emotional QOL, and reduced angina frequency. The significant benefit of DDSA, DDMA, emotional QOL, and angina frequency were maintained at the 6 month follow up. Furthermore, there were significantly improved levels of anxiety observed at the 6 month follow up.

The feasibility of the new web-based CR programme was explored using qualitative methodology; semi-structured interviews. Qualitative data revealed favourable changes in terms of exercise, diet, psychological and angina symptom related improvements. Specific intervention components were perceived positively, these were the comprehensiveness of the programme, tailoring aspect, exercise diary, end of stage quiz, and the ease/convenience aspect. The contact and communication with healthcare professionals via the chat room and e-mail link were also valued. Potential challenges to the programme were as follows; family and work commitments, bad weather, older age, receiving the programme late following the diagnosis of angina and levels of self-motivation.

8.3 Bringing both Quantitative and Qualitative Findings Together

The use of mixed methods was a strength of the study. Employing both an RCT and semi-structured interview design was helpful in examining the effectiveness of the programme while also exploring participants' experiences of the intervention with in-depth exploration analysis. Previous studies of home-based CR employed similar methodologies. Both Jolly et al (2007) and Dalal et al (2007) also evaluated home-based CR with an RCT that incorporated an embedded qualitative component, exploring issues pertinent to the different interventions. The current study examined a new innovative approach to rehabilitation and focused on specifically those with angina.

The trial design allowed us to suggest that a web-based approach improves overall PA, self-efficacy, weight, emotional QOL and angina symptoms at the 6 week follow up. These improvements were apparent in the qualitative data. The qualitative theme of 'self-reported improvements' confirms the statistically significant benefits reported revealed within the RCT findings.

The theme 'programme facilitators' derived from the semi-structured interviews provides a deeper understanding and possible explanations for how the significant intervention benefits reported from the RCT were achieved. This theme is important as the RCT generated effectiveness data with no insight of how the programme was effective. In this sense, the qualitative data was valuable in providing an understanding of how certain programme features were useful in achieving the effects and thus provides some explanation for the trial findings. Participants described that the following intervention features were important, comprehensiveness of the

programme, tailoring aspect, exercise diary, end of stage quiz, the ease/convenience aspect and contact and communication with the cardiac professionals. Level of self-motivation and interest in the programme were also viewed as helpful when engaging with the programme. Therefore, the intervention components and personal characteristics (levels of self-motivation and interest) appear to be important and can help to explain how the significant benefits were achieved.

There was a disparity between the qualitative and quantitative findings in that during the semi-structured interviews participants spoke about improvements to their diet and reduced levels of worry. However, any impact on diet was not present within either short or medium-term quantitative data. Similarly, the benefit upon anxiety was not present at post intervention follow up. This is interesting as it illustrates the participants perceived the online programme to favourably affect dietary habits and anxiety levels, but this was not confirmed with the quantitative data. However, the non-significant finding is equally important as it suggests that although improved diet and anxiety were found in the qualitative study, the benefits were not sufficient to be shown statistically significant. Therefore more research may be required to investigate how a dietary change can be supported. One possibility is the dietary advice on the programme should be improved, and perhaps a longer intervention period would result in improved diet outcomes. This discrepancy highlights the value of mixing methods as in this case the qualitative data was able to detect an improvement made as a result of the programme that was undetected within the quantitative data. There is also a need to consider that the disparity between the qualitative and quantitative findings may have been due to a case of 'selection bias' in the qualitative sample. It is likely that those willing to be interviewed and share

feedback were more enthusiastic and engaged with the programme than those less willing to share feedback.

Importantly the qualitative findings provided data regarding challenges to fully engaging with the intervention; the theme labeled 'programme barriers'. This demonstrates while significant intervention effects were present within both sets of data we should still consider that patients may face some challenges to engaging with the intervention. Difficulties around family and work commitments, bad weather, older age and receiving the intervention late within angina diagnosis can prohibit intervention use. There is a need to be conscious of these factors that were clearly perceived as barriers to fully engaging with the programme by participants. This again emphasises the value of the qualitative study within this project as without the qualitative data information regarding programme barriers would otherwise been left unknown. Even though the intervention was found to be effective there is a need to consider the barriers to programme use. This is especially important for intervention implementation as it highlights those patients that may face challenges and therefore may require more assistance.

8.4 *What Caused These Effects?*

It should be acknowledged the present study did not measure the value of each intervention component contained in the programme. The intervention comprised multiple behaviour change techniques and therefore it was impossible to determine the impact of each. However, speculations regarding the importance of each intervention component/strategy and its impact in stimulating improvements can be made.

One programme feature was 'tailoring' in the form of tailored goal-setting and tailored secondary prevention advice. Since tailoring is *'customised health information to match select characteristics for each person'* it attracts more attention than general information as it is perceived as personally relevant and meaningful (Nguyen et al. 2004). Nguyen et al (2004) suggest participants invest more effort in interventions that are tailored, which consequently leads to greater improvements. The use of tailoring to be successful in web-based behaviour change interventions has been reported in improving PA (van den Berg, Schoones and Vliet Vlieland 2007) and smoking cessation (Civljak et al. 2010).

The programme comprised a 'self-monitoring' feature, which previous research indicates to be important in modifying levels of PA. Self-monitoring was inbuilt in the programme's online exercise diary. Ferrier et al (2011) reported self-monitoring of PA within home-based CR programmes to be associated with favourable PA improvements. The reason given for this is the notion that self-monitoring helps create feelings of empowerment and perceived control which in turn leads to PA improvements (Ferrier et al. 2011). This is supported within the research literature. Furber et al (2010) demonstrated favourable impact upon PA following a home-based CR programme that comprised this self-monitoring component. Aldcroft et al (2011) endorses this, and reports this technique influences PA change within CR programmes. However, the value of self-monitoring may be questionable as a recent meta-analysis showed this technique was associated with small or no significant impact upon behaviour (Webb et al. 2010).

The communication with cardiac professionals through the e-mail and chat room facilities may have contributed to the significant improvements detected. This is consistent with reviews carried out by Webb et al (2010) and Vandelanotte et al (2007) who report the effectiveness of web-based interventions is enhanced with increased communication. A speculation is the communication with cardiac professionals in the current intervention increased 'perceived sense of support' which in turn resulted in the observed significant benefits. This was evident within the qualitative findings, participants expressed that communication with healthcare professionals led to them feeling supported and reassured. However, whether or not this communication increased support is unknown as data regarding chat room/e-mail link usage was not available and 'perceived sense of support' was not measured.

Past research consistently demonstrates 'goal-setting' is an effective feature used in web-based interventions (Ramadas et al. 2011, Webb et al. 2010). Goal-setting has been described as a successful technique in modifying PA in both hospital-based (Aldcroft et al. 2011) and home-based CR (Ferrier et al. 2011, Furber et al. 2010). The 'Goal-setting theory' can help to provide a clearer understanding of why this strategy is useful (Locke and Latham 2002). This theory states that goal-setting helps to achieve behaviour change via 4 mechanisms; increased attention, effort, persistence and motivation. When goals are set both the attention and the effort invested in achieving the desired outcome increases. Goal-setting also increases persistence, particularly for harder goals the effort invested in achieving the goal is prolonged. The fourth mechanism is that goal-setting increases concentration and motivation invested in behaviour change.

Adopting a 'stage-based' approach is likely to support progress through the website as it may create the impression that the intervention is more manageable and the participant may feel satisfaction once reaching the end of a stage. In the current intervention participants were congratulated at the end of each stage. Even though the stages were not mapped onto any stage-based theory of health behaviour change this may have contributed to the significant intervention benefits. Murray et al (2008) state that an advantage to web-based interventions is information can be given to participants in small accessible stages so that they are not overwhelmed with vast amounts of information. Therefore simply splitting the intervention in stages may have created a feeling that the programme was more manageable.

This section described how the following intervention strategies may have contributed to the favourable intervention improvements; tailoring, self-monitoring of PA, communication with healthcare professionals, goal-setting, and stage based delivery. It is unlikely that one individual strategy/component was solely responsible for the intervention effects. It is more likely that the combination of components caused the improvements observed. Murray et al (2005) state the exact mechanism underlying web-based interventions effects are unclear, and postulate that a combination of intervention strategies is required. This was reiterated in a meta-analysis carried out by Webb et al (2010) who reported that web-based interventions incorporating more behaviour change techniques result in larger improvements than those with fewer techniques, implying that more than one technique is required for intervention effectiveness.

8.5 Study Strengths

The originality of the study was a key strength; this has been described previously in this chapter within section 8.2. The study had a high level of internal validity. Randomisation of participants to study groups ensured that the influence of confounding variables was equally spread in both groups and the influence of selection bias was eliminated. Additionally, the same researcher introduced all intervention group participants to the web-based CR programme, ensuring all participants received the same programme introduction. The use of the objective measure of PA also increased validity as the potential biases present in self-report measures were eliminated. The overall low dropout rate was an additional strength, dropout rate was only 11% at the 6 week follow up and 22% at the 6 month follow up. Further, all participants were included in the data analysis regardless of intervention adherence; this is a strength considering that overall 60% of participants did not complete the entire intervention.

A reasonably large primary care sample was recruited within the location, time and funding restrictions of this PhD study. The location was restricted to Coventry and Warwickshire and to a fairly timely schedule with no additional funding allocation to support GP practices. Associated with this was the strength of recruiting participants via NHS primary care GP practices. This ensured all participant details and angina diagnoses were genuine. For instance if participant recruitment was carried out solely online the authenticity of participant characteristics may have been questionable. Though, it should be acknowledged that whether these findings can be replicated in an uncontrolled entirely web-based set-up is debatable. There is a possibility that the

face to face contact with the researcher could have increased compliance and adherence to both the trial and the intervention.

8.6 *Study Limitations*

Limitations to this study should be acknowledged. It was not possible to blind the researcher to data collection as this was a PhD project and thus all field work was carried out by one researcher.

The sample employed was self-selected motivated volunteers. It should be acknowledged that those who volunteer for research studies often differ from those who do not volunteer, creating volunteer bias. The sample recruited was ethnically homogeneous (White British), thus limiting the generalisability of data to other groups underrepresented such as those from ethnic minority groups. It may also be difficult to generalise RCT findings more broadly to other populations (such as those excluded by the study exclusion criteria) and therefore external validity may be lacking. It should also be acknowledged that only 15.5% of those invited to take part went on to join the study. This further limits generalising the findings as only a small percentage of participants joined the study and therefore may not be entirely representing the broader angina population.

An issue to consider is 'measurement reactivity'; where 'measurement results in changes in the people being measured' (French and Sutton 2010). Even though the study measured PA objectively there still remains the possibility that participants may have adjusted behaviour whilst the activity monitor was worn. It could be argued that if measurement reactivity was present then this would be the case in both groups and

at each measurement occasion. However French and Sutton (2010), state that the precise circumstances that result in measurement reactivity are still unknown. Due to the current lack of understanding it is unknown whether measurement reactivity occurred equally across both groups and at each measurement occasion. A speculation is that measurement reactivity was perhaps similar across both groups at baseline but there was a stronger influence in the intervention group at follow up. The reason for this is because the intervention group had been encouraged to do more PA, whereas the control group had not. Therefore it is plausible that measurement reactivity was present in the intervention group at the 6 week follow up, while this was not the case in the control group. This may have contributed towards the short term intervention effect.

