

**PSYCHOLOGICAL FACTORS ASSOCIATED WITH WALKING IN PATIENTS
WITH
PERIPHERAL ARTERIAL DISEASE**

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CONTENTS

1. INTRODUCTION	1
OVERVIEW	2
PERIPHERAL ARTERIAL DISEASE	2
TREATMENT	9
PSYCHOSOCIAL FACTORS AND PAD	23
COMMON-SENSE MODEL OF SELF-REGULATION OF HEALTH AND ILLNESS	25
SUMMARY	30
2. RATIONALE AND GENERAL AIMS	31
OVERVIEW	32
PATIENT POPULATION	32
BEHAVIOUR	32
THEORETICAL BASIS	33
SCOPE OF THE THESIS	35
MRC FRAMEWORK FOR DEVELOPING AND EVALUATING COMPLEX INTERVENTIONS	36
GENERAL AIMS	37
SUMMARY	38
3. PSYCHOLOGICAL FACTORS ASSOCIATED WITH WALKING IN PATIENTS WITH INTERMITTENT CLAUDICATION – A QUALITATIVE STUDY	39
ABSTRACT	40
INTRODUCTION	42
METHOD	46
RESULTS	54
DISCUSSION	72
SUMMARY AND IMPLICATIONS	77
4. GENERAL METHODS	78
OVERVIEW	79
ILLNESS REPRESENTATIONS	80
TREATMENT REPRESENTATIONS – CONSEQUENCES AND PERSONAL CONTROL	81
INTENTION TO PERFORM THE BEHAVIOUR	83
HEALTH BEHAVIOURS	84
HEALTH RELATED QUALITY OF LIFE	85
GENERAL QUALITY OF LIFE	87
WALKING BEHAVIOUR – IC	87
WALKING BEHAVIOUR – PEDOMETER	88
WALKING BEHAVIOUR - IPAQ	89
DESIGN OF INTERVENTION	90
5. APPLYING LEVENTHAL’S COMMON-SENSE MODEL TO PATIENTS WITH INTERMITTENT CLAUDICATION – A CROSS-SECTIONAL STUDY	98
ABSTRACT	99
INTRODUCTION	101
METHOD	104
RESULTS	108
DISCUSSION	128
SUMMARY AND IMPLICATIONS	134

6.	MODIFYING ILLNESS AND TREATMENT REPRESENTATIONS TO INCREASE WALKING IN PATIENTS WITH INTERMITTENT CLAUDICATION – A PILOT RANDOMISED CONTROLLED TRIAL	135
	ABSTRACT	136
	INTRODUCTION	138
	METHOD	146
	RESULTS	157
	DISCUSSION	188
	SUMMARY AND IMPLICATIONS	197
7.	GENERAL DISCUSSION	199
	OVERVIEW	200
	SUMMARY OF FINDINGS	200
	THEORETICAL IMPLICATIONS	203
	IMPLICATIONS FOR CLINICAL PRACTICE	210
	LIMITATIONS	213
	DIRECTION FOR FUTURE RESEARCH	215
	WHAT DOES THIS THESIS ADD?	218

LIST OF TABLES

Table 3.1	Demographic characteristics of the participants (n=20)	47
Table 3.2	Set questions asked in each interview	49
Table 3.3	Final themes	54
Table 4.1	Summary of measures used in each study	80
Table 4.2	Steps in developing a theory based behavioural intervention	91
Table 4.3	Techniques used in the intervention	96
Table 5.1	Characteristics of the sample by group	109
Table 5.2	Current walking behaviour by attempt to increase walking (n=87)	110
Table 5.3	Participants' (n=91) beliefs about the causes of PAD	113
Table 5.4	Correlations, means and standard deviation of all variables in the no claudication pain group	116
Table 5.5	Correlations, means and standard deviations of all variables in the claudication pain group	119
Table 5.6	Logistic regression to predict adherence to recommended walking levels	125
Table 5.7	Multiple regression of illness and walking representations on health-related quality of life in participants who have claudication pain	127
Table 6.1	Baseline Characteristics: Control Group, Intervention Group and Overall Study Population	159
Table 6.2	Correlations, means and standard deviations of all variables at baseline	162
Table 6.3	Factor loadings based on principal components analysis with varimax rotation for baseline variables	164
Table 6.4	Outcome variable scores in the intervention and control groups at baseline and 4 month follow-up (intention-to-treat data)	167
Table 6.5	IPAQ scores at baseline and follow-up	168
Table 6.6	Self-report walking through the pain at baseline and follow-up	169
Table 6.7	Self-report walking for at least half an hour at baseline and follow-up	170
Table 6.8	Pain-free walking distance across the trial period	171
Table 6.9	Clinical Outcome by Experimental Group	171
Table 6.10	Comments about the action plan by participants in the intervention group	187

LIST OF FIGURES

Figure 2.1	The Common-sense model of self-regulation of health and illness. Adapted from Horne (2003)	33
Figure 2.2	MRC Framework – Key phases of the development and evaluation process (Craig et al, 2008)	36
Figure 5.1	Pain-free walking distance by adherence to recommended walking levels in group with claudication	112
Figure 5.2	Plot of the first 2 components in rotated space	122
Figure 6.1	CONSORT flowchart of trial design	152
Figure 6.2	Mean daily steps at baseline and follow-up	166
Figure 6.3	Dietary behaviour at baseline and follow-up	172
Figure 6.4	General quality of life over time	174
Figure 6.5	Walking personal control at baseline and follow-up	175
Figure 6.6	Beliefs in positive walking consequences at baseline and follow-up	176
Figure 6.7	Beliefs in negative walking consequences at baseline and follow-up	177
Figure 6.8	Intention to walk at baseline and follow-up	178
Figure 6.9	Intention to walk through pain at baseline and follow-up	179
Figure 6.10	The mediating effect of walking personal control and intention to walk on the relationship between group and walking behaviour	185

LIST OF APPENDICES

Appendix 1	Example of letter of invitation, information sheet and consent form given to participants (Chapter 3)	244
Appendix 2	Questionnaire (Chapters 4, 5 & 6)	248
Appendix 3	Schedule of questions used in Session One of the RCT (Chapter 6)	257
Appendix 4	Information sheet used in Session One of the RCT (Chapter 6)	258
Appendix 5	Template for action and coping plan used in Session Two of the RCT (Chapter 6)	260
Appendix 6	Schedule of questions used in the telephone calls (Chapter 6)	262
Appendix 7	Example of letter of invitation, information sheet and consent form given to participants (Chapter 5)	265
Appendix 8	Example of letter of invitation, information sheet and consent form given to participants (Chapter 6)	269

Abstract

Objectives This thesis aimed to explore psychological factors associated with walking behaviour in patients with Peripheral Arterial Disease, within the framework of Leventhal et al's (1998) Common-sense Model of Self-regulation of Health and Illness. The objective was to identify psychological factors which could be modified to increase walking behaviour in these patients.

Method A series of three studies were conducted to achieve these aims. The first study was an exploratory qualitative study, to explore the illness and treatment beliefs and walking behaviour of patients with intermittent claudication. The second study was a cross-sectional postal questionnaire to a cohort of patients with intermittent claudication, which tested the influence of the psychological factors identified in the qualitative study, in a larger sample. The final study was a randomised controlled trial of a brief psychological intervention designed to modify the illness and walking beliefs of patients with intermittent claudication, in order to increase walking behaviour.

Results Beliefs about intermittent claudication, and beliefs about walking were both found to be associated with walking behaviour in the qualitative study. The results from the cross-sectional postal questionnaire confirmed this relationship – taken as a set, illness and walking beliefs accurately predicted adherence to minimum walking levels for 93.4% of the sample. The brief psychological intervention successfully modified illness and treatment beliefs and increased walking behaviour in patients newly diagnosed with intermittent claudication.

Conclusion This thesis highlights the importance of illness and walking beliefs to the walking behaviour of patients with intermittent claudication. The thesis has added to the body of knowledge about intermittent claudication, and the findings of this thesis have implications for the treatment of patients with intermittent claudication within the health service. Theoretical and clinical implications of this research are discussed.

CHAPTER ONE

INTRODUCTION

CHAPTER ONE

Overview

This chapter aims to give an introduction to Peripheral Arterial Disease (PAD), highlighting the causes and consequences of the disease, and considering the treatments that are currently available. PAD has behavioural risk factors, and treatment of PAD involves health behaviour change, therefore application of psychological theory to increase understanding of PAD may enhance the current treatment of patients with PAD. The potential contribution of the Common-Sense Model of Self-Regulation to our understanding and treatment of PAD will therefore be considered.

Peripheral Arterial Disease

Peripheral Arterial Disease is caused by atherosclerosis in the leg arteries, which leads to a reduction in blood supply to the lower limbs. Atherosclerosis is the build-up of fatty plaque on the wall of an artery which causes the artery wall to thicken. Over time, atherosclerotic plaque may rupture into the lumen of the artery, causing stenosis (narrowing) of the artery. This narrowing reduces the volume of blood which can flow through the artery. Narrowing of the arteries which supply blood to the legs or arms is known as Peripheral Arterial Disease (PAD).

Risk factors for atherosclerosis and PAD include hypercholesterolemia (high cholesterol levels), diabetes, hypertension (high blood pressure), smoking, obesity, and older age (Murabito et al, 2002). In a study of middle-aged adults in the US, Murabito et al (2002) found that there was a 2.6 fold increase in the prevalence of

CHAPTER ONE

PAD for each 10 year increment in age, and hypertension and smoking were each found to double the odds of PAD.

The symptoms of PAD are commonly classified using the Fontaine stages as described by Rutherford et al (1997) - Fontaine Stage I is classified as asymptomatic disease, Fontaine Stage II is classified as intermittent claudication, Fontaine Stage III is classified as ischemic rest pain, and Fontaine Stage IV is classified as tissue loss.

Fontaine Stage I, asymptomatic disease, is thought to be the most prevalent stage of PAD; however, it is rarely diagnosed as there are no symptoms. Fowkes et al (1991) analysed the prevalence of both asymptomatic and symptomatic PAD in a large general population-based sample of 55 to 74 year olds in the Edinburgh Artery Study and found that 24.6% of the sample had asymptomatic PAD causing a major impairment to blood flow. In the US-based PAD Awareness, Risk and Treatment: New Resources for Survival (PARTNERS) programme, Hirsch et al (2001) studied a large group of patients aged 70 years or older, or aged 50 to 69 but with a history of cigarette smoking or diabetes, and found clinical evidence of PAD but no, or atypical leg symptoms in 41.8% of the sample - this increased prevalence is probably due to the increased number of risk factors for PAD present in the sample.

Fontaine Stage II, intermittent claudication (IC), is leg pain when walking, which relieves immediately upon resting. The pain can take the form of cramping pain, discomfort, weakness or a heavy feeling and can occur in the hip, buttock, thigh, calf or foot (Rutherford et al, 1997). IC tends to occur more quickly if walking up an incline,

CHAPTER ONE

up stairs or at a faster pace. Claudication pain is thought to be a result of a build up of lactic acid in the muscle due to anaerobic metabolism. As the muscle has to work harder during exercise, the reduced blood flow through the narrowed artery does not deliver enough oxygen for aerobic metabolism, and so lactic acid is produced in the muscle, causing the claudication pain (Tan, de Cossart & Edwards, 2000). The pain is relieved within 1 or 2 minutes of rest, as the lactic acid dissipates.

A number of large scale population studies have attempted to measure prevalence of IC within the population. Fowkes et al (1991) found that 4.5% of 55 to 74 year olds who participated in the Edinburgh Artery Study had IC, this figure rose at 5 year follow-up to 7.1% of the sample (Leng et al, 1996). While in a US study of PAD, Criqui et al (1985) found a 3.1% prevalence of IC among participants under age 60, rising to 5.4% prevalence in 60 to 69 year olds, and 7.7% prevalence in the over-70s. Similar rates of IC were found in a Dutch study with 4.7% of 45 to 54 year olds, 6.9% of 55 to 64 year olds and 9% of 65 to 74 year olds being found to have IC (Stoffers, Rinkens, Kester, Kaiser & Knottnerus, 1996). Hirsch et al (2001) found a 4.9% prevalence of classic claudication symptoms in the PARTNERS programme. The incidence of PAD is thought to be increasing, due to an ageing population (Golomb, Dang & Criqui, 2006) and increasing levels of obesity and diabetes in the population (Sumner, Eid, Parks, Edris & Reed, 2007).

Stage III and IV PAD are less prevalent in the population. Stage III PAD, critical limb ischemia is characterised by resting leg pain. Prevalence has been found to be around 0.25% of 40 to 69 year olds (Jensen, Vatten & Mhyre, 2006). Stage IV PAD, the

CHAPTER ONE

presence of non-healing ulcers on the foot or leg, and tissue loss, is thought to occur in approximately 25% of patients with critical limb ischemia (Jensen et al, 2006). In the 5 year follow-up of the Edinburgh Artery Study, Leng et al (1996) found 1.4% of the sample originally diagnosed with IC went on to develop leg ulceration. The risk of a patient with IC developing critical limb ischemia and requiring amputation is estimated to be less than 1% a year (Burns, Gough & Bradbury, 2003).

Atherosclerotic build-up of plaque on the walls of arteries is not confined to the legs; therefore a diagnosis of PAD is an indicator of generalised atherosclerosis in other parts of the body. Patients diagnosed with PAD are at increased risk of cardiovascular co-morbidity and mortality. Caro, Miglicciaio-Walle, Ishak & Proskorovsky (2005) analysed a large Canadian database of patients with PAD, diagnosed through the health service, and found that subsequent to a diagnosis of PAD, angina, myocardial infarction and stroke each occurred in approximately 10% of the PAD population. 33.2% of PAD patients died, mainly from cardiovascular events, within 5 years of diagnosis of PAD (Caro et al, 2005). By comparing the PAD database, with databases for stroke and myocardial infarction patients, Caro et al (2005) found that the PAD mortality rate is lower than for that for stroke patients (41.8% mortality rate within 5 years of stroke), but higher than the mortality rate for patients suffering a myocardial infarction (26.6% mortality rate within 5 years of myocardial infarction). In the 5 year follow-up of the Edinburgh Artery Study, Leng et al (1996) found that 9.1% of patients who had PAD at baseline, went on to have a myocardial infarction, compared to 6.7% of participants who had no PAD at baseline. Rates of angina (7.2% vs. 5.3%) and stroke (4.5% vs. 2.8%) were also higher for participants with PAD at baseline than those with

CHAPTER ONE

no PAD at baseline. Mortality in the Edinburgh Artery Study was higher for participants with PAD at baseline (18.9%), than for participants with no PAD at baseline (10%); approximately 53% of the deaths among participants with PAD were cardiovascular, although there was also a high incidence of non-cardiovascular death in this group, mainly due to bronchogenic neoplasms, possibly due to the high levels of cigarette smoking in the PAD group (Leng et al, 1996). The difference in mortality rates between the Canadian study and the Scottish study is probably due to sampling methods, as the Canadian study used a database of patients diagnosed within the healthcare services, who probably therefore had more severe, symptomatic disease. The Scottish sample was population-based, with a large proportion of participants with asymptomatic and therefore less severe PAD. Many patients with asymptomatic PAD remain un-diagnosed, however when a diagnosis of PAD is made, it should be seen as an important early warning sign of future cardiovascular problems, and should trigger measures to reduce the risk of death and vascular co-morbidity (Cassar, 2006).

Golomb et al (2006) have suggested that in addition to atherosclerosis causing increased risk of co-morbidity and mortality among people with PAD, PAD may itself be causally involved in increasing the risk of cardiac and cerebrovascular disease. A possible mechanism for this may be that symptomatic PAD reduces walking behaviour, which is itself protective against cardiovascular problems due to its effect on insulin resistance, hypertension and dyslipidemia (Golomb et al, 2006).

As well as having an increased risk of co-morbidity and mortality, patients with IC have been found to have poorer quality of life than age and sex matched controls due to

CHAPTER ONE

pain, restricted mobility, and reduced energy (Breek, Hamming, De Vries, Aquarius & Van Berge Henegouwen, 2001). Barletta et al (1996) used the McMaster Health Index to investigate quality of life and found that patients with IC had significantly lower scores on the global, physical function, emotional function and social function domains than controls. Dumville, Lee, Smith & Fowkes (2004) analysed quality of life data from the Edinburgh Artery Study, measured using the SF-36, and found patients with IC had significantly worse scores in all domains except social functioning and mental health, compared to participants with asymptomatic PAD or no PAD. The mean physical component score of the SF-36 for the IC participants in this study was 39, worse than the US population physical component scores for arthritis (US score = 43), cancer (US score = 45), chronic lung disease (US score = 42), but better than angina (US score = 36) and congestive heart failure (US score = 31) (Dumville et al, 2004). This comparison of SF-36 physical component scores indicates that IC has similarly serious physical consequences as these other major diseases.

Hunt, McKenna & Pope (1982) and Khaira, Hanger & Shearman (1996) used the Nottingham Health Profile to examine the quality of life of patients with IC, compared to healthy older adults. Participants with IC in both studies reported significantly worse energy levels, pain levels, sleep, emotional reactions and physical mobility than controls. Hunt et al (1982) reported that 37.8% of PAD participants reported that their health problems affected their ability to do jobs around the home, 32.2% reported that PAD affected their social life, 68% reported that PAD affected their hobbies, and 30.3% reported that PAD affected their holidays. These results show that PAD impacts on all aspects of patients' lives.

CHAPTER ONE

Severity of PAD has been found to only partially predict health-related quality of life (Breek et al, 2001; Breek, Hamming, De Vries, Van Berge Henegouwen & Van Heck, 2002; Chetter, Dolan, Spark, Scott & Kester, 1997), indicating that factors other than pain and functional limitation may also play a part in the quality of life of patients with PAD. Poorer quality of life in patients with PAD has also been associated with a greater number of co-morbidities, in particular stroke (Breek et al, 2002; Cook & Galland, 1997); greater body mass index (Muller-Buhl, Engeser, Klimm & Wiesemann, 2003); and older age (Izquierdo-Porrera et al, 2005).

PAD has also been associated with depression. Waldstein et al (2003) found that participants with IC (mean BDI=8, SD=8.0) scored significantly higher than both age-matched healthy controls (mean BDI=3.7, SD=3.3), and patients with hypertension (mean BDI=4.8, SD=4.5) on the Beck Depression Inventory; and had comparable depression scores to patients who had had a stroke (mean BDI=8.4, SD=7.0). Arseven, Guralnik, O'Brien, Liu & McDermott (2001) examined the association between PAD and depression, and found that participants with PAD reported depression twice as often as non-PAD participants. Participants with more severe PAD had a significantly greater number of depressive symptoms. Greater walking ability, in terms of distance the participant could walk in 6 minutes, was significantly associated with lower depression scores among participants with PAD. This relationship between walking ability and depression may be bi-directional, as impaired physical ability is a risk factor for depression (Turner & Noh, 1988) and older adults with depression are at increased risk of physical decline (Pennix, Guralnik & Ferrucci, 1998).

CHAPTER ONE

Finally, PAD has been shown to affect cognitive function, due to generalised atherosclerosis. Waldstein et al (2003) found that IC patients performed significantly worse than healthy controls, and patients with hypertension, but better than stroke patients, on a range of cognitive tests measuring nonverbal memory, concentration, executive function, perceptuo-motor speed and manual dexterity; these results were independent of age, education and depression scores. Waldstein et al (2003) concluded that these results suggest that cognitive impairment becomes steadily worse with increasing levels of cardiovascular disease. The cognitive deficits of patients with IC may affect their ability to follow complicated treatment instructions, for example detailed advice about how and when to exercise.

Treatment

Patients with PAD have been described as 'a high risk, but neglected, disease population' (Tomson & Lip, 2005), because the disease is thought to be both under-detected and under-treated. A number of reviews of PAD have been critical of the way PAD is currently under-diagnosed in primary care, and of the less intensive management of risk factors of patients with PAD compared with patients with other cardiovascular diseases (e.g. Golomb et al, 2006; Khan, Cleanthis, Smout, Flather & Stansby, 2005; Tomson & Lip, 2005).

There are reliable, non-invasive methods for diagnosing PAD including measuring the Ankle Brachial Pressure Index (ABPI), which is the ratio of systolic blood pressure in

CHAPTER ONE

the legs to systolic blood pressure in the arms. An ABPI of less than 0.9 is taken as an indication of the presence of PAD, with lower ABPI indicating more severe disease (Fowkes et al, 1992). Golomb et al (2006) suggested that assessment of ABPI should take place as part of a general assessment of cardiovascular risk in primary care. However, in the PARTNERS programme, Hirsch et al (2001) found that primary care doctors are often not aware that their patients have PAD. Savader, Porter, Ehrman & Haikal (2001) assessed patient compliance with physician recommendations following screening for PAD in a community hospital. Patients could either self-refer for screening or be referred by physicians. Of the 205 patients who attended screening, 48 (23%) were found to be at high or moderate risk of developing PAD, with 77% of the moderate to high risk group reporting symptoms of IC. However, at seven month follow-up, 31 (70%) of those patients at high or moderate risk of developing PAD had not complied with advice to seek out care from a vascular specialist after the screening. Savader et al (2001) suggest this may be due, at least in part, to lack of insurance, however, the low compliance with recommendations may also be due to an inability to remember verbal instructions, poor understanding of written instructions, and a poor attitude to self-care (Savader et al, 2001).

Several studies have shown that once a diagnosis of PAD has been made, atherosclerotic risk factors are not managed as intensively as they are in patients who have coronary artery disease (e.g. Hirsch et al, 2001; McDermott, Mehta, Ahn & Greenland, 1997). McDermott et al (1997) found that patients with coronary artery disease were more likely to be taking aspirin or warfarin than patients with PAD; patients with coronary artery disease and high cholesterol levels were significantly

CHAPTER ONE

more likely to have their cholesterol treated than patients with high cholesterol levels and PAD; and significantly more coronary artery disease patients were likely to exercise regularly, or recall their physician's instructions to exercise than patients with PAD.

Cassar (2006) proposed that treatment of PAD should target two fronts – firstly aiming to reduce cardiovascular risk factors, and secondly aiming to improve the symptoms of the disease. Cardiovascular risk factor reduction includes smoking cessation, diabetes control, weight loss, exercise, and drug therapy to lower cholesterol and blood pressure (Cassar, 2006). Treatment to improve the symptoms of PAD includes drug therapy, exercise, percutaneous transluminal angioplasty and bypass surgery (Cassar, 2006).

Smoking cessation

Smoking is a major risk factor for the development of atherosclerosis, and severity of PAD is related to the amount smoked (Fowkes et al, 1992). Amputation rate and mortality rates are higher among patients with PAD who continue to smoke than non-smokers (Khan et al, 2005). Graft failure rate after bypass surgery for PAD has also been found to be significantly higher for smokers than non-smokers (Giswold et al, 2003). Smoking cessation slows the rate of development of further atherosclerosis and reduces the risk of mortality from cardiovascular causes (Cassar, 2006). The Scottish Intercollegiate Guidelines Network (SIGN, 2006, p.3) recommends that patients with PAD 'should be actively discouraged from smoking'.

CHAPTER ONE

Clarke & Aish (2002) surveyed smokers with PAD about their beliefs about the consequences of continuing to smoke, and found that 34% of the sample believed smoking was unlikely to cause the development of further circulatory problems, 57.6% believed continuing smoking was unlikely to increase the risk of amputation, and 38.8% felt health risks and health problems would not be reduced by quitting smoking. A survey of Dutch PAD patients' awareness of vascular risk factors found 48% were not aware of the risk of smoking, and half the sample who had been smokers at diagnosis of PAD continued to smoke after diagnosis (Willigendael et al, 2004). In a similar survey in the US, Bloom, Stevick & Lennon (1990) found that only 44% of PAD patients who were active smokers considered PAD to be smoking related. In a study of PAD patients in New Zealand, Muthu, Chu, Le Heron, Roake & Lewis (2007) found that 81% of patients were aware that smoking was a risk factor for PAD, but despite this 33% of patients continued to smoke.

Parry, Thomson & Fowkes (2002) conducted a qualitative study with older smokers with arterial disease to explore how smoking behaviour is influenced by social context. Parry et al (2002) found that participants who were debilitated by disease and had reduced social contact used smoking as a coping strategy to keep occupied and pass the time; and that as social support was a crucial factor in smoking cessation, the isolated smokers therefore received little encouragement and support to quit, and in fact had few constraints on their smoking behaviour.

CHAPTER ONE

These studies have highlighted the lack of awareness of smoking as a risk factor among patients with PAD, and the need for interventions beyond giving advice alone, to help patients with PAD to stop smoking.

Exercise

Exercise is thought to be beneficial to patients with PAD, both to reduce cardiovascular risk factors and to reduce symptoms of PAD (Khan et al, 2005). There is a lack of experimental evidence in PAD research as to whether patients with PAD who take part in exercise interventions live longer than patients with PAD who do not receive exercise interventions. However, evidence from observational research suggests that PAD patients in the highest quartile of daily physical activity levels at baseline have significantly reduced mortality and cardiovascular morbidity compared with PAD patients in the lowest levels quartile of physical activity levels at baseline, and that this effect is independent of confounding variables (Garg et al, 2006; Gardner, Montgomery & Parker, 2008). In addition, evidence from coronary artery research shows better survival rates for patients who exercise, with a Cochrane review finding a 27% reduction in all cause mortality for patients with heart disease who had taken part in exercise interventions (Jolliffe et al, 2001).

Walking benefits patients with PAD as it reduces blood pressure, improves the lipid profile of the blood, and encourages development of a collateral blood supply (Eberhardt, 2002). Exercise training has also been found to improve oxidative capability in patients with IC by increasing mitochondrial function in the muscles - this

CHAPTER ONE

reduces the reliance on anaerobic metabolism, which reduces the production of lactic acid and therefore reduces muscle pain (Tan et al, 2000).

A review by Spronk, Bosch, den Hoed & Hunink (2005) investigated quality of life after exercise training for patients with IC and found significant improvement in the physical functioning and bodily pain domains of the SF-36 at 3 month follow-up (mean change, 8 and 10, respectively). A review comparing the efficacy of generic and disease-specific quality of life measures in assessing change in quality of life after exercise-based interventions for IC (Guidon & McGee, 2010) concluded that while generic quality of life measures like the SF-36 do detect quality of life changes in physical functioning domains, disease-specific measures are more sensitive to change in quality of life following both supervised and unsupervised exercise programmes. In two studies which used both generic and disease-specific quality of life measures for unsupervised exercise programmes (Cheetham et al, 2004; Imfeld et al, 2006), the SF-36 showed minimal changes in quality of life while the disease-specific measures showed clear improvements in quality of life.

In a Cochrane review of exercise for intermittent claudication, Leng, Fowler & Ernst (2000) found significant improvements in walking distance following exercise therapy, the most effective exercise regimens involving walking to near-maximal pain, three times a week. The studies reviewed by Leng et al (2000) used treadmill based walking outcomes, measuring maximal walking distance until the participant had to stop walking due to leg pain. Overall, a 150% improvement was found in maximal walking distance for participants who received some form of exercise therapy. However, trials

CHAPTER ONE

with several different types of exercise therapy were included in this review, ranging from advice alone to supervised exercise programmes.

Leng et al (2000) called for further research to determine the degree of supervision required in an exercise programme, and how long changes in exercise could be expected to last following participation in an exercise programme.

A further Cochrane review (Bendermacher, Willigendael, Teijink & Prins, 2006) compared supervised exercise therapy with non-supervised exercise therapy for patients with IC, again using treadmill based walking outcomes. Supervised exercise programmes mainly consisted of 3 exercise sessions a week for 12 weeks, each session lasting for half an hour. Bendermacher et al (2006) found that supervised exercise programmes had a significantly greater improvement in maximal walking distance compared to non-supervised programmes, with an approximately 150m better improvement in the supervised walking groups at 3 months. Although this is not a large improvement in maximal walking distance, it is believed to be clinically significant because of the low walking capability of patients with IC (Bendermacher et al, 2006). Only two of the included trials repeated outcomes at 12 months, however, the effect was maintained in both these trials. Mechanisms by which supervised exercise programmes achieve improved maximal walking distance compared to non-supervised programmes may include the higher level of intensity of exercise in supervised programmes leading to improved physical condition of the patient, and the added motivation and encouragement given to the patient in a supervised programme.

CHAPTER ONE

Although there is a clear improvement in walking *capability* as a result of supervised exercise programmes, there are a number of questions about these programmes which have not been addressed in the research to date, including what proportion of patients attend programmes when provided by the health service, how acceptable patients find supervised exercise programmes, and what the drop-out rate is from supervised programmes. Gelin et al (2001) found that 32.8% of patients assigned to a supervised exercise group were either unwilling or unable to complete the programme over a 1 year period, most dropping out after attending only a small number of classes. In a Dutch study of exercise behaviour and attitudes towards exercise of patients with IC, Bartelink, Stoffers, Biesheuvel & Hoes (2004) found that only a few participants were in favour of treatment which involved walking on a treadmill, or having regular appointments with a physiotherapist. Finally, although supervised exercise programmes have been shown to increase walking capability in patients with IC, there is no evidence that these programmes lead to long-term behaviour change outside the gym. In a small-sample study of a 12 month supervised exercise programme for patients with IC, Crowther et al (2008) also measured physical activity by pedometer at baseline and 1 year follow-up and found that although walking *performance* had improved significantly over time, there was no significant increase in daily steps from baseline to follow-up, indicating that supervised exercise programmes may not change day-to-day behaviour.

At present in the UK, supervised exercise programmes for patients with IC are relatively uncommon, therefore exercise for claudication is usually promoted by

CHAPTER ONE

advice alone. In a recent survey of UK vascular surgeons, Shalhoub, Hamish & Davies (2009) found that only 24% of responders had access to supervised exercise programmes for patients with IC. Of those who did have access to supervised exercise programmes, 46% referred less than half of their IC patients to supervised exercise, because of patient co-morbidities, geographical constraints and patients being in work when the programme was running. 72% of responding surgeons who did not have access to supervised exercise programmes for patients with IC believed they did not have access to a supervised programme because of lack of resources. 63% of responding surgeons who did not have access to supervised exercise programmes gave advice to patients to walk, and 34% gave a leaflet about walking to patients.

Stewart & Lamont (2007) indicated a number of reasons why advice alone may not be appropriate for patients with IC, including patients' loss of confidence/self-efficacy in their ability to walk, their embarrassment at having to stop and rest, and their concerns that pain may be an indication that walking is harmful to them. In a qualitative study of barriers for walking in individuals with IC, Galea, Bray & Martin-Ginis (2008) found that there were personal, activity-related and environmental barriers to walking. Personal barriers included uncertainty about the benefits of walking, and concerns about the potential harm caused by leg pain; activity-related barriers included the need for frequent breaks due to leg pain when walking; and environmental barriers included stairs, hills and not having an appropriate place to stop for a rest (Galea et al, 2008).

CHAPTER ONE

The Scottish Intercollegiate Guidelines Network (SIGN, 2006, p.17) recommends that patients with PAD 'should be encouraged to exercise'. However, it is unclear whether patients with PAD realise the benefits of walking, or that insufficient physical activity is a risk factor for further cardiovascular health problems, for example, Willigendael et al (2004) found that only 23% of PAD patients recognised scarce physical exercise as a PAD risk factor, and only 48% of PAD patients felt that exercise was a measure they could undertake to improve the symptoms of PAD. Bartelink et al (2004) found that while 70% of Dutch patients with IC reported that they had received advice to walk, the content of the advice was generally not specific, and those who did walk did not tend to do so at optimum intensity or optimum frequency.

There is some evidence that patients with PAD do not undertake the same level of exercise as older adults without PAD. McDermott et al (2002) used accelerometers over 7 days to compare the two groups, and found that participants with PAD had significantly lower physical activity levels (Mean = 783.8kcal/day, SD=426.2) than those without PAD (Mean =1109.0kcal/day, SD =640.1). Gardner, Montgomery, Scott, Afaq & Blevins (2007) compared daily walking activity between participants with and without IC, and found that participants with IC took significantly fewer daily strides (IC = 3149 strides/day +/- 1556; no IC = 4230 strides/day +/- 1708), spent significantly less time walking (IC=264 mins, SD=109; no IC=312 mins, SD=96), and took significantly fewer strides at a moderate and high pace than age and sex matched participants without IC. Two previous studies have measured the walking behaviour of patients with IC by waist-mounted pedometer, Nasr, McCarthy, Walker & Horrocks (2002) found that patients with IC walked a median of 5728 steps/day (interquartile range

CHAPTER ONE

4037-7956); Crowther et al (2007) found patients with IC walked a mean 4156.1 steps/day (SD=572.6). Tudor-Locke, Washington & Harte (2009) compared the median steps/day measured by waist-mounted pedometer, for patients with a range of chronic illnesses. The median steps/day for patients with IC, based on the Nasr et al (2002) and Crowther et al (2007) studies is 4942.05 steps/day. This is a greater number of daily steps than that found for patients with chronic obstructive lung disease (median = 2237 steps/day), patients receiving dialysis (median = 3448 steps/day), and patients with arthritis (median = 4086 steps/day) and is similar to the daily walking activity of patients who have received a joint replacement (median = 4892 steps/day) (Tudor-Locke et al, 2009). However, in a review of several studies measuring daily walking activity by waist-mounted pedometer, Tudor-Locke & Myers (2001) found that healthy older adults walk between 6,000 and 8,500 steps/day, indicating that patients with IC generally walk less than healthy older adults.

Galea & Bray (2006) used the Theory of Planned Behaviour (TPB) to model walking behaviour in patients with IC, and found that while attitudes, subjective norms and perceived behavioural control explained 67% of the variance in intention to walk for half an hour, three times a week, there was no correlation between walking intentions and walking behaviour. This indicates that there may be other factors which over-ride intention and influence walking behaviour in patients with IC. Investigation of beliefs about walking and beliefs about the disease may shed light on modifiable constructs which could be targeted in an intervention to increase walking in patients with PAD.

CHAPTER ONE

Endovascular and vascular intervention

Both endovascular and vascular intervention can be performed to improve the symptoms of PAD. Endovascular intervention involves the use of balloon angioplasty and stent implantation to improve blood flow. These procedures are minimally invasive, and involve a balloon tipped catheter being inserted into the artery and guided to the narrowing, the balloon is then inflated to open the artery, and in the case of stenting, a small tube is placed into the artery to hold it open. Success of endovascular intervention depends on both the size and location of the narrowing of the artery, and on the number of lesions in the artery (Norgren et al, 2007). In a review of the success of angioplasty procedures, Wilson, Gelfand, Jimenez & Gordon (2006) found primary patency (lack of obstruction) rates of 71.1% for angioplasty plus stenting, and 58.3% for angioplasty alone. This means that a considerable number of patients who receive angioplasty will need to receive repeat treatments, to treat re-obstruction of the artery, which increases risk for the patient, and costs for the health service.

While endovascular intervention has been found to improve symptoms of PAD in the short term, it does not reduce cardiovascular risk, and studies have failed to show a significant long-term benefit of angioplasty over exercise training for patients with IC (e.g. Perkins, Collin, Creasy, Fletcher & Morris, 1996; Whyman et al, 1997). Only two studies have been carried out comparing the long-term outcomes of angioplasty and exercise for patients with IC. In Oxford, Creasy, McMillan, Fletcher, Collin & Morris (1990) randomly assigned patients to receive either angioplasty, or to attend a supervised exercise programme for 6 months. There was a significant increase in

CHAPTER ONE

distance to claudication and a non-significant increase in maximal walking distance in the angioplasty group at 3 months, but then a decline to just above baseline measure at 6, 9 and 12 months. In contrast, distance to claudication and maximal walking distance increased steadily at each time point in the exercise group, with significant increases at 6, 9, 12 and 15 months. In a six year follow-up of this study, Perkins et al (1996) found that distance to claudication, and maximum walking distance were significantly longer in the exercise therapy group than in the angioplasty group. In Edinburgh, Whyman et al (1996) found an initial advantage at 6 month follow-up of angioplasty over advice to exercise in terms of distance to claudication, maximum walking distance, ABPI and pain rating. However, this advantage was lost at 2 year follow-up, with no significant difference between the two groups on any of the outcome measures, representing a worsening of scores in the angioplasty group over time, and an improvement over time in the advice to exercise group. More recent research has compared supervised exercise therapy alone, and angioplasty alone, with a combined treatment of exercise and angioplasty and found significant improvement in claudication distance and maximal walking distance at 3 month follow-up in each of the three groups, with best outcomes in the combined therapy group (Mazari et al, 2010). The authors concluded that a supervised exercise programme should be the primary treatment for patients with IC, due to lower costs and lower risk to the patient. However, as noted, supervised exercise programmes are not readily available in the NHS and may not change walking behaviour in the long-term.

CHAPTER ONE

Quality of life has been found to improve following angioplasty. Spronk et al (2005) reviewed quality of life after angioplasty for patients with IC and found a significant improvement in the physical role functioning and general health domains of the SF-36.

SIGN (2006, p.18) guidelines state 'endovascular and surgical intervention are not recommended for the majority of patients with intermittent claudication.' However, rates of angioplasty to treat the symptoms of claudication have dramatically increased in recent years as angioplasty has become more widely available (Vogel, Su, Symons & Flum, 2007).

Vascular surgical intervention tends to be considered for patients with IC when the patient experiences severe disability, or when the patient has a narrowing which is not suitable for angioplasty. Surgical intervention for IC involves either bypass surgery, the insertion of a healthy blood vessel to bypass the narrowed artery; or endarterectomy, removal of plaque from the diseased artery. Surgery is a more invasive option for symptom management than either exercise therapy or angioplasty, carrying a greater risk of serious complication (Campbell & Birchley, 2010). However, Campbell & Birchley (2010) argue that surgery is the only treatment option which can restore walking ability to normal levels in patients with PAD. Although surgery can be used to treat patients with IC, it is more commonly used in treatment of patients with more severe PAD (critical limb ischemia).

CHAPTER ONE

Psychosocial factors and PAD

A small number of qualitative studies have investigated patient and family experiences of coping with PAD. Crosby, Ventura, Frainier & Wu (1993) asked 115 patients with PAD open-ended questions about their concerns about the disease. The majority of concerns related to leg pain, being unable to walk, and fears about having a foot or leg amputated. Only 2 participants stated a concern about a general deterioration in their health. This highlights that patients with PAD may have erroneous beliefs about the consequences of PAD, seeing amputation as a more likely consequence of PAD than the risk to their general health. This lack of understanding of the consequences of PAD has also been identified in a qualitative study by Leavitt (1990), who interviewed patients with PAD who had received vascular surgery and their family members. Leavitt (1990) found that family members and the patients themselves had insufficient knowledge of the disease, of the serious consequences of the disease, or of the importance of lifestyle change. Treat-Jacobsen et al (2002) interviewed 38 PAD patients with a wide range of disease severity and found a poor understanding of the causes of PAD, and a poor understanding of which behaviours to change to improve health, or of how to make the changes. Treat-Jacobsen et al (2002) noted some participants had a feeling of lack of control over the progression of PAD, and found that those participants with a greater sense of control tended to also be the participants who knew more about the disease. Gibson & Kenrick (1998) interviewed patients who had received surgery for PAD and found that patients were unclear about the causes of PAD, tending to attribute disease to external causes or to chance, rather than seeing the disease as having been caused primarily by their own behaviour.

CHAPTER ONE

Leavitt (1990) found that patients with PAD and their families tended to think of PAD as an acute rather than chronic condition, and believed that surgery could repair or cure the disease. Gibson & Kenrick (1998) also noted this belief by PAD patients that surgery is a cure for PAD, with patients viewing PAD as an acute illness. Leavitt (1990) hypothesised that this belief that PAD was curable led to patients not taking responsibility to change lifestyle factors to limit disease progression.