Another limitation is that the study relied on GP practice staff to generate a list of patients that met the inclusion and exclusion criteria. Depending on each individual GP this was either carried out manually or electronically. Practices doing this manually went through a list of stable angina/ PTCA patients and used their own knowledge of each patient to make a judgement as to whether the patient met the other inclusion and exclusion criterion. Other practices carried out electronic searches, using electronic search codes to generate patient lists. There was an entire reliance on the GP practice to carry out this task. A limitation is that it is unknown how accurate or precise each practice was in applying the exclusion and inclusion criterion. However it should be acknowledged that the researcher carried out an initial screening of potential participants who took an interest in the trial to further ensure participants consenting to the study met the inclusion and exclusion criterion. This screening was carried out prior to taking study consent.

Missing data among the questionnaire measures were due to either participant withdrawal or when questionnaires were returned with individual items missing. Some loss of data due to these two reasons was inevitable, and therefore only available data was used in the data analysis. However, missing data due to participant withdrawal was not treated as a huge issue, as the dropout rate was only 11% at the 6 week follow up and 22% at the 6 month follow up. However, there was missing PA data due to participants not adhering to wearing the PA monitor for the required time period. Due to the issue of missing PA data it was decided to use data for 2 week days chosen at random at each measurement point. It was decided to use week day data only as prior research indicated there to be a difference between weekdays and weekend days in activity levels (Tudor-Locke et al. 2004b). Therefore participants' week day PA data was used as prior research indicated this to be more stable activity compared to weekend days. It later became apparent that excluding weekend day data meant the legitimacy of claiming the data to represent a weekly average is questionable. This is for the reason that data which is known to alter the weekly average was not used. Weekend day data, which is known to have different PA levels to week day data would have altered the weekly average. Therefore it is not possible to claim that the data represented a weekly average of PA. In hindsight it would have been better to include both weekday and weekend day data. Future, larger trials of the intervention should take this into account.

Finally, demand characteristics should be considered when interpreting the findings. Demand characteristics have been defined as 'the qualities of a particular experimental setting that simply, by nature, invite certain kinds of behaviours' (Reber, Reber and Allen 1985). Those in the web-based CR group were following an

intervention which encouraged more PA, while the control group did not. Intervention group participants may have interpreted the experiment's purpose and changed their behaviour to fit that interpretation. This issue was not equal across both groups. Instead the control group were instructed to continue with their usual activities. Thus the demands being put on each group were very different. It is possible that those in the intervention group aimed to please the researcher in light of what was being asked and consciously made a choice to wear the monitor during their more active days. Whereas this issue was not present in the control group as there were no such demands being placed on the control participants. This issue could be reduced in future trials by comparing the web-based CR programme with an attention placebo control group. The attention placebo control group would receive an online information only website and the experimental group would receive the web-based CR programme. Therefore, effectively both groups would receive an intervention. This would help to equalise the influence of experimenter demands across both groups. The inclusion of an attention placebo control group would also make it possible to blind participants to group allocation.

Our assumption in our sample size of a difference of 3501 steps (based on Tudor-Locke et al, (2004a) proved to be overly optimistic. As such (although we over-recruited) this study was under-powered to detect the observed difference and further work with larger samples will be needed to confirm the positive benefit.

8.7 *Challenges with Web-based Interventions*

There is a need to recognise the current challenges with web-based interventions. The 'digital divide' is a reason why the use of internet interventions in healthcare may be

viewed negatively. This is the term used to refer to the divide between those who have access and use the internet and those who do not. The Office for National Statistics reported high equipment/access costs and lack of skills constituted a few of the reasons why households in the UK did not have internet connection in 2008 (Natitional Statistics 2008). This could therefore increase health inequalities between those with and without internet access. However, this is debatable. Recent internet usage statistics reported that approximately 73% of UK households in 2011 had access to the internet (Dutton and Blank 2011). Additionally, there is evidence of internet usage growing as the percentage of Britons who had never used the internet decreased from 28% in 2009 to 23% in 2011 (Dutton and Blank 2011). Furthermore, the report outlined that the retired population accessing the internet increased from 34% in 2009 to 37% in 2011 (Dutton and Blank 2011). The growth in internet use among this population is encouraging given that it is generally older adults or elderly that require interventions for long term conditions requiring self-management and self-care. However this issue is only a temporary one, and will inevitably disappear given the evolution and rapidly growing use of this technology. Aside from this a 'one size fits all' strategy is not realistic as all patients have different needs and requirements and therefore being able to offer some patients internet-based alternatives is useful.

Murray et al (2008) describe an ethical issue of false, misleading information or misinterpretation of accurate information may result from internet interventions. Murray et al (2008) also describes a concern regarding the privacy of users and how information provided by users is used.

Online health interventions may also be viewed as 'impersonal' and interventions carried out entirely online diminish the holistic personal nature of rehabilitation. An online version of rehabilitation thus may lessen the traditional interface held with cardiac professionals inherent within conventional CR. However this issue was addressed as the current web-based CR programme involved communication between participants and cardiac professionals via the e-mail and online chat room components. The programme also made efforts to personalise the programme to the user, in that each time the user logged into the website a welcome message addressing the user by their first name appeared.

Even though there are challenges with web-based interventions there are many advantages with delivering interventions via the internet. These advantages were described in full in the thesis introduction (chapter 1). Therefore, one should consider the trade off in terms of balancing and considering both the advantages and potential pitfalls with web-based interventions.

8.8 *Broad Study Implications*

This study demonstrated that this web-based CR programme is both an effective and feasible programme for those with angina in primary care, a population not routinely included within conventional CR. Therefore, this programme could be provided for a population usually excluded from traditional CR. This programme would thus provide an opportunity to include a wider range of CHD populations into rehabilitation services. Extending the reach of CR would increase the capacity of CR services. Even though this programme is yet to be studied in other CHD populations, the programme could be considered as an alternative to those unable to commit to a

conventional programme, therefore providing more choice within rehabilitation services once effectiveness has been established. A home-based version of CR also has the added advantages of convenience and accessibility for patients unable to travel.

Further as the programme is home-based it promotes independent 'lifestyle change' possibly more than centre based programmes. This enables healthcare providers to subtly shift the responsibility of self-care from the healthcare providers to the individual which allows patients to take/gain greater control over self-managing their own health. Through this health professionals can become more efficient providers of care. In addition, home-based programmes allow the possibility of involving the patients' partner, family, and/or carers who may be able to help engage the patient with lifestyle change.

An internet version of CR also has the potential to standardise the content of CR & secondary prevention advice. For instance the NACR report outlined the content of CR changes over time in terms of programme's level of comprehensiveness (NACR 2011). This is likely to be due to varying levels of funding and staff availability. A web-based programme could help to reduce this variability as programme content could be standardised, thus would not rely heavily on physical resources. Consequently, web-based interventions reduce 'traditional' barriers such as the unavailability of skilled professionals and long waiting lists (Ritterband and Tate 2009). There is also potential for the programme to be cost effective as it is not highly dependent on resources or staff availability. Therefore, due to both the behaviour change potential and additional practical advantages of web-based

interventions the internet should be considered as a viable option and resource to helping those with angina reduce their CHD risk.

8.9 *Recommendations for Future Research*

Future research should examine how this intervention compares with standard CR and with other CHD self-management programmes. In addition, the value of providing this web-based programme alongside standard CR could be examined to assess whether this could maximise standard CR, although this would increase the cost of delivering rehabilitation. Studies should also include higher risk groups such as those recovering from an MI, CABG and PCI, there is no reason why this intervention would not be either acceptable or effective but clearly this requires formal testing. A low risk group were recruited in this study; it is possible this intervention may be even more effective for higher risk groups when motivation levels may be higher. Motivation levels are potentially greater in post MI, CABG and PCI patients due to the acuteness of the event, and the level of physical function is likely to be lowered by the impact of the MI or the surgery. Thus, these groups may be willing to invest more effort in behaviour change to facilitate a faster recovery. This research question may be best answered with a preference based randomisation similar to that employed in the CHARMS study carried out by Dalal et al (2007). This would indicate whether patient choice affects study outcomes, one might speculate that allowing for patient preference for an online version of CR increases uptake to the study and improves effectiveness. However, there are some challenges associated with this approach. Ultimately this would be consistent with the Department of Health guidelines that state patients need to be offered a choice regarding the mode of rehabilitation delivery (Department of Health 2006).

The cost effectiveness of the programme should also be examined, in terms of whether there are any differences in resulting healthcare utilisation compared to a traditional rehabilitation programme. Currently in the UK the average cost of traditional CR is reported at £550 per patient (NICE 2012). This study did not examine the cost of delivering the online version of rehabilitation; future research should do this and compare the cost with the cost of traditional CR.

The present study examined the intervention's impact up to a 6 month follow up. A suggestion for future research is to examine the longer term improvements, for instance 12 or even 18 months follow up. This would help to provide an illustration of the programme's longer term impact on lifestyle related cardiac risk factors. Further, the current study was a pilot study; follow on work should comprise larger participant sample sizes. Future studies could also investigate whether providing sustained access to the programme results in increased programme effectiveness.

In addition, follow on studies may consider incorporating post intervention maintenance strategies. This could be through perhaps post intervention e-mail or telephone contact, this on-going support may increase sustainability of post intervention benefits. Intervention effectiveness could also be improved by incorporating cognitive-behavioural techniques which are known to be effective. NICE (2007b) provide a report for social and behavioural scientists. This report does not support the use of any particular model of health behaviour change and instead recommends the cognitive-behavioural techniques that behavioural scientists should use within behavioural change interventions. The report recommends that interventions should help users to accurately understand the consequences of their

behaviour, increase personal relevance, and promote positive feelings towards the outcomes of behaviour change (NICE 2007b). Behaviour change interventions should also aim to improve self-efficacy. In addition, it is important to enhance the social approval of those important to the intervention user (NICE 2007b). The report also describes that the promotion of personal and moral commitments towards changing behaviour are important (NICE 2007b). Interventions should also help users to form plans/goals for changing behaviours, these plans/goals should then be shared with others (NICE 2007b). Finally, NICE (2007b) suggest that interventions should also include a component that helps develop skills to cope with relapses (NICE 2007b). It is also useful to consider the techniques found to be useful in specifically CHD populations. Janssen et al (2012) conducted a systematic review and a meta-analysis, including 23 trials and examined the efficacy of lifestyle modification programmes for CHD. This review reported that interventions incorporating goal setting, planning, self monitoring, and feedback techniques were successful in changing exercise behaviour and dietary habits in CHD. Future developments of the web-based CR programme should use these guidelines provided by NICE (2007b) and Janssen et al (2012) when developing the intervention further.

In terms of the technological advances in health care the programme could also be developed into an application for use on a smartphone, and thereby enable the programme to be available via mobile phone technology and for participants to enter data whilst bouts of activity are being performed, for example. This would provide an innovative alternative to conventional CR as patients could be offered additional choice; either a website version accessible via a PC, laptop or a smartphone application version. It might also be important to consider translating the site into

other languages to provide an opportunity for ethnic minorities.

The current study monitored how often participants logged into the programme. If possible future research should assess intervention use more thoroughly by monitoring intervention components used most and duration of time spent using the programme. This information could be used to discern which components of the programme are most popular and the average amount of time participants actively utilised the programme. Additionally, it would have been useful to keep a record of the goals set by the intervention and whether they were achieved by the participant. This would have been a useful measure for both intervention success and intervention compliance.

A suggestion for future qualitative research is to study the experiences and perceptions of participants who do not engage with the programme to gain a broader and wide ranging account of participant experiences. In contrast, the current study examined the experiences of mostly compliant participants.

In the current study PA was of primary interest due to the high importance of PA in CHD and because this measure was both feasible and practical given funding and logistical concerns. Future research should consider monitoring cardiovascular fitness using specialist gym equipment in order to assess physical fitness. This would indicate the effectiveness of the programme to improve cardio-respiratory fitness. It would also be useful to include a self-report measure of PA. This would have added strength to the primary outcome measure. Incorporating a self-report measure of PA would also provide a back-up for the case of missing accelerometer data. Measuring

blood pressure twice at each measurement point would have also improved the robustness of the SBP and DBP outcomes. In the present study blood pressure was measured once at each measurement occasion, Jamieson et al (1990) suggest that two measurements should routinely be taken, and the average recorded.

It would also be useful to assess whether the programme helped patients to achieve national recommendations. The Department of Health (Department of Health 2011) recommend that adults are active at a moderate intensity for at least 150 minutes per week. This activity should be in bouts of 10 minutes or more, and the overall guide is that the activity is accumulated 30 minutes on at least 5 days a week (Department of Health 2011). Future research should examine the change in the number of participants meeting this national recommendation before and after the intervention. Another national recommendation is to eat at least 5 portions of fruit and vegetables each day (NHS. 2011). Future research should examine the change in the number of participants meeting this recommendation before and after the intervention. It would also be useful to be able to compare outcomes of web-based CR with conventional CR. For this reason it would be useful for outcome measures to reflect the outcome measures included in the NACR. NACR (2012) measures the impact of CR at a 3 month follow up and also at a 12 month follow up. The NACR (2012) assess the percentage of patients at follow up with a BMI <30, exercising 5x30 minutes a week, being a non-smoker, those with SBP <140, DBP <90, total cholesterol <4, cholesterol LDL <2, waist <102cm (men) waist <88cm (women). In addition HADS measured anxiety and depression are reported in terms of the percentage change of participants scoring within the normal, borderline, or clinical levels of both anxiety and depression before and after rehabilitation. In addition, in line with the NACR future research

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could also use the Dartmouth COOP (Nelson, Johnson and Hays 1996) to measure QOL. The NACR also reports patients' medication record; aspirin, ACE inhibitor, beta blocker, statin. Synchronising and measuring the same outcomes as the NACR in future trials of the web-based CR programme would enable direct comparisons of web-based CR with conventional CR nationally.

Additionally, it would be valuable to assess if this intervention has an impact on smoking behavior. The current intervention does comprise a smoking cessation component, although the affect of this component was not examined in the current study as only 2 (4%) and 6 (13%) participants in the intervention and control group respectively were smokers at baseline. Future research should examine the intervention's impact on smoking cessation.

The feasibility of implementing this programme in practice should also be investigated. GPs and practice nurses should actively refer patients to the programme and then this process should be evaluated to determine the feasibility of implementation. A similar study could also be carried out within a secondary care setting. Related to this future studies should evaluate the programme with an 'online study' which recruits participants online and comprises no face to face contact. This would reflect how the intervention might be intended in practice.

Considering the non-significant diet change at the short and medium-term follow ups future work could further refine and develop the dietary component of the programme. This further development work may involve emphasising the importance

of diet, develop the dietary advice and guidance, and perhaps extend the length of the programme to allow more time to stimulate dietary changes.

Further it would have also been useful to incorporate a more comprehensive measure of angina symptoms. An angina diary would enable a daily record of angina episodes, severity, and duration of angina episodes. Participants could keep this diary for a week at each follow up.

8.10 *Comparison with Previous Angina Management Trials*

8.10.1 *Comparison with Previous Angina Management Trials: Intervention Characteristics*

It is useful to put the findings of this RCT into context with previous trials of angina management. Prior to comparing the findings of this RCT with previous research it is useful to outline what was involved in each intervention. Table 16 summarises intervention characteristics of the present web-based CR programme and previous angina management programmes.

Table 16 - Characteristics of the Angina Management Interventions

	Web-based CR	Angina Plan (Lewin et al 2002 Furze et al 2012 Zetta et al 2009)	Angina Management Programme (Lewin et al 1995)	Stress Management Programme (Bundy et al. 1994)	Stress Management Programme (Gallacher et al. 1997)	The Chronic Angina Self-Management Programme (CASMP) (McGillion et al. 2008b)	Pain Management Porgramme (Payne et al. 1994)	Negative Cognitions Programme (Ma and Teng 2005)
Evaluated using RCT method?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Led by	✗	Nurse with a structured interview	Clinical psychologist and physiotherapist	Clinical psychologist	Not identified	Nurse	Not identified	Physician
Intervention style	Individualised Web-based	Individualised Manual based	Group based & Individual sessions	Group based	Group & Manual based	Group based & workbook	Group based	Not reported
Setting	Home based	Home based	Hospital based	Not reported	Primary Care Setting	Classroom setting	Not reported	Not reported
Duration	6 weeks	12 weeks	8 weeks	7 weeks	10 weeks	6 weeks	3 weeks	8 week.
Intensity (no. of sessions)	n/a	n/a	2 morning sessions weekly	1.5 hours weekly	3 sessions spread over 10 weeks	One hour session twice per week	Weekly sessions	Not reported
Addressed multiple areas of CHD or targeting one aspect?	Multiple	Multiple	Multiple	Stress management	Stress management	Multiple	Managing chest pain	Targeted negative cognitions, and angina misbeliefs,
In home based programmes was there contact with healthcare professional	✔ yes, email or online chat option available	✔ 4 telephone contacts	n/a	n/a	n/a	n//a	n/a	Not reported
Exercise component	Home based walking programme	home based walking programme	Group exercise component	Group exercise component	✗	✗	✗	✗

Stress management addressed?	✔ Relaxation techniques	✔ Audio-taped relaxation programme	✔ Targeted using relaxation and yoga	✔ Relaxation training, simple deep breathing exercises, muscular relaxation & audio tape of exercises	✔ Relaxation tapes	✔ Programme included relaxation and stress management. Exact way this delivered is not reported	✔ Relaxation training via diaphragmatic breathing	✘
Target cardiac misconceptions	✘	✔	✔	✘	✘	✘	✘	✔
Goal-setting	✔	✔	✔	✘	✘	✔	✘	✘
Self monitoring	✔ targeted using the exercise diary	✔	✔	✔ Recorded stress management attempts in a diary	✘	✘	✔ Self monitoring of chest pain episodes	✘
Feedback provided	✔ At the end of each stage the participant receives feedback regarding success with goals	✔ Success with goals rewarded with praise at the follow up phone calls	✔ Feedback sessions carried out in groups, reporting progress of achieving goals	✘	✔ Feedback on participants home work given	✘	✘	✘

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As can be seen from table 15 this study is the first secondary prevention of angina programme that has been delivered via the internet. Previous interventions have used other strategies/formats; paper based manual (AP; Lewin et al 2002, Zetta et al 2009, Furze et al 2012), group based with one to one individual sessions with health professionals (AMP; Lewin et al 1995), group based with a paper based manual (Gallacher et al 1997, McGillion et al 2008b) or group based only (Bundy et al 1994). The description of the intervention format was not provided in Ma and Teng (2005).

The current web-based approach, AP, AMP and the CASMP targeted multiple risk factors. Whereas other interventions have targeted one specific area of CHD. Bundy et al (1994) and Gallacher et al (1997) evaluated programmes that focused specifically on stress management. Payne et al (1994) assessed a programme focused on managing chest pain only and Ma and Teng (2005) evaluated the effectiveness of a programme focussed on managing negative emotions and angina mis-beliefs.

The current web-based intervention was an individualised programme carried out independently. Previous interventions have been facilitated by nurses (AP; Lewin et al 2002 and Zetta et al 2009 and CASMP; McGillion et al 2008b) clinical psychologists (AMP; Lewin et al 1995 and Stress Management Programme; Bundy et al 1994), physio-therapists (AMP; Lewin et al 1995), physicians (Negative Cognitions Programme; Ma and Teng 2005) and lay people with experience of heart disease (AP; Furze et al 2012). The intervener was not described in Gallacher et al (1997) and Payne et al (1994).

In terms of intervention setting the current programme and the AP were home-based, with healthcare professional contact and support available. Other programmes have been set in a hospital (AMP; Lewin et al 1995), in primary care (Gallacher et al 1997) or in a classroom setting (McGillion et al 2008b). The intervention setting was not described in Bundy et al (1994), Payne et al (1994), or Ma and Teng (2005). The length of interventions ranged from 3 weeks (management of chest pain programme; Payne et al 1994) to 12 weeks (AP; Lewin et al 2002, Furze et al 2012, Zetta et al 2009).

The following section will compare outcomes of this trial with outcomes in previous trials. Table 16 to table 20 compares the physiological (weight, body fat %, SBP, DBP), lifestyle (physical activity, diet), psychological (anxiety, depression, self-efficacy), QOL and angina symptom related outcomes of this trial with previous secondary prevention of angina trials.

8.10.2 Comparison with Previous Angina Management Trials: Physiological Outcomes

Table 17 outlines the physiological outcomes of the present study with previous trials.