A number of these qualitative studies have also highlighted the emotional burden of having PAD, with patients describing loss of independence (Treat-Jacobsen et al, 2002; Wann-Hansson, Hallberg, Klevsgard & Andersson, 2005), loss of identity and limitations in social functioning (Treat-Jacobsen et al, 2002) leading to feelings of social isolation (Treat-Jacobsen et al, 2002; Wann-Hansson et al, 2005; Gibson & Kenrick, 1998). Patients described feelings of powerlessness in relation to how they could affect the course of the illness (Wann-Hansson et al, 2005; Gibson & Kenrick, 1998), and had unrealistic expectations about treatment (Leavitt, 1990; Gibson & Kenrick, 1998). Instead of actively changing health behaviours to reduce the impact of the illness on their lives, patients described maladaptive coping strategies of reorientation – reducing physical activities, walking distance and walking speed; or resignation – giving up physical activities (Treat-Jacobsen et al, 2002; Wann-Hansson et al, 2005; Gibson & Kenrick, 1998).

There are some methodological limitations with these studies which mean the results are not necessarily generalisable, for example, small sample size (Gibson & Kenrick,

CHAPTER ONE

1998), patients with different levels of severity of PAD included in the study as a homogenous group (Gibson & Kenrick, 1998; Wann-Hansson et al, 2005; Crosby et al, 1993; Leavitt, 1990; Treat-Jacobsen et al, 2002), and patients at different stages of treatment included in the study as a homogenous group (Treat-Jacobsen et al, 2002; Crosby et al, 1993).

That said, these qualitative studies have raised issues about PAD patients' erroneous beliefs about the causes of the disease, the consequences of the disease, whether the disease is acute or chronic, and whether the disease is curable or controllable, which may be related to how patients cope with their illness, and whether they choose to change their health behaviours. These illness beliefs are considered in Leventhal, Leventhal & Contrada's (1998) Common-sense Model of Self-regulation of Health and Illness which focuses on mechanisms underlying how patients make decisions about how to self-manage their health.

Common-sense model of self-regulation of health and illness

Leventhal et al's (1998) Common-sense model of self-regulation of health and illness (CSM) is a three stage perceptual-cognitive model which proposes that when individuals experience a health threat or illness (perceptual stage) their subsequent coping behaviour (response stage) is influenced by their cognitive and emotional representations of the illness, their cognitive representation of their coping actions, and their representation of themselves. This process is dynamic, with the individual

CHAPTER ONE

evaluating (appraisal stage) how their actions affect their goals, and adjusting their representations and coping actions in light of changes in physiological signals.

Representations are common-sense definitions or schemas which the individual develops through past experience and through social interaction, and which function at both a concrete (symptom based) and abstract (disease label) level (Leventhal et al, 1998).

Illness representations are thought to contain information about the identity of the illness, both in terms of the label of the illness, and its symptoms; the temporal features of the illness, both subjective and objective; the imagined and real consequences of the illness; the causes of the illness; and beliefs about whether the illness can be cured or controlled (Leventhal et al, 1998). The model proposes that the content of these representations determines the cognitive and behavioural actions which the individual will take to cope with the illness and also the goals which the individual is trying to achieve.

Leventhal et al (1998) argue that the bi-level nature of illness representations can lead to the individual making poor decisions about treatment efficacy. For example, in the case of IC (symptom) and PAD (illness label), claudication pain is a relatively poor indicator of the extent of the underlying atherosclerotic disease, and treating the symptom will not treat the disease, however, many patients believe they have an acute illness that can be treated by surgery (Leavitt, 1990; Gibson & Kenrick, 1998).

CHAPTER ONE

Leventhal, Breland, Mora & Leventhal (2010) propose that representations of coping actions or treatments will also influence the self-regulation process and can be characterised using the same framework as illness representations. Actions have an identity (e.g. the name of the action), time lines (e.g. the length of time the behaviour will take to achieve the goal, and when and for how long the behaviour has to be carried out), consequences (e.g. outcome expectations about the consequences of the behaviour; judgement about the risk of performing the action), causes (e.g. the mechanism by which the coping action will work) and control (e.g. whether the action will cure or control symptoms or the underlying disease; the individual's beliefs about their ability to carry out the behaviour).

Horne & Weinman (2002) studied the role of illness representations and treatment beliefs in adherence to asthma medication, and found that illness representations influenced adherence both directly, and indirectly, via treatment beliefs. The Beliefs About Medicines Questionnaire (BMQ) (Horne, Hankins & Weinman, 1999) was developed to assess treatment beliefs – specifically beliefs about the necessity of medication, and concerns about taking medication. The BMQ contains items which can be classified within the five illness representation labels e.g. 'My medicines are a mystery to me' could be classified as a treatment representation about how taking medication works to treat illness (causal mechanism); 'My medicines protect me from becoming worse' could be classified as a control treatment representation.

The CSM has been widely used to understand how individuals think about illness and how this relates to coping behaviour across a wide range of chronic diseases including

CHAPTER ONE

myocardial infarction (e.g. Weinman, Petrie, Sharpe & Walker, 2000), chronic fatigue syndrome (Moss-Morris, Petrie & Weinman, 1996), rheumatoid arthritis, chronic obstructive pulmonary disease and psoriasis (Scharloo et al, 1998). Petrie, Weinman, Sharpe & Buckley (1996) found that behaviour after myocardial infarction in terms of attendance at rehabilitation clinic, return to work and disability was significantly predicted by the content of illness representations. In a later randomised controlled trial, Petrie, Cameron, Ellis, Buick & Weinman (2002) tested an intervention to modify illness representations and found significant, positive changes in illness representations in the intervention group, and an impact on behaviour in relation to significantly faster return to work rate in the intervention group than the control group.

Leventhal et al (2010) argues that for an intervention to change health behaviour based on the CSM to be successful, the interventionist must understand the patient's treatment representations, their illness representations and the coherence of the treatment representations with the illness representation, in terms of the patient's understanding of the causal link between their representation of the illness and their representation of how the treatment will cure or control the illness.

Other models from health psychology have been used to understand walking behaviour in patients with IC, for example Pochstein & Wegner (2010) used Schwarzer et al's (2003) Health Action Process Approach (HAPA), and Galea & Bray (2006) used Ajzen's (1985) Theory of Planned Behaviour (TPB) to explore psychological determinants of walking behaviour in people with IC. However, Galea & Bray (2006)

CHAPTER ONE

found that while attitudes, subjective norms and perceived behavioural control explained 67% of the variance in intention to walk; intention and perceived behavioural control only explained 8% of the variance in walking behaviour, and intention made no significant contribution to the model of walking behaviour in patients with IC. Galea & Bray (2006) suggest that the pain experienced when walking may over-ride good intentions to walk, indicating that the TPB may not take enough factors into account to determine walking behaviour in this particular population. Further, Armitage & Conner (2000) argue that motivational models, of which the TPB is one, do not provide adequate explanation of how intention leads to behaviour. The TPB is a static model, designed to predict behaviour at one point in time, and may therefore not be the best model to understand the ongoing process of day-to-day walking behaviour in patients with IC, where experience of pain on previous days, and beliefs about illness and walking may all also influence walking behaviour.

Pochstein & Wegner (2010) used the HAPA to design an intervention to change walking in patients with IC. The HAPA is a two-stage model of behaviour change - in the motivational stage the individual forms an intention to perform a behaviour; and in the volitional stage, the individual turns intention to action through planning (Schwarzer et al, 2003). Pochstein & Wegner (2010) found that IC patients with high intentions to walk, who received a volitional intervention which involved action and coping planning, had a significant increase in walking behaviour over time compared to a control group. However, Armitage & Conner (2000) argue that while the HAPA provides a useful extension to motivational models of behaviour with the addition of the volitional stage, the HAPA is vague about how volitional components change

CHAPTER ONE

behaviour, and about how volitional components should be measured. Further, Leventhal & Mora (2008) argue that the HAPA is a descriptive model useful for predicting behaviour, but which does not identify health and illness factors which affect behavioural outcomes. Leventhal & Mora (2008) suggest that somatic and functional changes are critical factors in the self-regulation of health behaviour, which are not accounted for in the HAPA. A dynamic model, like the CSM, which takes somatic experience into account in explaining behaviour, may be more appropriate as the basis for designing an intervention to change walking in patients with IC.

Summary

PAD is a relatively common chronic disease in older adults which affects both physical and social functioning. PAD is an indication of widespread arterial disease, and people with PAD are at increased risk of heart attack and stroke. Behaviour change, both in terms of quitting smoking, and increasing walking can have positive effects on future health and on symptoms of PAD. However, there is evidence that patients with PAD do not tend to change their health behaviours, possibly as a result of their beliefs about the illness.

The relationship between beliefs about PAD and subsequent health behaviour will be explored in this thesis, within the framework of the CSM.

CHAPTER TWO

RATIONALE AND GENERAL AIMS

CHAPTER TWO

Overview

This chapter outlines the aims and overall structure of this thesis. In order to present the aims in context, the population and behaviour targeted by the research, the theoretical basis underpinning the research, the scope of this thesis, and the framework within which this thesis has been developed will be discussed.

Patient population

This thesis will focus on patients with Stage II PAD (intermittent claudication). Patients with IC are the largest diagnosed group of people with PAD, and for most patients with IC, conservative treatment including behavioural risk factor management is the recommended first line of treatment. Patients with IC face additional barriers to walking compared to other older adults due to walking related pain, and this warrants the design of psychological interventions specifically for this patient group.

Behaviour

Patients with IC are routinely recommended to lose weight, stop smoking and increase their exercise (Cassar, 2006). Particular barriers to exercise have been identified for patients with PAD (Stewart & Lamont, 2007; Galea et al, 2008). There is evidence that patients with IC carry out less daily exercise than older adults without PAD (McDermott et al, 2002). However, several studies have demonstrated that increasing walking is particularly important in reducing symptoms of IC (e.g. Leng et al, 2000),

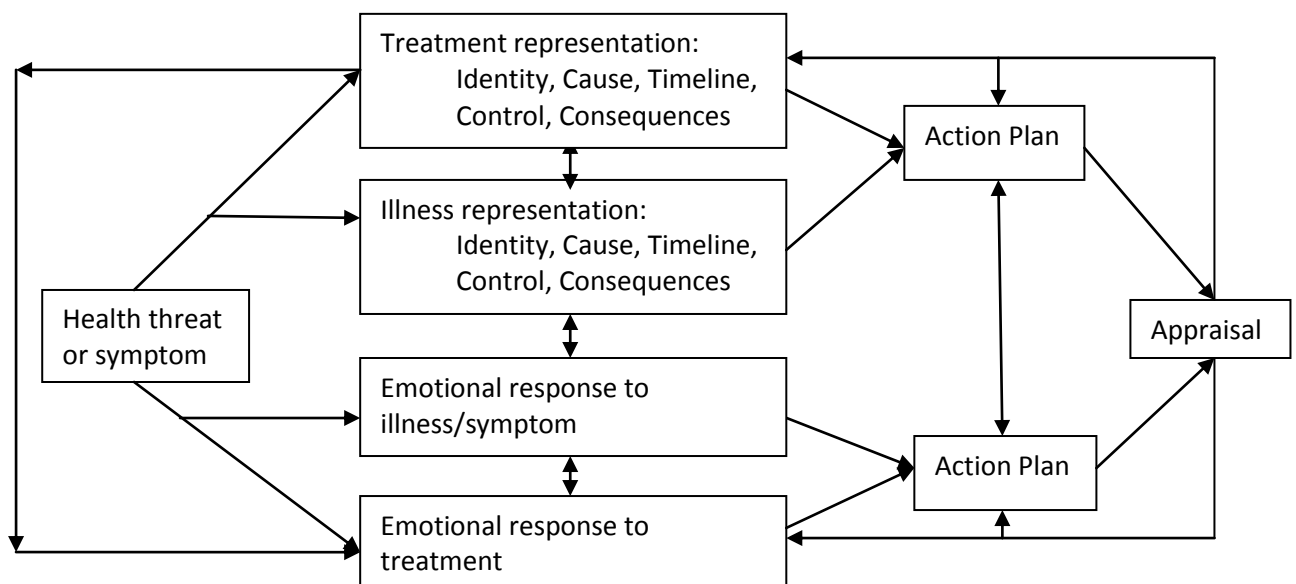
CHAPTER TWO

and may reduce cardiovascular risk (Khan et al, 2005). This thesis will therefore focus on walking behaviour of patients with IC.

Theoretical basis

The findings from several qualitative studies into the experience and behaviour of patients with IC (Gibson & Kenrick, 1998; Wann-Hansson et al, 2005; Crosby et al, 1993; Leavitt, 1990; Treat-Jacobsen et al, 2002) suggest that both beliefs about PAD and beliefs about treatment influence the walking behaviour of patients with IC.

Leventhal et al's (1998) Common-sense model of self-regulation of health and illness (CSM) is a dynamic model which considers both the role of illness representations and treatment representations in an individual's coping actions (see Figure 2.1). The CSM focuses on both cognitive and emotional aspects of illness, and therefore provides a consideration of how pain and anxiety may influence behaviour.



**Figure 2.1 The Common-sense model of self-regulation of health and illness
Adapted from Horne (2003)**

CHAPTER TWO

The CSM is a self-regulatory model, and therefore is built on the underlying assumption that individuals, (i) are actively engaged in solving health problems, consciously selecting coping actions to deal with health threats, and capable of changing their illness and treatment representations in light of new evidence; (ii) that any coping actions used to solve a problem will be used in context; and (iii) that attention and effort will be expended on the threat which is perceived to be most urgent, and are limited by resources available to the individual (Leventhal et al, 1998). A critical component of the CSM is the individual's appraisal of how the effects of treatment (in the case of IC this could be walking) relate to the individual's experience and understanding of the disease, and whether treatment brings them closer to their goals (Leventhal et al, 2010).

The CSM differs from social-cognition models of health behaviour change such as the Health Belief Model (Rosenstock, 1974), Protection-Motivation Theory (Rogers, 1983) and the Theory of Planned Behaviour (Ajzen, 1985), because it is a dynamic model, which allows for beliefs and behaviour to change within the self-regulatory framework. Social-cognition models tend to treat behaviour change as a static event focusing on the decision or commitment to change behaviour rather than on the long-term process of behaviour change (de Ridder & de Wit, 2006). In social cognition models, the motivation or intention to perform a behaviour change is viewed as being sufficient to predict successful behaviour change, and most models fail to consider either the difference between intention to change behaviour and real behaviour change, or the factors which may be associated with maintaining changed behaviour.

CHAPTER TWO

Unlike social cognition models, the CSM focuses on setting both immediate and longer term goals (Leventhal & Mora, 2008), and how both the cognitive and the emotional aspects of illness influence behaviour towards achieving those goals (Leventhal, Weinman, Leventhal & Phillips, 2008).

Leventhal et al's (1998) CSM therefore provides the underlying theoretical framework for this thesis.

Scope of the thesis

Little work has been conducted into IC from a psychological perspective. Most studies into IC to date have focused on either prevalence of PAD, suitable medical or surgical treatment of stages of the disease, or have been small-sample qualitative studies of the experience of living with PAD, with small and heterogeneous samples. Therefore, this thesis will explore psychological factors associated with walking behaviour in patients with IC (Chapters 3 & 5), and will include a pilot brief psychological intervention to modify these psychological factors to increase walking (Chapter 6).

Because this thesis includes an intervention, the MRC framework for developing and evaluating complex interventions (Craig et al, 2008) will be used as a guide to the structure of this thesis.

CHAPTER TWO

MRC framework for developing and evaluating complex interventions

The MRC has recently published new guidance on developing and evaluating complex interventions in order to guide the choice of appropriate methods in health research (Craig et al, 2008). The guidance focuses on methodological design to identify whether interventions are effective and how the intervention works. The framework suggests that the development of a complex intervention should involve a number of phases (see Figure 2.2).

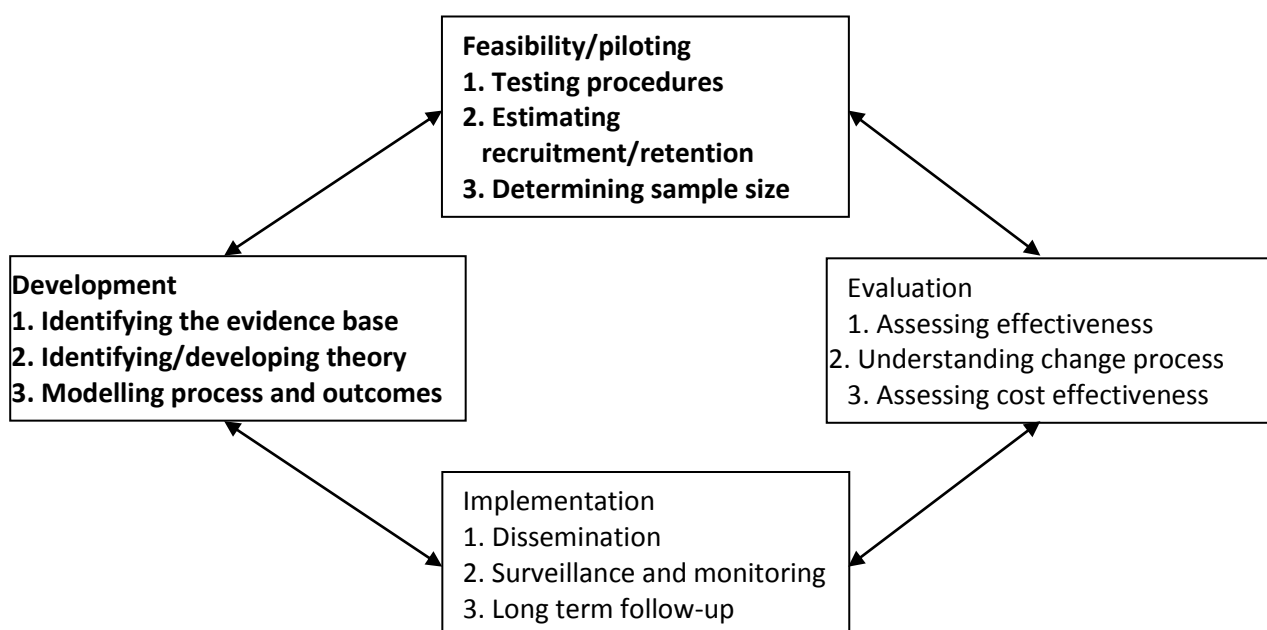


Figure 2.2 MRC Framework – Key phases of the development and evaluation process (Craig et al, 2008)

A complex intervention is one which has several interacting components. The CSM proposes that illness representations, treatment representations, and emotional representations interact to influence coping actions, therefore an intervention to change behaviour using the CSM as a theoretical base, would be a complex

CHAPTER TWO

intervention. This thesis will carry out the steps in the Development and Feasibility/Piloting phases of the MRC Framework to design an intervention to change walking behaviour in patients with IC.

General aims

The overarching aim of this thesis is to identify modifiable psychological constructs which play a part in influencing the walking behaviour of patients with IC. To this end, an initial, exploratory study was carried out to understand the walking behaviour of patients with IC, and their illness and treatment representations (Chapter 3). Bowling (2002) notes that qualitative research can be used inductively to develop and refine hypotheses. As little research has been conducted into psychological factors associated with walking in patient with IC, qualitative methods have been used in Chapter 3.

Chapter 4 describes the design of the measures used in the subsequent two empirical chapters, along with the process followed to design the brief psychological intervention.

Chapter 5 describes a cross-sectional study designed to model key psychological constructs with walking behaviour in a cohort of IC patients. These psychological constructs were identified in the qualitative study (Chapter 3) and appropriate

CHAPTER TWO

measures were chosen and designed (Chapter 4) to test these constructs within a larger, representative sample of patients with IC.

Chapter 6 presents the results from the pilot intervention to modify illness and treatment representations in order to change walking behaviour in a sample of patients newly diagnosed with IC. The results of this study will enable the process and outcomes of the pilot behaviour change intervention to be modelled, which will provide information for the Evaluation and Implementation phases of future work to increase walking in patients with IC.

Summary

This thesis presents a series of studies, based on the Development and Feasibility/Piloting phases of the MRC Framework (marked in Bold in Figure 2.2), which aim to identify and modify psychological constructs which influence walking behaviour in patients with IC.

CHAPTER THREE

**PSYCHOLOGICAL FACTORS ASSOCIATED WITH WALKING IN
PATIENTS WITH INTERMITTENT CLAUDICATION – A
QUALITATIVE STUDY**

CHAPTER THREE

Abstract

Background:

Patients with intermittent claudication (IC) are recommended to increase their walking levels, as walking has been found to reduce symptoms of claudication, and may improve overall cardiovascular health. The Common Sense Model (CSM, Leventhal et al, 1998) proposes that behaviour will be influenced by the patient's illness and treatment representations. However, little is known about the illness or treatment representations, or the walking behaviour of patients with IC.

Method:

Semi-structured interviews were conducted with 20 participants who had previously received a vascular intervention for IC. Transcripts were analysed using a Framework Approach. Interviews explored participants' illness and treatment representations, based on the CSM, and their health behaviour.

Results:

Participants described a high level of symptoms in their legs, despite having received vascular intervention. They viewed their illness as an acute condition, and controlled symptoms by avoiding walking and slowing their pace. Participants were to some extent unaware of the causes of the disease, and were unaware of their increased risk of future cardiovascular health problems.

Conclusion:

The findings highlight that patients with IC have dysfunctional representations about their illness and about walking, which may influence their behaviour. These representations could be addressed in a psychological intervention to increase walking

CHAPTER THREE

behaviour in patients with IC.

CHAPTER THREE

Introduction

As outlined in Chapter 2, this thesis focuses on psychological factors associated with walking in patients with IC, and is based within the framework of the CSM. No research has previously been conducted to study the illness or treatment representations of patients with IC, and little is known about their walking behaviour.

In NHS Forth Valley, the NHS board where the research for this thesis was conducted, the majority (approximately 56%) of patients receive either angioplasty or surgery, usually within 6 months of diagnosis with IC. Surgery and angioplasty are performed for symptom management and aim to improve quality of life, but do not reduce the risk of future cardiovascular events due to atherosclerosis. The decision about what kind of treatment to offer is made by the Vascular Consultant after reviewing ultrasound charts of the artery, and is based on the size and location of the narrowing of the artery, and the general health of the patient. In NHS Forth Valley, patients with IC are advised to 'stop smoking and start walking', however detailed advice is not routinely given to patients about the recommended intensity or frequency of walking, or about the benefits of walking to IC or to general health. Patients who receive angioplasty or surgery are reviewed periodically in outpatient clinics following their surgery, however the focus of the clinics is on checking that the wound has healed and that the blood pressure in the affected leg has increased, rather than on the patient's walking behaviour, or on how IC affects their life. In a qualitative study of PAD patient-physician communication, Collins et al (2006) found that patient-physician communication about exercise was an important factor in whether or not patients with PAD exercised, and that it was common for patients to feel they did not

CHAPTER THREE

understand the disease, or the benefits of walking to the disease, due to poor patient-physician communication.

Two qualitative studies have explored the effect of PAD on life after vascular intervention. Wann-Hansson, Hallberg, Klevsgard & Andersson (2008) interviewed fourteen patients with PAD, 6 months and 2.5 years after revascularisation, about their long-term experiences of living with PAD. These interviews revealed that while patients experienced less pain, and were able to sleep better after revascularisation, they still experienced symptoms of PAD, struggled to come to terms with the fact that they had a chronic disease, and had slowed down and changed their behaviour to cope with the restrictions in their daily lives. Wann-Hansson et al (2008) concluded that providing information and education to patients with PAD could increase knowledge about PAD, promote self-management and prevent unhealthy behaviour choices. Gibson & Kenrick (1998) interviewed nine patients who had received bypass surgery within the previous 18 months. They found that patients had unrealistic expectations of surgery, and thought of themselves as having an acute illness which could be cured with surgery. Gibson & Kenrick (1998) also found that participants had adapted to their illness by slowing down and restricting their activities, and concluded that further research was needed to investigate the potential for patients with PAD to become more involved in self-managed care activities.

These studies have highlighted that patients with PAD still have leg symptoms and restricted activity after revascularisation, and that in coping with these restrictions choose to slow down and reduce activity levels. While slowing down and reducing

CHAPTER THREE

activity levels helps the patient to experience less leg pain symptoms, the opposite behaviour, increasing speed and activity levels, is recommended for patients with IC – both to reduce symptoms and to improve cardiovascular health.

Although interesting, these studies involved relatively small heterogeneous samples of patients with both IC and critical limb ischemia, which means conclusions drawn from these studies about the experience and behaviours of patients with PAD may not be generalisable. In addition, the focus of the studies was on the experience of life after revascularisation, not on health behaviour or on psychological factors which might influence health behaviour.

Patients' beliefs about IC and its treatment are likely to vary according to their stage in the overall process from diagnosis to post-treatment, therefore it is important to recruit a homogeneous group of patients into the present study, who are all at a similar point in the treatment of IC. In NHS Forth Valley, patients are diagnosed with IC by a Vascular Assessment Nurse, and are then seen at an outpatient clinic by a Vascular Surgeon who agrees treatment with the patient, and places the patient on a waiting list. This study focuses on patients who have already received either angioplasty or surgery to treat IC, because the majority of patients diagnosed with IC in NHS Forth Valley go on to receive vascular intervention fairly quickly after diagnosis. The rate of patients being diagnosed with IC in NHS Forth Valley is around 2 patients per week, therefore a pragmatic decision was made to recruit patients after, rather than before vascular intervention to meet the overall time constraints of the PhD. An added benefit of recruiting patients after revascularisation is that they are able to take

CHAPTER THREE

a long-term view of their illness and treatment, and how their behaviour and beliefs have changed over time.

The main objective of this study is therefore to explore the health behaviours and illness and treatment representations of patients with IC after they have received vascular intervention.

Research Questions

This study is exploratory, in that little is known about the illness beliefs or health behaviours of patients with IC. The research questions are therefore:

1. What are the illness representations of patients with IC?
2. What are the treatment representations of patients with IC?
3. What is the health behaviour of patients with IC?

Method

Design

A qualitative approach was taken to exploring these research questions, in order to gain a deep understanding of the cognitive representations of patients with IC. Semi-structured, one to one interviews were conducted with participants in their own homes. Interview transcripts were analysed using Framework Analysis based on initial themes taken from the CSM.

Participants

20 consecutive patients who met the study inclusion criteria were recruited from NHS Forth Valley Vascular Outpatient Clinics. Inclusion criteria included a diagnosis of IC, and revascularisation surgery or angioplasty between 6 months and 2 years previous to recruitment. Potential participants were excluded from the study if they were unable to speak English, had a psychiatric illness or were known to be taking part in other studies. 25 patients who met the inclusion criteria were invited to participate in the study, of these, 3 patients did not want to participate, and 2 patients failed to attend the scheduled interviews. The remaining 20 patients took part in the study. Sample size was determined by data saturation, recruitment ended when no new themes emerged from the interviews, and information gathered confirmed themes already identified from previous interviews.

CHAPTER THREE

Participants were aged between 58 and 81 years with a mean age of 70.9 years (SD=6.6). All except one of the participants were retired. Eleven males and 9 females participated in the study. Five participants were current smokers, 3 had never smoked, and 12 had given up smoking (range 3 months to 35 years since quitting), the mean time since quitting was 9 years (sd = 10 years). Demographic characteristics of the participants in this study are shown in Table 3.1.

Table 3.1 Demographic characteristics of the participants (n=20)

<i>Demographics</i>	n	%
<i>Living Arrangements</i>		
Living alone	12	60
Living with relative	8	40
<i>Risk factors</i>		
Diabetes	5	25
Smoker		
Yes	5	25
Never	3	15
Given Up	12	60
<i>Co morbidities</i>		
Heart Disease	9	45
Stroke	3	15
<i>Vascular Interventions</i>		
Bypass graft	12	60
Angioplasty	8	40

Procedure

Participants were recruited from the Vascular Outpatient Clinic at Stirling Royal Infirmary, NHS Forth Valley. Consecutive patients attending the clinic for review of their IC following angioplasty or bypass surgery were approached by the researcher (MC). Patients were given a Participant Information Sheet and a brief verbal description of the study, and were then asked if they would be willing to receive a

CHAPTER THREE

telephone call in two days to confirm whether they would participate in the study. No patients refused to consider taking part in the study, or to give the researcher their phone number. Of the 25 patients who were called, 3 declined to take part in the study at that point; reasons given were because they felt they had nothing to say (n=2), and there had been a death in the family (n=1). The remaining 22 patients agreed to participate in the study, and a suitable time was agreed for the researcher to interview the participants in their own home. Of the 22 interviews which were scheduled, 2 participants failed to answer their door when the researcher arrived at their house, therefore 20 interviews were conducted.

Consent was taken prior to the interview commencing. All interviews were taped. The interviews were semi-structured, with the researcher having some set questions which were always asked (see Table 3.2), to ensure areas of interest were covered in the interview. The opening question was "I understand you have been having circulation problems. Can you tell me all about what has happened with your legs?" Probing questions were used to explore participants' behaviour and beliefs about their health. Interviews lasted from forty-five minutes to two hours. The researcher ended the interview by undertaking to send participants a summary of key findings once analysis was completed, and asking participants to review this and give feedback on the analysis. All interviews were transcribed verbatim and their accuracy checked against the original tapes.

CHAPTER THREE

Table 3.2 Set questions asked in each interview

What are your current symptoms?
What do you think caused your current condition?
What do you think will happen to your health in the future?
Have you changed any of your health behaviours since the operation?
How do you control your condition?
How has your life been influenced by having intermittent claudication?
Can you tell me about the treatment you've had for intermittent claudication?

Analysis

The interview transcripts were analysed using framework analysis (Ritchie & Spencer, 1994), concurrent with data collection. Framework analysis is both a deductive and inductive form of thematic analysis, in that initial themes are pre-set based on the research questions, and further themes develop from the interviews with participants (Rabiee, 2004). This approach was used as the research questions in this study specified particular themes which were being sought in the interviews e.g. the illness representations and treatment representations of patients with IC. Framework Analysis provides systematic and visible stages to the analysis process. The key stages of Framework Analysis are as follows (Pope, Ziebland & Mays, 2000):

- Familiarisation – with the data e.g. by listening to audio tapes of the interviews and re-reading transcripts;
- Identification of a Thematic Framework – both deductively and inductively, by identifying a-priori themes from the research questions, and recurring themes which emerge from the data, and creating an index of themes;
- Indexing – applying the thematic framework systematically to all the interviews, identifying and labelling all instances of each theme;

CHAPTER THREE

- Charting – rearranging the data to create a chart of each theme, with summaries of the views and experiences of participants under each theme heading;
- Mapping and Interpretation – using the charts to describe the themes, and find associations between themes to explain the findings. This step is influenced by the research questions and the themes which have emerged from the interviews.

The thematic framework used in this study was initially based on illness and treatment representations and health behaviour. However, other issues emerged during the 'familiarisation' and 'identification of a thematic framework' stages which were incorporated into the thematic framework. Therefore, the thematic framework was developed and refined on an ongoing basis as more data was collected.

Indexing was carried out by applying the thematic framework to the data - this was done manually by going through each transcript and highlighting sections of text relevant to each theme. The data was then charted by theme. The mapping and interpretation stage of analysis was guided by Rabiee's (2004) criteria for interpreting coded data, namely considering the words used and their meaning, the context of comments made by participants, the frequency and extensiveness of comments, the intensity of comments, checking internal consistency of comments between participants, and considering the specificity of responses.

CHAPTER THREE

Reliability and validity

A number of strategies have been outlined to increase the rigour of qualitative healthcare research, in order to ensure that the findings drawn from qualitative research are valid and relevant (e.g. Mays & Pope, 2000; Long & Johnson, 2000). These strategies, and a description of how they have been incorporated into the design of the current study, are outlined below:

- Respondent validation or member checking – the participants were given a summary of the findings of the study, and asked to comment on the summary.
- Clear exposition of methods of data collection and analysis – the framework approach to data analysis was used in this study. The steps taken in the analysis process have been documented, and quotations from participants are given in the Results section of this study to illustrate how interpretation is supported by raw data.
- Reflexivity – reflection on the impact of the researcher’s own beliefs and experience on the research process is considered to be an important part of qualitative research (Long & Johnson, 2000). The researcher (MC) was 32 at the time the interviews were conducted, and is a psychology doctoral student with no previous experience of working with people with IC. The researcher’s ideological perspective is of a biopsychosocial model of health i.e. that health and illness should be considered in terms of biological, psychological and social factors. Although the ‘distance’ (Mays & Pope, 2000) between the researcher and participants was quite large in terms of age and educational qualifications, there were other factors which reduced the

CHAPTER THREE

distance between the researcher and the participants, including, the researcher is Scottish and lives locally and so could discuss local issues with participants, the researcher is a similar age to the children of participants, and the researcher has children of a similar age to the grandchildren of participants, enabling social discussion on areas of common ground.

- Peer debriefing – Long & Johnson (2000) suggest that presenting methods and findings at national research conferences increases credibility of the research because it opens the design and analysis of the research to criticism from other researchers, and allows an evaluation of the relevance of the study by people who are knowledgeable in the field. This study has been presented at the East of Scotland Vascular Research Day (2008), the British Psychological Society Division of Health Psychology Annual Conference (2009) and the Vascular Society Annual Meeting (2009).
- Inter-rater reliability/peer debriefing – Long & Johnson (2000) suggest that involving knowledgeable colleagues in key parts of the analysis process enables the consideration of other points of view and provides a check on premature ending of the data collection or analysis phases of the study. In this study, Maggie Cunningham typed up the transcripts and carried out the initial framework analysis. A Vascular Consultant and a Vascular Assessment Nurse were given copies of the transcripts and the thematic framework and asked to independently review the transcripts and check (i) if they agreed with the coding of the themes and (ii) if they could identify other themes from a clinical perspective which they felt might be important to the

CHAPTER THREE

analysis. Discussion of the transcripts with RH and VS then fed back into the interpretation stage of the analysis.

Ethics

Fife and Forth Valley Research Ethics Committee approved this study. The letter of invitation, participant information sheet and consent form are included in Appendix 1.

Results

Table 3.3 sets out the a-priori themes which were sought in the data based on the research questions, and other themes which emerged during the analysis process.

Table 3.3 Final themes		
	Theme	Summary of theme
A Priori Themes	Identity	Current symptoms that patient sees as being part of their illness
	Cause	Things the patient attributes to causing the illness
	Timeline	Length of time the patient believes the illness will last
	Consequences	Patient’s beliefs about the severity of the condition, and the consequences the illness has on the patient’s life. Including: Sense of loss Concerns about future health
	Cure/Control	What the patient believes can be done or has been done to improve the illness.
	Health behaviour Treatment	Past, current and intended behaviour Including: Beliefs about vascular treatment Beliefs about walking Confidence in walking
Emergent Themes	Doctor Patient Communication Coping	Patient’s account of interaction with health service / patient’s understanding of the illness Including: Adapting to limited mobility Accepting limitations as due to age Making downward comparisons with others

Identity

All participants reported having current symptoms of IC, although symptoms varied greatly in severity. Eight (40%) participants felt that they had the same symptoms as they had had prior to revascularisation. Seven (35%) participants felt that the

CHAPTER THREE

procedure had made a difference and had reduced their symptoms but they still had problems with their leg. Five (25%) felt that their leg was much improved, symptoms were dramatically reduced and they only had occasional leg pain after walking a long distance.

The main symptom of Stage II PAD is intermittent claudication, leg pain which comes on while walking and disappears soon after stopping to rest. However, in this study, all participants described currently having some or all of the following symptoms - swelling in the legs, pain in the scar, tightness, throbbing, numbness, cramps at night, problems bending the knee, and pain when kneeling, which they attributed to their circulation problems. Participants had not expected to have these symptoms after treatment. While some of these symptoms are attributable to PAD, others occur as a result of surgery, and this reporting of symptoms indicates unrealistic expectations about revascularisation, and lack of knowledge about the consequences of surgery.

Participant 4 Swelling, a lot of swelling, especially in this one... But in my bed, I get quite a lot of pain up here where the operation was.

Participant 21 (talking about gardening) I've got to come in and sit down. I have to. I take a cushion out with me and I kneel down, because kneeling is worse. In fact it's sore, I've got to get up and sit down. I know how far I can go.

CHAPTER THREE

Most participants noted that they could only manage a slow pace when walking on the flat, and that hills and stairs still caused them problems. However, most participants were happy that they could walk around the ground floor of their house pain free.

Several participants felt that their legs had lost their power, and that they felt tired very quickly when they tried to walk. Almost all participants were limited in how far they could walk on the flat. Only 2 participants felt they could walk more than a few hundred yards.

Participant 11 I walk very, very slowly... Hills are very, very difficult, even now. I can tell you when there's an incline, where you wouldn't even notice that there's an incline. It's not so much the cramp, but just, as if my muscles, because I've had this for so long and I wasn't using my muscles, my muscles I think have wasted a bit. I haven't the power I used to have.

Participant 18 I was in the forces for 16 year, so I used to be quite fit, you know? But now I just feel, I'm getting awful tired easy. I don't know whether that's something to do with the legs, I should imagine so.

CHAPTER THREE

Cause

Participants cited a wide variety of factors which they felt may have caused their PAD.

The main cause mentioned by participants was smoking, 14 of the 17 (82%) participants who either are current or past smokers, mentioned smoking as a possible cause of their disease. However, several participants mentioned that they were reporting this as a cause because their doctor had said smoking was a cause, but indicated through body language and tone of voice that they did not necessarily believe this:

Participant 19 It's cos of this (waves cigarette). Well, that's what they said anyway.

Participant 14 Well, they say the smoking. I mean, I don't know.

Several participants said that they had no idea what had caused their disease. Of this group, some were or had been smokers, and some were diabetics – therefore they had risk factors for the disease but were not aware of this:

Participant 12 I've no idea, that's what I'm saying I just wondered if the metformin for the diabetes had anything to do with it, I don't know. But eh, just maybe like an oil change in a car, the older you get it's maybe needing renewed ken, like your blood supply, ken? I don't know. I don't know. As I say, I thought maybe the medication had something to do with it.

CHAPTER THREE

Five (25%) participants suggested that the disease may be due to old age. Only three (15%) participants mentioned diet as a possible cause of the disease.

Other causes mentioned by participants included Crohn's disease, a hernia, air travel, hard physical work, carrying twins in pregnancy, walking dogs in damp weather, stress, standing for long stretches of time, an 'emotional stroke' and walking gait. It is interesting that several perceived causes included physical activity, as lack of physical activity is a risk factor for developing IC.

Participant 22 Right, I had two dogs, three actually, and I used to take them a walk every day and every night, I always walked them. So I don't know whether that could have been it, maybe going out in the damp weather, I used to go out in all weather, you know? And I don't know whether that caused it, you know?

Later in the interview, this participant went on to describe how he had given up his dog because he didn't feel able to take it for walks due to the leg pain. The participant's model of his illness was logical and coherent (to him) and clearly led to his choice of behaviour – non-adherence to walking advice.

Participant 22 I had to give my wee Yorkshire terrier away because I wasnae able to take him a walk, and I was breaking my heart, I was breaking my heart. And eh, it was beautiful tae, but I had to get rid of it, it was a shame, he was always wanting oot, and I couldnae.

CHAPTER THREE

Timeline

Participants discussed their illness as acute and treatable, rather than a chronic condition, focusing on the symptom (IC) rather than the disease (PAD). Surgery was therefore deemed successful if the symptom of IC was relieved, and participants didn't think about the ongoing implications of atherosclerosis to their legs or general health. Those participants who still experienced IC symptoms generally viewed the disease as something which they hoped could be treated by further surgical interventions, although participants accepted that without further surgical intervention they would continue to have symptoms - the symptoms would not just disappear or spontaneously resolve.

Participant 2 If it's no going to get any worse, ten year down the line if it was to get really bad then I'd say OK lets see what we can do, but it's no that bad at the moment. I mean, I wanted the operation thinking obviously this was going to cure it. As it turned out, it's no, in my case it's no exactly worked.

Some participants were gradually coming to realise that they may always have some symptoms, although they had a lack of knowledge and understanding about the timeline and likely outcomes of the disease.

CHAPTER THREE

Participant 9 In fact I was thinking the other day, I must say to my own doctor, is this likely to get even worse or what? You know I don't know what the outcome is.