Table 17: The Present Trial Compared with Previous Angina Management Trials: Physiological Outcomes

Physiological Outcomes		Previous Angina Management Studies measuring physiological outcomes.		
	Web-based CR.	Angina Plan (Lewin et al 2002, Furze et al 2012, Zetta et al 2009)	Stress Management Programme (Bundy et al, 1994)	Stress Management Programme (Gallacher et al, 1997)
Short term (follow up ≤ 3 months).				
Weight (kgs)	Significant reduction in the intervention group (-0.56kgs) compared to the control group (+0.41kgs), p=0.02.			
Body Fat (%)	Non-significant difference in change between the intervention group (-0.42%) and the control group (+0.67), p=0.49.			
SBP (mmHg)	Significant reduction in the control group (-9.00mmHg) compared to the intervention group (-0.55mmHg), p=0.00.		Non-significant effects in blood pressure at 8 weeks follow up (post intervention), DBP and SBP not specified, p value not reported.	
DBP (mmHg)	Non-significant difference in change between the intervention group (-3.92mmHg) and the control group (-4.00), p=0.97.			
Medium-term (follow up 4-6 months).				
Weight (kgs)	Non-significant difference in change between the intervention group (-0.20kgs)			Significant decrease in the intervention group (-0.96kgs) compared to the

	compared to the control group (0.89kgs), p=0.13.			control group (-0.24kgs) at 6 months follow up, p<0.05.
Body Fat (%)	Non-significant difference in change between the intervention group (-0.04%) and control group (-0.46%), p=0.83.			
SBP (mmHg)	Non –significant difference in change between the intervention group (-1.06mmHg) compared to the control group (-4.48mmHg), p=0.33.	Non-significant changes in blood pressure at 6 month follow up (p-value not reported) (Lewin et al 2002). Non-significant difference in change between groups at the 6 month follow up in SBP (intervention group: +1.13, control; +2.65), p=0.50 (Zetta et al 2009). Non-significant difference between groups at the 6 month follow up in SBP was -0.96, p=0.76 (Furze et al 2012).	Non-significant effects at 16 week follow up in blood pressure, DBP and SBP not specified, p value not reported).	Non-significant difference between groups in change in SBP at 6 months in intervention group (-4.60mmHg) and control group (-3.60mmHg), p-value not reported.
DBP (mmHg)	Non-significant difference in change between the intervention group (-1.47mmHg) and control group (-1.33mmHg), p=0.95.	Non-significant changes in blood pressure at 6 month follow up, values not reported (p-value not reported) (Lewin et al 2002). Non-significant difference in change between groups at the 6 month follow up (control +3.59, intervention group +2.06), p=0.27 (Zetta et al 2009). DBP not reported in Furze et al (2012).		Non-significant difference between groups in change at the 6 months follow up in intervention group (1.2mmHg) and control group (-2.7mmHg), p-value not reported.
Other relevant physiological outcomes		**BMI**: Non-significant change in BMI, p value not reported, (Lewin et al 2002). Significantly improved BMI in the intervention group (-0.13) compared to the control group (+0.37), (p=0.005) (Zetta et al 2009). Non-significant change between groups in BMI, (p=0.30) (Furze et al 2012). **Waist/hip ratio:** Higher waist/hip ratio in the control group (0.98) compared to the AP group (0.95), p=0.05. (Furze et al 2012).		

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In the present study there was a significant short term intervention effect upon weight, $p=0.02$. Unfortunately, it is not possible to compare this finding with previous research as no other trials have measured weight change in the short term. In terms of medium term weight change the significant short term effect was not maintained at the 6 month follow up. This is inconsistent with previous research. A stress management programme evaluated by Gallacher et al (1997) resulted in a significant reduction in weight at a 6 month follow up, $p<0.05$. This was in contrast to the present study, which like Gallacher et al (1997) recruited primary care angina patients. It would be useful to compare baseline levels of weight in both studies; however, a direct comparison of baseline weight is not possible as Gallacher et al (1997) report change values only. The reduction in weight is interesting given that the main emphasis of the intervention was stress management. The intervention style adopted by Gallacher et al (1997) may explain some of the difference in findings. Gallacher et al (1997) combined a group based setting with a home-based manual. Previous qualitative research has demonstrated those taking part in group-based rehabilitation gain motivation and support from others (Jones et al. 2009). It is possible that participants gained support and motivation from other members in the group which led to an increased focus to improve other areas of CHD alongside stress management, namely losing weight. Previous research indicates that the AP is also effective at reducing weight in the medium term. At a 6 month follow up Zetta et al (2009) reported participants taking part in the AP significantly reduced BMI (-0.13), compared to the control group (+0.37), $p=0.005$. In addition, at a 6 month follow up Furze et al (2012) reported a higher waist/hip ratio in the control group (0.98) compared to the intervention group (0.95), $p=0.05$, indicating greater abdominal fat in the control group. The difference in findings between the current study and the

evidence outlined by Zetta et al (2009) and Furze et al (2012) may be due to the nature of samples recruited. Zetta et al (2009) recruited patients hospitalised with angina and Furze et al (2012) recruited patients newly diagnosed with angina. It is possible that these participants were more motivated towards losing weight even 6 months after the intervention, compared to the sample with a long history of angina recruited in the current study. Another possibility is the length of AP and the programme evaluated by Gallacher et al (1997) could account for some of the differences in findings. Both the AP and the stress management programme evaluated by Gallacher et al (1997) were of 12 weeks and 10 weeks duration respectively. The current programme was comparatively shorter; 6 weeks. It is possible that a longer intervention length is required to induce a change in weight.

It is not possible to compare the non-significant effect upon body fat percentage, as previous research has not yet included this as an outcome measure. In terms of blood pressure outcomes the current trial demonstrated a non-significant intervention effect upon SBP and DBP in both the short and medium term. Bundy et al (1994) also reported a non-significant change (systolic or diastolic blood pressure not specified) at post intervention (8 week follow up) following a group based stress management intervention. This is also consistent with medium term findings reported for the AP (Lewin et al 2002, Zetta et al 2009, and Furze et al 2012) and previous stress management interventions (Bundy et al 1994, Gallacher et al 1997). In the present study the non-significant short and medium term effect upon SBP and DBP may not be surprising considering the normal range of both SBP and DBP at baseline. Although SBP significantly reduced in the control group compared to the intervention group at the 6 week follow up, p=0.00, which is difficult to explain.

In terms of physiological outcomes the current study demonstrated significantly improved weight in the short term. It is not possible to compare this finding to previous literature as prior studies have not assessed short term weight change. However in the medium term it appears that the AP and the stress management programme evaluated by Gallacher et al (1997) have been more effective than the current web-based approach at inducing a favourable weight change. However there remains a need to be cautious as even though Furze et al (2012) detected a significant effect upon waist/hip ratio, a non-significant intervention effect upon BMI was also reported. In addition Lewin et al (2002) reported a non-significant change in BMI following the AP, and therefore the evidence supporting the AP for a medium term change in weight is not entirely conclusive. Also given that the study carried out by Gallacher et al (1997) was carried out 15 years ago the extent to which these findings might be applied to current practice is questionable.

8.10.3 *Comparison with Previous Angina Management Trials: Lifestyle Outcomes*

Table 18 outlines the lifestyle related outcomes in both the current trial and previous secondary prevention of angina interventions.

Table 18: The Present Trial Compared with Previous Angina Management Trials: Lifestyle Outcomes

Lifestyle Outcomes		Previous Angina Management Studies measuring lifestyle outcomes
	Web-based CR.	Angina Plan (Lewin et al 2002, Furze et al 2012, Zetta et al 2009)
Short term (follow up ≤ 3 months).		
Physical Activity	Significantly increased daily steps (intervention group: +497steps, control group: -961 steps, p=0.02), daily EE (intervention group: +43.94kcal, control group: -133.01kcal, p=0.01), DDSA (intervention group: -7.79 mins, control group: +23.23 mins, p=0.01) and DDMA (intervention group: +6.31 mins, control group: -22.29 mins, p=0.01). Non-significant intervention effect for DDVA (p=0.27).	Significantly more participants meeting the 5x30mins per week national PA recommendation in the intervention group compared to the control group (intervention group 53.6% vs control 32.1%, p=0.01) at the 3 month follow up (post intervention) (Furze et al 2012).
Diet	Non- significant intervention effects for fat or fibre intake.	
Medium-term outcomes (follow up 4-6 months).		
Physical Activity	Non-significant intervention effects for daily step p=0.19, daily EE p=p=0.14, DDSA p=0.16, DDMA p=0.24, and DDVA p=0.26.	Non-significant differences between groups at the 6 month follow up in participants meeting the national recommendation of 5x30 minutes per week PA criteria, (intervention group 38.6% vs control group 36.5%, p=0.78) (Furze et al 2012). Significantly more intervention group participants increased daily walking (23.5%) compared to control group (1.6%), p<0.001, (Lewin et al 2002).
Diet	Non-significant intervention effects for fat or fibre intake.	Significantly more intervention group participants improved their diet (31.5%) compared to the control group (16.2%) at the 6 month follow up, p<0.001 (Lewin et al 2002).
Other relevant lifestyle outcomes		**Motivation to change:** Significantly more participants in the intervention group were more likely than the control participants to move from the 'non-active' stage to the 'active' stage at the 6 month follow up (percentage of patients not reported) (p=0.02) (Zetta et al 2009).

In the short term the present study demonstrated significant intervention benefits upon daily step count (p=0.02), daily EE (p=0.01), DDSA (p=0.01), and DDMA (p=0.01). The AP is the only previous secondary prevention of angina intervention that has been evaluated in terms of lifestyle related outcomes. Consistent with this study Furze et al (2012) reported significantly increased PA in the short term. At a 3 month follow up Furze et al (2012) reported significantly more intervention group participants (53.6%) compared to the control group participants (32.1%) met the national recommended PA guidelines (5x30minutes per week), p=0.01. It is not possible to directly compare the size of PA change as the data in the current study was not collected or presented in the same way. It is encouraging that the current findings are consistent with Furze et al (2012) who recruited newly diagnosed angina patients, a stage when motivation levels may be higher than the sample recruited in this study who had a longer established diagnosis of angina. As suggested by previous literature, home based interventions for CHD that utilise goal setting, self monitoring and providing feedback techniques are effective at improving exercise behaviour (Janssen et al 2012). Given that both the AP and the current web-based approach used these techniques, a speculation is that these techniques were useful in improving PA

In terms of medium term change there were non-significant effects upon PA detected at the 6 month follow up. In contrast, at a 6 month follow up Lewin et al (2002) demonstrated significantly more participants taking part in the AP (23.5%) increased daily walking compared to participants in the control group (1.6%), p<0.001. It is also interesting that Zetta et al (2009) reported increased motivation to carry out PA in AP participants compared to controls at a 6 month follow up, p=0.02. Prior trials carried out by Lewin et al (2002) and Zetta et al (2009) therefore indicate that the AP

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is more effective than current web-based CR study at inducing PA changes in the medium term. The difference in facilitation style between interventions may explain some of the difference in findings. In the AP the nurse maintained close contact with the patient throughout the intervention period via telephone calls. The web-based programme was not facilitated in this way. A speculation is that the telephone contact throughout the AP may have encouraged the medium term effect upon PA. Previous research offers support for this. Dubbert et al (2002) demonstrated that nurse telephone contact is an effective technique in maintaining increased walking amongst primary care elderly patients. After taking part in a nurse led walking intervention Dubbert et al (2002) randomised participants to 1 of 3 conditions; nurse-initiated calls only, both nurse-initiated and motivational calls or no phone contacts. Participants receiving a combination of nurse-initiated and motivational phone calls were found to walk significantly more at a medium term follow up than those with no phone contacts. This demonstrates that nurse contacts can help to maintain increased PA following an intervention in the medium term. Given the findings of Dubbert et al (2002) and the evidence supporting the AP a suggestion is that closer healthcare facilitation is required for medium term PA effects. There are also subtle differences in participants recruited; the present study recruited a sample with a long established diagnosis of angina, a stage where motivation levels may be low. In contrast, motivation levels may have been higher in previous studies given that Lewin et al (2002) recruited those newly diagnosed with angina and Zetta et al (2009) examined those hospitalised with angina. However there is a need to be mindful that in contrast to the present study Furze et al (2012) and Lewin et al (2002) used self-report methods to assess PA and Zetta et al (2009) measured change in motivation to exercise and not PA per se.

Another lifestyle outcome in this study was change in diet. This study demonstrated non-significant intervention effects upon diet, in both the short and medium term. Whereas Lewin et al (2002) reported 6 months following the AP participants were significantly more likely than the control group to change their diet (p<0.001). Even though there is little detail regarding the exact changes in diet (Lewin et al 2002) the data does provide support for the effectiveness of the AP in improving diet in the medium term. The difference in findings could be partially due to the difference between the length of the current programme and the AP. The AP extends over 12 weeks, which is comparatively longer than the current intervention. It appears a longer duration of time may be required to stimulate dietary changes, suggesting a dose response effect or a need to improve the diet advice and support on the website. There is a body of literature indicating that a longer time period may be required (Brunner et al. 1997). Brunner et al (1997) conducted a meta-analysis of dietary advice in primary prevention of chronic disease. This review included 17 RCTs of dietary behaviour interventions of at least 3 months duration and reported favourable changes in diet at a 3–6 month follow up (Brunner et al. 1997).

In terms of lifestyle outcomes it appears that the current web-based approach produced similar findings to Furze's lay facilitated version of the AP in the short term. The current findings may be somewhat more robust than Furze et al (2012) given the objective measure of PA, although this may be questionable given the limitations with missing data discussed earlier (section 8.6). Whereas in the medium term it appears that the web-based approach has been less successful than the AP. Lewin et al (2002) reported increased walking and improved diet in comparison to the control group at the 6 month follow up and Zetta et al (2009) reported increased

motivation to exercise at the 6 month follow up. However, it is necessary to remain cautious towards the findings of Zetta et al (2009) as motivation to exercise was measured and not PA as such. It is also necessary to remain cautious for the reason that the evidence is not completely supportive as Furze et al (2012) detected a non-significant PA effect 6 months following a lay facilitated version of the AP.

8.10.4 Comparison with Previous Angina Management Trials: Psychological Outcomes

Table 19 outlines the present and previous trials of angina management that have measured psychological related outcomes.

Table 19: The Present Trial Compared with Previous Angina Management Trials: Psychological Outcomes

Psychological Outcomes		Previous Angina Management Studies measuring psychological outcomes				
	Web-based CR	Angina Plan (Lewin et al 2002, Furze et al 2012, Zetta et al 2009)	Stress Management Programme (Bundy et al, 1994)	The CASMP (McGillion et al 2008b)	Pain Management Programme (Payne et al 1994)	Negative Cognitions Programme Ma and Teng (2005)
Short term (follow up ≤ 3 months).						
Anxiety	Non-significant difference in anxiety score change between the intervention group (-1.47) and control group (-0.64), p=0.20.	Significantly lower anxiety in the AP group (score 5.13) compared to control (score 7.07) at 3 month follow up (post intervention) (p=0.001) (Furze et al 2012).	Non-significant anxiety effect at 8 weeks (post intervention (p value not reported).		Non-significant anxiety effect at post intervention and 1 month follow up, (p value not reported).	Significantly lower anxiety in the intervention group compared to control at 2 month follow up (post intervention) p<0.01, details of the measure not available.
Depression	Non-significant difference in depression score change between the intervention group (-0.43) and control group (-0.01), p=0.30.	Non-significant difference in depression score between the AP group (score 3.40) and control group (score 4.05), (p=0.11) (Furze et al 2012).			Non-significant depression effect at post intervention and 1 month follow up, (p-values not reported).	Significantly lower depression in the intervention group compared to the control at 2 month follow up (post intervention), p<0.01, details of the measure not available.
Self efficacy	Significant self-efficacy score change between the intervention (+2.68)			Significant effects for self-efficacy at 3 months follow		

	and control group (+0.13), p=0.04.				up, (p=0.004).		
Other relevant psychological outcomes		**Angina beliefs** - AP group had a lower score of misconceptions (4.28) compared to control (5.15), p=0.02 (Furze et al 2012).				
Medium-term outcomes (follow up 4-6 months).						
Anxiety	Significant anxiety effect p=0.04, intervention improved score by 1.88, whereas the control group decreased by 0.5, p=0.04.	Significantly lower anxiety in the AP group (score 6.27) compared to control (score 7.70) (p=0.03) (Furze et al 2012). Significantly reduced anxiety, change in anxiety score in the intervention group (-1.03) compared to the control group (0.00), p=0.05 (Lewin et al 2002). Non-significant difference between groups in anxiety, AP baseline 2.51, follow up 2.16. Control group baseline 2.65, follow up 2.41, p=0.32 (Zetta et al 2009).	Non-significant anxiety effect at the 16 week follow up (p value not reported).		Non-significant anxiety effect at 6 month follow up, p value not reported.	
Depression	Non-significant depression effect, p=0.15	Significantly lower depression in the AP group (score 3.11) compared to control (score 4.21), p=0.05 (Furze et al 2012). Significantly reduced depression in the intervention group (-0.48) compared to the control group (0.41), p=0.01 (Lewin et al 2002). Non-significant differences between groups in depression, AP baseline 2.07, follow up 2.00. Control group baseline 2.07, follow up 2.15, p=0.18 (Zetta et al 2009).			Non-significant effect at the 6 month follow up, p value not reported.	
Self-efficacy	Non-significant self-efficacy effect, p=0.72					
Other relevant psychological outcomes		**Angina beliefs:** AP group had a lower score of misconceptions compared to control, p<0.001 (Furze et al 2012). At a 6 month follow up the AP participants significantly improved their knowledge and misconceptions (p<0.00) (Zetta et al 2009).				

In the short term there was a non-significant intervention effect upon anxiety in this study. Previous trials report contrasting findings. Furze et al (2012) demonstrated improved anxiety immediately following a lay facilitated version of the AP (p=0.001) and Ma and Teng et al (2005) also report significantly lower anxiety immediately after an intervention targeting negative cognitions and angina mis-beliefs (p<0.01). The difference in findings could be partially due to intervention content. Given that both of these previous interventions targeted cardiac misconceptions/angina mis-beliefs a speculation is that this may have helped to reduce anxiety. Alongside the decrease in anxiety Furze et al (2012) reported significantly improved angina misconceptions (p=0.02), although unfortunately Ma and Teng et al (2005) did not measure change in angina mis-beliefs. Consistent with this speculation the current intervention and the programmes evaluated by Bundy et al (1994) and Payne et al (1994) did not target cardiac misconceptions and like this study report a non-significant effect upon anxiety at the short term follow up. Another possible explanation could be due to differences in samples recruited. Furze et al (2012) recruited a newly diagnosed angina population which were perhaps more anxious at baseline than the sample recruited in this study. Even though previous studies have also used HADS to measure anxiety a direct comparison of baseline anxiety scores is not possible as Furze et al (2012) did not report baseline values. It is also not possible to compare baseline anxiety scores with Ma and Teng (2005) as the full details of this study are not available in English. In contrast to the short term there was however, a significant intervention effect upon anxiety in the medium term in the current study (p=0.04). This is somewhat surprising considering there was no short term impact. This improvement in anxiety is consistent with the medium-term anxiety improvements reported from the AP. At a 6 month follow up Furze et al (2012) and

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Lewin et al (2002) reported a significant improvement in anxiety at a p=0.03 and p=0.05 level respectively. However, Zetta et al (2009) failed to demonstrate an improvement in anxiety. Baseline levels of anxiety were below the classification for mild anxiety in Zetta et al (2009) and could therefore explain the non-significant effect upon anxiety. However, low baseline levels of anxiety were also the case in the present study and medium-term improvements were still detected.

The current findings outlined a non-significant intervention effect upon depression in both the short and medium term. Baseline depression scores were below the threshold for mild depression in both groups and therefore it is reasonable to speculate that this could help to explain why there was a non-significant effect. In the short term it appears that the psychological intervention evaluated by Ma and Teng (2005) has been most effective in terms of reducing depression, p<0.01. Whereas in the medium term it appears that the AP has been the most effective intervention for reducing depression. There was significantly improved depression after the AP compared to a control group at a 6 month follow up reported by both Lewin et al (2002) (p=0.01), and Furze et al (2012) (p=0.05). It is possible that previous samples were more depressed at baseline than the current sample. Both Lewin et al (2002) and Furze et al (2012) recruited those with a new diagnosis of angina and thus could have been more depressed than the current sample. While previous studies also assessed depression using the HADS it is not possible to compare baseline values of depression as Lewin et al (2002) and Furze et al (2012) report change scores values only and not baseline levels. As previously described it is also possible that the 'correcting angina misconceptions' component of the AP could have contributed towards reducing depression.

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In terms of self efficacy, the web-based approach is consistent with McGillion et al (2008b) who reported significantly improved self-efficacy in the short term (p=0.004). It is encouraging that the current web-based intervention, an individualised programme carried out at home without a facilitator produced a comparable self-efficacy outcome as McGillion et al's programme, CASMP, a group based, nurse facilitated programme. However the favourable short term improved self-efficacy wasn't maintained at the 6 month follow up in the current study and McGillion et al (2008b) did not measure self-efficacy in the medium term. It is reasonable to assume that perhaps it is more difficult to keep up a self efficacy increase in the long term.

In terms of psychological outcomes the AP and the psychological intervention evaluated by Ma and Teng et al (2005) are more successful in the short term than the current web-based intervention. Ma and Teng (2005) reported significant improvements in both anxiety and depression, while Furze et al (2012) demonstrated that the AP was successful at significantly improving anxiety in the short term. It is possible that the 'correcting angina misconceptions' components in both the AP and the psychological intervention evaluated by Ma and Teng (2005) mediated the improved anxiety. However it is questionable whether the findings of Ma and Teng (2005) could be applied to the UK as the study was carried out in China, and cultural differences may limit the extent to which these findings could be applied in this Country. In terms of the short term gains in self efficacy, the current web-based approach produced similar self-efficacy outcomes to the CASMP programme evaluated by McGillion et al (2008b). When evaluating psychological outcomes in the medium term it appears that the current web-based programme was consistent

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with the AP in terms of improved anxiety. However the AP may be considered more

effective given that the evidence reports improvements in both anxiety and depression

(Lewin et al 2002, and Furze et al 2012), while the current study reported improved

medium term anxiety only.

8.10.5 <u>Comparison with Previous Angina Management Trials: QOL Outcomes</u>

Table 20 outlines the present and previous trials of angina secondary prevention that

have measured QOL outcomes.