Participant 14 I felt a wee bit disappointed on Monday because I just felt "Well, is this me? Am I just going to be stuck with this? Am I going to have to say well I've walked far enough, I'll have to rest?" And I don't feel like being an old wifey.

Consequences

Participants felt that intermittent claudication had an enormous impact on how they led their day to day lives, describing at length their experience of loss due to IC.

Participants missed being able to walk, and felt curtailed and restricted. All participants talked about not being able to do the things they wanted to do, and many felt trapped and lonely. Loneliness was highlighted by the fact that they couldn't join in normal activities with others, for example at parties, or playing with grandchildren.

Participant 6 Now that I cannae walk, I want to walk. You don't realize how much your legs mean to you, till you cannae use them. Then you find oot.

CHAPTER THREE

Participant 23 You cannae walk so far. I dinnae get out so much. And you're no prepared to go out so much when your legs are like that. I'm stuck here.

Despite this restriction in daily activities, participants did not appear to view the long-term consequences of having PAD as life-threatening. No participants mentioned any concern or awareness about their risk of stroke or heart trouble. Concerns for future health were around whether or not participants would be offered or would require further vascular intervention on their legs. For those who had not been offered further vascular intervention, there was concern about what would happen to their mobility in the future. Most participants felt that they were dependent on their family to some extent for help with transport, shopping and housework. Several participants expressed their fear of increased need of care in the future. They felt that they may become a burden to their family, and didn't want to be troublesome or hold their families back.

Participant 18 Well, I'm not getting any younger, I'm 63 year old. I hate to think my legs would ever get that bad, and my son, would have to look after me, I don't want that, you know what I mean? Sometimes I think my whole life's went, I cannae walk, I just sit in the house.

Cure/control

As previously mentioned in the Timeline theme, participants viewed their illness as an acute, potentially treatable condition, rather than as a chronic disease. Whether the

CHAPTER THREE

illness was 'cured' or not was seen by participants as being entirely the responsibility and under the control of the surgeons. 'Cure' was defined by participants as an eradication of leg pain symptoms, rather than treatment of atherosclerosis.

Participant 22 So I'm hoping and praying that (the surgeon) will be able to cure me.

Participants tended to control their symptoms by slowing down, and reducing their walking. Most participants talked about how they planned excursions from the home, thinking about where they would park, and where they could sit down to stop and rest. Several participants said that they avoided physical activities and had reduced the amount they went out because of their IC.

Participant 25 And you're just uncomfortable, cos you're having to sit down in the centre (Thistle Centre) in every seat, just like an old wife... I don't go out much at all... As you can see I'm needing to decorate, and I just cannae be bothered. I just cannae be bothered.

Participants had come up with a variety of practical aides to help control their claudication, for example using a stick to help with balance, having a banister on both sides of the stairs to pull themselves up, carrying a walking stick with a seat, rubbing cream or olive oil on the legs, putting feet up on a stool when sitting, having a walk-in shower, buying a special bed which tilts, and having an electric mobility scooter.

CHAPTER THREE

Health behaviour

Most participants said they were aware that they should be trying to exercise, because their doctor had told them to. However, they did not have a clear understanding of how much walking they should be doing, the recommended intensity of walking, or the mechanism by which walking would improve their health.

Most participants felt they couldn't exercise because of the pain they experienced when walking. As a result of claudication pain, most participants had given up trying to exercise.

Participant 1 Again it just comes down to the walking, so you can't exercise as much. I mean even going round the shopping centre, you cannae, I mean you've jut got to stop and rest.

Several participants mentioned that they had gained weight, or that they felt very overweight as a result of not being able to exercise.

Participant 19 I'm no exercising. As I say to my lassies, I'd like to get rid of that (shakes tummy). That's frae sitting here, ken?

Participants were divided over changes to eating habits – half the sample had made no changes to their eating habits, half had made some changes, although not necessarily as a result of IC. Changes to diet included cutting down sugar and salt intake, reducing fat intake, eating anti-cholesterol products and eating more fruit.

CHAPTER THREE

12 (60%) participants had been smokers but had given up smoking. Of these participants, only one had given up as a result of being diagnosed and treated for PAD. The other 11 participants who had given up smoking had generally given up due to other health events or health scares, for example stroke, heart disease, lung collapse and suspected heart problems. In a number of cases, these other health events took place after diagnosis with IC.

Most participants talked about looking after their health in terms of their medication regime, for example taking statins to lower their cholesterol and taking aspirin to thin their blood. When asked whether she had made any changes to her health behaviours since being diagnosed with IC, one lady answered:

Participant 21 Not really, no. They keep a watch on my blood pressure. I take quinine for my legs. I don't know if it helps. They say it's supposed to help. And I take an aspirin a day.

Many participants also talked about a heavy use of and reliance on painkillers. Participants seemed to feel that taking medication was the way they could contribute to improving their health, rather than making dramatic changes to health behaviours. This may be linked to their lack of knowledge of risk factors for developing PAD (see Causes theme).

CHAPTER THREE

Treatment

Only one participant felt that the surgical treatment they had received was not worthwhile:

Participant 4 Personally, no really (worthwhile). Then again, I don't know what like it would have been without.

All other participants felt that vascular intervention had been worthwhile, whether it had reduced their leg pain symptoms or not. Reasons given for this were because the treatment was worth a try, and because the treatment was possibly preventing further decline in the legs. However, despite feeling that treatment had been worthwhile, several participants mentioned their disappointment with the outcome. There was clearly a gap for many participants between their expectations of treatment and the outcome – with participants expecting vascular intervention to completely eradicate claudication symptoms, and not being aware of potential side-effects of surgery like swelling and nerve damage (see Identity theme). This was particularly the case for patients who had undergone angioplasty, with many participants noting that although it had made a tremendous difference at the time, the effects hadn't lasted long. As one man said of angioplasty:

Participant 5 It worked for a wee while. I was delighted at first. I didnae go out and start running on it, but after a couple of days it was brilliant. With walking it never came on, I could walk as far as I wanted to and as quick as I wanted. It never bothered me. I think it was up till about 6

CHAPTER THREE

weeks ago... So it lasted quite a while. But I could just feel the calf muscles started to get sore. It came on gradually and then it got worse very quickly, I thought. I don't know whether something's come to block the artery or what.

Most participants did not view walking as a treatment for IC, although two participants talked about trying to keep walking to help with their circulation:

Participant 9 I don't stop the minute it gets sore, I keep trying to go, because I feel I've probably got to try and make it, make the blood go through. To be honest I don't know if that helps though.

Participant 5 The only reason I don't slow down is walking's supposed to be good for it, to try and alleviate it, the blood tries to find other ways.

Many participants wanted to be able to walk more, and missed going out walking, but felt they couldn't walk more because of leg pain. Some participants had lost confidence in their walking abilities, not trusting their balance, or feeling a loss of strength and power in their legs. Participants also mentioned avoiding walking into the claudication pain in case the pain was an indication of damage to the leg.

CHAPTER THREE

Participant 2 I'm also a wee bit more careful cos I don't want to damage anything.

Doctor patient communication

A theme which emerged from the interviews was the communication between participants and medical staff during the course of treatment for PAD. A number of participants commented that they did not understand the vascular surgeons, and that they used complicated, technical language. Some participants felt that they did not have much time with the surgeons, and consultations were rushed. These factors contributed to make several participants feel that they were unable to question the doctors, and that they were not clear why decisions had been made. This was especially the case for participants who were suffering claudication pain, but had had no further procedures offered - they didn't understand why. One lady mentioned her lack of understanding about surgical decisions several times in the interview - at diagnosis:

Participant 9 At that point he said he didn't think there was really too much they could do, where it was or something. He showed me all the x-rays, I tried to look intelligent (laughs). I said "oh well, you know, fair enough".

At a follow-up to angioplasty:

CHAPTER THREE

Participant 9 On Monday when I saw them, I don't know what tests the sister was taking but she wrote them on the end of the bed, and I saw him look at one of them, because he was sitting right at the end of the bed, so I saw him sort of making a face, so I thought "Oh oh, something's not right."

And in relation to further vascular intervention:

Participant 9 And in fact, well he doesn't advise it again, so that's OK, and maybe you don't do it a second time, I don't know, but I thought well if he suggested it, I was saying to the girls, I said "Well if they suggest doing it again, I'd be happy after the last time" but then maybe that's not wise, I don't know.

Several participants spoke about the lack of information they were given about their post-operative health, especially nerve damage and swelling after surgery.

Participant 8 So, after I was out my leg swelled up. I had to go and buy size 10 slippers cos I couldn't get my shoes on, they were two sizes too big. So, it was painful, I had to wear the slippers for a long, long time, weeks and weeks and weeks, and I went to the doctor (GP) and he said "You've got an infection, you'll need to take antibiotics" Didn't work, I was back 2 or 3 weeks later, I said to him "This leg's no getting any better", I think this was 12 or 13 or 14 weeks after the operation

CHAPTER THREE

and I was still swelled up. He said “I’ll send you back to see the specialist”. So I went to see the specialist, he says “Oh this could happen, this is not unusual, go and get an elastic stocking”. Anyway – I got an elastic stocking and after a week it was a lot better, and after a fortnight it was OK, I could put my shoe back on again. I think maybe I should have had an elastic stocking when they threw me out, and a wee bit more kind of instructions.

The above quote also highlights the lack of knowledge about PAD outwith the vascular specialism. A number of participants spoke about the length of time they had claudication symptoms, and the number of times they visited their GPs about leg pains before they were referred to the vascular clinic. Participants described being given conflicting messages from GPs about the cause of their leg pains and possible treatments, which added to their confusion about what was actually wrong with them, and what they should do about it.

Participant 12 Anyway, I kept mentioning it to him (GP), and he’d give me pain killers, different drugs... Anyway, I read in a magazine one time about intermittent claudication, the next time I was there, I mentioned it to him, I says “And that’s exactly the same symptoms that I’ve got”.

Participant 18 When I first went to the doctors my arteries were actually sticking out, and they gave me cream for it. Then the new doctor, he took one look at it, he felt the pulses

CHAPTER THREE

in my foot and he says “there’s nae pulse in there”, so there’s no enough blood getting through “You’ll need to see a specialist”. 6 year. It just shows you. A different doctor – right away! He says “there’s something wrong there”, and that was it.

Coping

Participants described three ways in which they coped with their illness - adapting to limited mobility, accepting limitations as being due to age, and making downward comparisons with others.

Participants adapted to having limited mobility by changing the way they spent their leisure time, giving up hobbies which involved physical activity like golf, dancing and fishing, and instead finding hobbies where they didn’t need to walk, for example sewing, knitting, growing bonsai trees and collecting things. Several participants had given up their dogs, or had not got a new dog when their old dog died. By reducing their physical activity levels, participants were less likely to experience claudication pain.

Participant 23 I never got another dog, because I wasnae fit to take him walks, wi’ my legs. I never got another dog. That’s the first time I’ve been without a dog all my life.... I’m quite content. I collect models, of tractors and dumpers and things like that. I’ve got quite a lot.

CHAPTER THREE

Many participants seemed to rationalise their limited mobility by accepting it as part of the ageing process.

Participant 3 What could ye dae at my age? I'm 82.

Participant 16 I can still get about, like ken. I used to go fishing, I used to play golf. I couldnae dae that now, ken? Nuh. I stop for rests now, at times, aye. I'm 73 you see.

Another common way that participants coped with their illness was to make downward comparisons with people who they perceived as being worse off than themselves. The majority of participants mentioned that they felt lucky that they didn't have a different disease, for example comparing themselves to people with cancer, or to people in wheelchairs.

Participant 24 I keep saying to myself there's worse than me... I would say it's affected my life, but no as extreme as whit some people have. I mean, I'm no in a wheelchair.

Discussion

The aim of this study was to explore the illness and treatment representations and health behaviour of patients who had received a vascular intervention to treat their claudication symptoms.

In general, participants in this study continued to experience a debilitating level of symptoms, including claudication pain, after receiving vascular intervention. These symptoms led to restrictions in activities outside the home and often led to feelings of frustration. However, while participants felt the consequences of PAD were severe in terms of everyday life, they did not appreciate the long-term health implications of PAD. Participants appeared to view their illness as an acute, rather than chronic condition; and those who were still experiencing symptoms generally viewed the disease as something which could be successfully 'cured' by further vascular interventions. This perception of the illness as acute rather than chronic has been found in other samples of patients with PAD, Gibson & Kenrick (1998) suggested that the acute medical style of treating PAD led to patients having unrealistic expectations about the disease and their recovery, and ultimately contributed to patients' feelings of powerlessness. In the present study, patients viewed the management of their disease as being controlled by the surgeons, and did not take steps to alter their own health behaviours. However, the present study recruited patients who had received either angioplasty or surgery as treatment for IC, and these patients may have had a 'medical model' of their illness due to their experience of surgical treatment for their

CHAPTER THREE

symptoms. Further research could investigate the beliefs of patients who have been diagnosed with IC but who have not yet received treatment.

Some of the symptoms which participants reported in their legs were a result of the vascular intervention they had received, and were unexpected. However, vascular intervention was generally regarded by participants as being worthwhile. This mirrors findings from a study of patients with limb threatening ischemia following revascularisation (Seabrook, Cambria, Freischlag & Towne, 1999) – 53% of the sample reported problems with their revascularised limb despite successful surgery, however 91% reported that they were glad they had had the surgery. In the present study, participants felt treatment had been worthwhile because it was ‘worth a try’.

However, participants did report a gap between their expectations prior to treatment and the reality of their condition after treatment, this was particularly marked for participants who had had angioplasty. Both Cook & Galland (1997) and Chetter et al (1998) also found a decline in perceived health state and quality of life scores between the period immediately after angioplasty and at 6 month and 1 year follow up, despite no change in walking distance scores. They suggested this perceived drop in quality of life may be due to the development of co morbidities, or that participants’ expectations had increased as their activity levels increased. However, in the present study there was no evidence that participants’ activity levels had increased after vascular intervention, in fact, many participants spoke about their reduced activity levels.

CHAPTER THREE

Many of the causes of PAD are behavioural and therefore modifiable, for example smoking, high cholesterol, obesity, and lack of exercise. Many participants were either unaware of the causes of the disease, or had misattributed causality. The most common cause cited in this study was smoking, but several participants indicated they stated this as a cause because they had been told this by their doctor, not because they necessarily believed it. Participants did not understand the way that risk factors acted on the body to progress disease, and appeared unaware of future health risks as a result of continuing unhealthy behaviours. Some participants had changed health behaviours due to other more acute health crises, for example heart problems and stroke; however, very few had made any changes to their health behaviours as a result of IC. This is a concern because continuation of health risk behaviours could lead to re-stenosis of the arteries and long term cardiovascular problems.

Some participants thought different kinds of physical activity may have caused their PAD, for example walking dogs in the rain, standing for long periods of time, hard physical work and walking gait. This is particularly interesting as walking has been found to improve the symptoms of IC (Leng et al, 2000), however, beliefs that physical activity caused PAD may lead participants to avoid physical activity. Although many participants were aware they should be exercising, they felt that walking was too painful, may damage their legs, and they lacked confidence in their ability to walk, therefore they slowed down and avoided exercise. Galea et al (2008) also found that there were many barriers to walking for people with IC. Giving information may therefore not be enough to elicit behaviour change, patients may also need some assistance with how to overcome barriers and turn knowledge into action.

CHAPTER THREE

Participants may have been given information about the causes and consequences of their disease and the need to change health behaviours in their consultations with medical staff, however, they don't appear to have integrated this information into their cognitive framework of how they view the illness. Several participants commented that they did not understand the language the surgeons used, felt consultations were rushed, and felt they were unable to question the surgeon – these factors may affect how well patients process the information given to them during a consultation. Ley (1985) found that communication between doctors and patients is often not understood by patients and results in non-compliance with health advice. Collins et al (2006) suggested that improving patient-physician communication may be an important factor in increasing the exercise behaviour of patients with PAD. The results from the present study suggest that it may be useful to look at alternative ways of imparting important information about PAD to patients, to improve their understanding of the disease and enable them to make informed decisions about their health behaviours.

Participants were found to have different ways of coping with their illness. Some participants had accepted the reality of their illness and had adapted their lives to accommodate any limitations, changing hobbies to more sedentary activities so they could keep busy. Some participants rationalised the effects of PAD as a part of the ageing process. That said, most participants felt curtailed to some extent by their current symptoms, and felt that the pain in their legs negatively affected their quality of life. Almost all participants made downward comparisons, comparing their health

CHAPTER THREE

and situation with those who they perceived to be physically worse off. Making downward comparisons appeared to provide some comfort to participants. Wann-Hansson et al (2005) also found that PAD patients awaiting surgery made downward comparisons, and concluded this helped them to accept their illness and reduce its impact.

Previous questionnaire based studies into the effect of revascularisation on patients with IC have found significant improvements in self reported physical functioning, walking distance, bodily pain, ABPI and leg symptoms for patients with IC who underwent surgery and angioplasty (e.g. Feinglass, McCarthy, Slavensky, Manheim & Martin, 2000; Currie, Wilson, Baird & Lamont, 1995; Chetter et al, 1998; Pell & Lee, 1997). No significant improvement was found in the social and emotional domains as measured by the SF-36 in these studies. In the present study participants were found to be negatively affected socially and emotionally by their IC, reporting frustration, loneliness and a sense of loss, indicating that current questionnaire based methods of analysing the success of revascularisation do not sufficiently illustrate the overall quality of life of these patients.

CHAPTER THREE

Summary and implications

This study found that most participants had not changed their health behaviours as a result of being diagnosed with IC, viewing the disease as an acute condition over which they had little control. Control was primarily achieved through avoiding walking, and slowing walking pace, to avoid pain. Many participants felt they could not increase their walking distance without further surgical intervention. Participants were largely unaware of the causes of the disease, or of their increased risk of future health problems.

The findings of this study indicate that patients with IC have dysfunctional illness and treatment representations of PAD. These dysfunctional representations appear to lead to sub-optimal coping actions, including reducing walking and slowing pace. An intervention aimed at increasing the walking behaviour of patients with IC, based on the CSM, would need to modify illness representations, and representations of walking behaviour. However, patients with PAD who have already received a vascular intervention have a strongly held view that the disease is curable by surgery, possibly because of the acute manner in which the disease is managed in the hospital system. Therefore an intervention aimed at changing walking behaviour may be more successful if targeted at patients who have just been diagnosed with PAD, and are not entrenched in the acute management style of the hospital system.

CHAPTER FOUR

GENERAL METHODS

CHAPTER FOUR

Overview

This chapter aims to describe the measures used in the subsequent two empirical studies – the cross-sectional questionnaire (Chapter 5) and the randomised controlled trial (Chapter 6); and the design of the brief psychological intervention used in the randomised controlled trial.

The cross-sectional questionnaire study (Chapter 5) aimed to examine whether the CSM was a useful model for understanding the walking behaviour and health-related quality of life of patients with IC, by measuring the illness and walking representations of participants and testing how these related to walking behaviour and quality of life.

The randomised controlled trial (Chapter 6) was carried out to test whether a brief psychological intervention based on the CSM would modify participants' illness and walking representations and lead to an increase in physical activity and an improvement in quality of life.

A summary of the measures used in the individual studies is provided in Table 4.1. As Study One used a qualitative methodology, it will not be considered in this chapter, and is discussed in detail in Chapter 3.

CHAPTER FOUR

Table 4.1 Summary of measures used in each study

Measures	Study 2 – Cross-sectional questionnaire	Study 3 - Intervention
Illness representations	✓	✓
Treatment Representation – Consequences	✓	✓
Treatment Representation – Personal Control	✓	✓
Intention to walk	✓	✓
Health Behaviours	✓	✓
Health related quality of life	✓	✓
Walking behaviour - IC	✓	✓
Walkingbehaviour – pedometer		✓
Walking behaviour - IPAQ		✓

Illness Representations

The Brief Illness Perception Questionnaire (BIPQ) developed by Broadbent, Petrie, Main & Weinman (2006) provides a measure of both cognitive and emotional illness representations (see Appendix 2). The 9-item questionnaire has five items assessing cognitive illness representations including consequences ('How much does the illness affect your life?'); timeline ('How long do you think the illness will continue?'); personal control ('How much control do you feel you have over your illness?'); treatment control ('How much do you think your treatment can help your illness?'); and identity ('How much do you experience symptoms from your illness?'). Two items in the questionnaire assess emotional representations including concern ('How concerned are you about your illness?') and emotions ('How much does your illness affect you emotionally?'). One item in the questionnaire assesses illness comprehensibility ('How well do you feel you understand your illness?'). Causal representation is assessed by participants listing the three most important factors which they believe caused their illness. All items other than causal representations are

CHAPTER FOUR

rated using a 0-to-10 response scale. The questionnaire can be adapted to a specific illness by renaming the word 'illness' in each question with the name of a particular illness. As participants with IC frequently do not know that they have an underlying disease, PAD (see Chapter 3), the word 'illness' was replaced with 'intermittent claudication (cramping leg pain)' in the questionnaires in the subsequent two empirical studies. Therefore, in these studies, the BIPQ was used to measure symptom, rather than illness, representations. The word 'treatment' in the treatment control item can also be replaced with the name of a specific treatment, however, as participants may have received or be scheduled to receive a range of different treatments, it was decided to leave the general word 'treatment' in the question.

It has been demonstrated by previous researchers that the questionnaire has good test-retest reliability at 6 weeks (personal control: $r=0.42$, $p<0.01$; all other items $r=$ between 0.61 and 0.75, $p<0.001$) (Broadbent et al, 2006); good concurrent validity with the IPQ-R (Moss-Morris et al, 2002), a longer questionnaire which also measures illness representations ($r =$ between 0.32 and 0.63, $p<0.001$, Broadbent et al, 2006); and good predictive validity of outcomes following myocardial infarction, with different items in the questionnaire predicting different outcomes related to mental and physical functioning (Broadbent et al, 2006).

Treatment Representations – Consequences and Personal Control

The most effective regime for walking to improve symptoms of IC, involves participants walking to near maximal pain, for half an hour at least three times a week

CHAPTER FOUR

(Leng et al, 2000). It is IC patients' representations of this treatment behaviour which this thesis aims to explore. There are no existing measures of IC patients' treatment representations of the consequences of performing this behaviour, or of their personal control to perform the behaviour. Elicitation interviews were conducted to elicit beliefs to be used in the design of suitable treatment–consequences and treatment–personal control scales (Francis et al, 2004). Elicitation interviews were conducted with 8 patients recently diagnosed with IC, during a visit to the IC Outpatient Clinic. Patients were interviewed individually in a private room at the hospital. Treatment-consequences beliefs were elicited by asking participants a range of open questions relating to the advantages and disadvantages of walking to near maximal pain, for half an hour at least three times a week. Treatment-personal control beliefs were elicited by asking participants to describe what makes walking to near maximal pain, for half an hour three times a week easier or more difficult (see Appendix 2).

The elicitation study was used to develop a measure of treatment-consequences beliefs (see Appendix 2) based on methods described in Schwarzer et al (2003). Items were designed using if/then statements with the common stem specifying the target behaviour - 'If I walk for at least 30 minutes, at least 3 times a week until the claudication pain is almost unbearable before stopping for a rest then...'. The thirteen 'then' statements specify possible positive or negative consequences of performing the behaviour, taken from the most common responses in the elicitation interviews. The measure consists of eight positive consequences (e.g. 'it will be good for my heart') and five negative consequences (e.g. 'I will be embarrassed because I have to

CHAPTER FOUR

stop regularly'). There are four possible answers for each item on a Likert scale from (1) not at all true to (4) exactly true. The measure is scored by calculating the mean positive treatment-consequences and the mean negative treatment-consequences.

The elicitation interviews were also used to develop a measure of treatment-personal control (see Appendix 2) using methods described in Francis et al (2004). Answers to the questions about what makes walking easier and harder were used to create a 9-item measure of confidence in completing the target behaviour in a series of graded scenarios. A common stem was used to specify the target behaviour - 'How confident are you that you can do a walk of at least 30 minutes, at least 3 times a week, walking until the claudication pain is almost unbearable before resting, when...'. The nine items specified the most common situations described in the elicitation interviews as making walking easier or more difficult, for example, 'the weather is good', 'the walk is uphill' and 'there is nowhere to stop for a rest'. Participants answer each item on a scale from 0 (Not at all confident) to 10 (Extremely confident). The measure is scored by calculating the overall mean.

Intention to perform the behaviour

The recommended walking behaviour can be split into two distinct behaviours (i) walking to near maximal pain before stopping to rest, and (ii) walking for at least half an hour three times a week. The CSM proposes that an individual forms an action plan to cope with illness, based on illness and treatment representations. Intention to perform each of the recommended behaviours is therefore used as a measure to

CHAPTER FOUR

determine whether the individual has formed a decision to perform the behaviour. A measure of intention to perform each of the behaviours was developed (see Appendix 2) using 3 items, with the stems - 'I intend to...', 'I would like to...', and 'It is likely that I will...'. These items measure intention to perform the behaviour, desire to perform the behaviour and expectation that the individual will perform the behaviour (Schwarzer et al, 2003). Participants answer each item on a scale from 0 (Strongly disagree) to 10 (Strongly agree). The measure is scored by calculating the mean intention to walk to near maximal pain before stopping for a rest, and the mean intention to walk for half an hour three times a week.

Health Behaviours

This thesis focuses on the walking behaviour of patients with IC. However, patients with IC are routinely recommended to also lose weight and stop smoking as well as being recommended to increase their exercise (Cassar, 2006). For this reason, smoking and dietary behaviour are also measured in the subsequent empirical studies.

Smoking is measured (see Appendix 2) by asking if the participant is a regular smoker, occasional smoker, ex-smoker or non-smoker. If the participant is a smoker they are asked how many cigarettes they smoke on an average day.

Dietary behaviour is measured (see Appendix 2) in a 4 item scale consisting of two positive dietary behaviours and two negative dietary behaviours. Two items are from Toobert, Hampson & Glasgow's (2000) Summary of Diabetes Self-Care Activities – 'On

CHAPTER FOUR

how many of the last 7 days did you eat five or more servings of fruit and vegetables?’ and ‘On how many of the last 7 days did you eat high fat foods such as red meat or full-fat dairy products?’. Two items are adapted from Weinman, Petrie, Sharpe & Walker (2000) into a similar format to the Self-Care Activities items – ‘On how many of the last 7 days did you eat fried food?’ and ‘On how many of the last 7 days did you eat breakfast?’. Items were chosen based on relevance to the IC population.

Participants circle the number of days from 0 to 7 that they have performed an activity. The measure is scored by calculating the mean of the 4 items, reverse scoring the negative dietary behaviours.

Health related quality of life

Quality of life in patients with IC has frequently been measured using generic quality of life instruments like the SF-36 (e.g. Dumville et al, 2004), the McMaster Health Index (e.g. Barletta et al, 1996) and the Nottingham Health Profile (e.g. Khaira et al, 1996). In a review of quality of life assessment in patients with IC, Mehta, Subramaniam, Chetter & McCollum (2003) concluded that generic quality of life measures are not sufficiently sensitive to detect clinically relevant variation in the quality of life of patients with IC. Two disease-specific quality of life measures have been developed in English for patients with IC, the Claudication Scale (Marquis, Comte & Leher, 2001), a 47-item scale with five domains: daily living, pain, social life, disease specific anxiety and mood; and the Intermittent Claudication Questionnaire (ICQ, Chong, Garratt, Golledge, Greenhalgh & Davies, 2002), a 16-item scale with a single domain. Due to the length of the overall questionnaire, it was decided to use the

CHAPTER FOUR

shorter ICQ (see Appendix 2) as a measure of health-related quality of life in the subsequent two empirical studies. The ICQ was developed through semi-structured interviews with newly diagnosed patients with IC to identify how IC affected their daily lives. The 16-item questionnaire includes one item about pain e.g. 'During the past 2 weeks, how severe were your leg pains?'; seven items about ability to perform various walking tasks ranging in difficulty from going out of the house to walking more than a mile; one item about frequency of stopping for rests when walking; three items about how IC affects mood; and four items about how IC affects activities like work and shopping. The pain item is scored on a 6-point Likert scale with responses ranging from 'None, I had no leg pain' to 'Very severe'. All other items are scored on a 5-point Likert scale. The instrument is scored by summing up patient responses to individual items and transforming to a 0 to 100 scale, where 0 is the best possible and 100 the worst possible health-related quality of life score.

It has been demonstrated by previous researcher that the instrument has good test-retest reliability at 3 months ($r=0.94$) (Chong et al, 2002). The instrument has good construct validity, significantly ($p<0.001$) correlating with verbal reports of walking ability, treadmill walking results, EuroQol scores, and SF-36 scores (Chong et al, 2002). The ICQ has also been found to be responsive at 3 months following angioplasty, showing a significant improvement in quality of life scores for patients who received successful angioplasty ($p<0.01$) and no change in quality of life scores for patients whose angioplasty was unsuccessful (Chong et al, 2002).

CHAPTER FOUR

General quality of life

All participants were contacted by telephone at 6 and 12 weeks after recruitment into the study. The purpose of the telephone calls was to maintain contact and prompt review of behavioural goals for patients in the intervention group, however, the telephone calls also provided the opportunity to ask a few questions about each participant's ongoing health. Therefore, a single item question was asked at baseline, 4 month follow-up and during the two telephone calls about general quality of life, taken from the World Health Organisation Quality of Life (WHOQOL)- BREF (Murphy, Herman, Hawthorne, Pinzone & Evert, 2000) – 'How would you rate your quality of life', to which there are five possible responses on a Likert scale 'Very poor', 'Poor', 'Neither poor nor good', 'Good', and 'Very good'.

Walking behaviour – IC

As previously stated, the recommended walking behaviour can be split into two distinct behaviours (i) walking to near maximal pain before stopping to rest, and (ii) walking for at least half an hour three times a week. The behaviour of walking to near maximal pain before stopping to rest, is measured in the subsequent studies by the question 'In general, do you carry on walking after the pain has started in your leg?', to which there are three possible responses – 'never', 'for a few steps' and 'until the pain is nearly unbearable'.

The behaviour of walking for at least half an hour three times as week is measured in the subsequent studies by the question 'How often do you walk for at least 30

CHAPTER FOUR

minutes?’ to which there are 6 possible responses – ‘never’, ‘once or twice a month’, ‘1-2 times per week’, ‘3 times a week’, ‘4-5 times a week’, and ‘everyday’.

Self-reported walking ability is measured with the question ‘How far can you walk, aided or unaided, under normal circumstances before the onset of pain?’ to which there are 6 possible responses – ‘0 yards’, ‘up to 100 yards’, ‘up to 250 yards’, ‘up to half a mile’, ‘up to 1 mile’, ‘more than a mile’. The question is adapted from Mondillo et al’s (2003) Claudication Self-Assessment with the distances being re-formatted from metres to yards to reflect the fact that older patients are more likely to be confident measuring distance in imperial units. This question was asked at baseline, follow-up and in the telephone calls at 6 and 12 weeks. In order to measure frequency of walking to the onset of pain, participants are asked ‘In general, how frequently do you walk that distance?’ with 6 possible responses – ‘never’, ‘once or twice a month’, ‘once a week’, ‘2-3 times a week’, ‘4-5 times a week’, and ‘everyday’.

Walking behaviour – pedometer

Previous studies of walking in patients with intermittent claudication have tended to measure maximal walking distance on the treadmill. While this measure gives an accurate idea of how far a patient *can walk* before they experience claudication pain, and before they have to stop, it does not give any idea of how much walking the patient *does* in their day to day life, and therefore lacks ecological validity. For this reason, day-to-day walking in the intervention study is measured using pedometers. The Omron-2 (HJ 113) pedometer was selected as an easy to use mid-price range

CHAPTER FOUR

pedometer with good validity – Sugden et al (2008) found a significant correlation between walking as measured by an accelerometer and steps measured by the Omron 2 pedometer ($r = 0.78$, $p = 0.01$). Batteries were checked at each pedometer fitting, each participant's stride length was measured and programmed into the pedometer, and participants were shown how to use the pedometer and asked to walk for 50 steps to check the pedometer was accurately recording their walking. Participants were visited one week apart for pedometer drop-offs and pick-ups, meaning that information was gathered for six full days at each time point. The measure is calculated by averaging the six full day readings. Participants were encouraged to seek help from the researcher if they encountered any problems or lost the pedometer.

Walking behaviour - IPAQ

A self-report measure of walking was also taken in the intervention study, as a comparison for walking as measured by pedometer. The International Physical Activity Questionnaire (IPAQ, Craig et al, 2003) is a self-report measure of physical activity with 4 items measuring time spent in vigorous and moderate activity, time spent walking, and time spent sitting. The measure is scored by calculating metabolic fitness levels (METs) based on reported activity levels. The MET level for each type of activity is multiplied by the number of minutes spent doing that activity per day and the number of days that the activity was performed, producing an overall score of MET minutes/week for each activity. The sum of these MET minutes/week is then calculated to produce an overall score of total activity. MET minute scores are equivalent to kilocalories for a 60kg person (IPAQ, 2005). The IPAQ has good test-

CHAPTER FOUR

retest reliability at 1 week ($r = 0.8$) (Craig et al, 2003) and moderate criterion validity when compared to maximal oxygen uptake ($r = 0.31$, $p < 0.01$) (Kurtze, Rangul & Hustvedt, 2008).

Design of intervention

Participants in the intervention study were randomly allocated to two groups, a control group who received usual care, and a treatment group who received usual care and a brief psychological intervention. The process of randomisation is described in Chapter 6. The techniques used in the brief psychological intervention are described below.

Description of techniques used in the brief psychological intervention

Hrisos et al (2008) recommend six steps in developing a theory based behavioural intervention, summarised in Table 4.2. These steps were followed in designing the intervention study in this thesis.

Table 4.2 Steps in developing a theory based behavioural intervention

1. Specify target behaviour(s).
2. Select theoretical framework.
3. Conduct a study with a sample drawn from the population of interest, to identify modifiable variables that predict the target behaviour(s). Based on the findings of this study, choose which variables to target. These variables are the proposed mediators of behaviour change.
4. Map targeted variables onto behaviour change techniques and select techniques that (a) are likely to change the mediator variables and (b) it is feasible to operationalise.
5. Choose appropriate method(s) of delivery of the techniques.
6. Operationalise intervention components (techniques) in appropriate combination and order.

Adapted from Hrisos et al (2008)

Specification of the target behaviours

As previously outlined in Chapter 2, this thesis focuses on walking behaviour of patients with IC. Recommended walking levels for patients with IC (Leng et al, 2000) can be split into two distinct behaviours which are the target behaviours for the intervention (i) walking to near maximal pain before stopping to rest, and (ii) walking for at least half an hour three times a week.

Select theoretical framework.

As previously outlined in Chapter 2, the theoretical framework for the intervention is Leventhal et al's (1998) Common-sense model of self-regulation of health and illness (CSM). This choice of theoretical framework was guided by findings from qualitative studies into the experiences and behaviour of patients with IC (e.g. Gibson & Kenrick, 1998; Wann-Hansson et al, 2005; Crosby et al, 1993; Leavitt, 1990; Treat-Jacobsen et

CHAPTER FOUR

al, 2002), and by findings from a previous qualitative study (Chapter 3) which explored the illness representations and walking behaviour of patients with IC. The CSM explains behaviour in terms of modifiable cognitions about the illness and about potential treatments, and is self-regulatory in that it proposes that individuals constantly monitor their symptoms and the success of their coping actions (behaviour) to achieve their goals, and adjust their behaviour in light of this monitoring. Cognitions about illness have been found to be modifiable, and changes in illness representations have led to changes in behaviour (Petrie et al, 2002; Broadbent, Ellis, Thomas, Gamble & Petrie, 2009).

Conduct a study to identify modifiable variables that predict the target behaviour.

Results from the qualitative study (Chapter3) indicate that patients with IC have poor understanding about the causes of the disease, the timeline of the disease, and consequences of the disease. Participants interpreted symptoms (identity) as negative i.e. walking causes me pain; rather than positive i.e. walking when in pain will help my circulation and will ultimately improve the symptoms in my legs. In addition, participants tended to express scepticism about the benefits of walking and had low confidence in their ability to go out and walk. Participants also had a poor understanding of the timeline of walking in terms of how much to do, and the need to walk to near maximal pain. Participants did not intend to increase their walking and did not make plans to walk.

The findings from the qualitative study can be summarised as variables which have been demonstrated to be modifiable in other studies with other populations. Beliefs

CHAPTER FOUR

about causes, consequences, timeline, and identity fit within the illness representation construct of the CSM. Beliefs about the timeline of walking, consequences of walking, and personal control of walking fit within the treatment representation construct of the CSM. Forming intentions to perform the behaviour and planning to perform the behaviour fit within the coping action construct of the CSM.

Map targeted variables onto behaviour change techniques

Abraham & Michie (2008) documented recognised techniques which have been successfully used in a wide range of previous psychological interventions to achieve behaviour change. The intervention was designed by mapping the above psychological constructs related to walking identified in the qualitative study, to selected techniques. This process of mapping psychological constructs onto known behaviour change techniques means the brief psychological intervention used in this study is evidence-based.

To modify interpretation of symptoms (identity), increase patients' understanding of the disease and the link to walking behaviour, improve patients' understanding of the causes of the disease, and explain the causal mechanism by which walking improves symptoms, technique one of Abraham & Michie's (2008) taxonomy of behaviour change techniques was used – *'provide information about the behaviour-health link'*.

To increase patients' understanding of the consequences of PAD, their perception of future health risk, and the chronicity of disease (timeline), technique two of the

CHAPTER FOUR

taxonomy of behaviour change techniques (Abraham & Michie, 2008) was used – *‘provide information on consequences’*.

Technique twenty-five, *‘motivational interviewing’* (Abraham & Michie, 2008), was used to operationalise the above techniques, using motivational interviewing techniques to evoke change talk. Participants were asked open questions about their illness beliefs and then given information about the disease and the disease/behaviour link. Participants were prompted to evaluate their own walking behaviour, and to consider their motivation to increase their walking. The intention was to move participants to a point where they had expressed motivation/intention to change the target behaviour (walking).

Reframing treatment representations, including the identity of the treatment (walking), the interpretation of pain, and the timeline of the treatment (beliefs about the duration and intensity of walking behaviour required; patients’ expectations about the time until they will see a difference in symptoms), and modifying action plans to include a plan to increase walking, mapped onto technique ten (Abraham & Michie, 2008) – *‘prompting specific goal setting by defining the behaviour, and specifying when, where, how long for and with whom’*.

Patients with IC have reported many barriers to increasing walking (Stewart & Lamont, 2007; Galea et al, 2008). Identification of possible barriers to an activity, and forming plans to deal with anticipated barriers is known as coping planning. Sniehotta, Scholz & Schwarzer (2006) tested the efficacy of action planning to increase physical activity

CHAPTER FOUR

against combined action and coping planning, with a group of cardiac patients. They found that a combination of action and coping planning led to significantly greater physical activity levels at 2 months than action planning alone. Coping planning works by encouraging the participant to anticipate possible barriers to an activity and pre-plan coping responses to these barriers. This helps the participant to overcome situations where they are more likely to fail at self-regulation. Coping planning mapped onto technique five (Abraham & Michie, 2008) – *'prompting barrier identification and planning ways of overcoming them'*.

Action planning and coping planning were operationalised by creating a personalised action and coping plan with the participant, which was typed up, laminated and posted to them. The action plan was adapted from the Improving Health: Changing Behaviour – NHS Health Trainer Handbook (Michie et al, 2008).

A key part of the CSM is the dynamic process by which individuals assess their coping response against goal achievement. This assessment of goal achievement is proposed to take the form of an ongoing process matching experience to illness and treatment representations, which Leventhal terms the prototype check (Leventhal et al, 2010). Ongoing discussion about the maintenance of behaviour change and whether behaviour change was resulting in goal achievement mapped onto technique eleven (Abraham & Michie, 2008) – *'prompting review of behavioural goals'*.

CHAPTER FOUR

Choose appropriate method(s) of delivery of the techniques /Operationalise techniques in appropriate combination and order.

Patients with IC tend to be elderly and experience leg pain when walking. In order to make the intervention as acceptable as possible, it was decided to deliver the intervention in participants' homes at a time which suited them. The techniques used in the intervention and the order they were operationalised are summarised in Table 4.3.

Table 4.3 Techniques used in the intervention

Technique	Operation
Provide information about the behaviour-health link Provide information on consequences Motivational interviewing	Session One
Prompting specific goal setting by defining the behaviour, and specifying when, where, how long for and with whom Prompting barrier identification and planning ways of overcoming them	Session Two
Prompting review of behavioural goals	Telephone calls

The intervention was delivered over two, one-hour sessions, one week apart. The first session covered technique one – providing information about the behaviour-health link; technique two – providing information on consequences; and was operationalised using technique twenty-five – motivational interviewing. The pro-forma which was used to guide Session 1 can be found in Appendix 3. The information sheet used to provide participants with more information about PAD can be found in Appendix 4.

CHAPTER FOUR

The second session covered technique ten – prompting specific goal setting and technique five – prompting barrier identification. A copy of the action plan proforma can be found in Appendix 5.

Two telephone calls were conducted with each participant at 6 and 12 weeks after recruitment into the study. The purpose of the calls was to prompt review of behavioural goals (technique eleven), and give the participant a chance to discuss their progress with behaviour change, and make changes to their action or coping plans if necessary. Copies of the proforma used to guide the telephone calls can be found in Appendix 6.

CHAPTER FIVE

APPLYING LEVENTHAL'S COMMON-SENSE MODEL TO PATIENTS WITH INTERMITTENT CLAUDICATION – A CROSS-SECTIONAL STUDY

Abstract

Background:

The qualitative study presented in Chapter 3 indicated that many patients with PAD, who had received surgery or angioplasty for IC, still experienced a high level of leg pain symptoms, and controlled symptoms by avoiding walking and/or walking at a slow pace. The data suggested that participants had a poor understanding of the causes of PAD, the benefits of walking, and had low walking confidence. This study used measures based on the CSM to examine the walking activity and illness and walking representations of a cohort of patients with IC, to quantitatively test the relationships identified in the qualitative study.

Method:

This was a cross-sectional, correlational study. A cohort of patients diagnosed with IC (n=262) were sent a postal questionnaire, and 91 (34.7%) completed questionnaires were returned and analysed. The CSM was operationalised as described in Chapter 4; measures included walking activity, quality of life, symptom representations and walking representations. Outcome measures were adherence to minimum recommended walking levels and health-related quality of life.

Results:

Illness and walking representations predicted adherence to recommended walking levels with 93.4% accuracy (binomial logistic regression) in participants with IC. Illness and walking representations explained 69.7% of the variance in health-related quality of life of participants with IC.

CHAPTER FIVE

Conclusion:

Findings support the CSM for predicting walking behaviour and quality of life in patients with IC. The results from this study suggest that an intervention to modify illness and walking representations may improve walking and health-related quality of life in patients with IC.

Introduction

The qualitative study (Chapter 3) presented in this thesis examined the illness and treatment representations, and walking behaviour of patients with IC, and found that post-revascularisation, many patients with IC had dysfunctional illness and treatment representations and tended to avoid walking. The next logical step from the qualitative study is to examine the illness and walking representations and walking behaviour of a cohort of patients with IC, to test whether the findings from the smaller-scale qualitative study are valid for a larger sample of participants, before developing a psychological intervention to improve walking in patients with IC.

Only two studies have previously been conducted which measure psychological variables in relation to physical activity in patients with PAD. Rejeski, Tian, Liao & McDermott (2008) developed a questionnaire including measures of depression, walking ability, self-efficacy of overcoming barriers to walking, desire for physical competence, satisfaction with physical function, acceptance of leg pain and perceived control related to walking. Participants also completed a six minute walk test, measuring how far they could walk in 6 minutes. Splitting participants into three groups based on six minute walking test performance, Rejeski et al (2008) found that participants with the poorest walking ability also had significantly poorer acceptance of pain, significantly less willingness to walk into the pain, significantly lower self-efficacy to overcome barriers to walking, significantly lower desire for physical competence, significantly lower satisfaction with physical function, and significantly poorer perceived control over future walking ability. This study indicates that beliefs about walking may play a part in walking behaviour. However, the study did not

CHAPTER FIVE

measure walking *behaviour*, only walking *ability*, was not based on a specific theory of behaviour change, and included a heterogeneous sample of patients with PAD, of whom only 26% had IC.

Galea & Bray (2006) used the Theory of Planned Behaviour to predict walking activity in patients with IC. They found that while subjective norms, attitude and perceived behavioural control accounted for 67% of the variance in intention to walk; intention to walk and perceived behavioural control only accounted for 8% of the variance in walking activity. Galea & Bray (2006) suggested that the intention-behaviour gap in their study may be due either to floor effects with their measure of walking activity, or due to other factors like pain perception, and ability to cope with the pain, which may influence walking behaviour. Examining illness cognitions alongside behavioural cognitions may provide a better model for understanding walking behaviour in patients with IC.

A study which is theory-based and which measures actual walking behaviour rather than ability to walk is required to examine the relationship between psychological variables and walking behaviour in patients with IC. To this end, a questionnaire was developed based on Leventhal et al's (1998) CSM to investigate the illness and walking representations and walking behaviour of patients with IC. The questionnaire design is described in detail in Chapter 4.

As the previous qualitative study included a sample of participants who had received revascularisation, it was not representative of all patients with IC. Therefore a study to

CHAPTER FIVE

test the generalisability of the findings from the qualitative study for IC patients in general should also include patients who have been treated conservatively (i.e. without surgical or endovascular intervention).

The main objective of this study is therefore to explore the illness and walking representations and walking behaviour of a cohort of patients diagnosed with IC.

Health-related quality of life is considered an important outcome measure in the management of patients with IC because treatment aims to improve symptoms rather than treating the underlying disease. Therefore, a key aim of treatment for IC is to improve quality of life. A secondary objective of this study is to explore how the illness and walking representations of patients with IC relate to health-related quality of life.

Research Questions

The research questions are:

1. What is the walking behaviour of patients with IC?
2. What are the symptom and walking representations of patients with IC?
3. How do the symptom and walking representations of patients with IC relate to walking behaviour and quality of life?

Method

Design

This was a cross-sectional postal questionnaire study designed to analyse the relationship of illness and treatment representations with walking behaviour and quality of life in a cohort of patients with IC.

Recruitment

All patients who had attended vascular services in NHS Forth Valley and who met the study inclusion criteria were identified and sent a pack containing a covering letter from their vascular surgeon inviting them to participate, a participant information sheet, a consent form, the questionnaire, and a pre-paid envelope addressed to the researcher. Inclusion criteria included a diagnosis of IC between 9 months and 3 years prior to recruitment. This time frame was chosen to maximise the chances that patients would have received any surgery that would be organised as a result of diagnosis, and to ensure a reasonable sample size in the study. A sample size calculation carried out using Gpower3 (Faul, Erdfelder, Lang & Buchner, 2007), indicated that to carry out a regression to detect a medium effect size (0.15), with an alpha of 0.05, a power of 80% and 11 predictor variables, would require a sample of 123 participants. Assuming a 45% response rate (Iglesias et al, 2000) this would require 273 questionnaires to be sent out. Exclusion criteria included any amputations since diagnosis with IC. The full list of patients diagnosed with IC between 9 months and 3 years prior to recruitment was screened by the researcher using hospital

CHAPTER FIVE

databases for evidence of confirmation of diagnosis, death or amputation. Of the original 327 names on the list, 26 patients had died, 26 had been wrongly diagnosed as claudicants (no blockage identified by arteriogram), 2 patients had had a lower limb amputation, and 1 patient had a diabetic foot (several toes amputated). Therefore 272 questionnaires were sent out. A reminder letter was sent out 2 months later asking patients to complete the questionnaire and encouraging them to call the researcher if they required assistance or a new pack.

Participants

Of the 272 questionnaire packs sent out to patients, a further 2 patients were dead, 5 people called to say that the patients no longer lived at the address the pack was sent to, and 3 participants got in touch to say they had been mis-diagnosed and had never had IC. Therefore 262 applicable questionnaires were sent out to patients with IC and 92 questionnaires were returned to the researcher. Where data was missing from questionnaires, the researcher tried to call the participant and complete the questionnaire by telephone. However, this was not possible in 1 case where only a handful of questions had been completed and the participant was not available by phone – this questionnaire was therefore excluded from analysis, giving a questionnaire response rate of 34.7%. One blind participant called the researcher and asked for a home visit to help complete the questionnaire.

CHAPTER FIVE

Ethical approval

Fife and Forth Valley Research Ethics Service approved this study. The letter of invitation, participant information sheet and consent form are included in Appendix 7.

Measures

The design of the questionnaire used in this study is described in detail in Chapter 4. The questionnaire included measures of IC symptom representations, walking personal control, positive and negative walking consequences, disease-specific quality of life, intention to walk, and intention to walk through the pain, dietary behaviour and walking behaviour. Ankle Brachial Pressure Index (ABPI) at most recent outpatient clinic and treatment received since diagnosis were taken from participants' medical records.

Analysis

Some of the participants in the sample had received successful angioplasty or surgery for their PAD and no longer reported any symptoms of IC; also, 3 participants who had received conservative treatment no longer experienced any symptoms of IC.

Therefore, the data was split for analysis of psychological factors related to walking and quality of life, to consider two groups, those with IC and those who no longer had IC. The internal consistency of multi-item measures was assessed using Cronbach's alpha, using an acceptability criterion of $\alpha \geq 0.7$. The distribution of each measure was checked for significant skewness and kurtosis by group, and was found to have a

CHAPTER FIVE

normal distribution. The groups were analysed descriptively. Chi-square tests were used to test differences in categorical variables. Bivariate correlations were used to explore associations between variables within each group. An exploratory principal components analysis was conducted to identify a factor structure in the data, to provide an understanding of the underlying structure of symptom and treatment representations and their relationship with walking behaviour and quality of life (research questions 1 & 2). Binomial logistic regressions and multiple regressions were carried out with walking behaviour and quality of life as the dependent variables, and illness and walking representations as the independent variables to clarify the predictive value of the CSM in the outcomes of patients with IC.

Results

Internal consistency of the multi-item measures was satisfactory: Cronbach's alpha: Walking Personal Control (9 items) = 0.97; Intention to walk (3 items) = 0.83; Intention to walk through pain (3 items) = 0.90; Positive Walking Consequences (8 items) = 0.82; Negative Walking Consequences (5 items) = 0.70; Health-related Quality of Life (16 items) = 0.79.

Study population

Ninety-one patients returned completed questionnaires and consented to take part in the study. Mean time between diagnosis and return of questionnaire was 25.5 months (sd=12.3). Table 5.1 presents the characteristics of the sample split into two groups, reflecting the presence or absence of IC pain. There was a significant difference between the two groups in the number of people who had diabetes, $\chi^2(1)=3.894$, $p=.048$, with more participants with diabetes in the pain than no pain group; and a significant difference between the groups in the number of current smokers $\chi^2(2)=8.424$, $p=.015$, with a greater proportion of current smokers in the pain than no pain group. There was also a significant difference in dietary behaviour between the two groups, with participants in the group with no claudication pain having better dietary behaviour than participants in the group with claudication pain, $t(87)=3.483$, $p=.001$. ABPI in the no pain group was significantly higher (i.e. better) than ABPI in the group who still had claudication pain, $U=457.0$, $p=.032$, $r=.23$.

CHAPTER FIVE

Table 5.1 Characteristics of the sample by group

	IC (n = 71)	No IC symptoms (n = 20)
<i>Demographics</i>		
Age, mean (SD)	69.48 (10.6)	70.25 (8.2)
Male, no. (%)	46 (64.8)	12 (60)
Living alone, no. (%)	20 (28.2)	4 (20)
Retired, no. (%)	55 (77.5)	15 (75)
ABPI, mean (SD)	.92 (.30)	1.05 (.20)
<i>Risk Factors</i>		
Diabetes, no. (%)	12 (16.9)	0 (0)
Smoker, no. (%)		
Yes	30 (42.3)	4 (20)
Never	10 (14.1)	0 (0)
Given Up	31 (43.6)	16 (80)
Dietary behaviour, mean (SD)	4.66 (1.23)	5.73 (1.02)
<i>Co morbidities</i>		
Heart Disease, no. (%)	32 (45)	10 (50)
Stroke, no. (%)	10 (14.1)	2 (10)
<i>Treatment</i>		
Conservative, no. (%)	18 (25.4)	3 (15)
Angioplasty, no. (%)	16 (22.5)	10 (50)
Bypass surgery, no. (%)	37 (52.1)	7 (35)

Walking behaviour

Overall, 54 (61.4%) respondents did not recall receiving medical advice on how far or how long to walk because of IC.

Fifty-nine (67.8%) respondents had attempted to increase the amount they walked since diagnosis with IC, and of these 36 (61%) reported maintaining this increased walking behaviour. Therefore 41.4% of overall respondents claimed to have both increased walking behaviour and maintained this increase since diagnosis with IC.

CHAPTER FIVE

Significantly more participants who had attempted and maintained increased walking levels were walking at least the minimum recommended amount for patients with IC (at least half an hour three times a week) than participants who had never attempted to increase their walking, or had not maintained increased walking levels, $\chi^2(2)=15.309$, $p<.001$. Table 5.2 shows a breakdown of current walking behaviour by attempt to increase walking. Four participants in the group who no longer experience claudication pain did not give information about whether or not they had attempted to increase walking behaviour since diagnosis, all four of these participants did meet minimum recommended walking levels.

Participants who increased walking but did not maintain this increase, gave a variety of reasons why they could not maintain an increase in walking behaviour, including pain ($n=20$, 86.96%), lack of motivation ($n=8$, 34.78%), poor weather ($n=4$, 17.39%), having stopped hobbies which required walking ($n=4$, 17.39%), using the car ($n=3$, 13.04%), co-morbidities ($n=2$, 8.70%) and poor balance ($n=2$, 8.70%).

Table 5.2 Current walking behaviour by attempt to increase walking (n=87)

	Do not meet minimum walking recommendations	At least meet minimum walking recommendations
Never attempted to increase walking	20	8
Attempted to increase walking but did not maintain	20	3
Maintained increased walking	14	22

Overall, 37 (40.7%) participants reported currently meeting the minimum recommended walking levels for patients with IC. Significantly more participants who no longer experienced claudication pain met minimum recommended walking levels

CHAPTER FIVE

than participants who still experienced claudication pain, $\chi^2(1)=9.146$, $p=.002$. In the group of participants who no longer experienced claudication pain, 6 (30%) participants did not meet recommended walking levels, and 14 (70%) did meet minimum recommended walking levels. In the group of participants who still experienced claudication pain, 48 (67.6%) did not meet recommended walking levels, and 23 (32.4%) did meet minimum recommended walking levels.

Of those participants who still experienced claudication pain, 10 (14.1%) participants reported stopping for a rest as soon as they felt any pain in their leg, 20 (28.2%) participants reported continuing for a few steps before stopping for a rest, and 41 (57.7%) participants reported continuing until the pain was almost unbearable before stopping for a rest.

Pain free walking distance

Pain free walking distance for the group who still experienced claudication pain is shown in Figure 5.1. Participants in the group with claudication pain, who met the minimum recommended walking levels had significantly longer pain free walking distance than those who did not meet minimum recommended walking levels, $\chi^2(5)=13.148$, $p=.022$. Pain free walking distance by recommended walking behaviour is shown in Figure 5.1.

CHAPTER FIVE

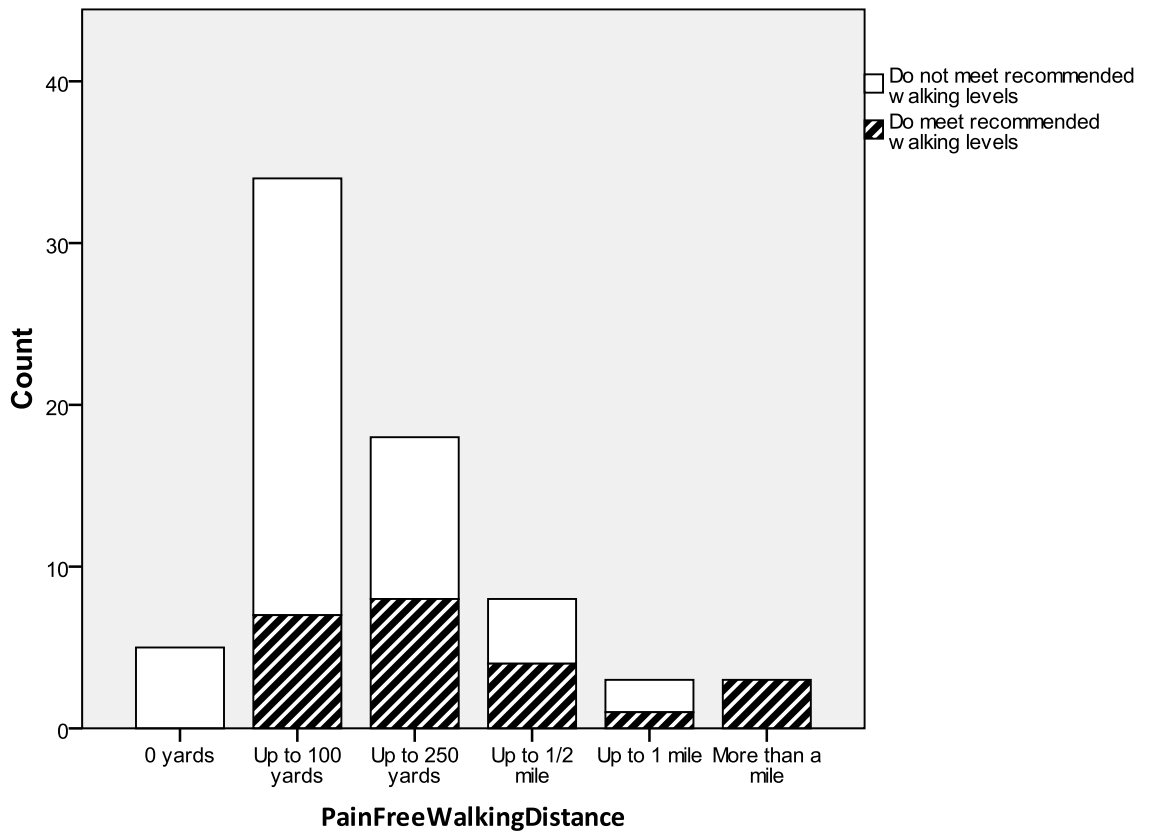


Figure 5.1 Pain free walking distance by adherence to recommended walking levels in group with claudication

Care

Overall, 33 (36.3%) participants reported receiving some level of help or support in the home from family, friends or other organisations because of problems with their health. Significantly more participants with claudication pain required help or support ($n=30/71$, 42.25%) than participants with no claudication pain ($n=3/20$, 15.0%), $\chi^2(1)=5.015$, $p=.025$. In the group of participants who reported having claudication pain, there was a marginally non-significant trend towards more participants who did not meet minimum recommended walking levels requiring care ($n=24/48$, 50.0%) than

CHAPTER FIVE

participants who did meet the recommended walking levels requiring care (n=6/23, 26.09%), $\chi^2(1)=3.644$, p=.056.

Causal beliefs

Table 5.3 lists factors which participants believed may have caused their illness. 12 (35.29%) of the 34 current smokers in the sample did not list smoking as a cause of PAD. 12 (75.0%) of the participants who believed exercise and strenuous work caused PAD did not meet the recommended walking levels for patients with IC.

Table 5.3 Participants' (n=91) beliefs about the causes of PAD

Cause	n (%)
Smoking	49 (53.85%)
Diet	28 (30.77%)
Exercise and strenuous work	16 (17.58%)
Hereditary	15 (16.48%)
Lack of exercise	13 (14.29%)
Don't know	8 (8.79%)
High blood pressure	6 (6.59%)
Old age	5 (5.49%)
Stress	4 (4.40%)
Varicose veins	4 (4.40%)
Medication	2 (2.20%)
Dust inhalation	2 (2.20%)
Diabetes	2 (2.20%)
Bad chairs	2 (2.20%)

Pearson correlations between variables for participants with no pain

Table 5.4 illustrates the correlations between variables in the group who reported having no claudication pain. The sample (n=20) is too small to conduct a Principal

CHAPTER FIVE

Components Analysis. The variables BIPQ Identity (level of symptoms) and intention to walk to maximal pain were removed from the correlation analysis as they were not relevant for participants who no longer experience leg pain when walking.

A belief in more serious consequences of IC was significantly positively correlated with beliefs that PAD would last for a longer time, a greater emotional effect of IC and disease specific quality of life, where higher scores of disease-specific quality of life indicate poorer quality of life; and significantly negatively correlated with illness comprehensibility.

A belief that PAD would last for a long time was significantly positively correlated with poorer disease specific quality of life.

Personal control over the illness was significantly positively correlated with walking behaviour.

Beliefs that treatment can help the illness were significantly positively correlated with intention to walk for at least half an hour at least three times a week.

Greater concern about the illness was significantly negatively correlated with illness comprehensibility.

Illness comprehensibility was significantly negatively correlated with the emotional effect of IC and poorer health related quality of life.

CHAPTER FIVE

The emotional effect of IC was significantly positively correlated with poorer health related quality of life.

Beliefs in the positive consequences of walking were significantly positively correlated with walking personal control, and intention to walk for at least half an hour at least three times a week.

Beliefs in the negative consequences of walking were significantly negatively correlated with walking personal control.

Walking personal control was significantly positively correlated with intention to walk for at least half an hour three times a week and with self-report walking behaviour.

Intention to walk for at least half an hour three times a week was significantly positively correlated with walking behaviour.

These correlations suggest that negative symptom representations related to poorer quality of life, and positive walking representations were related to increased walking behaviour.

CHAPTER FIVE

Table 5.4 Correlations, means and standard deviations of all variables in the no claudication pain group

	1	2	3	4	5	6	7	8	9	10	11	12	13
1.BIPQ Consequence	-												
2.BIPQ Timeline	.61**	-											
3.BIPQ Personal Control	-.04	.12	-										
4.BIPQ Treatment Control	.14	.12	.34	-									
5.BIPQ Concern	.398	.40	.07	.21	-								
6.BIPQ Illness	-.63**	-.29	.30	.05	-.53*	-							
Comprehensibility													
7.BIPQ Emotions	.56*	.36	-.39	.14	.40	-.66**	-						
8.Positive Walking	.19	.31	.15	.09	.37	-.07	.08	-					
Consequences													
9.Negative Walking	.41	.15	-.09	.10	.12	-.09	.22	-.43	-				
Consequences													
10.Walking Personal Control	-.02	-.05	.24	.04	-.08	.03	-.24	.53*	-.64**	-			
11.Intention to walk	-.06	-.09	.43	.60**	.08	.12	.12	.59*	-.31	.49*	-		
12.Walking for ½ hour	.14	-.09	.59**	.47*	.04	-.05	.07	.08	-.15	.49*	.56*	-	
13.HRQoL	.71**	.76**	-.05	.14	.39	-.64**	.56*	.12	.16	.05	-.03	.09	-
Mean Score	1.05	1.05	7.40	9.15	2.05	8.95	1.25	3.42	1.13	8.39	8.53	3.75	3.15
SD	1.67	3.07	4.01	2.43	3.09	1.79	2.36	.50	.24	2.54	2.49	1.45	6.89

* Correlation is significant at the .05 level, ** Correlation is significant at the .01 level

CHAPTER FIVE

Pearson correlations between variables for participants with pain

Table 5.5 illustrates the correlations between variables in the group who reported having claudication pain (n=71).

Consequences of IC was significantly positively correlated with beliefs that the illness would last for a longer time, illness identity, concern about IC, the emotional effect of IC, and poorer disease specific quality of life; and significantly negatively correlated with personal control over the illness and walking personal control.

A belief that IC would last for a long time was significantly positively correlated with illness identity, concern about IC, the emotional effect of IC, beliefs about the negative consequences of walking and poorer health related quality of life; and significantly negatively correlated with treatment control.

Personal control over IC was not significantly correlated with any other variable.

Treatment control (belief that treatment can help IC) was significantly positively correlated with illness comprehensibility, intention to walk to maximal pain before stopping for a rest, walking behaviour; and significantly negatively correlated with poorer health related quality of life.

CHAPTER FIVE

Illness identity was significantly positively correlated with concern about IC, the emotional effect of IC, and poorer health related quality of life; and significantly negatively correlated with walking personal control.

Concern about IC was significantly positively correlated with the emotional effect of IC and poorer health related quality of life. Illness comprehensibility was significantly negatively correlated with beliefs about the negative consequences of walking, and poorer health related quality of life.

The emotional effect of IC was significantly positively correlated with poorer health related quality of life.

Beliefs in the positive consequences of walking were positively correlated with walking personal control, intention to walk for at least half an hour three times a week, intention to walk to maximal pain before resting, and walking behaviour; and significantly negatively correlated with poorer quality of life.

Beliefs in the negative consequences of walking were significantly positively correlated with poorer health related quality of life; and significantly negatively correlated with walking personal control, intention to walk for at least half an hour three times a week, and intention to walk to maximal pain before resting.

CHAPTER FIVE

Table 5.5 Correlations, means and standard deviations of all variables in the claudication pain group

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1.BIPQ Consequence	-														
2.BIPQ Timeline	.63**	-													
3.BIPQ Personal Control	-.27*	-.08	-												
4.BIPQ Treatment Control	-.23	-.37**	.12	-											
5.BIPQ Identity	.71**	.56**	-.02	-.14	-										
6.BIPQ Concern	.65**	.40**	-.07	-.05	.66**	-									
7.BIPQ Illness Comprehensibility	-.04	-.09	.22	.28*	.02	.04	-								
8.BIPQ Emotions	.64**	.30*	-.12	-.18	.49**	.59**	-.07	-							
9.Positive Walking Consequences	-.16	-.16	.22	.19	-.23	-.22	.14	-.09	-						
10.Negative Walking Consequences	.16	.28*	-.07	-.31	.14	.05	-.25*	.14	-.14	-					
11.Walking Personal Control	-.31**	-.17	.06	.22	-.24*	-.04	.07	-.24	.46**	-.43**	-				
12.Intention to walk	-.13	-.05	.11	.24	-.08	.03	.11	-.17	.50**	-.33**	.80**	-			
13.Intention to walk through pain	-.13	-.12	.07	.40**	-.11	-.04	.20	.01	.38**	-.33**	.45**	.66**	-		
14.Walking for ½ hour	-.22	-.09	.01	.28*	-.11	-.09	.03	-.19	.37**	.11	.71**	.74**	.44**	-	
15.HRQoL	.68**	.49**	-.18	-.33**	.61**	.47**	-.23*	.50**	-.37**	.43**	-.56**	-.40**	-.33**	-.36**	-
Mean Score	6.80	7.42	4.55	6.71	6.32	6.62	6.85	5.35	2.85	2.03	3.21	5.46	6.41	1.83	46.44
SD	2.48	2.98	2.92	3.09	2.78	3.17	3.14	3.25	.67	.62	2.87	2.91	3.35	1.81	21.79

* Correlation is significant at the .05 level, ** Correlation is significant at the .01 level

CHAPTER FIVE

Walking personal control was significantly positively correlated with intention to walk for at least half an hour three times a week, intention to walk to maximal pain before stopping for a rest, and walking behaviour; and significantly negatively correlated with poorer health related quality of life.

Intention to walk for at least half an hour three times a week was significantly positively correlated with intention to walk to maximal pain before resting and walking behaviour; and significantly negatively correlated with poorer health related quality of life.

Intention to walk to maximal pain before resting was significantly positively correlated with walking behaviour; and significantly negatively correlated with poorer health related quality of life.

Walking behaviour was significantly negatively correlated with poorer health related quality of life.

Principal components analysis was conducted with the 15 variables listed, to identify clusters of variables which correlated highly with each other. The Kaiser-Meyer-Olkin measure of sampling adequacy was .734, and Bartlett's test of sphericity was significant ($\chi^2(105) = 462.209, p < .001$), indicating suitability of the data for principal components analysis. The initial eigenvalues showed that the first factor explained 33.86% of the variance, the second factor 18.18% of the variance, a third factor 9.20%

CHAPTER FIVE

of the variance, and a fourth factor 7.11% of the variance. None of the other factors had an eigenvalue over 1.

The two factor structure, explaining 52.04% of the variance was examined using a varimax rotation and results are shown in Figure 5.2. This principal components analysis revealed two clusters - illness personal control, walking personal control, treatment control, intention to walk, intention to walk through the pain, beliefs about positive walking consequences, illness comprehensibility, and walking behaviour were all positively loaded onto the first cluster, and beliefs about negative walking consequences and quality of life (where lower scores indicate better quality of life) were negatively loaded onto the first cluster. Illness consequences, timeline, concern about the illness, emotional effect of the illness, illness symptoms and quality of life (where higher scores indicate worse quality of life) were all positively loaded onto the second cluster. This principal components analysis indicates that negative symptom representations are negatively related to quality of life, and positive illness and walking representations are positively related to walking and quality of life.

CHAPTER FIVE

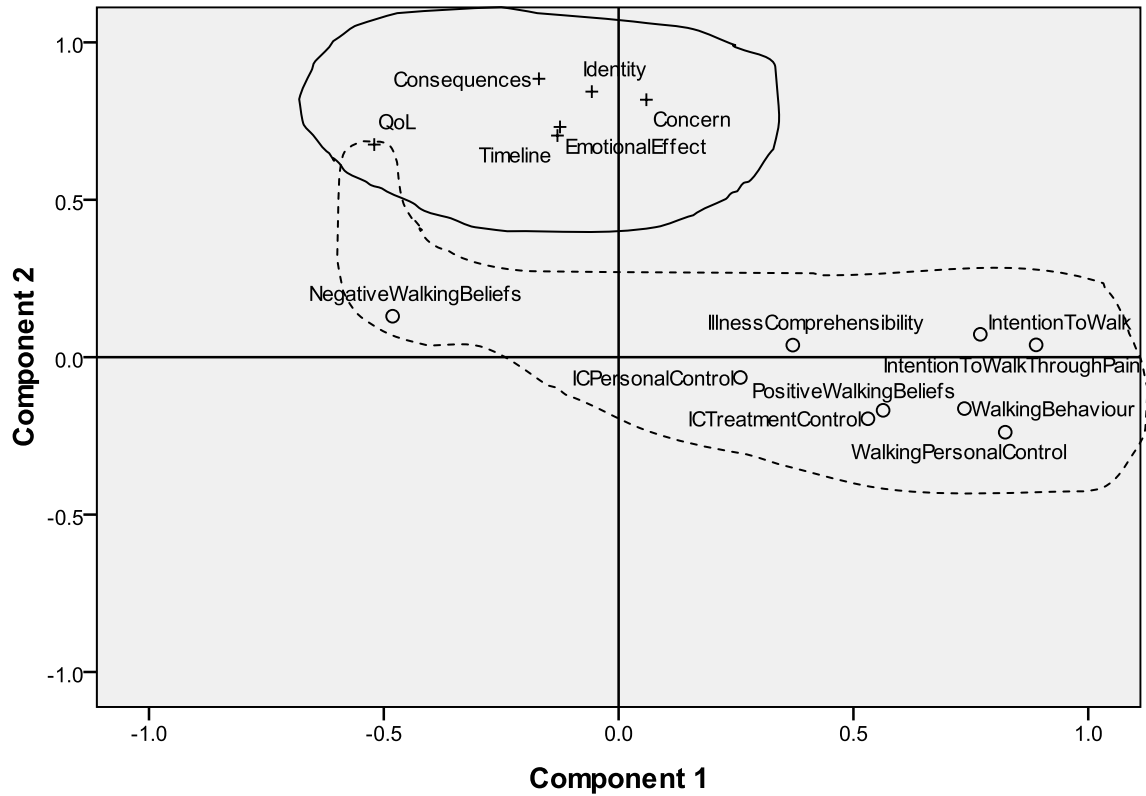


Figure 5.2 Plot of the first 2 components in rotated space

---- Cluster 1
___ Cluster 2

Regression analyses

The sample size of the group of participants who no longer had claudication pain was too small to perform regression analysis, therefore the following analyses only apply to the group (n=71) who still had claudication pain.

CHAPTER FIVE

Adherence to minimum walking recommendations

Separate binomial logistic regression analyses were conducted with adherence to minimum recommended walking levels as the dependent variable and firstly symptom representations as the independent variables; secondly walking representations as the independent variables; and thirdly the full model of illness and walking representations as the independent variables. The dependent variable was dichotomous – participants either walked the minimum recommended amount of at least half an hour three times a week (n=23), or they did not (n=48).

Results of the first logistic regression with symptom representations as the independent variables showed that prediction success of the full model was 75.4% (91.5% for non-adherence to recommended walking levels and 40.9% for adherence to recommended walking levels), whereas the prediction success of the constant only model was 68.1%. This improvement in prediction of the full model against the constant only model was not significant, $\chi^2(8) = 14.37$, $p=.073$.

Results of the second logistic regression with walking representations as the independent variables showed that the prediction success of the full model was 84.1% (90.2% for non-adherence to recommended walking levels and 72.7% for adherence to recommended walking levels), whereas the prediction success of the constant only model was 65.1%. This improvement in prediction was significant, $\chi^2(3) = 39.765$, $p<.001$. Nagelkerke's R^2 of .645 indicated a moderate relationship between prediction and grouping. The Wald criterion demonstrated that only walking personal control

CHAPTER FIVE

made a significant contribution to prediction, $B=1.106$, $SE=.314$, $Wald(1)=12.453$, $p<.001$. The other walking representations were not significant predictors.

To test whether symptom representations added to the predictive value of walking representations in predicting whether participants would meet minimum recommended walking levels, a final logistic regression was conducted entering walking representations in the first block and symptom representations in the second block. Results are shown in Table 5.6. The addition of symptom representations to the walking representations only model, was statistically significant, $\chi^2(8) = 18.657$, $p=.017$. The full model indicated that illness and walking representations as a set reliably distinguished between adherers and non-adherers to recommended walking levels, $\chi^2(11) = 57.503$, $p<.001$. Nagelkerke's R^2 of .843 indicated a strong relationship between prediction and grouping. Prediction success overall was 93.4% (95% for non-adherence to recommended walking levels, and 90.5% for adherence to recommended walking levels). The Wald criterion demonstrated that only walking personal control, made a significant contribution to prediction, $B=3.102$, $SE=1.434$, $Wald(1)=4.683$, $p=.030$. The other variables were not significant predictors. $Exp(B)$ value indicates that an increase in walking personal control by one unit makes the odds ratio 22 times as large and therefore participants are 22 times more likely to adhere to walking recommendations.

CHAPTER FIVE

Table 5.6 Logistic regression to predict adherence to recommended walking levels

	<i>B (SE)</i>	95% CI for exp(B)		
		Lower	exp(B)	Upper
Included				
Constant	-29.81 (13.81)			
Walking personal control	3.10 (1.43)	1.34	22.30	369.50
Positive Walking Beliefs	4.95 (2.93)	.00	.01	2.21
Negative Walking Beliefs	-4.50 (2.46)	.74	90.39	1103.74
Timeline	1.24 (.81)	.70	3.45	16.95
Consequences	-.001(.50)	.38	1.00	2.64
Illness Personal Control	-.45 (.38)	.30	.64	1.33
Identity	.47 (.37)	.77	1.60	3.31
Concern	-.26 (.27)	.46	.78	1.30
Illness Comprehensibility	.35 (.32)	.76	1.41	2.64
Emotional Effect	-.71 (.47)	.20	.49	1.24
Illness Treatment Control	2.06 (1.09)	.93	7.83	66.08

Health-related quality of life

A series of multiple regression analyses were conducted with health-related quality of life as the dependent variable and firstly symptom representations as the independent variables; secondly walking representations as the independent variables; and thirdly the full model of illness and walking representations as the independent variables.

Results of the first multiple regression with symptom representations as the independent variables showed that the model provided a significant fit of the data, $F(8,60)=9.698$, $p<.001$. The R for the model was .749, and the R^2 was .561 (adjusted $R^2=.503$), indicating that the model accounted for 56.1% of the variability in health-related quality of life in this sample. Consequences ($B=3.90$, $SE=1.46$, $t(8)=2.672$, $p=.010$) and Identity ($B=2.26$, $SE=1.06$, $t(8)=2.137$, $p=.037$) had significant regression coefficients in the model. No other symptom representations were significant predictors in the model.

CHAPTER FIVE

Results of the second multiple regression with walking representations as the independent variables showed that the model provided a significant fit of the data, $F(3,59)=14.267$, $p<.001$. The R for the model was .648, and the R^2 was .420 (adjusted $R^2=.391$), indicating that the model accounted for 42% of the variability in health-related quality of life in this sample. Walking personal control ($B=-3.52$, $SE=.92$, $t(3)=-3.810$, $p<.001$) had a significant regression coefficient; neither positive nor negative walking beliefs were significant predictors in the model.

To test whether walking representations explained variation in health-related quality of life beyond that explained by symptom representations, a final multiple regression was conducted with symptom representations entered in the first block and walking representations entered in the second block. Results are shown in Table 5.7. The addition of treatment representations significantly improved the fit of the model, compared to symptom representations alone ($R^2=.56$), $F(3,49)=7.358$, $p<.001$. The full model provided a significant fit of the data, $F(11,49)=10.225$, $p<.001$. The R for the model was .835, and the R^2 was .697 (adjusted $R^2=.628$) indicating that the model accounted for 69.7% of the variability in health-related quality of life in this sample. Only Illness Consequences and Walking Personal Control had significant regression coefficients in the model.

CHAPTER FIVE

Table 5.7 Multiple regression of illness and walking representations on health-related quality of life in participants who have claudication pain

	B	SE B	β
Constant	22.12	13.81	
Consequences	3.71	1.45	.41*
Timeline	-.21	.93	-.03
Illness Personal Control	.34	.73	.04
Treatment Personal Control	-.45	.70	-.06
Identity	1.26	1.04	.15
Concern	.09	.91	.01
Illness Comprehensibility	-.72	.59	-.11
Emotional Effect	.37	.79	.05
Positive Walking	-.37	3.15	-.11
Consequences			
Negative Walking	6.64	3.44	.18
Consequences			
Walking Personal Control	-1.94	.84	-.26*

*p<.05

Discussion

The aim of this study was to investigate the walking behaviour and illness and walking representations of a cohort of patients diagnosed with IC.

Seventy-one participants in the study (78.0%) continued to experience leg symptoms at the time of the postal questionnaire. This reflects the findings of the qualitative study, that despite treatment, including revascularisation, many participants continue to experience leg pain and other symptoms in the leg.

There was a marked difference in walking behaviour between those participants who still experienced leg pain, and those who no longer experienced leg pain – with a significantly greater proportion of those who no longer experienced leg pain meeting the minimum recommended walking levels for patients with PAD of half an hour, three times a week. Only 32.4% of participants who still experienced leg pain reported meeting the minimum walking levels, compared to 70% of participants who no longer experienced leg pain. As this is a cross-sectional study, it is impossible to determine the direction of causality – whether the walking led to the improvement in leg symptoms or whether the improvement in leg symptoms led to more walking.

The majority of participants (61.4%) did not recall receiving advice from medical professionals about walking, despite all patients being given advice about walking by the Vascular Assessment Nurse at the time of diagnosis. Possibly patients are overwhelmed with information at diagnosis, which causes them to forget key

CHAPTER FIVE

information about the benefits of walking. However, 59 participants (67.8%) reported attempting to increase their walking levels after diagnosis with IC, which suggests that participants become aware that walking may be beneficial for them. Ultimately, only 41.4% of all participants in the study both attempted to increase walking levels after diagnosis with IC, and maintained that increase. Reasons given for not maintaining increased walking levels included physical barriers such as pain and co-morbidities; environmental barriers such as the weather; and personal barriers such as lack of motivation, and having given up hobbies which required walking. This reflects Galea et al's (2008) findings that patients with IC have personal, environmental and activity-related barriers to walking.