Table 20: The Present Trial Compared with Previous Angina Management Trials: QOL Outcomes

Quality of Life Outcomes		Previous Angina Management Studies measuring psychological outcomes	
	Web-based CR	Angina Plan (Lewin et al 2002, Furze et al 2012, Zetta et al 2009)	The CASMP (McGillion et al 2008b)
Short term (follow up ≤ 3 months)			
Quality of life	Measured using the MacNew Emotional QOL: significant intervention group improvement (+0.31) compared to the control group (+0.04), p=0.04. Physical QOL: Non-significant difference in change in the intervention group (+0.04) compared to control group (+0.11), p=0.62. Social QOL: Non-significant difference in change in the intervention group (+0.21) compared to the control group (+0.73), p=0.34.	Measured using EQ-5D: Significantly higher QOL in the intervention group (score 0.82) compared to the control group (score 0.70), p=0.01 at the 3 month follow up (post intervention) (Furze et al 2012).	Measured using SF-36: Significant intervention effects upon physical functioning (p<0.001) and general health perception (p=0.001). There were no significant differences between groups on other SF-36 subscales; role physical functioning, role emotional functioning, bodily pain, social functioning, vitality, and mental health, p-values not reported.
Medium-term outcomes (follow up 4-6 months)			
Quality of life	Emotional QOL: Non-significant difference between the intervention group change score (+0.43) and control group (+0.07), p=0.06. Physical QOL: Non-significant changes in the intervention group (+0.02) compared to the control group (-0.18), p=0.21. Social QOL: Non-significant difference in change in the intervention group (+0.06) compared to the control group (-0.10), p=0.24.	Measured using EQ-5D: Significantly higher QOL in the intervention group (0.82 score) compared to the control group (0.68 score), p=0.008 (Furze et al 2012). Measured using the SF-36: Significantly favourable improvements in general health perception in the intervention group compared to the control group, p=0.03 (Zetta et al 2009). Zetta et al (2009) used The Cardiovascular Limitations and symptoms profile (CLASP), at the 6 month follow up there were significant difference in social and leisure p=0.04 and non-significant differences between groups in other CLASP subscales – angina p=0.27, shortness of breath p=0.62, ankle swelling p=0.78, tiredness p=0.29, mobility p=0.29, concerns p=0.29, sex p=0.34, home activities p=0.17.	

In the short term emotional QOL significantly improved compared to the control group, while there were no significant intervention effects upon perceived quality of physical and social life. Likewise Furze et al (2012) and McGillion et al (2008b) also report significantly improved QOL. Furze et al report improved QOL using a general measure (p=0.01) and McGillion et al (2008b) report improved QOL in terms of perceived physical functioning (p<0.001) and general health perception (p=0.001). Overall it seems that the current web-based approach, the AP, and the CASMP show some evidence for improved QOL in the short term. It is difficult to conclude which intervention has been the most effective due to the differences in instruments used. It is reasonable to assume that in this study a 'ceiling effect' might help to explain the non-significant effects upon the physical and social QOL. The maximum score available on the MacNew subscales is 7. Participants in both study groups scored towards the maximum at baseline on the physical QOL (median score was 6.50) and social QOL (median score was 6.54) subscales. Therefore it is likely that baseline scores for these variables suffered from a 'ceiling effect', which occurs when a large portion of participants score towards the upper limit (Hessling, Traxel and Schmidt 2011).

When medium term QOL evidence is compared across studies it appears that the AP is the most effective. The current study reported non-significant changes in emotional, physical, and social QOL in the medium term. In contrast, significantly improved QOL at a 6 month follow up was reported by Furze et al (2012) and Zetta et al (2009), p=0.008 and p=0.03 respectively. It is possible that the significant reduction in both anxiety and depression demonstrated by Furze et al (2012) helped participants to perceive a better QOL. The evidence therefore suggests that the AP

has been more effective than the current intervention in terms of improving QOL in the medium term.

8.10.6 *Comparison with Previous Angina Management Trials: Angina Symptoms*

Table 21 outlines the present and previous trials of angina secondary prevention that have measured angina symptoms.

Table 21: The Present Trial Compared with Previous Angina Management Trials: Angina Symptoms

Angina Outcomes		Previous Angina Management Studies measuring psychological outcomes				
	Web-based CR	Angina Plan (Lewin et al 2002, Furze et al 2012, Zetta et al 2009)	Angina Management Programme (Lewin et al 1995)	Stress Management Programme (Bundy et al 1994)	Stress Management Programme (Gallacher et al, 1997)	The CASMP (McGillion et al 2008b)
Short term (follow up ≤ 3 months)						
Seattle Angina Questionnaire (higher scores indicates better functioning).	Angina frequency: Significant difference in intervention group improvement (+10.23) compared to the control group (-11.59), p=0.00. Non significant intervention effects upon physical limitations (p=0.57), angina stability (p=0.98), treatment satisfaction (p=0.36) and disease perception (p=0.48).	Non-significant between groups in physical limitations (p=0.19), angina frequency/perception (p=0.07) or treatment satisfaction (p=0.35) at post intervention (Furze et al 2012).				Angina frequency: significant difference between groups in score change (intervention group +11.4, control group -2.2, p=0.02). Angina stability: significant difference between groups in score change (intervention group +18.0, control group 2.9, p=0.001). Non significant intervention effects for other subscales, p-values not reported.
Other relevant angina outcomes			Significantly reduced episodes of angina (p<0.001), severity of angina (p<0.05), medication use (p<0.001), disability	Significant intervention effects in duration of angina (p<0.005) and medication use (p<0.005) at post		

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			(p<0.001) at post intervention in the intervention group (measured using a diary).	intervention. (measured using a diary).		

Medium-term outcomes (follow up 4-6 months).

| Seattle Angina Questionnaire (higher scores indicates better functioning). | Angina Frequency: Significant difference between groups in change (intervention group +4.88, control group -10.73, p=0.03).

Non significant intervention effects upon physical limitations (p=0.71), angina stability (p=0.73), treatment satisfaction (p=0.72) and disease perception (p=0.58). | Non-significant differences between groups in physical limitations p=0.98, angina frequency/perception p=0.36, treatment satisfaction, p=0.31, (Furze et al 2012).

Significant improvements in the physical limitations subscale among the AP group compared to the control group (p<0.001), no differences between groups in score change for other subscales; angina stability p=0.40, angina frequency p=0.72, treatment satisfaction p=0.50, disease perception p=0.21 (Lewin et al 2002).

Significant intervention effects for physical limitations (intervention group +10.01, control group +2.35, p=0.02), Non-significant effects for | | | | |

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		angina frequency (p=0.12), disease perception (p=0.56), treatment satisfaction (p=0.49) and angina stability (p=0.60) (Zetta et al 2009).			
Other relevant angina outcomes		The incidence rate ratio for control (n=57) vs LAMP (n=58) was 0.96, (95% CI: 0.39-2.38, p=0.926) (Furze et al 2012). There were greater improvements in angina episodes per week (p=0.016) and medication use per week (p=0.018) (measured using an angina diary) compared to the educational control group (Lewin et al 2002).	At the 4 month follow up there were significant improvements within the intervention group in angina episodes (p<0.001), angina severity (p<0.01), angina duration (p<0.001), medication use (p<0.001), disability (p<0.001) (Lewin et al 1995) (measured using an angina diary).		Recorded using an angina diary. Frequency of chest pain when at rest was significantly improved in the intervention group compared to the control at the 6 month follow up, p<0.02. Non-significant difference between groups in chest pain on exertion at the 6 months, p value not reported. (measured using a fortnightly angina diary).	

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In the short term the current web-based approach and previous angina interventions have demonstrated improvements in angina symptoms. The current study detected significant short term improvements to the SAQ angina frequency subscale (p=0.00), whilst McGillion et al (2008b) detected significant short term improvements to both the SAQ angina frequency (p=0.02) and SAQ angina stability (p=0.001) subscales. The CASMP programme evaluated by McGillion et al (2008b) may be considered more effective in the short term than the current web-based approach as improvements were detected on 2 SAQ subscales as opposed to only 1 subscale, which was the case in the current study. Other angina management studies carried out by Lewin et al (1995) and Bundy et al (1994) also report improved angina symptoms in the short term. Both Lewin et al (1995) and Bundy et al (1994) collected data using an angina diary measurement tool and reported significant improvements in angina symptoms. It is difficult to compare the current findings with Lewin et al (1985) and Bundy et al (1994) due to variations in measurement instruments. It is interesting that prior research carried out by McGillion et al (2008b), Lewin et al (1995), Bundy et al (1994) and Gallacher et al (1997) adopted a group based approach. As previously described prior qualitative research has demonstrated the benefit of group based settings as participants gain motivation and support from others (Jones et al. 2009).

In the medium term the current web-based approach, the AP, the AMP and the stress management programme evaluated by Gallacher et al (1997) report significant improvements in angina symptoms. The current study detected significantly improved SAQ measured angina frequency, p=0.03 and evidence supporting the AP demonstrated significant improvements to the SAQ physical limitations subscale (Lewin et al 2002 and Zetta et al 2009). In contrast the current study did not detect an

improvement to the physical limitations subscale. The difference in findings could be due to differences in the baseline level of physical functioning. Unfortunately it is not possible to compare baseline scores with Lewin et al (2002) as the findings outline change values only. However, when the baseline physical limitations score is compared with Zetta et al (2009) the AP participants had a lower level of physical functioning (baseline physical function score was 53.67) than the participants in the current study (baseline physical function score was 64.84) at baseline. This could help to partially explain why Zetta et al (2009) detected a significant effect upon physical functioning while the current study did not. More support for the AP to improve angina symptoms has been demonstrated by Lewin et al (2002). Lewin et al (2002) also employed an angina diary tool and reported significantly reduced angina symptoms and medication use at a 6 month follow up. In addition the AMP (Lewin et al 1995) and the stress management programme evaluated by Gallacher et al (1997) also demonstrated significantly improved angina symptoms at a medium term follow up. Gallacher et al (1997) reported a significant reduction in the frequency of chest pain when at rest compared to a control group at a 6 month follow up and Lewin et al (1995) demonstrated significant improvements in angina episodes, angina severity, angina duration, medication use and disability at a 4 month follow up.

When comparing angina symptom outcomes in the present trial with past interventions the current web-based approach, the CASMP programme (McGillion et al 2008b), the AMP (Lewin et al 1995) and the stress management programme evaluated by Bundy et al (1994) have all demonstrated significant intervention effects upon improving angina symptoms in the short term. It is difficult to determine which intervention has been most effective. It may be possible that the AMP has the

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strongest short term evidence as significant improvements were detected on multiple aspects of angina symptoms (frequency, severity, medication use, and disability). This was also the case in the medium term. In the medium term the web-based CR programme, the AP, the AMP and the stress management programme evaluated by Gallacher et al (1997) all demonstrated some indication of improved angina symptoms. However it is possible that the AP and the AMP have the strongest medium term evidence for improvements in angina symptoms. The use of angina diary by Lewin et al (2002) and Lewin et al (1995) demonstrated improvements for multiple aspects of angina symptoms. However, there may be a need to remain cautious with the medium term AMP evidence, as the 4 month follow up findings were not compared to a control group (Lewin et al 1995).

8.11 Conclusion

This doctoral research project was carried out to determine the effectiveness and feasibility of a new web-based alternative to conventional CR for those with angina in primary care. Data derived from an RCT indicated the programme's potential to significantly improve levels of daily steps, daily EE, DDSA, DDMA, weight, self-efficacy, anxiety, emotional QOL, and angina symptoms. These improvements were significantly more favourable compared to a usual care control group in the short-term (PA, weight, self-efficacy, emotional QOL, and angina symptom frequency) and medium-term (anxiety, and angina symptom frequency). Semi-structured interviews provided further support for these effects and in addition highlighted the issues that might challenge engagement in the programme (family and work commitments, bad weather, older age, receiving the programme late in angina diagnosis, and level of self-motivation). Overall the study indicated that this web-based CR programme

could be considered as both an effective and feasible programme for those with angina in primary care, a population seldom included within standard CR practice.