Participants in the group who still experienced leg pain, who met the recommended walking levels, had significantly greater pain-free walking distance than participants who did not adhere to recommended walking levels. This result is to be expected as it has been well-documented that increased walking in patients with IC leads to improvement in pain-free walking distance (e.g. Leng et al, 2000). However, causality and direction of effect cannot be determined from this study.

An interesting finding was the number of participants (36.3%) who reported needing some form of care or support because of problems with their health. Significantly more participants in the group with leg pain required care than the group with no leg pain, which suggests that the need for care may be at least partly related to decreased general mobility as a result of IC. This mirrors the finding in the qualitative study that many participants with IC feel dependent on their families for help with transport,

CHAPTER FIVE

shopping and housework. However, this need for care and support has not been reflected in the literature about PAD and IC to date. It would therefore seem that further work would be beneficial in this area.

Participants reported a range of factors as causes of their PAD. Of particular interest is the low number of participants with diabetes who recognised their diabetes as a risk factor for development of PAD, out of the 12 participants who had diabetes, only 2 cited diabetes as a cause of PAD. Similarly, 12 of the 34 current smokers did not list smoking as a cause of PAD. Also of interest is that more participants believed that exercise or strenuous physical work had caused PAD (n=16) than the number of people who recognised lack of exercise as a cause of PAD (n=13). Although many participants listed genuine risk factors of PAD like smoking, diet, family history, old age, high blood pressure and lack of exercise, several participants also listed causal beliefs which have nothing to do with the development of PAD, for example exercise and strenuous work, medication, stress, varicose veins, bad chairs and dust inhalation. Also, 8 participants reported that they had no idea what might have caused their PAD. These causal attributions mirror the findings from the qualitative study, that while patients with PAD have some idea of causes of their disease, several are unaware of behavioural risk factors which are relevant to them and which cause PAD. Some participants in both studies believed walking and exercise caused their PAD. This dysfunctional causal attribution may lead participants to avoid walking. This conclusion is supported by the fact that 75% of participants who believed walking caused PAD did not meet the minimum recommended walking levels.

CHAPTER FIVE

Principal components analysis of psychological data from the group who still experienced pain revealed two key factors which accounted for over 50% of the variance in the data – one factor related to negative illness beliefs and was strongly associated with worse quality of life; the other factor related to positive illness and walking beliefs and was strongly positively associated with walking behaviour and less strongly positively associated with quality of life.

Regression analysis revealed that walking representations were the most significant predictors of adherence to recommended walking levels, although the addition of symptom representations to the model further significantly improved the accuracy of prediction of adherence to recommended walking levels. Although the model as a whole accurately predicted walking behaviour 93.4% of the time, the only significant predictor within the model was walking personal control. Galea & Bray (2006) found that perceived behavioural control, a similar construct to walking personal control, was the only significant predictor of walking behaviour when applying the Theory of Planned Behaviour to walking activity in participants with IC. Given that patients with IC experience a range of barriers to walking, including pain, loss of power in the legs and concerns about potentially harming themselves by walking, it makes sense that confidence in walking, walking personal control, would play an important part in walking behaviour.

Symptom representations as a set accounted for the greatest percentage of variability in health-related quality of life scores (56%), however the addition of walking representations to the model accounted for a further 13.7% of the variance in health-

CHAPTER FIVE

related quality of life. Overall, the psychological variables accounted for 69.7% variance in quality of life, however only consequences and walking personal control were significant predictors within the model.

Limitations

There are a number of limitations to this study. The study had a low response rate of 34.7%. There are a number of possible reasons for this including the fact that this cohort of patients are elderly and have poor health, a large proportion of the cohort have walking pain and therefore may find posting mail difficult, and the cohort had been diagnosed up to 3 years before and therefore addresses may not have been current for all patients, it is therefore unknown how many people received the questionnaire.

The majority of participants in the study (76.9%) had either received angioplasty (n=26) or surgery (n=44); 21 participants in the sample had received conservative treatment. The rate of angioplasty/surgery in NHS Forth Valley is around 56%, therefore disproportionately more participants who had received angioplasty or surgery returned the questionnaire than participants who were treated conservatively. This may be because patients who are treated conservatively are discharged from the vascular service at 3 month follow-up, therefore a considerable amount of time would have passed between discharge and the questionnaire being sent out to this group – this may have affected response rate.

CHAPTER FIVE

Although the questionnaire asked a number of questions about walking behaviour, it would have benefited from a validated physical activity questionnaire to get a clearer idea of the amount and intensity of walking which participants undertake.

Because participants had been diagnosed between 9 months and 3 years previously and had then been followed up for varying lengths of time by the vascular service depending on treatment, there was no consistent, recent measure of ABPI for this sample. A clinical measure of PAD severity would have been useful to control for disease severity in the prediction of walking behaviour and quality of life.

Because some participants in the study reported no longer having any claudication pain, the overall sample was split into two groups – those with claudication pain, and those without. This, combined with a low response rate, meant that the sample sizes for statistical analysis were small - resulting in low power, and increasing the risk of a Type II error. While the regression analysis found that symptom and walking representations as a set reliably distinguished between adherers and non-adherers to recommended walking levels, only walking personal control made a significant contribution to prediction. It is possible that with a greater sample size, and therefore more power, other symptom and treatment representations may also have been found to provide a significant contribution to prediction in this analysis. Finally, this study is cross-sectional, and as such no conclusions can be drawn about causality or direction of effect.

Summary and implications

This study found that the majority of participants still experience leg pain years after diagnosis of PAD and treatment of IC, and that the majority of participants who still experience leg pain do not meet minimum recommended walking levels. This confirms the findings of the qualitative study about the experience and behaviour of PAD patients after treatment for IC. Psychological variables from the CSM do appear to be related to both walking behaviour and health-related quality of life in patients with IC, and are strong predictors of walking behaviour and health-related quality of life.

Walking personal control has emerged as a particularly important variable in relation to both walking behaviour and health-related quality of life in this study.

The findings from this study suggest that while surgery and angioplasty are performed for symptom management, many patients still experience leg pain after revascularisation, and do not appear to change their walking behaviour to recommended levels as a result of revascularisation. The success of psychological variables in predicting walking behaviour in this study indicates that a psychological intervention to modify these psychological variables may increase walking behaviour in patients with IC.

**MODIFYING ILLNESS AND TREATMENT REPRESENTATIONS TO
INCREASE WALKING
IN PATIENTS WITH INTERMITTENT CLAUDICATION
– A PILOT RANDOMISED CONTROLLED TRIAL**

CHAPTER SIX

Abstract

Background: Supervised exercise has been shown to increase pain free walking distance and reduce symptoms of claudication (Leng et al, 2000). However, supervised exercise programmes are not widely available, require patient commitment to attend, and may not lead to lasting behaviour change beyond attendance at the programme. Psychological variables related to the initiation and maintenance of increased walking in claudicants include beliefs about Peripheral Arterial Disease (PAD) and beliefs about walking (Chapter 3). This pilot trial (ISRCTN28051878) studied whether a brief theory-based psychological intervention to modify beliefs about PAD and beliefs about walking would lead to increased walking.

Method: Sixty patients newly diagnosed with claudication were randomised into 2 conditions. The control condition received usual care, and the treatment condition received usual care and a brief psychological intervention to modify illness and walking beliefs and develop a walking action plan. Participants were followed up after 4 months. Daily steps were measured by pedometer.

Results: There was a significant group*time interaction on mean daily steps ($p=.001$) with participants in the intervention group significantly increasing daily steps from baseline to follow-up (Mean=1303.45, SD=1813.00), and participants in the control group significantly decreasing daily steps from baseline to follow-up (Mean=-226.53, SD=1385.13). At follow-up participants in the intervention group reported significantly greater ($p=.007$) pain free walking distance than participants in the control group. Participants in the control group were 4 times more likely ($p=.009$) to opt for surgery at the 3 month meeting with the vascular surgeon than participants in the intervention group.

CHAPTER SIX

Conclusion: This trial demonstrates that a brief psychological intervention for patients with claudication can increase daily walking, increase pain free walking distance and reduce the demand for surgery at this stage of the disease. This has important implications for the design of services to treat patients with intermittent claudication.

Introduction

This introductory section reviews relevant literature on walking in patients with IC.

As outlined in Chapter 1, walking has been found to benefit patients with IC in terms of symptom reduction (Leng et al, 2000) and may also reduce cardiovascular morbidity and mortality (Khan et al, 2005). Garg et al (2006) found that PAD patients in the lowest quartile of levels of physical activity during daily life (as measured by accelerometer at baseline) had significantly higher mortality (Hazard ratio = 3.48) at 5 year follow-up than those PAD patients in the highest quartile of physical activity levels during daily life, independent of age, sex, race, body mass index, hypertension, smoking, co morbidities, cholesterol levels, leg symptoms and ankle-brachial pressure index. In a similar study, Gardner, Montgomery & Parker (2008) classified patients with IC as either sedentary if they rated themselves as avoiding physical activity or only undertaking light physical activity occasionally; or physically active if they rated themselves as undertaking moderate physical activity regularly for a period of less than 1 hour per week, up to more than 3 hours per week. The physically active group of patients had significantly higher ambulatory function at baseline than the sedentary group, as measured by how far they could walk in metres in 6 minutes (Sedentary group M=341m (sd=86); Physically active group M=400m (sd=92)). An analysis of mortality rates after 5 years found that the risk of mortality in the physically active group was 0.51 that of the sedentary group; and 0.693 that of the sedentary group when controlling for all confounding variables. This study suggests that even low levels

CHAPTER SIX

of physical activity performed at a moderate intensity would be beneficial for patients with IC in terms of all-cause mortality.

Supervised exercise programmes have been found to be more effective than advice alone in improving leg symptoms of patients with IC (Bendermacher et al 2006).

However, in a recent survey of UK vascular surgeons (Shalhoub et al, 2009), only 24% of respondents had access to a supervised exercise programme for patients with PAD, with 72% of respondents claiming that they did not have access to a supervised exercise programme due to lack of resources. Where no supervised exercise programme was available, 63% of respondents gave verbal advice about walking to patients with PAD, and 34% offered leaflets. As well as low availability, other problems with supervised exercise programmes include the cost to patients, of transport to and from hospital several times a week to attend a supervised exercise programme in terms of time and money (Bendermacher et al, 2007); patients being too tired by the time they have arrived at hospital to comply with the training programme (Bendermacher et al, 2007); and high drop-out rates (up to 43%) from supervised exercise programmes which have been recorded in a number of studies (e.g. Cheetham et al, 2004; Kakkos, Geroulakos & Nickolaides, 2005). It is also unclear whether supervised exercise programmes lead to long-term behaviour change beyond the end of the training programme, or whether they change daily walking habits. Crowther et al (2008) found that while a 12 month supervised exercise programme which involved walking on a treadmill for at least 25 minutes three times a week, significantly increased the walking *capability* of patients with IC, the programme had no significant effect on physical activity levels as measured by pedometer.

CHAPTER SIX

It is clear from the qualitative study (Chapter 3) with patients who had already received surgical treatment or angioplasty for their IC, that some participants thought physical activity may have caused their IC, and most participants were unclear about how much walking they should be doing or the mechanism by which walking worked to improve their health. Most participants in the qualitative study had stopped walking for exercise due to claudication pain, and many expressed a lack of confidence in their walking abilities. In addition, participants were not aware of the long-term consequences of PAD, or reduced levels of physical activity, in relation to their risk of cardiovascular morbidity and mortality. This work has highlighted that many of the barriers to walking for patients with IC may be psychological, and indicates that an intervention to increase walking for patients could aim to address these maladaptive beliefs.

Results from the cross-sectional study (Chapter 5) confirm the findings from the qualitative study, and show that psychological variables based on the CSM accurately predict walking behaviour in patients with IC. These psychological constructs have been found to be modifiable in studies with patients who have had a myocardial infarction, and have led to positive changes in health behaviour among those patients (Petrie et al, 2002; Broadbent et al, 2009). The findings from the qualitative and cross-sectional studies in this thesis justify a trial to modify psychological variables based on the CSM to increase walking in patients with IC.

CHAPTER SIX

In a recent cross-sectional study of predictors of walking behaviour in patients with PAD and diabetes, Collins, Lunos & Ahluwalia (2010) measured participants' self-efficacy to manage a chronic disease, and walking ability on a treadmill walking test. There was a significant correlation between self-efficacy and walking ability ($r = 0.33$, $p = 0.0036$), and Collins et al (2010) suggested it may be beneficial to target self-efficacy in future interventions to increase walking in patients with PAD and diabetes. Bandura (1977) defined self-efficacy as an individual's confidence that they can successfully perform a given behaviour to achieve a specified outcome. Bandura (1977) proposed that an individual's level of self-efficacy determines the effort that they will invest in performing a given behaviour. In the context of the CSM, Leventhal & Mora (2008, p. 55) propose that self-efficacy is 'an indicator of the current status of an underlying causal process' rather than a mechanism which produces health behaviours. Leventhal (2010, personal communication) therefore suggests that interventions designed to change behaviour should focus on functional variables which cause behaviour, and therefore participant self-efficacy should be considered as sitting within the 'personal control' domain of a treatment representation, alongside the other domains of a treatment representation; identity (the treatment label), cause (the causal mechanism by which the treatment provides benefit), timeline (ideas about the level of activity required, and the timeline for anticipating benefit), and consequences (beliefs about the positive and negative consequences of the treatment).

Only two previous studies have been conducted which use psychological techniques to increase physical activity in patients with PAD. Collins, Krueger, Kroll & Sharf (2009) carried out a randomised controlled trial to compare a face-to-face communication

CHAPTER SIX

intervention with a video intervention to increase physical activity levels in patients with PAD. The communication intervention involved patients completing a 9-item survey about their awareness of PAD as a disease, their beliefs about the causes of PAD, their beliefs about walking for disease management, and their beliefs about factors which facilitate or hinder their walking behaviour; participants then met with a doctor for 15 – 20 minutes to discuss their responses to the survey and the doctor completed a prescription about walking levels specific to each participant's ability, describing how often and for how long the participant should exercise each week. The video intervention involved participants watching a 7 minute video about PAD, which gave an overview of PAD and advice to stop smoking and increase exercise levels. Participants in both groups were followed-up at 12 weeks to measure changes in self-reported physical activity. There were no changes in physical activity either between or within groups from baseline to follow-up. However, this was not a theory-based intervention, patients with both symptomatic and a-symptomatic PAD were included in the trial, and self-report measures of physical activity were used as the outcome measure rather than an objective measure of physical activity.

Pochstein (2010, personal communication) carried out an intervention based on the Health Action Process Approach (Schwarzer, 1999) to increase action and coping planning in patients with IC. A secondary outcome of the study was change in physical activity, measured by self-report. The purpose of the intervention was to help participants who were motivated to walk to translate this motivation into action by using a volitional intervention to increase action and coping planning. The control group in this study received the standard therapy for PAD, although further details of

CHAPTER SIX

this are not given. Pochstein & Wegner (2010) found that volitional competence and physical activity were significantly higher at follow-up in the intervention group than in the control group. This study indicates that a psychological intervention which incorporates action and coping planning for patients with IC may increase physical activity, however, limitations of this study include lack of information about allocation to group, the treatment received by the control group, and the content of the intervention, and the lack of objective measurement of physical activity.

A number of randomised controlled trials have tested whether theory-based psychological interventions can increase physical activity in a primary care setting, and have failed to show an improvement in physical activity in the intervention group compared to the control group (Kinmonth et al, 2008; The Writing Group for the Activity Counseling Trial Research Group, 2001; van Sluijs et al, 2005). All of these studies found that activity levels had increased from baseline to follow-up in both the intervention groups and the control groups. Kinmonth et al (2008) suggested that this increase in physical activity in the control groups may be due to measurement reactivity – the effect of measuring physical activity and its determinants on the behaviour of the person being measured.

Implications for the current study

The current study differs from the primary care studies (Kinmonth et al, 2008; The Writing Group for the Activity Counseling Trial Research Group, 2001; van Sluijs et al, 2005) because (i) the intervention was designed to address the barriers to walking

CHAPTER SIX

particular to patients with IC, whereas other studies included heterogeneous groups of patients facing a wide range of unknown barriers to physical activity; (ii) the patients included in this study have sought treatment for their disease and were therefore presumably more motivated to adhere to treatment than patients being offered unsolicited interventions to increase physical activity; (iii) this study objectively directly measured behaviour change, in the form of mean daily steps as measured by pedometer, rather than relying on self-report measures of physical activity, or objective measures of fitness as a proximal measure of behaviour change.

The present study aimed to assess whether a brief psychological intervention to modify illness and walking representations, based on the CSM, would increase physical activity in patients with IC.

Participants in the qualitative study (Chapter 3) had already received either angioplasty or surgery and tended to view their health in a medical model, believing their ability to walk was the responsibility of the surgeon, and believing they themselves had little or no control over their health outcomes. Therefore, this study focused on patients newly diagnosed with IC, as their beliefs about the outcomes of IC were less likely to be influenced by the acute medical style of management of PAD.

In NHS Forth Valley, patients are diagnosed with IC by a Vascular Assessment Nurse at an outpatient clinic, attend a further outpatient clinic for an ultrasound scan of their legs by a Vascular Technologist approximately 2 weeks later, and then meet with a Vascular Surgeon approximately 3 months after diagnosis to discuss possible

CHAPTER SIX

treatment options. The treatment options suggested by the Vascular Surgeon depend on the health of the patient, and the location and size of the narrowing of the artery, and are either for conservative management, angioplasty or bypass surgery.

Regardless of the treatment option chosen, patients are followed up at further outpatient clinics for a minimum of 3 months. Symptomatic benefits of physical activity for IC have been recorded as early as 6 weeks into an exercise intervention (Clifford, Davies, Hayne & Baird, 1980). As the intervention in this chapter would be delivered to all participants at diagnosis, and approximately 10 weeks before their meeting with a vascular surgeon to decide on surgical treatment, a further aim of this study was to determine whether fewer participants in the intervention group would opt for surgery for symptom management than participants in the control group.

Trial objectives

To examine whether:

- a brief psychological intervention can improve walking and quality of life for patients with intermittent claudication;
- a brief psychological intervention can reduce the demand for surgery for symptom management;
- improvement in walking is mediated by changes in illness and walking beliefs;
- the brief psychological intervention is acceptable and understandable to participants.

Method

Recruitment

Participants were recruited from the Intermittent Claudication Outpatient Clinic in NHS Forth Valley. This is a nurse-led clinic which diagnoses people with IC. People are referred from GPs based in Forth Valley. At diagnosis, the Vascular Assessment Nurse invited consecutive patients to take part in the trial. The letter of invitation to this trial, participant information sheets and consent forms for this study can be found in Appendix 8. In order to check representativeness of the participants who agreed to take part in the trial, the Vascular Assessment Nurse asked for verbal consent to retain all patients' age, gender and Ankle Brachial Pressure Index (ABPI) information, whether they agreed to participate in the trial or not.

Two hundred patients are diagnosed each year in the Forth Valley Intermittent Claudication clinic. A sample size calculation carried out using GPower3 (Faul et al, 2007), indicated that to carry out a (2) group by (2) time mixed ANOVA to detect a small group*time interaction effect size (0.2) with an alpha of 0.05, and a power of 80%, the trial would require 26 participants in each condition. A small effect size of 0.2 was selected in the sample size calculation based on a previous study of an exercise program for physical activity in patients with IC which measured walking outcomes using pedometers (Crowther et al, 2008). The sample size calculation was based on changes in the primary outcome measure. As this was a pilot study, a further aim was to determine the effect sizes achieved in the secondary outcome measures to help inform the sample size calculation for a larger, more definitive study. Based on a

CHAPTER SIX

previous study with patients from this population recruited at outpatient clinic, it was estimated that 25% of people may decline to participate in the study. Likely attrition rate from the study for this population was unknown, therefore a 10% attrition rate was estimated during the trial. The aim was to invite 80 patients to participate in the trial, of whom 60 were expected to agree to participate, and a further 6 to drop-out during the course of the trial. Based on typical numbers presenting at the clinic who are diagnosed with claudication, recruitment was estimated to take place at the rate of 2 participants/week.

Inclusion criteria

Newly diagnosed patients with IC in one or both legs were recruited into the study. A diagnosis of lower limb arterial disease causing IC was established by a vascular assessment nurse or consultant surgeon. This was based on a combination of investigations including post-exercise ABPI of below 0.9 (Cassar, 2006), and duplex ultrasound, magnetic resonance angiography (MRA) or computerised tomography angiography to provide an anatomic view of the arteries.

Exclusion criteria

Patients were excluded if they were unable to give informed consent (e.g. due to dementia) or if it was medically inadvisable for them to increase their daily walking, for example patients with severe cardiac disease, cancer, patients with severe debility e.g. who cannot walk unaided, or patients with a history of orthopaedic surgery which

CHAPTER SIX

affects walking. Patients with an ABPI of less than 0.35 were also excluded as they were likely to be offered emergency surgery.

Participants

One hundred and nine patients newly diagnosed with IC were assessed for eligibility, of whom 35 were excluded from the study by the vascular assessment nurse, and 74 were invited to take part in the study. Reasons for exclusion included personal acquaintance of researcher, dementia, unable to perform exercise test, cancer, critical ischemia, severe cardiac disease, severe debility due to arthritis, unable to walk unaided, and a history of orthopaedic surgery. Of the 74 who were invited to take part in the study, 14 were unwilling to participate, reasons given included didn't have time (n=4), the researcher couldn't get hold of them (n=4), no reason given (n=1), felt unable to contemplate walking (n=2), didn't want to talk about herself (n=1), felt depressed (n=1), worried walking would make legs worse (n=1).

Design

This was a randomised controlled trial with patients newly diagnosed with IC randomly allocated to one of two groups. The protocol of the trial is registered as ISRCTN28051878, and is published (Cunningham, Swanson, O'Carroll & Holdsworth, 2010). Allocation to group was carried out by RO'C, who used a computer generated random number table for allocation (<http://www.randomizer.org/>). The computer generated random number table was created at the start of the study by RO'C, who

CHAPTER SIX

was not involved in participant recruitment. MC assigned consecutive participant numbers to patients as their names were sent to her by the Vascular Assessment Nurse, each participant number corresponded to a treatment group as established in the computer generated random number table. MC assigned participants to groups before she had made any contact, and before she had received any information about them other than their name and phone number. Participants allocated to the control condition received usual care. Participants allocated to the intervention group received usual care and a brief, 2-session psychological intervention. The Vascular Assessment Nurse who provided usual care at diagnosis, and who recruited participants, was blind to participant allocation to groups. Other clinical staff in contact with participants during their care, e.g. Vascular Technologists and Vascular Surgeons, were also blind to participant allocation to groups. A CONSORT flowchart of the trial design is shown in Figure 6.1.

Setting

This was a single-centre community-based trial based in NHS Forth Valley, Scotland.

Ethical approval

Ethical approval was obtained from Fife and Forth Valley Research Ethics Committee (REC ref. no. 08/S0501/6).

CHAPTER SIX

Intervention

Participants in the intervention group received 5 visits from the researcher in their own home, including 2 visits to complete questionnaires, 2 one hour intervention sessions, and 1 other visit to drop off pedometers. The design of the intervention is described in detail in Chapter 4.

Session 1

The researcher elicited participant beliefs about their illness, or about walking. Information was provided about the consequences of the illness, and about the behaviour-health link in order to modify illness and walking beliefs. Motivational interviewing techniques were used to deliver the intervention, asking open questions, prompting the participant to make self-motivating statements and evaluations of their own walking behaviour and moving participants to a point where they had expressed motivation or intention to change their walking behaviour. The pro-forma which was used to guide Session 1 can be found in Appendix 3. The information sheet used to provide participants with additional information about PAD can be found in Appendix 4.

Session 2

The researcher worked with the participant to draw up an individualised walking action plan, based on the recommendation of walking to near maximal pain three times a week (Leng et al, 2000). Participants were encouraged to think about how they could adapt their daily routines to incorporate a half hour of continuous walking,

CHAPTER SIX

and were also encouraged to think of possible barriers which may prevent them from following their action plan, and strategies to cope with these barriers. Sniehotta et al (2006) found that a combination of action planning and coping planning led to much greater improvement in physical exercise than action planning alone. Action plans were typed up and laminated, and posted out to participants. A copy of the action plan proforma can be found in Appendix 5.

Control

Participants in the control group received 4 visits from the researcher, in their own home, including 2 visits to complete questionnaires and a further 2 visits to either drop off or pick up the pedometer. This is only 1 less visit from the researcher than participants in the intervention group. The researcher engaged control group participants in non-walking related conversation in an attempt to control for the potentially confounding effects of social contact.

CHAPTER SIX

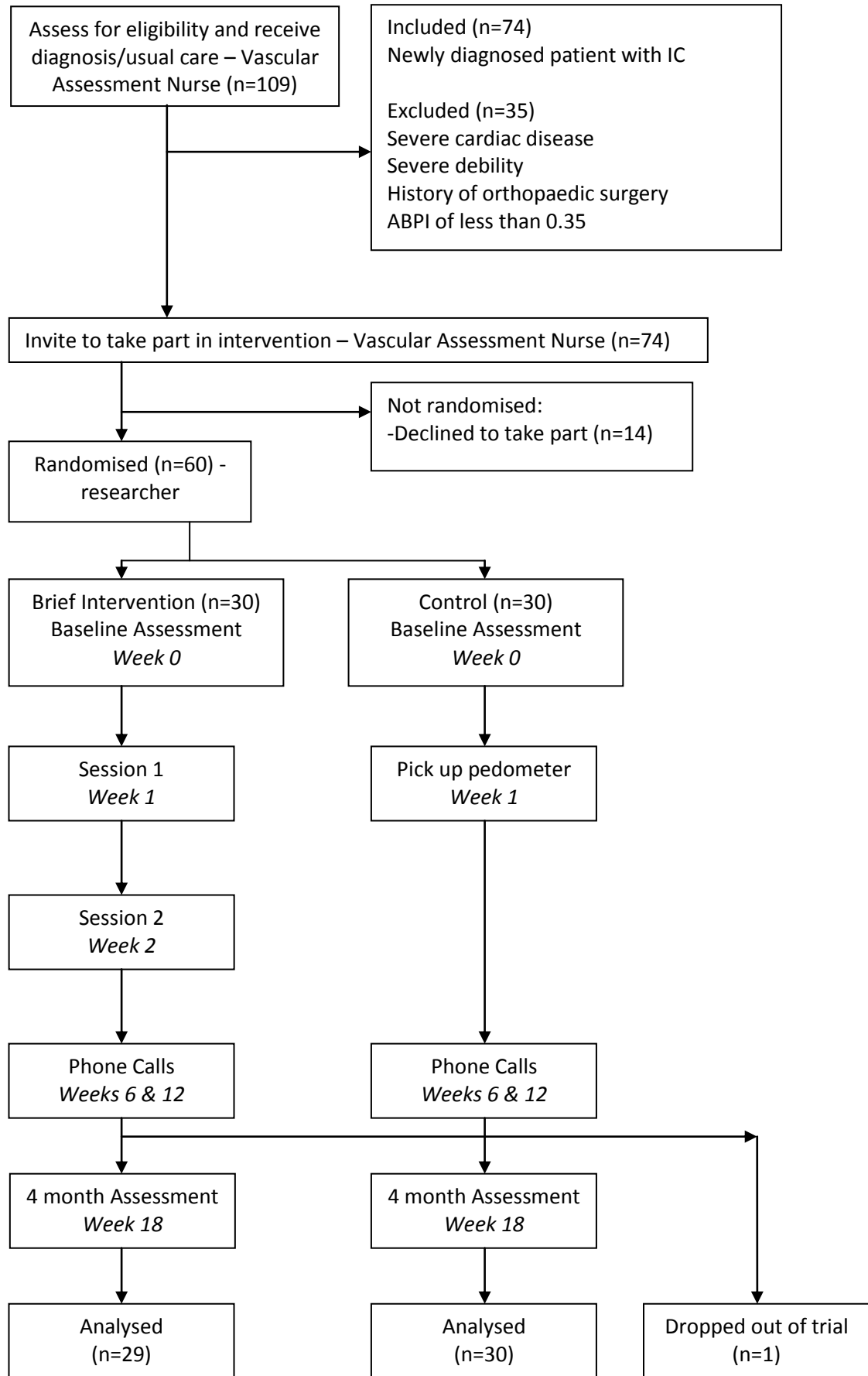


Figure 6.1 CONSORT flowchart of trial design

CHAPTER SIX

Usual care

Participants in the intervention group and control group received usual care while participating in the study. All participants were diagnosed as having IC by the Vascular Assessment Nurse, who provided all patients with an information sheet about PAD and advised patients to 'stop smoking and start walking'. All participants then attended an outpatient clinic to meet with a Vascular Surgeon, who discussed appropriate treatment with the patient. Appropriate treatment depends on the age and health of the patient, the size and location of the narrowing of the artery, and on the patient's wishes. If the patient chose surgical intervention they were put on a waiting list for surgery or angioplasty. If the patient chose conservative treatment, they were invited to attend a further outpatient clinic in 3 months time, and then discharged if their claudication symptoms remained stable. Patients who receive angioplasty are followed up by the surgeon for 1 year and then discharged; patients who receive surgery are followed up by the surgeon for 5 years. Prior to the start of this study, approximately 56% of patients diagnosed with IC in NHS Forth Valley went on to receive vascular intervention, usually within 6 months of diagnosis.

At the time of 4 month follow-up in the RCT, all patients had attended the outpatient clinic to meet the Vascular Surgeon, and a treatment decision had been made. Two participants in the control group and one participant in the intervention group had received angioplasty before 4 month follow-up; all other participants in this study were on a waiting list and had not received treatment.

CHAPTER SIX

Telephone calls

MC called participants in both groups, 6 and 12 weeks after recruitment into the study. The purpose of the call was to:

- Intervention group - discuss progress against the action plan with participants in the intervention group, paying particular attention to barriers to walking, and encouraging participants to use their coping plans, and come up with alternative strategies to overcome barriers. Changes to a participant's action plan or coping plan could be agreed with a participant in the phone call.
- Both groups - ask participants if they had heard from the hospital and what treatment, if any, had been agreed upon.
- Both groups - ask participants to answer 5 standard questions about general health, satisfaction with health, quality of life, pain rating, and pain free walking distance (see Chapter 4). Copies of the proformas used to guide the telephone calls for both groups can be found in Appendix 6.

Outcome measures

Measures were taken for participants in both arms of the study, at baseline and at 4 month follow-up. All questionnaires were administered by MC. A copy of the questionnaire used in this study can be found in Appendix 2.

The primary outcome measure for this study was walking behaviour as measured by pedometer (see Chapter 4). The secondary outcome measure for this study was clinical outcome, determined by demand for surgery/angioplasty versus conservative

CHAPTER SIX

treatment. Other outcome measures for this study included quality of life, symptom representations, walking representations, and intention to walk, which are described in Chapter 4.

Analysis

The internal consistency of multi-item measures was assessed using Cronbach's alpha, using an acceptability criterion of $\alpha \geq 0.7$. Bivariate correlations were used to explore associations between variables at baseline. An exploratory principal components analysis was conducted to identify a factor structure in the baseline data, to provide an understanding of the underlying structure of symptom and treatment representations and their relationship with walking behaviour and quality of life. The distribution of each measure was checked for significant skewness and kurtosis, and where necessary data was transformed to a normal distribution using logarithmic transformations (daily steps, negative walking consequences, positive walking consequences, intention to walk and intention to walk through the pain were transformed for both time points). Data screening revealed no outliers. Baseline demographic measures were compared between the two groups using t-tests and chi-squared tests, to check that participants in the groups were similar. Data was analysed using an intention to treat protocol in a repeated measures mixed design (2 groups*2 time points), to determine whether there were significant group*time interaction effects. Data was missing at 4-month follow-up for 1 participant (intervention group, dropped out of study), therefore their baseline data was carried forward to 4-month follow-up, assuming that this participant who did not take part in follow-up

CHAPTER SIX

measurement had no change from baseline values. The three participants who had received angioplasty prior to 4-month follow-up (1 intervention group and 2 control group) were analysed according to the group to which they had been assigned. One participant in the intervention group lost his pedometer during the baseline measurement and refused to wear a pedometer from then on, however he still wanted to take part in the study, therefore he was included in the analysis of all variables except walking by pedometer. Between-group differences in uptake of surgery, and categorical variables measuring walking behaviour were measured using a chi-square test. The mediation analysis was conducted using bootstrapping, using a script provided by Preacher & Hayes (2008). Data was entered into PASW Statistics 17, and all analysis was carried out using this software package. Bonferroni correction was not applied to the analysis as all inferential analyses were planned a-priori in line with theory. Bonferroni adjustments are considered unnecessary in planned, theory based analysis with specific a-priori hypotheses (Perneger, 1998).

Evaluation

On completion of the study, participants in the intervention group were asked additional semi-structured questions about their experience of the intervention including what they thought of their action plan, whether they followed their action plan, whether the barriers they had predicted prevented them from following their action plan, whether they used their coping plan, whether they intend to follow their action plan in the future, and whether they thought it was worthwhile to take part in the study.

CHAPTER SIX

Results

Internal consistency of the multi-item measures was satisfactory for most items:

Cronbach's alpha: Walking personal control (9 items) = 0.96; Intention to walk (3 items) = 0.83; Intention to walk through pain (3 items) = 0.93; Positive Walking Consequences (8 items) = 0.74; Health-related Quality of Life (16 items) = 0.88.

The Cronbach's Alpha for Negative Walking Consequences (5 items) = 0.62, below the recommended cut-off of 0.70. This statistic could not be improved by removal of items from the scale. A Cronbach's alpha of less than 0.7 implies poor consistency within the scale. However, the calculation of Cronbach's alpha is affected by the number of items in the scale – with scales with less items (e.g. 5) having a greater chance of having a lower alpha score. While higher alpha values indicate more reliable scales, many scales measuring psychological constructs use 0.6 as the minimum acceptable alpha value (e.g. Baars et al, 2005; Hrisos et al, 2009).

Study population

Of 74 invited patients, 60 (81%) consented to take part in the study. Gender, age and ABPI data were collected for the 14 participants who were invited but declined to take part in the study, in order to check representativeness of the study population. There were no significant differences in age, gender or ABPI in the worst leg between the patients who declined to take part in the study and those who agreed to take part in the study.

CHAPTER SIX

Table 6.1 presents the characteristics of the study population at baseline. There were no statistically significant differences between the intervention group and the control group on the demographic or risk factor variables assessed, however significantly more participants in the intervention group reported having heart disease than in the control group ($\chi^2 (1) = 5.08, p = 0.024$). Heart disease (yes/no) was therefore entered as a covariate into the analysis of group differences.

CHAPTER SIX

Table 6.1 **Baseline Characteristics: Control Group, Intervention Group and Overall Study Population**

	Control Group (n=30)	Intervention Group (n=30)	Total (n=60)
<i>Demographics</i>			
Age, mean (SD)	64.50 (10.19)	66.07 (6.30)	65.28 (8.44)
Male, no. (%)	21 (70)	19 (63.3)	40 (66.7)
Living alone, no. (%)	5 (16.7)	3 (10)	8 (13.3)
Retired, no. (%)	21 (70)	26 (86.7)	47 (78.3)
ABPI, mean (SD)	0.74 (0.22)	0.75 (0.17)	0.75 (0.19)
<i>Risk Factors</i>			
Daily Steps, mean (SD)	3826.0(2312.8)	4095.1(2316.9)	3958.3(2299.0)
Diabetes, no. (%)	8 (26.7)	5 (16.7)	13 (21.7)
Smoker, no. (%)			
Yes	11 (36.7)	10 (33.3)	21 (35)
Never	3 (10)	2 (6.7)	5 (8.3)
Given Up	16 (53.3)	18 (60)	34 (56.7)
Dietary behaviour, mean (SD)	4.97 (1.31)	4.90 (1.35)	4.93 (1.32)
<i>Co morbidities</i>			
Heart Disease, no. (%)	5 (16.7)	13 (43.3)	18 (30)
Stroke, no. (%)	5 (16.7)	5 (16.7)	10 (16.7)

Correlations between variables at baseline

Table 6.2 illustrates the correlations between all variables at baseline.

A belief in more negative consequences of IC was significantly positively correlated with reporting a greater number of symptoms in the leg (BIPQ Identity), having higher levels of concern about IC, feeling more affected emotionally by IC, having poorer health-related quality of life, and reporting a better understanding of IC (BIPQ Illness Comprehensibility); and significantly negatively correlated with personal control over IC.

CHAPTER SIX

A belief that IC would last for a long time (IPQ Timeline) was not significantly correlated with any other variable.

Personal control over IC was significantly positively correlated with beliefs in positive walking consequences, and walking personal control; and significantly negatively correlated with beliefs in negative walking consequences, and having poorer health related quality of life.

The level of symptoms experienced as a result of IC was significantly positively correlated with concern about IC, emotional effect of IC, poorer health related quality of life and beliefs in negative walking consequences.

Concern about IC was significantly positively correlated with emotional effect of IC and poorer health related quality of life.

Emotional effect of IC was significantly positively correlated with beliefs in negative walking consequences and poorer health related quality of life.

A better understanding of IC was significantly positively correlated with walking personal control, intention to walk for at least half an hour at least 3 times a week, and intention to carry on walking until the pain is almost unbearable before stopping for a rest; and significantly negatively correlated with beliefs in negative walking consequences.

CHAPTER SIX

Belief in positive walking consequences was significantly positively correlated with walking personal control, intention to walk for at least half an hour at least 3 times a week, intention to carry on walking until the pain is almost unbearable before stopping for a rest, and mean daily steps; and significantly negatively correlated with beliefs in negative walking consequences and having poorer health related quality of life.

Belief in negative walking consequences was significantly negatively correlated with walking personal control, intention to walk and intention to walk through the pain; and significantly positively correlated with having poorer health related quality of life.

Walking personal control was significantly positively correlated with intention to walk, intention to walk through the pain and mean daily steps; and significantly negatively correlated with poorer health related quality of life.

Intention to walk was significantly positively correlated with intention to walk through the pain and mean daily steps.

Intention to walk through the pain was significantly positively correlated with mean daily steps.

Mean daily steps was significantly negatively correlated with poorer health related quality of life.

CHAPTER SIX

Table 6.2 Correlations, means and standard deviations of all variables at baseline

	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1.BIPQ Consequence	-													
2.BIPQ Timeline	.155	-												
3.BIPQ Personal Control	-.317*	-.152	-											
4.BIPQ Identity	.571**	.115	-.189	-										
5.BIPQ Concern	.575**	.012	-.158	.359**	-									
6.BIPQ Emotions	.590**	.096	-.237	.403**	.496**	-								
7.BIPQ Illness Comprehensibility	.284*	.000	.018	.099	.156	.217	-							
8.Positive Walking Consequences	.004	-.074	.453**	-.088	.066	-.085	.196	-						
9.Negative Walking Consequences	.119	.010	-.258*	.299*	.093	.297*	-.288*	-.370**	-					
10.Walking Personal Control	-.141	.004	.364**	-.069	-.106	-.218	.381**	.473**	-.409**	-				
11.Intention to walk	.149	.130	.207	.106	.160	-.053	.427**	.370**	-.286*	.650**	-			
12.Intention to walk through pain	.111	.012	.156	.062	.041	-.074	.292*	.280*	-.372**	.618**	.592**	-		
13.Mean daily steps	-.168	.181	.188	.032	-.137	-.073	.177	.324*	-.247	.509**	.282*	.379**	-	
14.HRQoL	.593**	.045	-.402**	.468**	.482**	.521**	.049	.335**	.485**	-.378**	-.047	-.213	-.339**	-
Mean Score	6.25	6.78	4.22	7.13	7.52	5.23	6.83	3.02	1.71	5.57	7.44	7.26	3958.27	35.62
SD	2.61	2.73	3.12	2.09	2.43	3.35	3.45	.60	.64	3.3	3.0	3.69	2298.76	17.23

* Correlation is significant at the .05 level, ** Correlation is significant at the .01 level

CHAPTER SIX

Principal components analysis was conducted with 13 of the 14 variables listed (excluding symptom representation Timeline as it did not correlate significantly with any other variable and was therefore not suitable for inclusion in a components analysis) to identify clusters of variables which correlated highly with each other. The Kaiser-Meyer-Olkin measure of sampling adequacy was .799, and Bartlett's test of sphericity was significant ($\chi^2(78) = 297.64, p < .001$), indicating suitability of the data for principal components analysis. The initial eigenvalues showed that the first factor explained 30.5% of the variance, the second factor 23.6% of the variance and a third factor 8% of the variance. None of the other factors had an eigenvalue over 1.

The two factor structure, explaining 54.1% of the variance was examined using a varimax rotation and results are shown in Table 6.3. This principal components analysis revealed two clusters:

- Walking personal control, intention to walk, intention to walk through the pain, beliefs about positive walking consequences, illness comprehensibility, personal control of the illness, and daily steps were all positively loaded onto the first cluster, and beliefs about negative walking consequences was negatively loaded onto the first cluster.
- Illness consequences, concern about the illness, emotional effect of the illness, and illness symptoms were all positively loaded onto the second cluster, and disease specific quality of life was negatively loaded onto the second cluster (because on this scale lower scores indicate better quality of life).

CHAPTER SIX

This principal components analysis broadly supports the theory that participants hold separate beliefs about walking (cluster 1) and about their illness (cluster 2).

Table 6.3 Factor loadings based on principal components analysis with varimax rotation for baseline variables

	Cluster 1	Cluster 2
Walking personal control	.853	
Intention to walk	.777	
Intention to walk through pain	.747	
Positive walking consequences	.637	
BIPQ - Illness comprehensibility	.613	
Negative walking consequences	-.576	
Daily steps	.567	
BIPQ – personal control	.403	
BIPQ – consequences		.873
Disease specific quality of life		.782
BIPQ – concern		.744
BIPQ – emotions		.740
BIPQ – identity		.696

Outcomes

The primary outcome for this trial was walking behaviour as measured by pedometer. This is presented alongside other measures of behaviour change – self-report walking, pain free walking distance, clinical outcome, and dietary behaviour. Secondary outcomes included quality of life and the psychological variables, these are presented after the behavioural measures. Finally, multi-variable mediation analysis is presented to identify psychological variables which mediate the relationship between trial group and walking behaviour.

CHAPTER SIX

Physical activity - pedometer

Results for mean daily steps at baseline and 4 month follow-up are shown in Figure 6.2 and Table 6.4. Analyses were carried out after controlling for baseline differences in heart disease and walking by entering baseline values as a covariate. There was a significant group*time interaction effect on mean daily steps $F(1,55)=12.284$, $p=.001$, partial $\eta^2=.183$. Specifically, although both groups had similar walking levels at baseline, the intervention group had significantly increased walking levels at 4-month follow-up, $t(28)=2.859$, $p=.008$, 95% Confidence Interval (CI) -.158 to -.026; whereas the control group had a significant decline in walking levels at 4-month follow-up, $t(29)=-2.268$, $p=.031$, 95% CI .008 to .154. Mean daily steps at baseline were entered as a covariate into the model since participants with diabetes, in both groups, had significantly lower levels of walking (Mean daily steps at baseline = 2607.67, SD = 1505.4) than participants without diabetes (Mean daily steps at baseline = 4339.96, SD = 2351.73), $t(30.404)=3.192$, $p=.003$. Lower walking levels in patients with diabetes may be due to peripheral neuropathy.

Contact time

A possible limitation of this study was the extra time which the researcher spent with participants in the intervention group, compared to time spent with participants in the control group. Total time spent with each participant and on the phone to participants was recorded during the trial. There was a non-significant correlation between time spent with participants in the intervention group and change in walking, $r=.082$, $n=29$,

CHAPTER SIX

$p=.673$, which provides some evidence that contact time was not an influential factor in whether participants increased their walking behaviour.

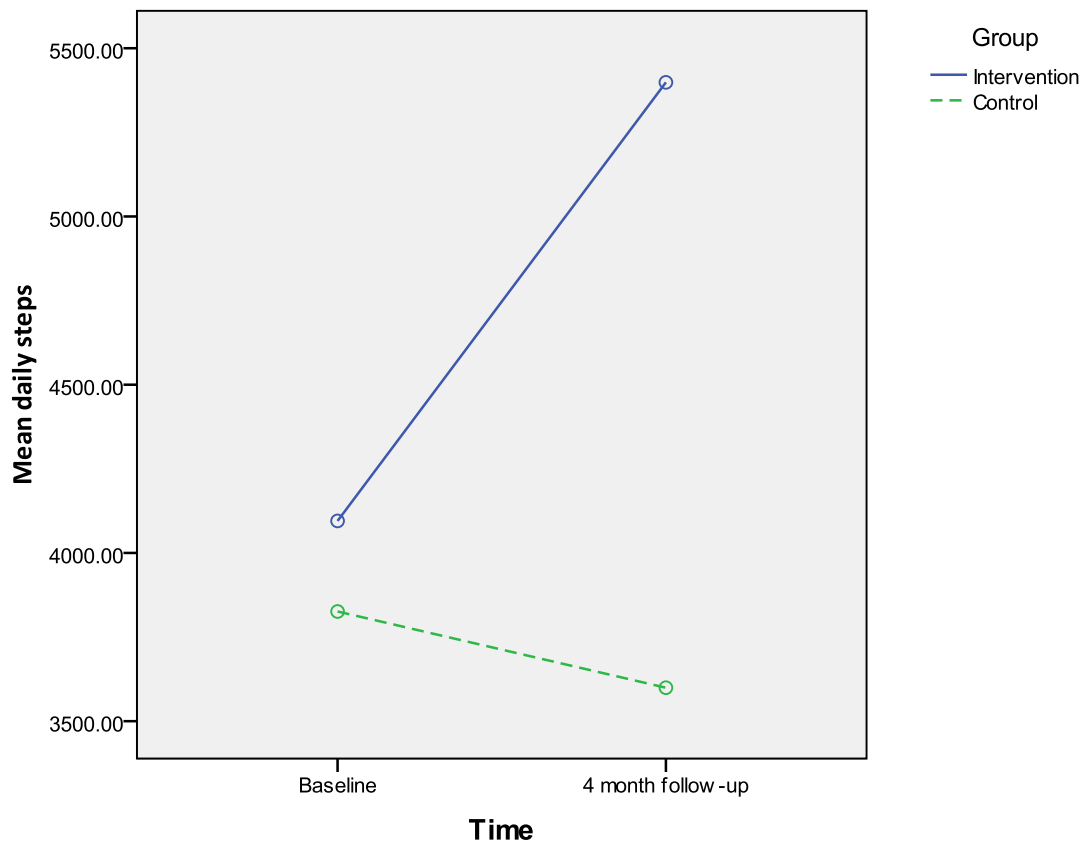


Figure 6.2 Mean daily steps at baseline and follow-up

Physical activity – IPAQ

Total activity score, and amount of time sitting, were calculated for participants using the IPAQ. Median scores, and interquartile ranges for activity and time sitting are presented in Table 6.5. There was no significant change in activity between the two groups from baseline to follow-up, $U=382.0$, *ns*. However, there was a significant difference between the two groups in change in time spent sitting, $U=301.0$, $p=.026$.

CHAPTER SIX

Table 6.4 Outcome variable scores in the intervention and control groups at baseline and 4 month follow-up (intention-to-treat data)

	Control			Intervention			F
	Baseline	Follow-up	t	Baseline	Follow-up	t	
PA - ped	3826.0 (2312.8)	3599.4 (2850.3)	-2.27*	4095.1 (2316.9)	5398.6 (3196.9)	2.86**	12.28**
QoL	40.36 (18.54)	35.03 (22.79)	-1.61	30.87 (14.62)	19.95 (18.10)	-3.47**	2.45
WPersControl	5.29 (3.55)	4.43 (4.08)	-1.61	5.85 (3.03)	7.49 (2.85)	4.05***	12.22**
WPosCons	2.98 (.58)	2.81 (.80)	-.82	3.06 (.63)	3.50 (.56)	3.13**	7.07*
WNegCons	1.69 (.70)	1.87 (.81)	1.12	1.73 (.58)	1.25 (.50)	-5.46***	11.44**
IntWalk	7.49 (3.17)	5.74 (3.21)	-2.89**	7.40 (2.89)	8.42 (2.44)	1.74	8.38**
IntPain	7.14 (3.99)	6.87 (3.93)	-.60	7.38 (3.43)	9.29 (1.68)	3.21**	6.53*
BIPQCons	6.63 (2.48)	6.20 (2.72)	.98	5.87 (2.71)	5.20 (2.68)	-1.13	1.40
BIPQTime	7.37 (2.87)	5.97 (3.62)	-1.87	6.20 (2.50)	6.17 (3.07)	-.07	.23
BIPQPersCont	3.87 (3.07)	4.43 (3.17)	.98	4.57 (3.18)	6.47 (3.38)	2.36*	5.02*
BIPQID	7.20 (2.20)	6.80 (2.38)	-.83	7.07 (2.02)	5.43 (2.57)	-2.98**	5.00*
BIPQConcern	7.63 (2.61)	6.90 (3.34)	-1.35	7.40 (2.28)	6.23 (3.22)	-1.76	.42
BIPQComp	7.87 (3.10)	8.60 (2.34)	1.18	5.80 (3.52)	8.27 (2.77)	3.46**	.02
BIPQEmotion	6.17 (3.13)	4.93 (3.48)	-2.43*	4.30 (3.35)	3.20 (3.03)	-1.95	.59
Diet	4.97 (1.31)	4.68 (1.46)	-1.53	4.90 (1.35)	5.27 (1.09)	1.71	8.46**

PA – ped, Physical activity measured by pedometer; QoL, Quality of Life measured by the Intermittent Claudication Questionnaire; WPersControl, Walking Personal Control; WPosCons, Positive Walking Consequences; WNegCons, Walking Negative Consequences; IntWalk, Intention to walk for at least half an hour at least 3 times a week; IntPain, Intention to walk through the pain until it is unbearable before stopping for a rest; BIPQCons, symptom representation Consequences; BIPQTime, symptom representation Timeline; BIPQPersCont, symptom representation Personal Control; BIPQID, symptom representation Identity; BIPQConcern, symptom representation Concern; BIPQComp, symptom representation Illness Comprehensibility; BIPQ Emotion, symptom representation Emotion.

Values given are unadjusted means (standard deviation)

'F' is the F statistic for the ANOVA test of the Null Hypothesis - no significant time*group interaction

*p<.05; **p<.01;***p<.001

CHAPTER SIX

Specifically, participants in the intervention group reported significantly less time sitting/day at follow-up compared to at baseline, $z=-3.166$, $p=.002$; while participants in the control group reported no significant change in the amount of time they spent sitting/day.

Table 6.5 IPAQ scores at baseline and follow-up

	Control		Intervention	
	Baseline	Follow-up	Baseline	Follow-up
Total Activity(METmins/week)				
Median	1141.50	599.75	1135.50	1359.50
Interquartile range	2259.00	2802.75	2943.38	2150.25
Sitting (mins/day)				
Median	480.00	450.00	480.00	360.00
Interquartile range	360.00	450.00	360.00	180.00

Walking behaviour – Intermittent Claudication

As discussed in Chapter 4, recommended walking behaviour for patients with IC can be split into two distinct behaviours (i) walking to near maximal pain before stopping to rest, and (ii) walking for at least half an hour three times a week.

(i) Participants were asked how often they carry on walking after the pain has started in their leg, with three possible responses, 'Never', 'For a few steps' and 'Until the pain is nearly unbearable'. The responses 'Never' and 'For a few steps' were amalgamated in the analysis to form a category 'Not continuing to maximal pain', to meet the minimum cell count requirements for the chi-square test. Results are shown in Table 6.6. There was no significant difference between the groups at baseline in walking into the pain behaviour, however, there was a significant difference between the groups at

CHAPTER SIX

4 month follow-up, $\chi^2(1)=12.273$, $p<.001$, with more participants in the intervention group continuing to walk through the pain to near maximal pain before stopping for a rest, than participants in the control group.

Table 6.6 Self-report walking through the pain at baseline and follow-up

		Not continuing to maximal pain	Continuing to maximal pain
Baseline			
Intervention	11 (36.67%)	19 (63.33%)	
Control	16 (53.33%)	14 (46.67%)	
4 month follow-up			
Intervention	2 (6.67%)	28 (93.33%)	
Control	14 (46.67%)	16 (53.33%)	

(ii) Participants were asked how often they walk for at least half an hour, with six possible responses. The responses 'Never', 'Once or twice a month' and '1-2 times a week' were amalgamated into one category, 'Walking less than 3 times a week'; and the responses '3 times a week', '4-5 times a week', 'Everyday' were amalgamated into one category 'Walking at least 3 times a week', to meet the minimum cell count requirements for the chi-square test. Results are shown in Table 6.7. There was no significant difference between the groups at baseline, although there was a trend towards more people in the control group walking for at least half an hour at least three times a week than in the intervention group. At 4 month follow-up, there was a significant difference between the groups, $\chi^2(1)=6.667$, $p=.010$, with more participants in the intervention group walking for at least half an hour three times a week, and more participants in the control group walking for less than half an hour three times a week.

CHAPTER SIX

Table 6.7 Self-report walking for at least half an hour at baseline and follow-up

		Walking less than 3 times/week	Walking at least 3 times/week
Baseline			
	Intervention	23 (76.67%)	7 (23.33%)
	Control	16 (53.33%)	14 (46.67%)
4 month follow-up			
	Intervention	10 (33.33%)	20 (66.67%)
	Control	20 (66.67%)	10 (33.33%)

Pain free walking distance

Pain-free walking distance was measured by asking participants how far they could walk until the onset of pain, with 6 possible choices from '0 yards' to 'More than a mile'. This question was asked at baseline, follow-up and in the two telephone calls. The final three categories, 'Up to ½ mile', 'Up to 1 mile' and 'More than 1 mile' were amalgamated to form one category, 'Over ½ mile', to meet the minimum cell count requirements for a chi-square test. Results are shown in Table 6.8. There was no significant difference in cell counts at baseline, however there were significant difference between the observed and expected cell counts between the two groups at the first call, $\chi^2(3)=8.691$, $p=.034$; at the second call, $\chi^2(3)=8.315$, $p=.040$; and at 4 month follow-up, $\chi^2(3)=12.038$, $p=.007$. Specifically, more participants in the intervention group reported longer pain free walking distances at all follow-ups than participants in the control group.

CHAPTER SIX

Table 6.8 Pain free walking distance across the trial period

	0 yards	Up to 100 yards	Up to 250 yards	Over ½ mile
Intervention				
Baseline (n=30)	5(16.67%)	14(46.67%)	10(33.33%)	1(3.33%)
Call 1 (n=28)	2(7.14%)	5(17.86%)	15(53.57%)	6(21.43%)
Call 2 (n=25)	3(12.0%)	6(24.0%)	8(32.0%)	8(32.0%)
Follow-up (n=30)	2(6.67%)	5(16.67%)	9(30.0%)	14(46.67%)
Control				
Baseline (n=30)	5(16.67%)	17(56.67%)	4(13.33%)	4(13.33%)
Call 1 (n=28)	8(28.57%)	9(32.14%)	6(21.43%)	5(17.86%)
Call 2 (n=22)	7(31.82%)	10(45.45%)	2(9.09%)	3(13.64%)
Follow-up (n=30)	9(30.0%)	11(36.67%)	3(10.0%)	7(23.33%)

Clinical outcome

Results for clinical outcome are shown in Table 6.9. Significantly fewer participants in the intervention group had opted for either angioplasty or surgery at 4-month follow-up than participants in the control group, $\chi^2(1)=6.787$, $p=.009$. The odds ratio for clinical outcome was 4.125, indicating that participants in the control group were 4.125 times more likely to opt for revascularisation than participants in the intervention group.

Table 6.9 Clinical Outcome by Experimental Group

	Control Group (n=30)	Intervention (n=30)
Revascularisation	18 (60%)	8 (26.67%)
No revascularisation	12 (40%)	22 (73.33%)

Dietary behaviour

Results for dietary behaviour are shown in Table 6.4, and Figure 6.3. There was a significant group*time interaction effect on dietary behaviour, $F(1,57)=8.463$, $p=.005$, partial $\eta^2=.129$. Participants in the intervention group showed a non-significant improvement in diet from baseline to follow-up, while participants in the control group showed a non-significant worsening in dietary behaviour.

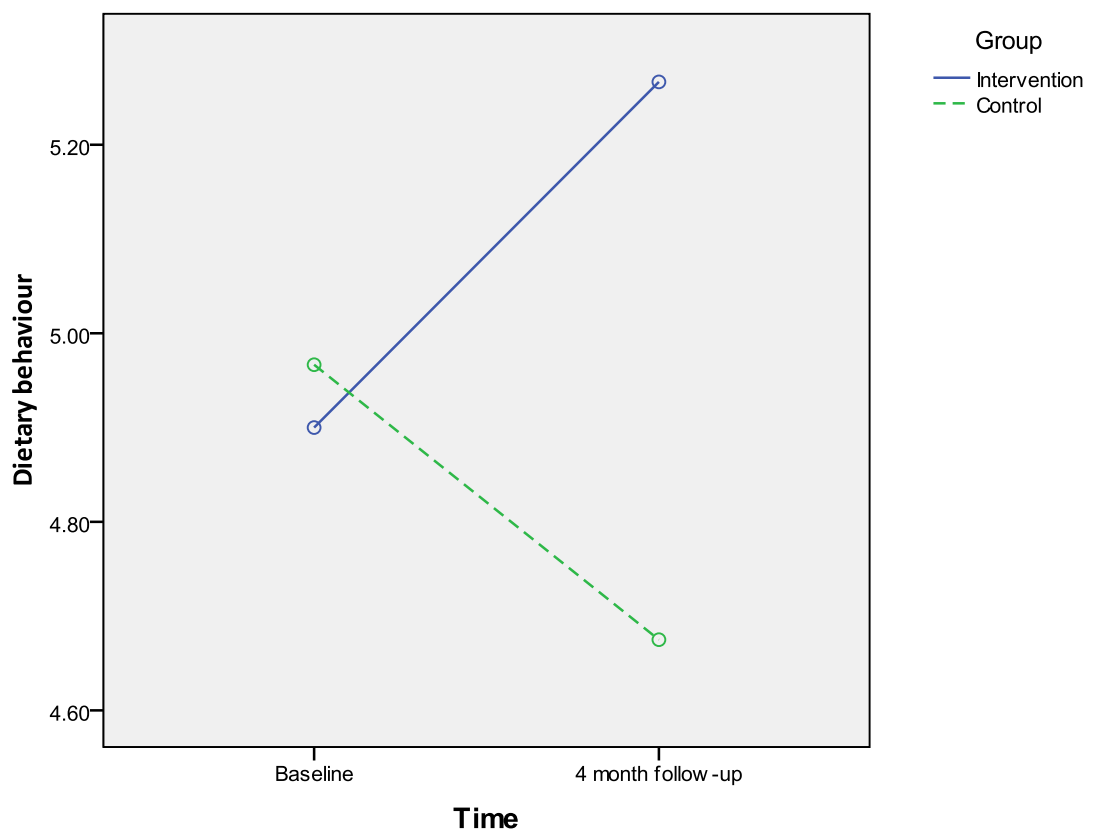


Figure 6.3 Dietary behaviour at baseline and follow-up

Quality of life

Results for the disease specific measure of quality of life are shown in Table 6.4. There was a significant difference between the groups on baseline measures of disease

CHAPTER SIX

specific quality of life, $t(58)=-2.200$, $p=.032$, with the intervention group reporting significantly better mean quality of life than the control group. Therefore quality of life at baseline was entered as a covariate in the analysis. There was no significant group*time interaction effect, and no significant main effects for group or time on quality of life after adjustment for baseline values. There was a significant within-group improvement in disease specific quality of life from baseline to follow-up in the intervention group, $t(29)=3.474$, $p=.002$, 95% CI 4.49 to 17.35; there was a non-significant improvement in control group disease specific quality of life.

Quality of life was also measured at baseline, 4 month follow-up and in the two telephone calls with the single item question 'How would you rate your quality of life?' which had five possible responses on a Likert scale, ranging from 'Very poor' to 'Very good'. Data was collected at all 4 time points for 25 participants in the intervention group and 22 participants in the control group. Results for general quality of life are shown in Figure 6.4. There was a significant group*time interaction effect on general quality of life, $F(3,132)=4.613$, $p=.004$, partial $\eta^2=.095$. Participants in the intervention group reported a significant improvement in general quality of life over time, $F(3,69)=5.504$, $p=.002$, partial $\eta^2=.193$; while participants in the control group reported a non-significant decrease in general quality of life over time.

CHAPTER SIX

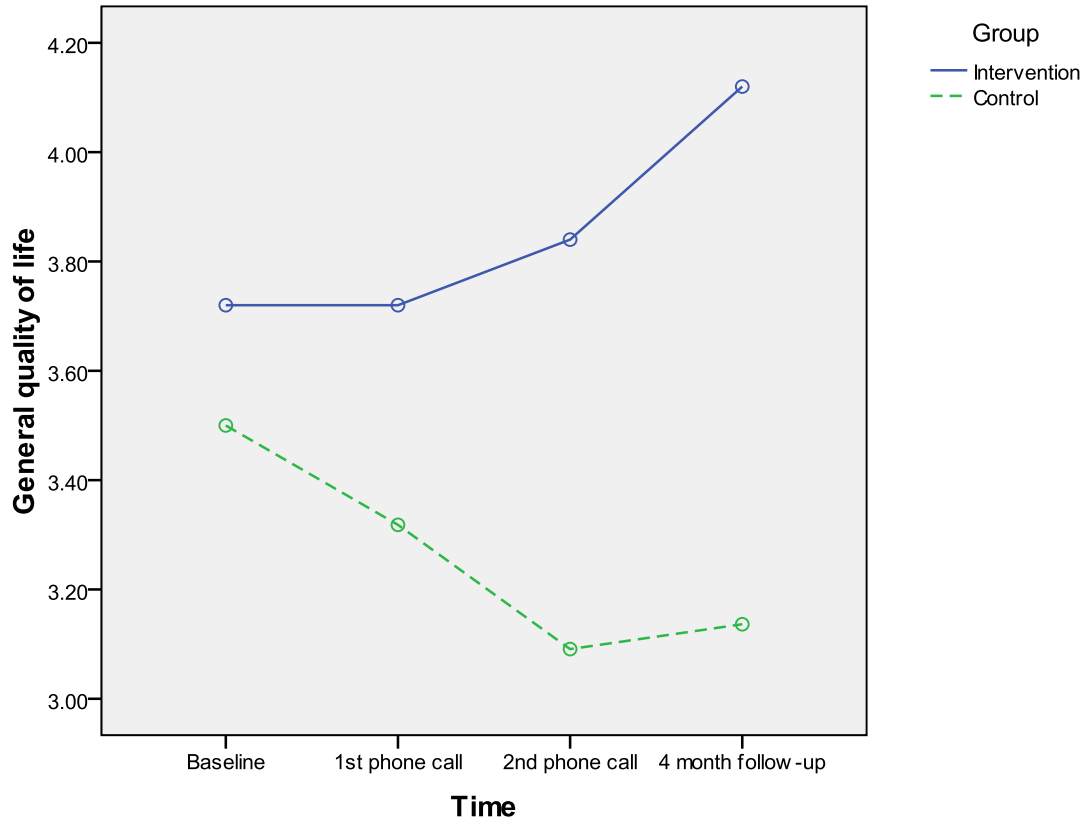


Figure 6.4 General quality of life over time

Walking personal control

Results for walking personal control are shown in Table 6.4 and Figure 6.5. There was a significant group*time interaction effect on walking personal control, $F(1,57)=12.219$, $p=.001$, partial $\eta^2=.177$. Specifically, although both groups had similar levels of walking personal control at baseline, the intervention group had significantly increased levels of walking personal control from baseline to 4 month follow-up, $t(29)=4.052$, $p<.001$, 95% CI .811 to 2.463; whereas there was a non-significant decrease in levels of walking personal control from baseline to follow-up in the control group.

CHAPTER SIX

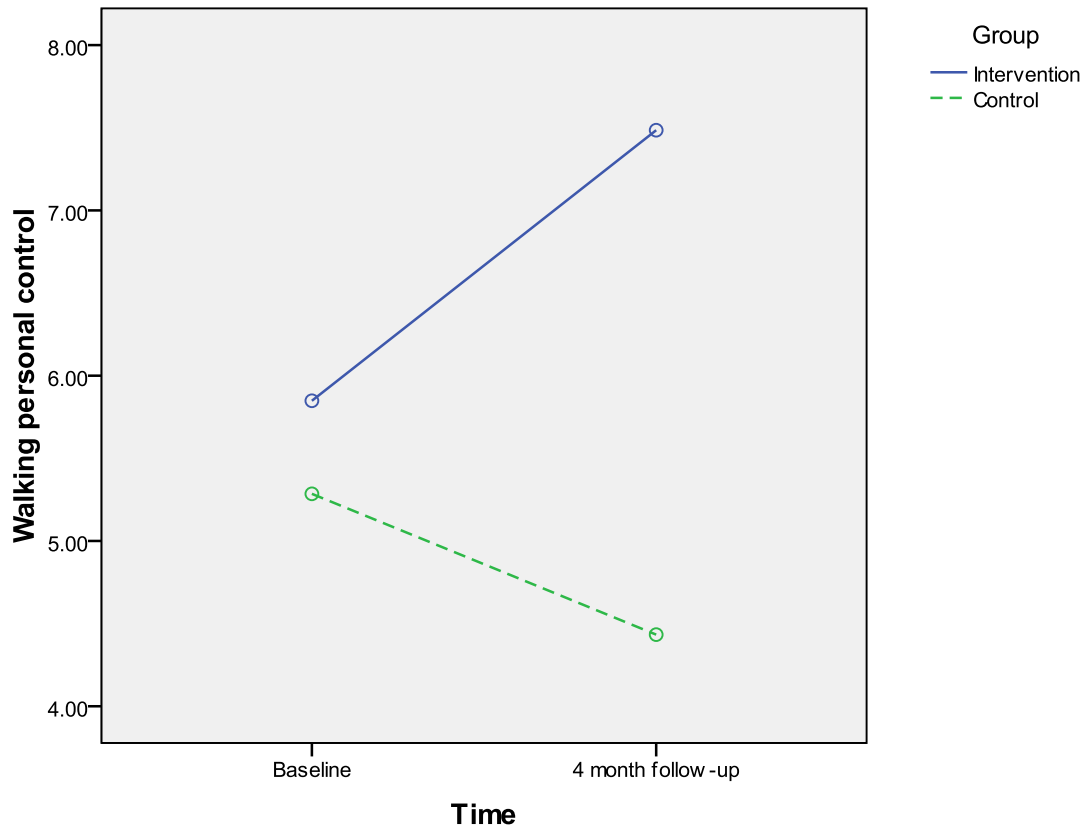


Figure 6.5 Walking personal control at baseline and follow-up

Positive walking consequences

Results for beliefs in positive consequences of walking are shown in Table 6.4 and Figure 6.6. There was a significant group*time interaction effect on beliefs about positive walking consequences, $F(1,57)=7.071$, $p=.010$, partial $\eta^2=.110$. Specifically, although both groups had similar levels of beliefs about the positive consequences of walking at baseline, beliefs in the positive consequences of walking increased significantly from baseline to follow-up in the intervention group, $t(29)=3.131$, $p=.004$, 95% CI .039 to .185; whereas there was a non-significant decrease in beliefs about the positive consequences of walking from baseline to follow-up in the control group.

CHAPTER SIX

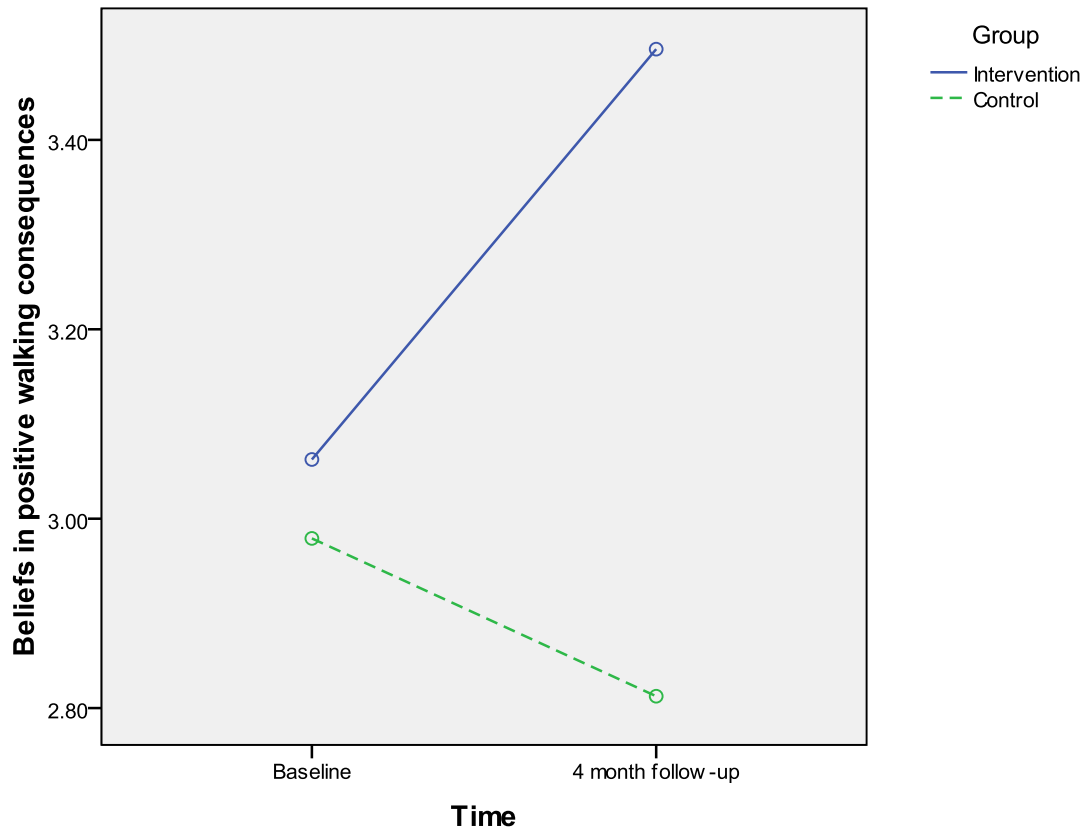


Figure 6.6 Beliefs in positive walking consequences at baseline and follow-up

Negative walking consequences

Results for beliefs about the negative consequences of walking are shown in Table 6.4 and Figure 6.7. There was a significant time*group interaction effect on negative beliefs about walking, $F(1,57)=11.438$, $p=.001$, partial $\eta^2=.167$. Post-hoc analysis revealed that negative beliefs about the consequences of walking decreased significantly from baseline to follow-up in the intervention group $t(29)=-5.463$, $p<.001$, 95% CI $-.117$ to $-.053$; whereas there was a non-significant increase in the negative beliefs about the consequences of walking from baseline to follow-up in the control group.

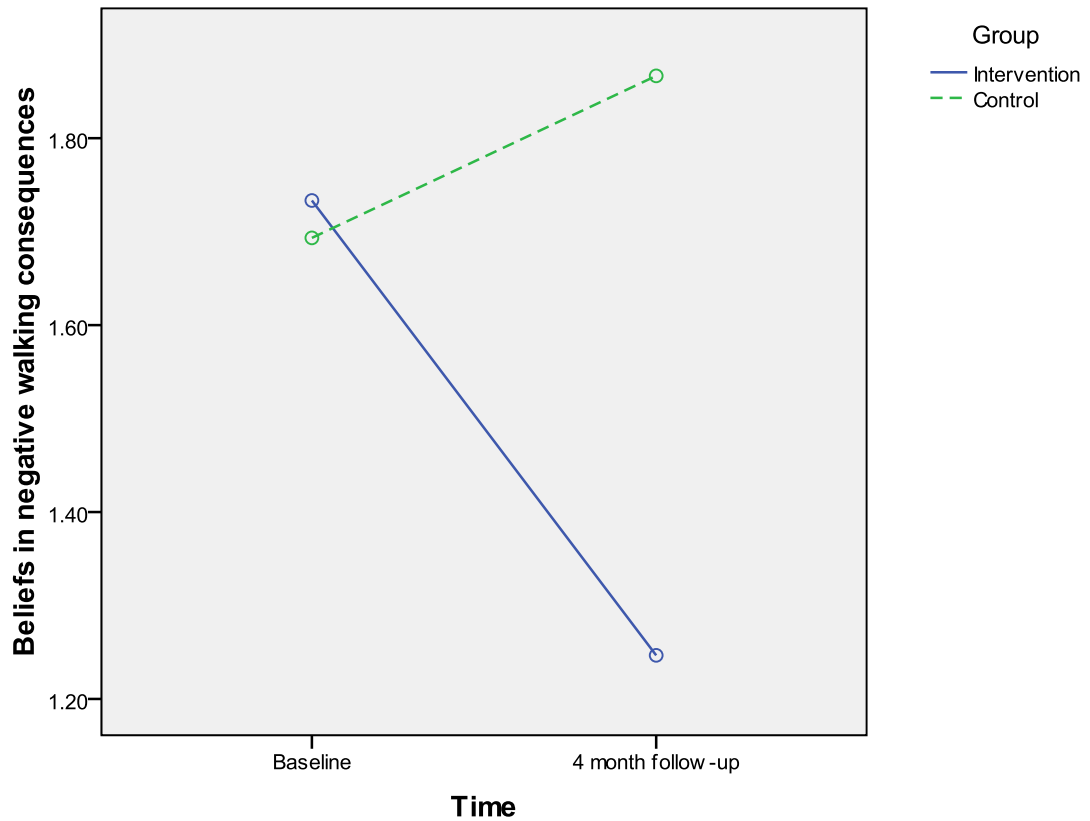


Figure 6.7 Beliefs in negative walking consequences at baseline and follow-up

Intention to walk

Results for intention to walk for at least half an hour at least three times a week are shown in Table 6.4 and Figure 6.8. There was a significant group*time interaction effect on intention to walk, $F(1,57)=8.380$, $p=.005$, partial $\eta^2=.128$. Post-hoc analysis revealed that there was a non-significant rise in intention to walk in the intervention group from baseline to follow-up; there was a significant decrease in intention to walk in the control group from baseline to follow-up $t(29)=-2.885$, $p=.007$, 95% CI $-.355$ to $-.060$.

CHAPTER SIX

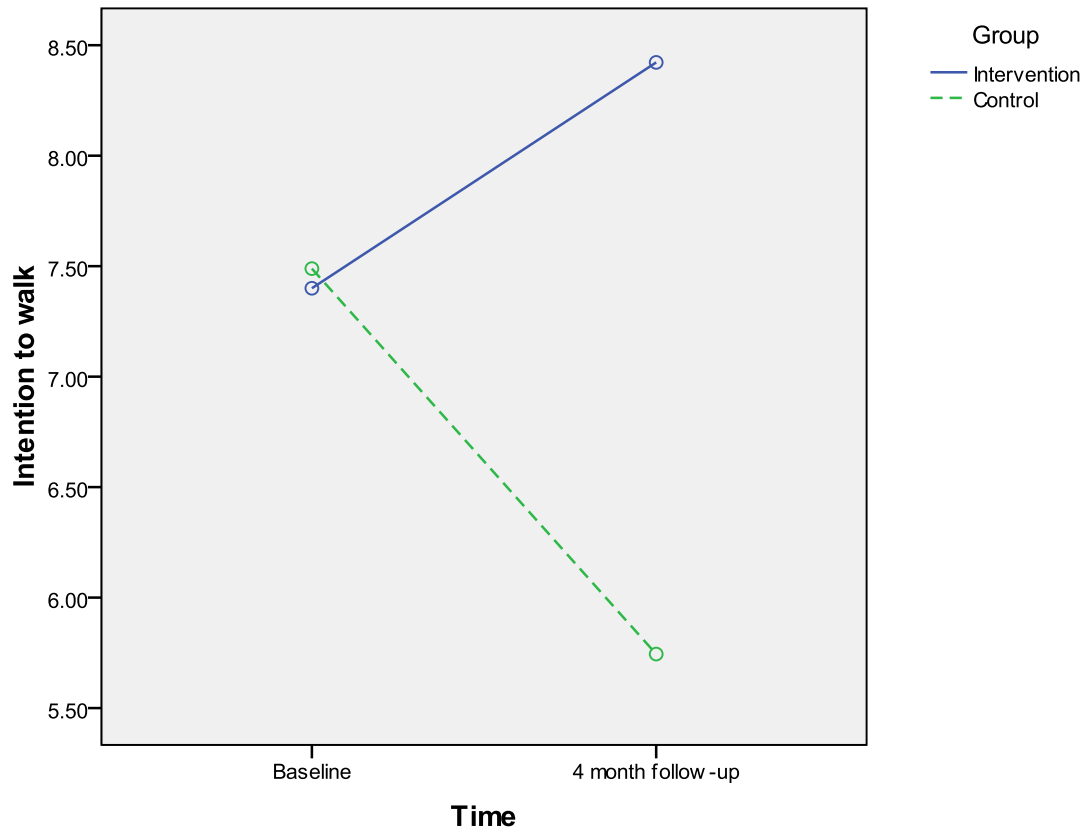


Figure 6.8 Intention to walk at baseline and follow-up

Intention to walk through pain

Results for participants' intention to carry on walking through the pain and only stop walking when the pain is unbearable are shown in Table 6.4 and Figure 6.9. There was a significant time*group interaction effect on intention to walk through the pain, $F(1,57)=6.529$, $p=.013$, partial $\eta^2=.103$. Post-hoc analysis revealed that intention to walk through the pain increased from baseline to follow-up in the intervention group, $t(29)=3.207$, $p=.003$, 95% CI .089 to .404; there was a non-significant decrease in intention to walk through the pain from baseline to follow-up in the control group.

CHAPTER SIX

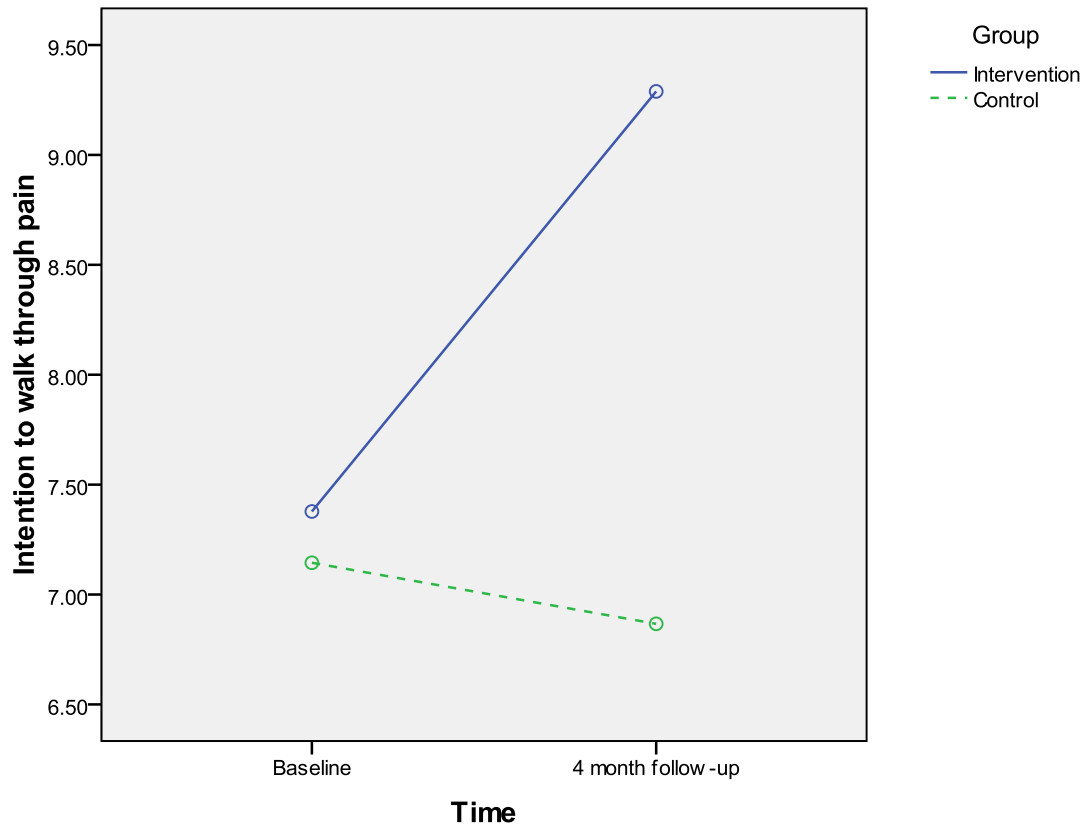


Figure 6.9 Intention to walk through pain at baseline and follow-up

Symptom representations

Results for symptom representations are shown in Table 6.4. Symptom representations data was analysed in a repeated measure ANCOVA with the baseline value of symptom representation variables entered as a covariate and change in the symptom representation over time as the dependent variable, following the analytic methods of Broadbent et al (2009) and Petrie et al (2002) when analysing illness representations.