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Appendix 1 – Participant invitation letter

Dear (Patient's name),

I am writing to you to ask you to take part in research being conducted at Coventry University. A new cardiac rehabilitation programme has recently been designed for patients to use on the internet. Researchers at Coventry University are investigating whether this programme is effective for patients with angina.

Please read the enclosed information pack which explains the study in more detail. Once you have read this please complete and return the reply slip using the stamped addressed envelop provided. It would be helpful if you could return the form within a week of receiving this letter.

If you have any questions please feel free to contact Reena Devi, a member of the research team at Coventry University via telephone or email – 024 7688 7455, reena.devi@coventry.ac.uk

Thank you for reading this letter.

Yours sincerely,

GP signature

Online Study of CArdiac Rehabilitation - The OSCAR

Participant Information Sheet

Before you decide whether or not you would like to take part in this research project you should understand why the research is being done and what it will involve. Please read this information pack to decide whether or not you would like to take part. If you have any questions please contact Reena Devi via telephone or email – 024 7688 7455, devir3@coventry.ac.uk

What is the purpose of the study?

Cardiac rehabilitation is a programme designed for heart disease patients, it helps patients achieve their full potential in terms of physical and psychological health. Cardiac rehabilitation also helps patients to effectively manage stress and provides information about healthy eating and exercise. The purpose of this study is to assess whether cardiac rehabilitation delivered on the internet is useful and successful for patients with angina.

Why have I been chosen?

You have been chosen for this study as you have angina. Staff at your local NHS Primary Care Trust have identified you as suitable for this study.

Do I have to take part?

It is your choice whether or not you decide to take part. If you do take part you will be given this information sheet to keep and be asked to sign a consent form. You are free to withdraw from the study at any time without having to provide a reason.

What do I have to do?

If you decide to take part you will be randomly selected to either receive the cardiac rehabilitation treatment or treatment as usual. If you are selected to receive the cardiac rehabilitation treatment you will be required follow the online programme.   This programme offers advice regarding lifestyle changes you could make to help reduce your risk of having a cardiac event. The programme also contains an individualised

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exercise training programme and questions to assess how much you understand about heart disease. However, if you are randomly selected to take part in the 'treatment as usual' group you will continue with your GP visits as normal.

What will happen to me if I take part?

Regardless of which treatment you receive you will be required to complete a range of assessments, each designed to assess your general health status. These assessments include taking a blood pressure, body fat, and body weight measure. Additionally the number of steps you walk will be measured using a physical activity monitor. This physical activity monitor is an armband which will assess your walking activity. You will be required to wear this armband on three separate occasions –

- For a period of one week prior to the study

- For a period of one week after the study

- For a period of one week six months after the study.

Further, you will be required to complete questionnaires which assess your diet, level of anxiety, level of depression, perceived health status, level of positivity, your quality of life, self confidence, and healthcare costs. All of these assessments will be taken at the start of the study, 6 weeks after randomization and 6 months after treatment. These measures will be repeated in order to assess how much progress you have made. If you are randomly selected to receive the cardiac rehabilitation treatment you may also be asked to take part in an interview with the researcher. This interview will ask questions about your attitudes and perceptions of the programme. This interview will be tape recorded and transcribed. Any quotes used will be anonymous when used in report writing.

What are the possible disadvantages and risks of taking part?

There are no foreseeable side effects of taking part.

What are the possible benefits of taking part?

If the internet based cardiac rehabilitation programme is found to be useful and helpful it will be patients with angina it will be offered to other patients.

What if something goes wrong?

If you are harmed by taking part, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms would be available to you.

Will my taking part in this study be kept confidential?

All data collected about you during the study will be kept strictly confidential. Any information given will be used for research purposes only. Results will be reported in such a way that completely preserves confidentiality.

What will happen to the data collected during the study?

The data collected in this study will be analysed and used to evaluate the internet programme. If requested you will be able to receive a summary of the research findings.

Who is organising and funding the research?

This study has been organised and funded by the Warwick and Coventry Primary Care Research Network.

Who has reviewed the study?

This study has been approved by local NHS research ethics committee and University ethics committee. This approval means that the committees are satisfied that your rights will be respected and that you have been given enough information to make an informed decision. Further, approval ensures that any risks have been reduced to a minimum and balanced against possible benefits.

Contact for further information

If you have any concerns or questions you are able to contact the researcher carrying out this project - Reena Devi, Tel: 024 7688 7455, devir3@coventry.ac.uk

Thank you for reading this.

Reply Slip

Please complete this reply slip in BLOCK CAPITALS and tick the relevant boxes.

Name: ……………………………………………………………………………….

I prefer <u>not</u> to take part in this study. ☐

Please indicate why you do not wish to take part (optional).

………………………………………………………………………………………

………………………………………………………………………………………

………………………………………………………………………………………

If you do not wish to take part please complete the attached 'patient details' sheet (optional).

I am interested in taking part in this study and

agree to a researcher from Coventry University to contact me. ☐

Address: ………………………………………………………………………….

……………………………………………………………………………..

Postcode: …………………………………………………………………………

Email address: ……………………………………………………………………...

Telephone: (daytime)   _____

(evening)   _____

(mobile)   _____

I have read the participant information sheet and understand ☐

that I can change my mind about participating in the study at any time

Please return the form in the pre-addressed envelope provided.

THANK YOU

Participant Consent Form

Please initial box

1. I confirm that I have read and understand the participant information sheet and have had the opportunity to ask questions.

☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

☐

3. I understand that sections of any of my medical notes may be looked at by responsible individuals where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

☐

4. If I am randomly selected to take part in the online cardiac rehabilitation programme I am willing to participate in a patient and researcher interview after the programme. I understand these interviews will be tape recorded and anonymous quotes used in report writing.

☐

5. I agree to take part in the above study.

☐

_____   _____   _____
Name of Patient   Date   Signature

_____   _____   _____
Name of Person taking consent   Date   Signature
(if different from researcher)

_____   _____   _____
Researcher   Date   Signature

National Research Ethics Service

Coventry Research Ethics Committee

2nd floor West Wing
University Hospital
Clifford Bridge Road
Coventry
CV2 2DX

08 January 2009

Tel: 024 7696 7529
Fax: 024 7696 5033

Ms Reena Devi
Research Student
Coventry University
Faculty of Health & Life Sciences
Whitefriars Building
Coventry
CV1 5FB

Dear Ms Devi

Study title:	**Evaluating an interactive web-based cardiac rehabilitation programme in terms of the programme's effectiveness and acceptability.**
REC reference:	**08/H1210/84**
Amendment number:	**AM01**
Amendment date:	**15 December 2008**

Thank you for submitting the above amendment, which was received on 23 December 2008. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMPs)	AM01	15 December 2008
Covering Letter	from Reena Devi	
Letter of invitation to participant	Version 3	15 December 2008

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

This Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority

Yours sincerely

Ms Pauline Pittaway
Committee Co-ordinator

E-mail: pauline.pittaway@uhcw.nhs.uk

Copy to: *Professor Sally Singh, University Hospitals of Leicester NHS Trust,*
                  Glenfield Hospital, Groby Road, LE3 9QP

                  R&D office for Coventry & Warwickshire Partnership Trust

Coventry **NHS**
Teaching Primary Care Trust

West Midlands (South) Comprehensive Local Research Network
CLRN Office
Fourth Floor Rotunda (ADA40017)
University Hospitals Coventry & Warwickshire NHS Trust
University Hospital
Clifford Bridge Road
Coventry
CV2 2DX

30th January 2009

Reena Devi
Faculty of Health & Life Sciences
Coventry University
Priory Street
Coventry
CV1 5FB

Dear Ms Devi

Re: *Online Study of CArdiac Rehabilitation, The OSCAR Trial*

MREC: AB/127011/1   R&D: COV100408

I am writing to confirm receipt of the following amendments sent on the 30th January 2009 in relation to the above research:

- Letter of Invitation to Participant Sheet Version 3

I can confirm that the Trust is happy to approve these amendments and they will be filed appropriately. Thank you for keeping R&D informed.

Yours sincerely

Luke Chaplin
R&D Facilitator

Reena Devi

From:	Denise Mclardy
Sent:	13 May 2009 11:58
To:	Reena Devi
Subject:	RE:Ethical approval
Importance:	High

Dear Reena

Thank you for your Ethics application. Your submission has undergone full consideration including final approval by the Chair of the University Applied Research Committee. I will send to you, for your records, the final decision recorded.

I am pleased to inform you that you may now proceed with your research. Should you have any further queries, please do not hesitate to contact me.

Best wishes,

Denise

Denise McLardy
Senior Registry Assistant
Registry Research Unit
Graduate and CPD Centre, Room 109
Coventry University
Priory Street
Coventry
CV1 5FB
Tel: +44 (0)24 7688 8217
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Comment [RD1]: Perhaps more suited to someone with a recent cardiac event

Comment [RD2]: Perhaps more suited to someone with a recent cardiac event

**Comment [RD3]:** Further along the line people become more relaxed

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Appendix 9   **–** Examples of coded data being placed into Categories, examples provided are for categories - 'easy to use', 'motivation', 'support on the programme', 'created awareness', and 'source of information'

Easy to use

Participant 1 Easy to use – line 85 - ▉ No, it is quite straight forward and its easy to find your way around and navigate around. No, there is no problem there.

Participant 6

1. Easy to use – line 50

    ▉: (laughs) But otherwise I found it very good, very useful, ermm very easy to use, for somebody who is not very good on computers it was very easy.

    ▉: Yep it was very good. It is simple enough for me to use so it's simple enough for anybody to use that's the way I look at it.

    Line 189

I didn't have any problems at all with it at all really. It was simple enough to use and yes no problems at all.

Participant 9

1. Programme easy - – line 113 - Participant: Errr (pause), If I had taken it a step further and you had said the exercise you should do is an hour or an hour and a half you know if you up the period and then if you up 1 or 2 of the other aspects then yes I might have found it a more, not stressful but hard going, err but as it is it was quite easy.

Participant 10

1. Easy to use – line 229 - Participant: Piece of cake, I mean I'm not a, I have been on the internet for a while now and I had to learn how to use a computer a few years ago now and just going onto a few websites is fine, this one navigating around it is a piece of cake, anybody could do it. And errr if I can do it anybody can, I'm no computer genius.

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Participant 11

1. The programme is easy to use – line 259 - Participant: Oh I didn't have any problems with that that was easy. Easy to get into errr, just put your password in and name or whatever it is in, errr and then learnt to go straight onto exercise programme and that was it then once a week click the button to take the test.

Participant 12

1. Easy to use – line 477 - ▇: Erm, I didn't find it difficult at all.

Participant 13

1. Easy to understand – line 11 - it's easy to understand, it's very easy to find your way about
2. Easy to use – line 11 - ermm I did print quite a lot of this stuff off actually
Line 22 - obviously when you find your way about err any sort of system like that it becomes easier to use and you feel more comfortable with it. There was nothing I found difficult or awkward it was all straight forward so I was pleased and happy with it.
Line 410 - Ermm I didn't, I'm not particularly brilliant on a computer, but I didn't have any problems with that. I got lost in it once or twice but going in and out of it into the different sections, you've got all the different pages and you can work your way through.