There was a significant group*time interaction for the personal control symptom representation, $F(1,56)=5.024$, $p=.029$, partial $\eta^2=.082$, such that participants in the

CHAPTER SIX

intervention group had significantly increased personal control from baseline to follow-up, $t(29)=2.358$, $p=.025$, 95% CI .252 to 3.548, whereas the control group did not.

There was a significant group*time interaction for the identity symptom representation, $F(1,56)=5.004$, $p=.029$, partial $\eta^2=.082$, such that participants in the intervention group reported experiencing significantly fewer symptoms from baseline to follow-up, $t(29)=-2.982$, $p=.006$, 95% CI -2.753 to -.513, whereas the control group did not.

There were no significant group*time interactions for the other symptom representations. However, there was a significant within group improvement in the illness comprehensibility symptom representation from baseline to follow-up in the intervention group, $t(29)=3.463$, $p=.002$, 95% CI 1.01 to 3.92; while there was a small non-significant improvement in illness comprehensibility in the control group. There was a significant within group reduction in the emotional effect of IC in the control group from baseline to follow-up, $t(29)=-2.434$, $p=.021$, 95% CI -2.27 to -.20; while there was a non-significant reduction in the emotional effect of IC in the intervention group.

Mediation analysis

A series of regression analyses was conducted to examine mediation effects in a multiple mediator model, following the procedure described in Preacher & Hayes

CHAPTER SIX

(2008). The procedure involves calculating the total effect of an independent variable (IV) on a dependent variable (DV), given as a regression coefficient; the direct effect of an IV on a DV after factoring out the effect of the mediators on the DV, given as a regression coefficient; and then calculating the effect of the mediators on the DV (total effect of IV on DV – direct effect of IV on DV). Mediation is considered to have occurred when the difference between the total and direct effects is significant.

Illness and walking representations as mediators of the group-walking behaviour relationship

In the first model considered, the IV was treatment group; the DV was walking at 4 month follow-up measured by pedometer; and the mediators were the illness and walking representations at 4 month follow-up (ten mediator variables). Baseline measures for all variables were entered as covariates in the model. Bootstrapping techniques were used to estimate the indirect effect of the IV on the DV, based on 5000 bootstrap samples. Bootstrapping is recommended when using small samples in multiple mediator models, as the assumption of normality of the sampling distribution of the total and specific indirect effects may not be met (Preacher & Hayes, 2008).

The results of the mediation analysis show that taken as a complete set, symptom representations and walking representations do not mediate the relationship between group and walking. The total effect of group on walking was .1906, $p=.0012$, and the direct effect of group on walking was .1134, $p=.1608$. The difference between the total and direct effects - the total indirect effect through the ten mediators (7 symptom representations and 3 treatment representations), had a point estimate of -.0772 and

CHAPTER SIX

a 95% bootstrap CI of $-.2874$ to $.1196$ (therefore the difference between the total and the direct effect of group on walking was not different from zero).

Illness and walking representations as mediators of the group-intention to walk relationship

In the second mediation model tested, the IV was group, the mediators were illness and walking representations and the DV was intention to walk. Baseline values for all variables were entered as covariates in the model. The results of the mediation analysis show that symptom representations and walking representations do mediate the relationship between group and intention to walk for at least half an hour at least three times a week. The total effect of group on intention to walk was $.3706$, $p=.0006$, and the direct effect of group on intention to walk was $.1174$, $p=.2508$. The total indirect effect through the ten mediators had a point estimate of $.2532$, and a 95% bootstrap CI of $.0084$ to $.5383$. Examination of the specific indirect effects indicates that only walking personal control was a mediator, 95% bootstrap CI $.0995$ to $.5203$; the 95% bootstrap CI's for all other mediators contain zero. Pairwise contrasts revealed that the indirect effect of walking personal control differed significantly from the indirect effect of the consequences symptom representation, 95% bootstrap CI $-.4872$ to $-.0706$; the timeline symptom representation, 95% bootstrap CI $-.5288$ to $-.1202$; the personal control symptom representation, 95% bootstrap CI $-.5375$ to $-.0751$; the identity symptom representation, 95% bootstrap CI $-.5967$ to $-.1092$; the concern symptom representation, 95% bootstrap CI $-.5076$ to $-.0765$; the illness comprehensibility symptom representation, 95% bootstrap CI $-.5376$ to $-.0997$; and the emotions symptom representations, 95% bootstrap CI $-.5624$ to $-.1025$. Pairwise contrasts revealed that the indirect effect of walking personal control did not

CHAPTER SIX

significantly differ from the indirect effects of beliefs in the positive consequences of walking or beliefs in the negative consequences of walking.

Walking personal control as a sole mediator of the group-intention to walk relationship

Testing the third model, effect of walking personal control as a sole mediator between group and intention to walk, revealed a total effect of group on intention to walk of .3037, $p=.0009$; and a direct effect of group on intention to walk of .0864, $p=.2601$.

The total indirect effect through the mediator, walking personal control, was .2174, 95% bootstrap CI .1121 to .3368. Therefore walking personal control does mediate the relationship between group and intention to walk for at least half an hour at least three times a week.

Illness and walking representations as mediators of the group-intention to walk through the pain relationship

The fourth model tested whether illness and walking representations mediated the relationship between group and intention to walk through the pain. The results of the mediation analysis show that illness and walking representations do not mediate the relationship between group and intention to walk through the pain. The total effect of group on intention to walk through the pain was .2090, $p=.0525$, and the direct effect of group on intention to walk was .1455, $p=.2999$. The total indirect effect through the ten mediators had a point estimate of .0636, 95% bootstrap CI -.2465 to .3984.

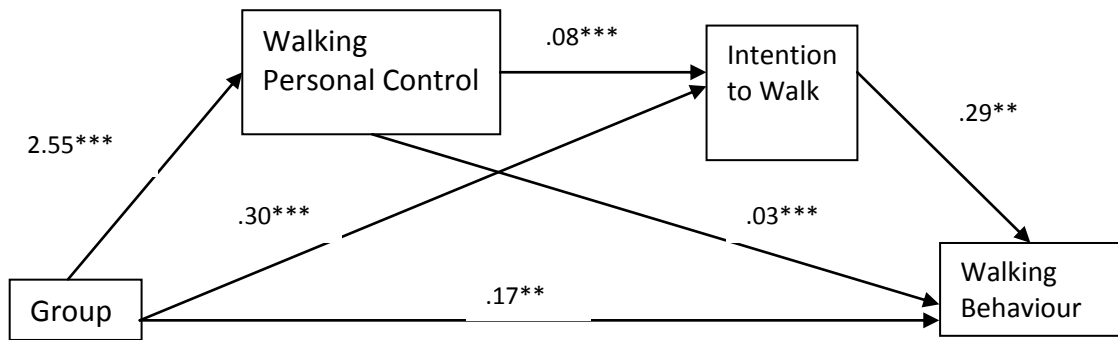
CHAPTER SIX

Intention to walk as a sole mediator of the walking personal control-walking behaviour relationship

The CSM proposes that illness and treatment representations influence coping plans which in turn influence behaviour (Leventhal et al, 1998). Intention to walk was measured as a proximal measure of formation of a coping procedure which involved increasing walking levels, in this study. Therefore, the final mediation model tested whether intention to walk for at least half an hour at least three times a week mediated the relationship between walking personal control (the only representation which significantly mediated the relationship between group and intention to walk) and daily steps as measured by pedometer. The results of the mediation analysis show that intention to walk does mediate this relationship. The total effect of walking personal control on walking was .0338, $p=.003$, and the direct effect of walking personal control on walking was .0100, $p=.3501$. The total indirect effect through the mediator, intention to walk, was .0238, 95% bootstrap CI .0090 to .0436.

As a result of these mediation analyses a mediation model is proposed for this data as shown in Figure 6.10. A two stage model is proposed, in line with the CSM, with walking personal control mediating the relationship between group and intention to walk; and intention to walk mediating the relationship between walking personal control and walking behaviour. Figure 6.10 shows the coefficients for the total effect of each relationship.

CHAPTER SIX



* $p < .05$, ** $p < .01$, *** $p < .001$

Figure 6.10 The mediating effect of walking personal control and intention to walk on the relationship between group and walking behaviour

Evaluation of intervention

Evaluation of the intervention included consideration of the feasibility and acceptability of the intervention, and examination of participant feedback on the intervention.

The intervention was feasible, it was possible to recruit participants at diagnosis, visit them in their own homes, and conduct the intervention over two, one-hour sessions. Participants understood the information about IC and walking, and were able to create action plans to increase walking, with the help of the researcher. Participants were happy to wear a pedometer, and although there were a few instances where the pedometer was lost, these were resolved without any problems, by the participants calling the researcher.

CHAPTER SIX

There was an extremely high retention rate of participants in the study (98.3%) indicating acceptability of the research. One participant dropped out of the intervention group, however the reason she gave for withdrawing from the study was that she had increased her walking, was getting about 'fine' now with little pain, and didn't see the point of seeing the researcher as she was much better.

Participants in the intervention group were asked a series of questions about the acceptability of the intervention at the end of the 4 month follow-up meeting. Of the 29 participants interviewed at follow-up, 25 reported trying to follow the action and coping plan, and 4 reported not following the action and coping plan. Reasons for not following the action and coping plan were – 'walking too painful' (n=2), 'couldn't be bothered' (n=1) and 'I don't like to be pinned down to a plan' (n=1). Both participants who found walking too painful were female, and both had low ABPIs (.57, and .62), although these ABPIs were not significantly different from the overall mean ABPI (.75, sd=.19). All four participants who reported not following the action plan also had a drop in mean daily steps from baseline to follow-up (Mean drop = -433.80, sd = 341.18). Removing these four non-adherers from the overall between group analysis of walking at baseline and follow-up reveals a more significant group*time interaction, $F(1,52)=19.365$, $p<.001$, partial $\eta^2=.271$.

All participants in the intervention group felt that it had been worthwhile to take part in the intervention, reasons given included the extra encouragement and motivation from the intervention, receiving extra information about their illness and about walking, having a personalised plan, being clear on what they needed to do,

CHAPTER SIX

understanding why walking was important and how it would help. Participants reported barriers which they had to overcome in order to follow their action plans including the weather, family members not wanting to walk, and other health problems (e.g. back pain, arthritis and a sprained ankle). Participants reported more use of their action plans than their coping plans. Several participants reported that as they increased their walking, they could see that their leg symptoms were reducing and this provided them with a strong motivation to stick to the action plan. All adherers reported that they intended to continue using their action plan in the future. Table 6.10 provides comments from a selection of participants about their action plans.

Table 6.10 Comments about the action plan by participants in the intervention group

Participant 57	It was worthwhile to take part because it has encouraged me. The doctor said 'keep walking' but I never did. But with this plan I've done it. I like to see the calories I've been burning on the pedometer.
Participant 20	It was an incentive to go out and walk. I liked the sheet (action plan), I passed it around my neighbours.
Participant 32	The action plan is great. It focused what was in my mind and it was in black and white. I made the change because I had to for my health, and then I found that I enjoy it. We're finding brilliant walks in places we've never heard of before. When we're driving about we scan for green signs that indicate country walks. I started to use walking as a tool to try and help my leg, and now we go out as often as we can.

Discussion

This study demonstrates that a brief psychological intervention significantly improves walking in patients with IC when compared to usual care. The intervention also significantly increased the number of participants who carried on walking through pain, and improved dietary behaviour in the intervention group compared to the control group. The intervention group had significant symptomatic improvement, with participants reporting an increase in pain-free walking distance compared to controls. Participants in the intervention group were also 4 times less likely to opt for surgery for symptom management than participants in the control group.

A previous review of walking for IC demonstrated that supervised exercise programmes led to greater symptomatic improvement in the leg than unsupervised exercise programmes (Bendermacher et al, 2006). This is thought to be because of the greater level of intensity of exercise in supervised walking programmes (Bendermacher et al, 2006). However, supervised exercise programmes measure walking *ability* rather than day-to-day walking *behaviour*, and little is known about whether supervised exercise programmes lead to long-term behaviour change beyond the end of the programme. The current study demonstrates that a home-based, unsupervised psychological intervention to increase walking, changes day-to-day walking behaviour, and leads to significant symptomatic improvement.

A further issue with supervised exercise programmes is the high drop-out rate from the programmes, of up to 43% (e.g. Cheetham et al, 2004; Kakkos et al, 2005). The

CHAPTER SIX

current study had a low drop-out rate (1.7%), and high reported adherence to the action plans (86%) indicating that this type of intervention was acceptable to participants.

Although the current study reports an improvement in walking behaviour at 4 month follow-up, it is unknown whether this increase in physical activity levels will be maintained, or have an impact on 5 year mortality risk. However, Gardener et al's (2008) analysis of mortality and physical activity levels in patients with IC indicates that even a small increase in physical activity levels may benefit the health of patients with IC and reduce their mortality risk.

There may be a number of reasons why participants in the intervention group were less likely to opt for surgery than participants in the control group. Participants in the intervention group had increased walking levels and greater pain free walking distance at follow-up, and they may have judged their new level of physical activity sufficient for their needs. Surgery is solely for symptom management and participants in the intervention group may have felt surgery was more risky than symptom management by walking, once they saw that walking did reduce their leg pain. The reduced demand for surgery may also have been due to changes in psychological variables – participants in the intervention group reported higher levels of walking personal control and illness personal control compared to the control group at follow-up. This increased confidence that they could walk and that they were in control of their illness may have reduced their need to be managed surgically.

CHAPTER SIX

The intervention did not significantly improve disease-specific quality of life compared to the control group, although there was a significant improvement in disease-specific quality of life in the intervention group from baseline to follow-up, representing a 35% improvement. The control group also had a non-significant 13% improvement in disease-specific quality of life from baseline to follow-up. This improvement in disease-specific quality of life in the control group may be due to a decrease in anxiety, possibly due to having received a surgical consultation and treatment decision; it may also be due to a reduction in symptoms experienced as a result of decreased walking, as several questions in the ICQ relate to symptoms. Two previous studies of supervised exercise therapy for IC have used the ICQ as an outcome measure of quality of life (Cheetham et al, 2004; Kakkos et al, 2005). Cheetham et al (2004) found a 43% improvement in quality of life in the exercise group at 6 months, compared to a 16% improvement in quality of life in the exercise advice alone group. The exercise group received exercise advice plus weekly exercise classes and motivation classes. Kakkos et al (2005) compared exercise advice with supervised treadmill walking three times a week for six months, and found a 17% improvement in quality of life in the supervised exercise group compared to no change in the advice alone group at 6 months. Neither of these studies had a usual care control group, and the sample size in the Kakkos et al (2005) study was small (n=21). However, they do show that the improvement in disease-specific quality of life in the current study was greater than improvements due to advice alone, indicating that the intervention in the current study did more than simply providing information on the benefits of walking.

CHAPTER SIX

There was a significant improvement in general quality of life in the intervention group compared to the control group, with the intervention group reporting no change in general quality of life at the first phone call (6 weeks), but then an increase in general quality of life at the second phone call (12 weeks) and again at the 4 month follow-up. The timing of the improvement in general quality of life gives some indication of the length of time it takes for patients to maintain increased walking levels before they notice the benefits. This is important information to feed back to patients to ensure they have realistic expectations of outcome.

The intervention was based on the Leventhal et al's (1998) CSM and aimed to modify participants' illness and walking representations. Changes in psychological variables from baseline to follow-up indicate that the intervention did change participants' illness and walking representations. In terms of treatment representations, the intervention significantly increased walking personal control and beliefs in the positive consequences of walking, and significantly decreased beliefs in the negative consequences of walking compared to usual care. In terms of symptom representations, the intervention significantly increased illness personal control and decreased illness identity compared to usual care.

The CSM proposes that an individual forms illness representations about a health threat which influence the efforts the individual makes to cope with the health threat. Modifying the illness and treatment representations of participants in the intervention group should therefore lead to changes in the way participants intend to cope with the health threat. Intention to cope with IC by walking, was measured in this study by

CHAPTER SIX

questions about intention to walk and intention to walk through the pain. Participants in the intervention group had significantly higher intention to walk for at least half an hour three times a week, and significantly higher intention to walk to maximal pain before stopping for a rest than control group participants at follow-up.

Mediation analysis indicated a possible two stage model, with walking personal control mediating the relationship between group and intention to walk, and intention to walk mediating the relationship between walking personal control and walking behaviour. However, this is a very tentative analysis, and the results of all the mediation analyses should be interpreted with caution. Mediation analysis with ten mediators would require a large sample of data to have sufficient power to reduce the risk of Type II error. A sample size of 60 will have had low power in these analyses. In addition, the mediators will be influenced by group and will therefore be highly correlated with the IV - this will have resulted in poor precision in estimation of the coefficients and may have increased the risk of Type I error. Also the follow-up data was all gathered at one time point, making it impossible to draw conclusions about the direction of effect. A larger sample and further follow-ups would help to shed light on the mediation analysis.

Limitations

There are a number of possible limitations to this study. Firstly, the intervention group spent more time overall with the researcher than the control group (approximately 110 mins), including one extra visit from the researcher. This extra interaction with the

CHAPTER SIX

researcher may have led to social contact effects in the intervention group. Analysis of data for the intervention group indicated no significant association between contact time with the researcher and improvement in walking, however, future research should include a control group with the same amount of researcher contact as the intervention group to properly control for social contact effects.

The current study used a number of measures which specify the ideal walking behaviour of patients with IC (walking for at least half an hour, at least three times a week), and used pedometers to measure physical activity, therefore it is possible that participants in this study may also have been affected by measurement reactivity. In a recent review of reactivity of measurement in health psychology, French & Sutton (2010) concluded that measurement reactivity may affect self-report measures of walking but does not seem to affect objectively measured physical activity. As the control group in the present study was measured in the same way as the intervention group, any measurement reactivity would have caused a systematic change to results in both groups, rather than a treatment group bias.

Pedometers were used at baseline and follow-up to measure daily walking. The screens of the pedometers were not covered, which means that participants' walking behaviour could have been affected by feedback from pedometer readings. This could have affected the two groups differentially, as the intervention group were aware they should be increasing their walking levels due to the action planning session. However, although providing feedback on performance is a recognised behaviour change technique (Abraham & Michie, 2008), pedometers were only used in the first and last

CHAPTER SIX

weeks of the study. Participants did not know which group they were in during the first week of wearing pedometers, therefore pedometer use should not have caused a bias between the groups at this time point. The intervention group showed changes in pain-free walking distance and general quality of life during the 6 and 12 week telephone calls, which confirms that they had increased walking behaviour prior to 4 month follow-up.

Kinmonth et al (2008) suggested that improvement in control group physical activity levels in their study may have been due to measurement reactivity, with all participants in the study increasing their physical activity levels because it was being measured. As there were several measures in the current study which specified desired walking behaviour and focused on walking, it is possible that either control group participants would also increase their walking, or that they would self-report an increase in walking at follow-up. As there was a significant drop in mean daily steps in the control group from baseline to follow-up it seems that control group participants did not actually increase their walking levels as a result of measurement, or may have initially increased walking levels but did not maintain this increase to follow-up. The self-report IPAQ results of physical activity were not as sensitive to changes in physical activity between the two groups as the pedometer data, although the IPAQ scores showed a similar decrease in physical activity in the control group over time, and an increase in physical activity in the intervention group. Despite having been used as the primary measure of physical activity in another intervention to increase walking in patients with IC (Pochstein & Wegner, 2010), the IPAQ is not particularly suitable for use with patients with IC because it asks the participants to judge the amount of time

CHAPTER SIX

they spent walking for at least ten minutes at a time. As many participants with IC can barely manage to walk for ten minutes at a time, there is the potential for floor effects with this scale. Also, as many patients with IC stop for a rest whenever they experience leg pain, it is difficult for them to judge how much time they actually spend walking e.g. they may be out of the house walking the dog for 20 minutes but only actually walk for 12 minutes of that time.

A further limitation of this study was that fidelity checks of the intervention were not carried out. However, all participants in the intervention group received the same information sheet about IC from the researcher, and the topics discussed and questions asked in both sessions was guided by detailed proformas. All sessions were conducted by the same researcher which will also have increased the fidelity of the intervention.

That said, using a single researcher to conduct the intervention can also be seen as a limitation of the study, as it is impossible to determine whether it was the intervention itself or a therapist effect of that particular researcher which led to changes in the intervention group. This is a pilot study, however future studies should include more than one therapist to enable comparison of effect between therapists.

The researcher conducting this trial was not blinded to group allocation. This was inevitable in this study, as the study formed part of a body of PhD research, was not funded, and was conducted by a single researcher. However, non-blinded assessment introduces the risk of conscious and un-conscious bias into the trial. The researcher

CHAPTER SIX

knew group allocation at baseline, and may have treated participants in the two groups differently; the researcher may also have asked questions differently when completing questionnaire measures. The researcher tried to minimise the risk of bias due to lack of blinding by following the exact wording of questionnaires, however, any future trial should be blinded, with different researchers delivering the intervention and gathering measurements.

This was a single-centre RCT and therefore results describing the uptake of revascularisation are specific to the NHS Board in which the research took place. The practice in this NHS Board is to offer revascularisation if the patient is sufficiently fit, and the location of the narrowing of the artery is amenable to surgical intervention. Other NHS Boards have different practices, offering e.g. supervised exercise programmes, angioplasty alone, exercise advice alone, or pharmacological management of symptoms, suggesting the study should be replicated in other NHS areas with different approaches to IC management.

This trial demonstrated initiation of behaviour change at 4 month follow-up. However, further follow-ups would be necessary to determine whether behaviour change is maintained in the long-run, and whether these changes lead to improved general health.

Summary and implications

This is the first study to use a brief psychological intervention based on the CSM to increase walking in patients with IC. The intervention is patient-centred, can be tailored to the specific needs of each individual, and has directly measured behaviour change as the primary outcome. Usual care for patients with IC usually involves either supervised exercise programmes or revascularisation for symptom management. Neither of the current treatment options are ideal – supervised exercise programmes are not widely available, require a large time and effort commitment from patients and have high drop-out rates; surgery is inherently risky for the patient, and is expensive for the NHS. A brief psychological intervention which increases walking and reduces leg pain symptoms may therefore provide a cheaper, safer and more accessible means of treatment of patients with IC.

The exclusion criteria for the RCT were not conservative, and no differences were found between participants and patients who did not agree to participate. There was also a very low drop-out rate from the study. Therefore, although this was a pilot RCT with a small sample size, the results provide preliminary evidence that a two hour psychological intervention delivered over two sessions in the participant's own home can increase intention to walk and day to day walking behaviour.

Further research should examine the effectiveness of the intervention in a multi-centre RCT, using a greater number of therapists to deliver the intervention, including nursing staff. A health economic evaluation should also be central to any further large-

CHAPTER SIX

scale trial of this intervention. Finally, dosage effects (length of intervention) and delivery effects (face-to-face, DVD or computer aided) should be considered in future studies.

CHAPTER SEVEN

GENERAL DISCUSSION

Overview

This final chapter aims to summarise the findings of the studies described in this thesis, considering theoretical implications of the research. Limitations of the thesis are discussed, with suggestions for possible directions for further research. What these findings add to the body of knowledge about PAD is then highlighted.

Summary of findings

The aim of this thesis was to explore the relationship between beliefs about PAD and health behaviour within the framework of the CSM. To this end, the three studies that comprise this thesis had the following aims (i) to qualitatively explore the relationship between the walking behaviour of patients with IC, and their illness and treatment representations; (ii) to model key psychological constructs with walking behaviour in a cohort of IC patients; (iii) to modify illness and treatment representations in order to change walking behaviour in a sample of patients newly diagnosed with IC. The findings of this research with regard to each of these aims is summarised below.

The relationship between walking behaviour and illness and treatment representations

The results of this thesis indicate that many patients with IC have dysfunctional illness and treatment representations of PAD, and that patients who had received revascularisation to treat symptoms of PAD did not tend to change health behaviours

CHAPTER SEVEN

as a result of diagnosis or treatment of IC (Chapter 3). Patients who had received revascularisation reported a high number of ongoing leg symptoms, which affected their hobbies, social life and general physical activity. Symptom control was achieved by avoiding walking and walking at a slow pace. Participants were largely unaware of the causes of the disease, or of their increased risk of future cardiovascular health problems. Participants believed they had an acute condition, curable with surgical intervention, rather than a long-term chronic condition which they could self-manage. Participants appeared to lack knowledge of how they could self-manage their condition.

Modelling key psychological constructs with walking behaviour

Findings from the cross-sectional questionnaire (Chapter 5) confirmed the results of the qualitative analysis in Chapter 3. Despite revascularisation treatment, the majority of participants reported leg pain when walking, and of those, the majority did not meet recommended minimum walking levels. Psychological constructs based on the CSM were strongly associated with both walking behaviour and health-related quality of life in patients with IC. Symptom and walking representations as a set were strong predictors of both walking behaviour and health-related quality of life. Walking personal control was found to be a particularly important predictor of walking behaviour and health-related quality of life.

Modifying illness and treatment representations in order to change walking behaviour

Results from the randomised controlled trial of the brief psychological intervention designed to modify illness and walking representations in patients newly diagnosed with IC (Chapter 6), showed that the intervention improved both walking behaviour and quality of life. Daily steps increased significantly over time in the intervention group, compared to a significant decrease in daily steps over time in the control group. The number of participants in the intervention group who walked through pain increased over time, as did the number of participants in the intervention group who met the minimum recommended walking levels, compared to those in the control group. Participants in the intervention group also reported an increase in pain-free walking distance over time. Participants in the control group were 4 times more likely to opt for surgery at the 3 month vascular outpatient clinic than participants in the intervention group. Most psychological variables improved significantly in the intervention group from baseline to follow-up, in comparison to the control group – walking personal control, positive walking consequences, negative walking consequences, intention to walk, intention to walk through the pain, symptom personal control and symptom identity changed as a result of intervention. The high (98.3%) retention rate in the trial, along with positive participant feedback, indicated that the intervention was acceptable. Self-reported adherence to the intervention was also high (86%) again indicating acceptability of the intervention.

Theoretical implications

Leventhal et al's (1998) CSM provided the underlying theoretical framework for this thesis. The CSM proposes that an individual's illness and treatment representations will influence the actions they undertake to cope with illness and return to a normal health state. Leventhal et al (1998) proposed that illness and treatment representations have similar content including an identity, timeline, beliefs about cause, consequences, and cure/control.

Coherence between an individual's illness representation and their representation of possible treatment is thought to be a key issue in self-regulation (Leventhal et al, 2008). Weinman et al (2000) found that when patients did not have congruence between their illness and treatment representations, they did not undertake that treatment. The intervention in this thesis was designed to modify illness and walking (treatment) representations, based on findings from the qualitative and cross-sectional studies. A goal of the intervention was to increase congruence between participants' representations of the illness, and their beliefs about walking. The intervention was therefore designed to elicit illness representations, and walking representations, and to modify dysfunctional representations by providing information about the behaviour-health link and providing information on the consequences of the illness and of low levels of walking. The success of the intervention in terms of its impact on walking behaviour and quality of life, lends support to the CSM.

CHAPTER SEVEN

Illness representations

The importance of illness representations to the walking behaviour and quality of life of patients with IC emerged in the qualitative study, and was confirmed in the cross-sectional study in this thesis. In the qualitative study, patients with IC were found to have dysfunctional illness representations in terms of the causes and consequences of IC. They tended to believe that treatment for IC was under the control of medical staff, rather than themselves; and they tended to view the disease as an acute symptom which could be cured by revascularisation, rather than a chronic condition to be managed. Symptom representations were found to significantly add to the predictive value of walking representations in predicting whether or not participants would meet minimum recommended walking levels. Symptom representations were also found to explain a significant proportion of health-related quality of life in patients with IC. The intervention aimed to modify illness representations by eliciting causal beliefs from participants and providing information about the true causes of PAD, providing information on the consequences of PAD, and increasing participants' understanding of what they could do to control their condition (walking).

Symptom representations were measured in the cross-sectional study and the trial with the Brief IPQ (Broadbent et al, 2006). Significant improvements in personal control and identity were found in the intervention group compared to the control group over time. The increase in personal control possibly reflects an increase in participants' understanding that there are treatment options (walking) which they can undertake to control the symptoms of IC. The significant reduction in identity score

CHAPTER SEVEN

over time in the intervention group reflects a reduction in leg pain symptoms as a result of increased walking.

There were no significant group*time interactions for the other symptom representations (consequences, timeline, concern, illness comprehensibility, emotional effect), although there was a significant within group improvement in illness comprehensibility over time in the intervention group. The lack of significant results in the other symptom representations could be interpreted in a number of ways (i) the intervention did not modify the other symptom representations; (ii) the scale used to measure symptom representations was not sensitive enough to detect change; (iii) the scale used to measure symptom representations did not measure the same representations that were changed by the intervention. Observations from the questionnaire sessions suggest that participants struggled to interpret and answer some of the questions in the Brief IPQ. For example, baseline data was gathered one week after diagnosis with PAD, and participants struggled to answer the timeline question 'How long do you think the intermittent claudication will continue?', frequently commenting that they had 'absolutely no idea'. Also, participants' frame of reference changed over time, possibly changing the meaning ascribed to numbers on the 0 to 10 response scale. Participants' comments when answering Brief IPQ questions indicated that they were taking different things into account when answering the questions at each timepoint, e.g. 'How much does the intermittent claudication affect your life?' was frequently answered in terms of pain at baseline, but was often answered in terms of time - 'I have to get out and walk, so I'm very busy', or surgery - 'I'm going in to hospital, and then I don't know what affect it will

CHAPTER SEVEN

have', at 4 month follow-up. This suggests that while the numbers that participants gave in answer to Brief IPQ questions may not have changed dramatically over time or between groups, the scale may not have captured the complex cognitive symptom representations of participants. This is important as it is these complex cognitive representations, and their congruence with treatment representations which determine coping actions. Leventhal et al (2010) suggests that IPQ instruments may not capture the perceptual-behavioural level of representations. This is a disadvantage common to most survey instruments used in Health Psychology, but is possibly more of a problem when attempting to measure multi-factorial illness cognitions, than specific behavioural beliefs.

In a recent randomised controlled trial to modify illness perceptions of patients following a myocardial infarction, Broadbent et al (2009) measured illness representations using the Brief IPQ and only found a significant group*time interaction for one illness representation – illness comprehensibility. In a very similar intervention with a similar patient group, Petrie et al (2002) measured illness representations using the IPQ (Weinman et al, 1996) and found significant group*time interactions for several illness representations – consequences, timeline, control/cure and symptom distress. The IPQ is a longer scale which asks several specific questions about illness perceptions, it includes 50 questions about illness beliefs plus detailed cause and identity sub-scales. A further illness perception questionnaire, the IPQ-R (Moss-Morris et al, 2002) was developed to measure emotional representations and illness coherence along with illness representations. The IPQ-R has 38 questions plus cause and identity sub-scales. It would have been interesting to measure participant

CHAPTER SEVEN

illness representations with the IPQ-R in this thesis, however, the questionnaire used in this thesis was already very long, and the need for detailed measurement had to be balanced with the need to retain participant commitment to the study. A shorter questionnaire was therefore judged to be more appropriate for use in the studies in this thesis.

Finally, it was decided to measure symptom, rather than illness representations in the studies in Chapter 5 and 6, as it emerged from the qualitative study in Chapter 3 that participants did not have a clear understanding of their illness, Peripheral Arterial Disease, and were very focused on their symptom, Intermittent Claudication. It would be interesting in future research to measure participants' symptom and illness representations as separate constructs. This is especially important in terms of measuring outcomes from a trial of the intervention, as the intervention is designed to modify both illness and symptom representations.

Walking representations

The intervention aimed to change participants' walking representations by firstly introducing the idea of walking as a possible treatment of PAD (identity), and then giving information about the benefits of walking to health in general, and specifically giving information about how walking could help to improve symptoms of IC (causal mechanism). Beliefs in the positive consequences of walking increased significantly, and beliefs in the negative consequences of walking decreased significantly in the

CHAPTER SEVEN

intervention group compared to the control group over time, indicating that the intervention did successfully modify walking (consequences) representations.

The intervention aimed to make participants aware of the temporal issues related to walking for IC (timeline), including the amount of walking recommended to achieve symptomatic improvement (dosage) and the length of time increased walking would have to be maintained before an effect was evident (response to treatment). It was an important part of the intervention to set participants' expectations about the length of time it would take for leg symptoms to reduce as a result of increased walking (around six weeks) as this delay between behaviour and positive feedback may affect motivation to perform the behaviour. Leventhal et al (2010) suggest that while illness and treatment representations 'create the context for management', change in an individual's behaviour is dependent on the creation of an action plan to change that behaviour. Therefore, temporal issues related to walking were addressed in both parts of the intervention, in Session One by giving information about the behaviour, and in Session Two, by embedding temporal issues into the action plan.

The intervention aimed to increase participants' sense of walking control, or self-efficacy by altering the participants' interpretation of physiological signals.

Participants in the intervention group were given information that leg pain as a result of IC would not harm them, and were encouraged to re-frame their interpretation of walking while in pain as something which could be beneficial to them – through the growth of a collateral blood supply. Bandura (1977) suggests that four factors influence self-efficacy – performance accomplishments, vicarious experience, verbal

CHAPTER SEVEN

persuasion and physiological states. The intervention aimed to change participants' interpretation of pain (physiological state) and provided verbal persuasion to increase walking. Mastery of particular steps in the action plan would also lead to feelings of performance accomplishment. Walking personal control increased significantly in the intervention group compared to the control group over time, and was the only psychological variable which emerged as a significant mediator between group and intention to walk. The importance of walking personal control in the walking behaviour of patients with IC was also highlighted in findings from the qualitative and cross-sectional studies.

Intention

The intervention was designed to change attitudes and intentions towards two distinct behaviours: (i) walking for at least half an hour at least three times a week; (ii) walking until the pain is nearly unbearable before stopping for a rest. Intention to perform each of these behaviours was measured as an indicator of the individual's readiness to act, and as a measure of the individual having made a decision to act. Leventhal et al (2008, p.488) state that 'intentions...are at home in any theory that conceptualizes action readiness at implicit and explicit levels.' The results from the randomised controlled trial show a significant change in intention to perform both behaviours in the intervention group compared to the control group. Interestingly, the significant interaction in intention to walk for at least half an hour three times a week consisted of a non-significant increase in intention to walk in the intervention group, and a significant decline in intention to walk in the control group. The findings from

CHAPTER SEVEN

the qualitative study indicated that participants had a medical model of their illness, believing that the management and outcomes of their disease were controlled by the surgeons, and as a result not taking steps to alter their own health behaviours. This may explain the significant decline in intention to walk among control group participants in the trial – they may have had a decline in intention to walk because they believed that the medical system would cure/control their disease, rather than their own actions (walking) controlling or curing their disease. Participants in the intervention group had a significantly greater intention to walk than participants in the control group suggesting that the intervention had counter-acted beliefs in the medical model of PAD, and increased beliefs in walking as an appropriate behaviour to manage the disease.

Implications for clinical practice

Existing treatment to reduce the symptoms of IC involves drug therapy, exercise, percutaneous transluminal angioplasty and bypass surgery (Cassar, 2006). Exercise treatment usually takes the form of advice to exercise (Shalhoub et al, 2009), however supervised exercise programmes are recommended because of the impact they have on walking *capability* (Bendermacher et al, 2006). Unsupervised exercise advice has been criticised for failing to address the barriers to walking faced by patients with IC (Stewart & Lamont, 2007). At present in the UK, supervised exercise programmes for IC are relatively uncommon (Shalhoub et al, 2009), have limited capacity, are dependent on patients' regular attendance, and may not lead to *behaviour* change. The findings from the qualitative and cross-sectional studies in this thesis show that

CHAPTER SEVEN

psychological variables, based on the CSM are strong predictors of walking behaviour in patients with IC. The brief psychological intervention which was tested in this thesis, was designed to modify these psychological variables, and could provide an alternative or supplementary exercise treatment. It was designed to overcome many of the barriers to walking identified by Stewart & Lamont (2007) and Galea et al (2008), and achieved a significant improvement in walking behaviour and significant symptom reduction in the intervention group. These improvements are not only statistically significant, they are also clinically significant as evidenced by the smaller number of participants who opted for surgery in the intervention group compared to the control group.

This thesis researched the outcomes of revascularisation treatment for patients with IC, studying outcomes of both angioplasty and surgery. SIGN (2006, p.18) guidelines state 'endovascular and surgical intervention are not recommended for the majority of patients with intermittent claudication.' However, rates of angioplasty to treat IC have increased in recent years (Vogel et al, 2007). This thesis has demonstrated in both the qualitative and cross-sectional studies, that many patients still experience high levels of symptoms in their legs after receiving revascularisation, which has an ongoing impact on their levels of physical activity and quality of life. In addition, many patients with IC report a continuing need for some level of care or support, despite having received revascularisation. These findings indicate that current measurement of outcomes following revascularisation may not adequately capture the experience of patients with IC post-revascularisation.

CHAPTER SEVEN

Many participants did not understand the causes or health consequences of PAD, did not recall receiving specific advice from medical staff about walking, and found communication with vascular surgical staff complicated. Collins et al (2006) found poor doctor-patient communication an issue for patients with IC, and suggested that improving patient-physician communication may be an important factor in increasing the exercise behaviour of patients with PAD. Participants in the studies in this thesis tended to have a medical model of their illness, and viewed surgical staff as having the power to cure the illness, rather than the illness being a chronic condition which could be managed with changes in health behaviour. This finding mirrors other studies into patients with IC (Gibson & Kenrick, 1998; Leavitt, 1990). These findings suggest that the current system in the NHS, of diagnosing and treating patients within a specialist surgical clinic leads patients to a surgical view of their illness, and possibly reduces their willingness to engage in self-care activities. A different structure of services in the NHS for diagnosing and treating individuals with PAD, with less focus on surgical and endovascular treatment of IC may lead to greater levels of behaviour change in IC patients. This would be a worthwhile area for future research.

Key drivers of the NHSScotland Healthcare Quality Strategy include person-centredness and clinical effectiveness; and priority areas for action within the strategy include supporting staff and patients in shared decision-making, informing and supporting patients to manage ill-health, and increasing the focus on preventative and anticipatory care and intervention (NHSScotland, 2010). These healthcare concepts also translate to other healthcare regions in the UK. The findings from this thesis begin to address these quality ambitions for patients with IC. The intervention is patient-

CHAPTER SEVEN

centred, can be tailored to the specific needs of each individual, and is capable of being delivered by trained non-specialist health workers in an NHS setting.

Limitations

The main limitations of this thesis are that all the studies were conducted in a single NHS centre, and that a single researcher designed and delivered the intervention and analysed the results. This reduces the generalisability of findings from the studies in this thesis. However, wherever possible, findings have been compared to other studies conducted with patients with PAD or with IC. There has been a high level of congruence between the findings about the beliefs and behaviour of patients with IC in this thesis, and the conclusions drawn from other research with patients from the same disease population.