Participant 14

1. Easy – line 379 - Just quite easy, yeah it was. It was quite an easy programme actually, basic and easy.

Participant 15

1. Found it easy to use – line 342 - Interviewer: Ok, did you find it ok to use, easy or difficult?
B▇ Oh I found it very easy to use.

Participant 16

1. Easy to use – line 139 - I thought it was a very easy programme to follow I mean, from that point of view it had been well laid out and you couldn't really go wrong and I thought it was very clear.
Line 416 - ▇: It was easy enough to use and follow. Once you show me how to get started.

Line 437 - ▇: No, I don't think so. I would have been obviously carefully thought out and it was easy enough to follow.

Line 437 - ▇ No, I don't think so. I would have been obviously carefully thought out and it was easy enough to follow.

Motivation

Participant 1 - Motivation – line 60 - ███ Well it makes you do something positive and up till going on the programme, I must admit I didn't think about it really, but its motivates you to think ohh I've got to get up and do 30 minutes exercise today. (laughs) Because I've got to go up and fill it in. Ermm its motivating.

line 91 - ██ Yes as I just said a few minutes ago, it does motivate you to think, its driving you along in a way.

It's a good motivator.

Participant 4

1. Motivated not to get worse – line 178 - ████: I don't know, determined not to get me worse I think. But it's difficult because I'm not in control, everything I do I have to think of him first, so I can't go out in the car and go and walk somewhere nice because I'd be away too long. It's not easy.

Participant 6

2. The programme gave motivation – line 125

██: I don't know really, because, I think the programme itself has made me, because I agreed to do it then it's made me lose weight. I've had to do it. I didn't want to let you down or anyone else down. Ermm so I knew I needed to lose weight and get some more exercise, and I think doing this programme has forced me to do it. Whereas I probably wouldn't have done it before on my own without some sort of help like this.

Participant 8

1. Increased motivation – line 49 - but once I realised that I had to get up and walk about err it made me self motivate.
   Line 99 - Participant: Err, (pause) well I think it's just got me self motivated, before I was perhaps idol or lazy (laughs) err and you know walked when I had to err and now I'm walking as much for pleasure

Participant 12

2. Now encouraged to push – line 79 - I was getting pains in my chest all the time I was frightened to push my heart, just in case I had a heart attack or whatever.
   Line 158 - But it's given me the push.

Line 164 - ■: Whereas before I would have just sat at home and just you know put up with it because I had angina but now I've got a focus now.

3. Feel motivated to lose weight – line 156 - I presume I'm gonna need to do more exercise to shift the weight and then feel a lot better and hopefully feel like how I used to like 10 years ago but that will take a lot you know, probably another 6 months or so. But it's given me the push.

Support on the programme

Participant 2

1. Support on the programme – line 68 - ■: There is a little thing there for people who need help I haven't tried that. I've just used the information on there and that enough. But it was nice to know that it was there, I, one of my problems is that I get angina here, at the top of my stomach and also in my throat. And I would have liked to have maybe talked to somebody about it, but I haven't had the nerve to do it (laughs).

Participant 3

1. Support – line 201 - ■: Yes I enjoyed the support, I think that's what I would say about you and the programme is that I feel I am supported now, whereas before although my medical centre are really good, they are really really really good, I would never criticise them but it's always you feel you are bothering them. Because there is so many sick people sitting in the waiting room and you know. But with this I think its great, its great!

Participant 6

3. Support – line 45

Ermm this programme, everything is on there that you need to know and you've got the back up from the doctors at the hospital if you need it.

4. Online support – line 157

■ Ermm and the back up is there, you can email the consultants with any queries or questions. Yeah.

Interviewer: So its easier than going to the hospital?

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■: Yeah, and if you are really concerned and you email the consultants the consultants are going to say well, I think you should go and see the GP or your own consultant. They know, like you might just email and say I'm getting chest pains but they're not too bad, you know. I don't think you can do yourself any harm through doing this programme at home but I do think you get some help from it.

Participant 10

2. Contact and support is available – line 260 - If you've got any problems I can give you a call, I can email you. I can even get in touch with the hospital.

Participant 13

3. Support – line 305 - As I said I didn't have to use the forum and I didn't have to ask any questions but had I wanted to you know the opportunity is there for you to do that

Participant 15

2. Helpful support on the programme – line 10 - And it's been very good to be able to contact the nurse on a Wednesday and I thought that was a brilliant idea because although I didn't have any particular worries I did ask about my heart beat and they said to see my doctor so I got that feedback which was there and then.
Line 83 - I could talk to someone without having to bother the doctor and you know it was between 7-8

Line 327 - I mean you know the Wednesday night thing was very good

Participant 16

2. Support on the programme – line 392 - ■: I would have thought so, I mean if you need help it did invite you to click here if you want some further information or whatever, that's all you've got to do. And hopefully someone will say what you're doing is right, or no I don't think you should be doing that.

Created awareness –

Participant 1 –

Created awareness – line 182 - ■: Initially it, you when you given the exercise it made it clear to me how unfit and unexercised I was really.

Interviewer: So it made you realise that?

■: Yeah, yeah. And that's the tool to do something about it. Otherwise I would have carried on not bothering really ermm it brings it all home really, it's a wake up call and that's good if you can carry on with the programme.

Participant 2

Raised awareness – line 37 - I found that very helpful, it also tells you why sometimes I also hadn't, well I knew stress did cause problems but I don't think it caused as much. It has made me look at myself a lot more, now I know a lot of mine has been stress related. We have had a lot on, ■■■■'s mum died in July so its been one of those years you know. We've had a lot of problems with other people but I do take a lot of it on myself you know so I'm now learning to try and step back which has (pause) I wouldn't have done it if it hadn't have been for the programme, with the programme explaining it to me. I found the whole thing very good.

Participant 2

2. Helped this participant realise that stress was brining angina on – increased awareness – line 89 - ■G: I think its because I feel more confident about it. Because I know now why its happened. Whereas before sometimes I'd think why am I getting angina I'm not doing anything but it was actually because I was getting stressed out about something, usually a family matter. So now when they start I have to say I can't deal with your problems as well as my own and I'm really able to do that now whereas before I would have jumped in the car, gone over and tried to sort out the problem. Whereas now I say no, I can't do that anymore. Because it does bring it on, so I say no. I say, I can help you and we'll talk about it, or you can come here and we'll talk about it. But I'm not coming to you, wherever, if its ■■■■ or ■■■■■■, so I'm being, that's helped me a lot to understand that it is. I mean I can feel it coming now, because I'm getting uptight, so I've got to (laughs).

Participant 3

Raised awareness – line 156 - I'm more conscious about the drinking, which I say is a good thing.

Participant 4

Created awareness of how unfit – 172 - ■■■: Well it's made me more aware of how unfit I am, which is a good thing I suppose but frightening in another way. Erm I think it's changed my attitude in some way,

Participant 4

Raised awareness and frightened the patient – line 231 - ■■■ Well at times I've been disappointed, because like I say it's really emphasising how I wasn't fit and this angina business wasn't really frightening for me at all to be honest I'm not being scared or started thinking oh my life is limited and that sort of thing.

Line 238 - ■■■: But it is slightly because of what I couldn't do, it made me more aware of, erm that I'm not as well as I should be.

Interviewer: So before the programme you weren't really.

■■■ Well I never got sort of scared not at all about it. And I don't know why, maybe I should have been I suppose.

Interviewer: And the programme frightened you?

■■■: Well it didn't frighten me it just made me more aware of what I couldn't do.

Line 252 - make you realise how you've deteriorated through the years you know. It's just one of those things you know.

Interviewer: And err,

■■■: I think it's been good in that it's made me aware, you know that I've got to sort of look after myself and try a bit more so I've appreciated doing it. Even if I had dreaded doing the walking, (laughs)

Participant 5

Created awareness with diet – line 322 - Interviewer: So the main change is the diet?

■■■: Yes the diet has changed, yeah, it's triggered that, it's made me think.

Participant 8

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Learning and increased awareness – line 38 - Participant: And err it gave me a better idea of what was happening and what had happened to me.

Line 60 - Participant: It just made me realise what I needed to do to see if it would make any improvement, err to the heart condition.

Participant 15

Learning and awareness – line 7 - Most importantly I found out about my irregular heartbeat, which I may not have done err had I err not undergone the programme, so its been very helpful in that way ermm because you know I would have thought I still had indigestion so I'm very thankful for that.

Participant 15

Increased awareness – line 21 - But ermm because I was doing it more frequently I noticed that my irregular heart beat which I thought was indigestion and I had one of those things to show you your heart beat and then I knew it was irregular.

Interviewer: Hmm

█: And so I would never have ermm found out had I not been doing regular exercise.

line 51 - Well you see I was very good with my diet, it's made me the diet thing I do errrm have 5 fruit and veg a day, but I was doing that I think anyway so erm its made me much more aware of all that and ermm

line 156 - █ No, but it was very good because it you know, it did make me much more aware, and it gave me the and made me carry on doing it, made me realise the importance of doing it and reassured me it's important to do it

Participant 13

4. Increased awareness – line 257 - █: Well yes, I think I've already gone through that as well I think it's sort of because you know whats happening and whats likely to be done about it and what you need to avoid things it makes you aware of the problems that are likely to becoming along you know and ermm ways in which you can probably try to avoid them. And as well as the tablets side of it, it gives you all the information about the pills so you know.
    Line 273 - █: Yes because it tells you on there about statins and the fact that if you get muscle pain you're to go I mean on the leaflet of the tablets if you get it, if you can't get hold of your doctor you have got to go to causality, so it's quite ermm you know. It's quite err, I've read it on the programme so I'm forewarned aren't I. So awareness yeah definitely absolutely.

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Source of information

Participant 3

2. Source of information – line 7 - Err, but this programme I found very helpful because when I was feeling a bit stressed I could go to see how to ease it.
3. Learning – 125 - Ermm, I did read about the heart, I didn't know much about the heart before, but I did read all that.

Participant 4

2. Information useful – line 93 - ███: The information about it was useful but I can't think of anything that is absolutely outstanding.

Participant 4

1. Learning – line 98 - ███: I don't really know, I can't think. I think there were 1 or 2 things where I thought oh I didn't know that. I can't just recollect anything specific.

Participant 10

3. Increased learning – line 206 - some of the questions you're asked at the end of each stage, some of the questions you're asked are the heart, whats this drug used for which are ones I take and it does actually make you stop and think what do I actually take and what does it mean to be in this situation. Its very very good.

Participant 13

5. Increased learning – line 105 - Interviewer: Is there anything else you feel is different?
███: Well I feel like I know more about it, I've certainly got more knowledge on the heart and what it does and what happens if it does wrong and what they do about it and things to do to try and prevent it going wrong.

Participant 16

3. Learning – line 58 - ███: Other than learning a little more about the function of one's heart, yeah, I think that was useful.