A further limitation of this thesis was that the intervention was designed to be delivered to patients newly diagnosed with IC, based on the results of the qualitative and cross-sectional studies which had samples of patients who had been diagnosed a long time ago, and many of whom had received revascularisation. Ideally, the qualitative and cross-sectional studies conducted in this thesis would have had samples of patients newly diagnosed with IC; or the intervention would have been designed to modify the beliefs and behaviours of patients post-revascularisation. The time constraints of the PhD meant that the rate of recruitment of people at diagnosis into the qualitative and cross-sectional studies would have been too slow to analyse results in time to then design and deliver an intervention. The intervention was

CHAPTER SEVEN

designed to modify the illness and walking representations of patients at diagnosis, because it was evident as a result of the qualitative study that patients have a very medical model of their illness post-revascularisation which affects their attitude towards self-management of their disease. Therefore, a pragmatic decision was taken to design the intervention for patients at diagnosis, to alter their illness and walking representations before their thinking became embedded in a medical model.

Another limitation of this research was the power of the statistical analyses in the cross-sectional study (Chapter 5) and the mediation analysis (Chapter 6). The sample size of the cross-sectional study was affected by both a low response rate to the questionnaire, and the division of the sample into two groups to reflect the presence or absence of claudication symptoms. The resulting low sample size meant that the statistical analyses conducted in the study had low power, increasing the risk of Type II error. While the overall regressions had significant results, it is possible that some psychological variables were not identified as significant predictors in the regression analyses due to low power. Further, the mediation analysis conducted to identify significant process variables in the intervention study, only identified walking personal control as a significant mediator between group and intention to walk. Again, this may be due to the small sample size and resulting low power of this mediation analysis. This was a pilot trial, however, the sample size of any future trial to test the brief psychological intervention should be sufficiently powered to conduct the mediation analysis with confidence.

Direction for future research

This thesis has highlighted a number of issues in the study of PAD which warrant further research.

This thesis has presented initial findings from a pilot randomised controlled trial to modify illness and walking representations and increase walking behaviour in patients with IC. While the initial results from this trial are very positive, further research could:

- test whether behaviour change is maintained over a longer time period by following participants up at 1 year and 2 years;
- test whether quality of life is improved in the longer term in the intervention group;
- test whether the intervention reduces the surgical intervention rate in the longer term;
- test whether participation in the intervention improves surgical outcomes (e.g. walking behaviour and quality of life post-surgery) for participants who go on to have surgery.

The pilot trial presented in this thesis was conducted in a single NHS centre, and the intervention was delivered by one therapist, who also analysed results. These factors reduce the generalisability of the research therefore a larger, blinded, multi-centre trial of the intervention could be conducted in future to test whether the results from the successful pilot can be replicated. Several nurses could be trained to deliver the intervention to participants. This would provide valuable information about the

CHAPTER SEVEN

feasibility of translating the intervention into the general healthcare system. In addition, dosage effects (length of intervention) and delivery effects (face-to-face, DVD or computer-aided) could be considered in future trials.

Treatment for IC should both reduce the symptoms of claudication, and improve cardiovascular health. Future research could consider whether the brief psychological intervention improves the cardiovascular fitness of participants, and whether it impacts on cardiovascular morbidity and mortality.

The pilot trial presented in this thesis compared a brief psychological intervention to usual care. Further research could compare the brief psychological intervention to supervised exercise programmes, to explore how each treatment changes walking capability and walking behaviour, and to compare the acceptability to patients of each type of treatment.

Any future comparison of the brief psychological intervention described in this thesis to either usual care, or to supervised exercise should include a full health economic analysis, to consider whether the intervention represents a cost-effective use of NHS resources.

This intervention measured day-to-day walking behaviour with a pedometer.

Pedometers were found to be acceptable to participants. However, pedometers only give an overall daily step count, and provide no more detailed information about e.g. length of time sitting, and type of walking behaviour. The recommended minimum

CHAPTER SEVEN

walking levels for patients with IC are to walk for at least half an hour three times a week, and to continue walking into the pain until it is almost unbearable before stopping for a rest. Future studies into the walking behaviour of patients with IC could use a more sophisticated measurement device to give information about the pattern of walking activity within the day. Analysis could compare this activity to the action plans set in the intervention.

An unexpected finding in this thesis was the large number of patients with IC who reported requiring some level of care because of their health. Further research could confirm this finding, and explore the nature of the care required by patients with IC.

This thesis suggests that the current procedure within the NHS, of diagnosing and treating patients with IC in surgical clinics, leads patients to have a medical model of their illness. Further research could explore this issue in more detail, and test whether alternative structures have a different impact on the illness representations of patients with IC. In addition, further research could design and test an intervention to modify the illness and walking representations of IC patients who are already 'in the system', and who have already received surgical or endovascular treatment for IC.

This thesis questioned the sensitivity of the Brief IPQ for measuring the symptom representations of patients with IC. Further research could look into alternative measurements of illness representations for patients with IC, for example using longer questionnaires like the IPQ-R, or using open questions to elicit more detailed responses from participants about their illness perceptions. In addition, questions

CHAPTER SEVEN

were designed in this thesis to capture participants' walking consequences, and walking personal control representations. Further work could validate these questions, and develop further questions to measure all walking representations of patients with IC (cause, timeline and identity).

Finally, the mediation analysis in the trial was tentative, due to small sample size and follow-up data being gathered at one time point. Future research could measure changes in psychological variables and behaviour at a number of time points to measure how changes in psychological variables change behaviour, and vice-versa. This could be modelled in a large trial with multiple follow-up points. Multiple follow-ups would also enable analysis of measurement reactivity effects, where participants were randomly allocated to groups with different numbers of follow-up sessions (van Sluijs, 2005). Alternatively a series of n of 1 trials could be analysed using time-series analysis to tease apart the dynamic relationship between illness and walking representations and walking behaviour.

What does this thesis add?

1. A brief psychological intervention to modify illness and walking representations increases the daily walking behaviour of patients newly diagnosed with IC.
2. Patients receiving usual care were 4 times more likely to opt for surgical or endovascular intervention to treat leg pain, than patients who received the brief psychological intervention.

CHAPTER SEVEN

3. Illness and walking representations accurately predict adherence to minimum recommended walking guidelines in patients with IC.
4. This thesis was the first to use the CSM to understand the beliefs and health behaviours of patients with PAD.
5. This thesis was the first to explore the treatment representations of the CSM in a context other than medication taking, and demonstrated that treatment representations add to the usefulness of the CSM as a model to understand health and illness behaviour.

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Appendix 1: Example of letter of invitation, information sheet and consent form given to participants (Chapter 3)



**UNIVERSITY OF
STIRLING**

DEPARTMENT OF
PSYCHOLOGY

University of Stirling
Stirling FK9 4LA Scotland

Dear

Experience of Peripheral Arterial Disease After Revascularization.

I am a postgraduate student from the Psychology Department of the University of Stirling.

As part of my course, I am conducting a research project into the experiences of people who have intermittent claudication and have undergone surgery to improve the blood flow in their legs. The study is being carried out in conjunction with Mr Holdsworth from the Stirling Royal Infirmary Vascular Surgery ward.

As you have previously undergone a surgical procedure for your intermittent claudication, your help in this research would be very valuable.

If you would like to take part in this study, details of which are given on the information leaflet enclosed, please let me know. You can either return the enclosed card to me with your details and I will contact you, or you can call me on the number below. I will then arrange a convenient time and venue with you to obtain your consent and conduct a short interview, which should last no more than one hour.

I would like to thank you for taking time to read this letter and hope to hear from you soon. If you have any queries, please feel free to contact me, on the telephone number below.

Yours sincerely,

Margaret Cunningham

Telephone : 01786 466 845

Experience of Peripheral Arterial Disease After Revascularization.

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

This study aims to understand the experience of patients with intermittent claudication who previously underwent a procedure in the hospital to improve the blood flow in their legs. This study involves a short interview of no more than an hour. The researcher will ask questions about how satisfied you were with the revascularization procedure, whether you have any symptoms at the moment, how you cope with these, and what your life is like now that you've had the procedure.

You have been chosen for this study because you had intermittent claudication, and you came into hospital to have a procedure carried out to improve the blood flow in your leg about a year ago. Twenty participants will be interviewed for this study.

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

If you decide to take part in this study, you will be scheduled to attend one interview, which should last no more than an hour. The interview can be carried out at a place and time that suits you, for example the researcher can come to your home if this is more convenient for you; alternatively, the interview can be carried out in a private interview room in Stirling Royal Infirmary. This research is being carried out as part of a PhD by a student at the University of Stirling, and there are no funds available to reimburse your travel expenses. The researcher will ask you some questions about the procedure you had in hospital, and how you have been since then. The researcher will use a tape recorder to tape your responses, so that they can be analysed once the interview is over.

Your participation in this study will not affect the clinical care you receive.

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. All information will be stored securely, and only the researcher and the project supervisor will have access to the information.

This research is important in order to understand how having a revascularization procedure affects people's lives, to understand whether there are continuing problems, and how these are dealt with by patients.

If you are harmed by taking part in this research project, 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 Procedure will be available to you (details are in the attached leaflet).

The results of this study will be summarised and given to you. You will be given the opportunity to discuss the summary of findings with the researcher. The research will then be written up in a report that will form part of the researcher's PhD qualification. In addition the research may be published in an academic journal. You will not be identified in any report or publication.

This is a PhD research project and is being sponsored by The University of Stirling. The research has been reviewed by the Fife and Forth Valley Research Ethics Committee.

If you require any more information about this study, please contact the researcher, Maggie Cunningham, on 01786 466 845.

CONSENT FORM

Title of Project: Experience of Peripheral Arterial Disease After Revascularization.

Name of Researcher: Maggie Cunningham

Please initial box

1. I confirm that I have read and understand the information sheet dated 23/2/6 (version 4) for the above study 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, without my medical care or legal rights being affected.
3. I understand that sections of any of my clinical records may be looked at by the researcher. I give permission for the researcher to have access to my records.
4. I agree to the interview being tape recorded and the tapes being destroyed once the interview has been transcribed.
5. I agree that Forth Valley Acute Operating Division can check my medical records for a copy of this consent form if auditing this research project.
6. 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

1 for patient; 1 for researcher; 1 to be kept with hospital notes

--	--	--	--

Please answer the following questions by ticking the answer that most applies to you or writing in the answer.

1. Are you? Male Female
2. How old are you?years old
3. Do you? Live alone
 Live with somebody else in the house
4. What is your occupation? If you are retired, please state your occupation before you retired.

Retired? Yes No

Please specify occupation.....

5. Do you or have you suffered from any of the following conditions?
(please tick one box on each line)

	No	Yes
a. Chest Trouble	<input type="checkbox"/>	<input type="checkbox"/>
b. Diabetes	<input type="checkbox"/>	<input type="checkbox"/>
c. Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>
d. Rheumatic Troubles	<input type="checkbox"/>	<input type="checkbox"/>
e. Cancer	<input type="checkbox"/>	<input type="checkbox"/>
f. Heart Troubles	<input type="checkbox"/>	<input type="checkbox"/>
g. Stroke	<input type="checkbox"/>	<input type="checkbox"/>
h. Back Trouble	<input type="checkbox"/>	<input type="checkbox"/>
i. Depression	<input type="checkbox"/>	<input type="checkbox"/>
j. Other (please specify) _____		

6. Do you **receive** help or support from family members, friends, neighbours or others because of problems with your health? (for example help with cleaning, or shopping)

No	Yes, 1-4 hours per week	Yes, 5-19 hours per week	Yes, 20 hours or more per week	Continuous care	Varies	Don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This part of the questionnaire asks for your views about your health. Answer every question by marking the questions as indicated. If you are unsure about how to answer a question, please give the best answer you can.

7. How would you rate your quality of life?

Very poor	Poor	Neither poor nor good	Good	Very good
1	2	3	4	5

BRIEF IPQ -The following questions ask about your intermittent claudication—the problems you have had with the blood flow in your legs. Please circle the number that best corresponds to your views:

8. How much does the intermittent claudication (cramping leg pain) affect your life?

0	1	2	3	4	5	6	7	8	9	10
No affect at all										Severely affects my life

9. How long do you think the intermittent claudication (cramping leg pain) will continue?

0	1	2	3	4	5	6	7	8	9	10
A very short time										forever

10. How much control do you feel you have over your intermittent claudication (cramping leg pain)?

0	1	2	3	4	5	6	7	8	9	10
Absolutely no control										Extreme amount of control

11. How much do you think your treatment can help the intermittent claudication?

0	1	2	3	4	5	6	7	8	9	10
Not at all										Extremely helpful

12. How much do you experience symptoms from your intermittent claudication?

0	1	2	3	4	5	6	7	8	9	10
No symptoms at all										Many severe symptoms

13. How concerned are you about your intermittent claudication?

0 1 2 3 4 5 6 7 8 9 10

Not at all
concerned

Extremely
concerned

14. How well do you feel you understand your illness (intermittent claudication)?

0 1 2 3 4 5 6 7 8 9 10

Don't understand
at all

Understand
very clearly

15. How much does your intermittent claudication affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)

0 1 2 3 4 5 6 7 8 9 10

Not at all affected
emotionally

Extremely affected
emotionally

16. Please list in rank order the three most important factors that you believe **caused** your illness (intermittent claudication). The most important causes for me:-

1. _____

2. _____

3. _____

ICQ -The questions below ask about the problems of pains and cramps patients with intermittent claudication get in their calves, thighs or buttocks when walking. The term 'leg pains' has been used to describe all of these problems. Please answer every question with a tick. If you are unsure about how to answer a question please give the best answer you can. Tick only one box per question.

17. Which of your legs has intermittent claudication?

(Please mark one)

Only Right

Only Left

Both

18. During the **past 2 weeks**, how severe were your leg pains?

**None, I had
no leg pain**

Very mild

Mild

Moderate

Severe

Very severe

19. The following questions ask about activities you might do during a typical day. Do your leg pains limit you in these activities? If so, how much?

	Totally limited	Very limited	Moderately limited	A little limited	Not limited at all
Crossing the road	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Using the bus or train	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking more than a mile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking 100 yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Going out of the house	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

20. During the **past 2 weeks**, how often have you had to stop walking and rest because of the pains in your leg?

More than 3 times a day	2 to 3 times a day	Once a day	Less than once a week	Not at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

21. During the **past 2 weeks**, how much of the time have you spent thinking about your leg pains?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

22. During the **past 2 weeks**, how much of the time have you felt downhearted and low because of your leg pains?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

23. During the **past 2 weeks**, how much of the time have you been worried that your leg pains will get worse?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

24. During the **past 2 weeks**, how much did your leg pains interfere with your normal work (including work both outside the home and housework)?
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Not at all | A little bit | Moderately | Quite a bit | Extremely |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
25. During the **past 2 weeks**, how much did your leg pains interfere with your hobbies or pastimes?
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Not at all | A little bit | Moderately | Quite a bit | Extremely |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
26. During the **past 2 weeks**, how much of the time have your leg pains interfered with social activities (like visiting friends and relatives etc)?
- | | | | | |
|--------------------------|--------------------------|--------------------------|-----------------------------|--------------------------|
| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
27. During the **past 2 weeks**, how much of the time have your leg pains interfered with doing errands (like shopping, going to the post office or bank, etc)?
- | | | | | |
|--------------------------|--------------------------|--------------------------|-----------------------------|--------------------------|
| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

General questions about walking behaviour:

28. How far can you walk, aided or unaided, under normal circumstances before the onset of pain?
- | | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 0 yards | Up to 100 yards | Up to 250 yards | Up to 1/2 a mile | Up to 1 mile | More than a mile |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
29. In general, how frequently do you walk the distance you wrote in question 32?
- | | | | | | |
|--------------------------|------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Never | Once or twice a month | Once per week | 2-3 times a week | 4-5 days per week | Everyday |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
30. In general, do you carry on walking after the pain has started in your leg?
- | | | |
|--------------------------|--------------------------|--|
| Never | For a few steps | Until the pain is nearly unbearable |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
31. How many steps do you usually take after the onset of claudication pain, before you stop for a rest?
32. How often do you walk for at least 30 minutes?
- | | | | | | |
|--------------------------|------------------------------|---------------------------|--------------------------|--------------------------|--------------------------|
| Never | Once or twice a month | 1-2 times per week | 3 times a week | 4-5 days a week | Everyday |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Questions about intention to walk, and intention to walk through the pain:

33. Please indicate the extent to which you agree or disagree with the following statements about **you doing a walk of at least 30 minutes**.

(please circle one number on each line)

- | | Strongly disagree | Strongly agree |
|---|------------------------|----------------|
| a. I intend to walk that distance 3 times a week | 0 1 2 3 4 5 6 7 8 9 10 | |
| b. I would like to walk that distance 3 times a week | 0 1 2 3 4 5 6 7 8 9 10 | |
| c. It is likely that I will walk that distance 3 times a week | 0 1 2 3 4 5 6 7 8 9 10 | |

34. Please indicate the extent to which you agree or disagree with the following statements about **you continuing to walk after the onset of claudication pain until the pain is almost unbearable, before stopping for a rest**.

- | | Strongly disagree | Strongly agree |
|--|------------------------|----------------|
| a. I intend to keep walking until the pain is almost unbearable | 0 1 2 3 4 5 6 7 8 9 10 | |
| b. I would like to keep walking until the pain is almost unbearable | 0 1 2 3 4 5 6 7 8 9 10 | |
| c. It is likely that I will keep walking until the pain is almost unbearable | 0 1 2 3 4 5 6 7 8 9 10 | |

Questions about advice, attempts to increase walking and maintenance of increased walking since diagnosis:

35. Do you recall receiving medical advice on how far or how long to walk because of your intermittent claudication? Yes No

36a. Since being diagnosed with intermittent claudication, have you attempted to increase the amount that you walk? Yes No

b. If yes, has this increase been maintained? Yes No

c. If the increase has not been maintained, please list the 3 most important reasons why not:

1. _____
2. _____
3. _____

This section asks about your views and opinions of walking at least 30 minutes, at least 3 times a week, walking until the claudication pain is almost unbearable before resting. There are no right or wrong answers. We would like you to think about what it is like for you to do a walk of that distance. Please tick the box that describes you or your opinion best. (Treatment representations - Personal Control and Consequences)

37. Where 0 is ‘not at all confident’ and 10 is ‘extremely confident’, how confident are you that you can do a walk at least 30 minutes, at least 3 times a week, walking until the claudication pain is almost unbearable, before resting, **when**:

	Not at all Confident										Extremely Confident	
	0	1	2	3	4	5	6	7	8	9	10	
a. the weather is good	0	1	2	3	4	5	6	7	8	9	10	
b. the walk is flat	0	1	2	3	4	5	6	7	8	9	10	
c. the weather is bad	0	1	2	3	4	5	6	7	8	9	10	
d. the walk is uphill	0	1	2	3	4	5	6	7	8	9	10	
e. you are on your own	0	1	2	3	4	5	6	7	8	9	10	
f. you are with someone who walks quickly	0	1	2	3	4	5	6	7	8	9	10	
g. there is a flight of steps	0	1	2	3	4	5	6	7	8	9	10	
h. you are tired	0	1	2	3	4	5	6	7	8	9	10	
i. there is nowhere to stop for a rest	0	1	2	3	4	5	6	7	8	9	10	

38. These questions ask about the **consequences** that walking for at least 30 minutes, at least 3 times a week until the claudication pain is almost unbearable, before stopping for a rest, might have for you.

If I walk that distance three times a week...

	Not at all true	Hardly true	Moderately true	Exactly true
I will feel better afterwards	1	2	3	4
I'll be left with bad leg pain	1	2	3	4
my quality of life will improve	1	2	3	4
it will be good for my heart	1	2	3	4
I will miss my television programmes	1	2	3	4
I can be more independent	1	2	3	4
I will be embarrassed because I have to stop regularly	1	2	3	4
the pain in my legs will go away	1	2	3	4
my legs will suffer from wear and tear	1	2	3	4
I will keep fit	1	2	3	4
I will damage my legs	1	2	3	4
I will be able to control my weight	1	2	3	4
the blood flow in my legs will improve	1	2	3	4

39. IPAQ—I am going to ask you about the time you spent being physically active in the last 7 days.

Now, think about all the vigorous activities which take hard physical effort that you did in the last 7 days. Vigorous activities make you breathe much harder than normal and may include heavy lifting, digging, aerobics or fast cycling. Think only about those activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do vigorous physical activities?
_____ days per week (if 0 skip to Q3)

2. How much time did you usually spend doing vigorous physical activities on **one** of those days?
_____ hours/minutes per day

How much time in total would you spend over the **last 7 days** doing vigorous physical activities?

_____ hours per week

3. During the **last 7 days**, on how many days did you do moderate physical activities?

_____ days per week

4. How much time did you usually spend doing moderate physical activities on **one** of those days?

_____ hours/minutes per day

What is the total amount of time you spent over the **last 7 days** doing moderate physical activities?

_____ hours per week

5. During the **last 7 days**, on how many days did you walk for at least 10 minutes at a time?

_____ days per week

6. How much time did usually spend **walking** on one of those days?

_____ hours/mins per day

What is the total amount of time you spent walking over the last 7 days?

_____ hours per week

7. During the last 7 days, how much time did you usually spend **sitting** on a **week day**?

_____ hours per weekday

What is the total amount of time you spent sitting last Wednesday?

_____ hours on Wednesday

This FINAL section asks you about some health related behaviours.

40. On how many of the **last 7 days** did you eat five or more servings of fruit and vegetables? (circle one number only)

0 1 2 3 4 5 6 7

41. On how many of the **last 7 days** did you eat high fat foods such as red meat or full-fat dairy products? (circle one number only)

0 1 2 3 4 5 6 7

42. On how many of the **last 7 days** did you eat fried food? (circle one number only)

0 1 2 3 4 5 6 7

43. On how many of the **last 7 days** did you eat breakfast? (circle one number only)

0 1 2 3 4 5 6 7

44. Do you usually use fat-reduced milk (e.g. skimmed milk)?

Yes No

45. What do you normally use as a choice of spread?

Butter Margarine

46. Are you a...

...regular smoker?

...occasional smoker?

...ex-smoker (I don't smoke any more but I used to smoke)?

...non-smoker (I don't smoke and I have never smoked)?

If you are a smoker, how many cigarettes do you smoke on an average day?

.....Number of cigarettes

THANK YOU VERY MUCH FOR COMPLETING THIS QUESTIONNAIRE

We are keen to hear your opinions about the questions you have just answered. If you have any comments about the questionnaire please share them with us by writing them in the space below.

Appendix 3: Schedule of questions used in Session One of the RCT (Chapter 6)

What is your understanding of intermittent claudication?

(I have some information about intermittent claudication, would you like to hear it?)

Looking at the risk factors, what do you think you can do about your circulation problems?

What are you thinking about your current walking behaviour at this point?

How would you like to be in 6 months time?

What would be the good things about doing more walking?

Rate on a scale of 0 to 10 (with 10 being the highest) how interested you are in making a change to your walking?

(Why did you not choose a higher number?)

Rate, again on a scale of 0 to 10, how confident you are that you can make the change?

(What would it take to get you to a higher number?)

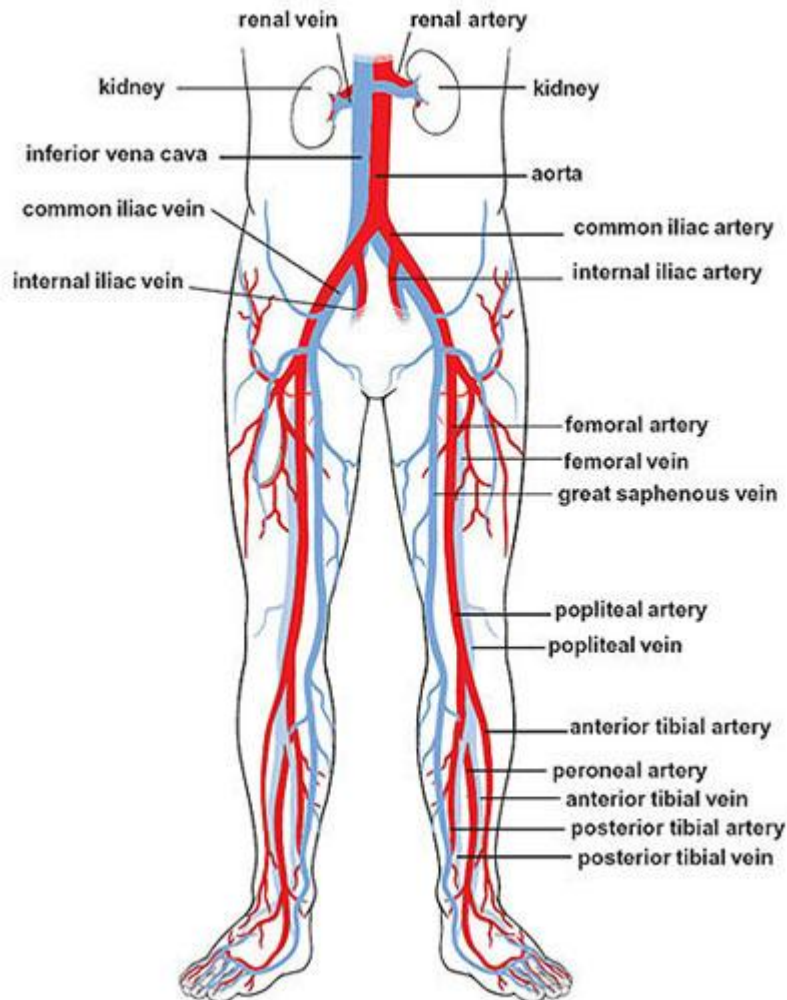
What personal strengths do you have that will help you succeed?

Who could offer you support in making this change?

Appendix 4: Information sheet used in Session One of the RCT (Chapter 6)

What is Intermittent Claudication?

Your arteries carry blood from your lungs around your body to all your different muscles.

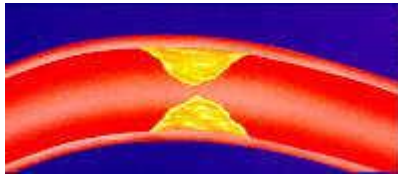


The blood provides oxygen to the muscles to make them work properly.

If your muscles don't get enough oxygen they start to hurt. The pain that you feel in your legs when you walk is because your leg muscles aren't getting enough oxygen. This is because you have a narrowing in one of the arteries supplying your leg which slows down the flow of blood to that part of your leg.

What causes intermittent claudication?

Intermittent claudication is usually the result of atherosclerosis, the development over many years of fatty plaques in the walls of the arteries. You may have heard of this as “furring up of the arteries”. This furring up of the arteries happens over the years in the arteries all over the body. When it happens in the legs, it can cause intermittent claudication.



There is no one thing which causes atherosclerosis, but there are some things which you can tackle to reduce the rate of build-up of fatty plaques in your arteries.

Risk factors you can change:

- Raised blood cholesterol
- Cigarette smoking
- Raised blood pressure
- Lack of physical activity
- Obesity
- Diabetes

Stopping smoking, eating a healthy diet, exercising regularly and taking your prescribed medications are all important ways to improve your condition.

How does walking help?

You may worry that walking will harm your legs because of the cramping pain you experience when you walk. There is no evidence that this is the case, in fact, lots of research has shown that walking more will help improve how far you can walk before the pain comes on.

Carrying out regular walking changes the blood flow in the leg, by encouraging the blood to find other routes to the muscles. This is known as stimulating collateral blood flow. In addition, regular walking can improve glucose metabolism and lower blood pressure.

Walking regularly will help reduce the rate of build-up up atherosclerosis and could therefore be beneficial to your heart as well as your legs.

In order for walking to help your intermittent claudication you need to do it regularly and consistently, otherwise the benefits will be lost.

**Appendix 5: Template for action and coping plan used in Session Two of the RCT
(Chapter 6)**

The changes I want to make are:

.....
.....
.....

The most important reasons why I want to make these changes are:

.....
.....
.....

My general goal is:

.....
.....

My first specific action

WHAT am I going to do?

WHERE am I going to do it?

WHEN am I going to do it?

WITH WHOM am I going to do it?

3 possible barriers which might hinder me from doing this activity?

- 1.
- 2.
- 3.

How am I going to overcome these barriers? (substitution of means, increased effort etc)

My second specific action

WHAT am I going to do?

WHERE am I going to do it?

WHEN am I going to do it?

WITH WHOM am I going to do it?

3 possible barriers which might hinder me from doing this activity?

- 1.
- 2.
- 3.

How am I going to overcome these barriers? (substitution of means, increased effort etc)

My third specific action

WHAT am I going to do?

WHERE am I going to do it?

WHEN am I going to do it?

WITH WHOM am I going to do it?

3 possible barriers which might hinder me from doing this activity?

- 1.
- 2.
- 3.

How am I going to overcome these barriers? (substitution of means, increased effort etc)

I will know my plan is working if:

.....
.....
.....
.....

Notes:

Re barriers, ask:

- Is there anything about the things around you or the places you are in that makes it difficult to do this behaviour? What can you do to change this?
- Are there any people I spend time with who make it difficult to do this behaviour? What can I do to change this?
- Is there anything I am thinking or feeling that makes it difficult to do this behaviour? How can I overcome these things?

Appendix 6: Schedule of questions used in the telephone calls (Chapter 6)

Follow-Up Phone Call (Control)

Date _____

How are you?

In general would you say your health is...?

Excellent	Very Good	Good	Fair	Poor

How satisfied are you with your health?

Very Dissatisfied	Dissatisfied	Neither Satisfied nor Dissatisfied	Satisfied	Very Satisfied

How would you rate your quality of life?

Very poor	Poor	Neither Poor nor Good	Good	Very Good

How are your legs?

During the past 2 weeks, how severe were your leg pains?

None, I had no leg pain	Very mild	Mild	Moderate	Severe	Very severe

How far can you walk before the onset of pain?

0 yards	Up to 100 yards	Up to 250 yards	Up to ½ a mile	Up to 1 mile	More than a mile

Have you heard anything from the hospital yet?

Duration of call _____

Follow-Up Phone Call (Treatment)

Date _____

How are you?

In general would you say your health is...?

Excellent	Very Good	Good	Fair	Poor

How satisfied are you with your health?

Very Dissatisfied	Dissatisfied	Neither Satisfied nor Dissatisfied	Satisfied	Very Satisfied

How would you rate your quality of life?

Very poor	Poor	Neither Poor nor Good	Good	Very Good

How are your legs?

During the past 2 weeks, how severe were your leg pains?

None, I had no leg pain	Very mild	Mild	Moderate	Severe	Very severe

How far can you walk before the onset of pain?

0 yards	Up to 100 yards	Up to 250 yards	Up to ½ a mile	Up to 1 mile	More than a mile

Have you heard anything from the hospital yet?

How is it going with your walking action plan?

Action 1:

Has anything got in the way of doing that?

How did you manage that?

Action 2:

Has anything got in the way of doing that?

How did you manage that?

Action 3:

Has anything got in the way of doing that?

How did you manage that?

Have you heard anything from the hospital yet?

Duration of call _____

Appendix 7: Example of letter of invitation, information sheet and consent form given to participants (Chapter 5)

Stirling Royal Infirmary
Livilands,
Stirling
FK8 2AU



Vascular Surgery

Enquiries to Maggie Cunningham

Direct Line 01786 466 845

Email mac1@stir.ac.uk

Investigation of Effect of Intermittent Claudication on Quality of Life

We are initiating research into the effect intermittent claudication on quality of life and walking behaviour, as part of our ongoing research into the relationship between intermittent claudication, quality of life and health behaviours. This work is being co-ordinated by a postgraduate Psychology student, based in the University of Stirling.

We are approaching patients who have previously been under our care who we feel would be appropriate to take part in this study. Your help would be greatly appreciated.

We enclose an information sheet regarding the current study. If you would be willing to help us with this study, we would be grateful if you could complete the enclosed consent form and questionnaire.

If you have any questions or queries regarding this study please feel free to contact the researcher, Maggie Cunningham on 01786 466 845. A postage paid envelope is provided for you to send in your completed questionnaires and consent form to the researcher. We would appreciate it if you could return the questionnaires as soon as possible if you have decided to take part in the study.

We would like to thank you for taking time to read this letter and hope to hear from you soon.

Yours,

Mr RJ Holdsworth
Mr M Yapanis

Investigation of Effect of Intermittent Claudication on Quality of Life

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

This study aims to understand the effect that intermittent claudication has on quality of life, and functioning. In addition, this study will investigate whether there are other factors, such as people's thoughts about their illness, and how they cope with their illness that influence quality of life and functional outcome. This study will involve you filling in a set of questionnaires that will ask you questions about your leg pain and what affect it has on you and your life. The set of questionnaires should take about half an hour to complete.

You have been chosen for this study because you were diagnosed with intermittent claudication within the last 3 years.

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

This research will all take place at one time, you will be asked to fill in one set of questionnaires, complete these and send them back to the researcher in a pre-paid envelope. The questions do not require a lot of thought, however, it is important to fill them in as accurately as possible. **If you have any questions, please contact the Chief Investigator, Maggie Cunningham, who will be happy to help you.**

Your participation in this study will not affect the clinical care you receive.

If you consent to take part in the research any of your medical records may be inspected by the researcher for purposes of analysing the results. All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. All information will be stored securely, and only the researcher and the project supervisor will have access to the information.

This research is important in order to understand the impact of intermittent claudication on quality of life and functioning; and to understand what psychological factors may be involved in coping with intermittent claudication.

If you are harmed by taking part in this research project, 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 Procedure will be available to you (details are available in leaflets at Stirling Royal Infirmary or your GP clinic).

The findings from this research will be written up in a report that will form part of the researcher's PhD qualification. In addition the research maybe published in an academic journal. You will not be identified in any report or publication.

This is a PhD research project and is being sponsored by the University of Stirling. The research has been reviewed by the Fife and Forth Valley Research Ethics Committee. **If you require more information about this study, please contact the researcher, Maggie Cunningham, on 01786 466 845.**

CONSENT FORM

Title of Project: **Investigation of Effect of Intermittent Claudication on Quality of Life**

Name of Researcher: Maggie Cunningham

Please initial box

1. I confirm that I have read and understand the information sheet dated 23/02/2007 (version 4) for the above study 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, without my medical care or legal rights being affected.
3. I understand that sections of any of my clinical records may be looked at by the researcher. I give permission for the researcher to have access to my records.
4. I agree that Forth Valley Acute Operating Division can check my medical records for a copy of this consent form if auditing this research project.
4. I agree to take part in the above study.

Name of Patient

Date

Signature

Appendix 8: Example of letter of invitation, information sheet and consent form given to participants (Chapter 6)

Stirling Royal Infirmary
Livilands,
Stirling
FK8 2AU



Vascular Surgery

Date 31st August 2009

Enquiries to Maggie Cunningham

Direct Line 01786 466 845
Email mac1@stir.ac.uk

**Changing illness perceptions of patients with intermittent claudication:
a pilot randomised controlled trial to increase walking**

We are initiating research into the effect of a brief psychological intervention to increase walking behaviour in patients newly diagnosed with intermittent claudication, as part of our ongoing research into the relationship between intermittent claudication, quality of life and walking behaviour. This work is being co-ordinated by a postgraduate Psychology student, based in the University of Stirling.

We are approaching patients who have been newly diagnosed with intermittent claudication who we feel would be appropriate to take part in this study. Your help would be greatly appreciated.

We enclose an information sheet regarding the current study. If you would be willing to help us with this study, we would be grateful if you could complete and return the enclosed reply paid slip and give your contact details so that the researcher can contact you and arrange a suitable time to visit you at home.

If you have any questions or queries regarding this study please feel free to contact the researcher, Maggie Cunningham on 01786 466 845.

We would like to thank you for taking time to read this letter and hope to hear from you soon.

Yours sincerely,

Val Sinclair
Vascular Assessment Nurse



**UNIVERSITY OF
STIRLING**

DEPARTMENT OF
PSYCHOLOGY

University of Stirling
Stirling FK9 4LA Scotland

Telephone: +44 (0) 1786 467640
Facsimile: +44 (0) 1786 467641
<http://www.stir.ac.uk/psychology>

Information about the research

Changing illness perceptions of patients with intermittent claudication: a pilot randomised controlled trial to increase walking

We would like to invite you to take part in a research study that is being conducted in part fulfilment of a Doctorate in Psychology degree at the University of Stirling. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this

What is the purpose of the study?

This study aims to understand the illness beliefs and walking behaviour of patients newly diagnosed with intermittent claudication. It involves a brief psychological intervention to clarify participants' beliefs about intermittent claudication and help participants set a walking action plan. Your involvement in the study will last for 4 months. The researcher will assign you to one of two groups. One group will receive usual care, and the other group will receive a brief psychological intervention of two 1 hour sessions. Regardless of which group you are in, you will be asked to fill in a set of questionnaires at the start and end of the study, and to wear a pedometer for one week at the start and end of the study.

Why have I been invited?

You have been chosen for this study because you have been newly diagnosed with intermittent claudication. Eighty participants will be involved in this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and a reply paid slip to send to me with your contact

details. I will then contact you and arrange a suitable time to visit you at home and ask you to sign a consent form. Your Vascular Consultant will also be informed that you are taking part in the study. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What if I do not wish to take part in this study?

It is important to check that there is no bias in this research caused by differences in age, gender or severity of intermittent claudication between those patients who decide to take part and those who do not wish to take part in the study. Therefore, if you do not wish to take part in this study the Vascular Assessment Nurse who approached you will ask for your permission to record a note of your age, gender and a clinical measure of your ankle artery pulses. This information will be passed to me in an anonymised form so that you cannot later be identified from it. Note however that you do not have to agree to this and you still have the right to refuse to take part without having to give any reason.

What will happen to me if I take part?

If you decide to take part in this study, please return the reply paid slip with your contact details. The researcher will contact you and arrange a suitable time to visit you in your home and go through a questionnaire with you. This will take no more than an hour. The researcher will also give you a pedometer to wear for one week, which will count the number of steps you take. A pedometer is a small, light box which clips onto the waistband of your skirt or trousers and counts the number of steps you take. If you are assigned to the usual care group, you will not be visited by the researcher again until the end of the study. If you are assigned to the intervention group, the researcher will visit your house for two 1 hour sessions to discuss your beliefs about intermittent claudication, and about walking, and to help you set a walking action plan. Regardless of which group you are in, the researcher will also make a brief telephone call to you in weeks 6, 10 and 14 of the study to ask you to rate your leg pain when walking. At the end of the study the researcher will visit you and ask you to wear the pedometer again for one week, and to complete another set of questionnaires. This visit will last no more than an hour.

If you decide to take part in this study, the researcher will need a clinical measure of your ankle artery pulses from your first visit to the Vascular Assessment Nurse. This measure gives an indication of the severity of your intermittent claudication. The researcher will ask your Vascular Consultant for a note of this measure.

The researcher will also ask you to nominate a close friend or relative to be involved with you in this study. They will be asked to fill in a questionnaire at the start and end of the study which asks what they know about intermittent claudication. If you are in the intervention group, your nominated close friend or relative will also be invited to attend the two 1 hour meetings to help support you set your walking action plan.

Your participation in this study will not affect the clinical care you receive.

Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. All information will be stored securely, and only the researcher and the project supervisor will have access to the information. Research records will be kept for 5 years. They will be kept in a locked filing cabinet in a locked office in the University of Stirling Psychology Department.

Will the sessions be taped?

A randomly selected 50% of intervention sessions will be taped. The tapes will then be transcribed, and destroyed. The transcripts will be anonymous and will not have anything which could identify you on them. The purpose of taping some sessions is so that the researcher's supervisor can check that the plan for the intervention has been followed, and the intervention has been delivered consistently.

What are the possible benefits of taking part?

The research is important in order to understand whether a brief psychological intervention can increase the amount that patients with intermittent claudication walk. The results from this study will be used to influence the future care of patients diagnosed with intermittent claudication.

What if there is a problem?

If you are harmed by taking part in this research project, 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 Procedure will be available to you (details are available in Stirling Royal Infirmary or through your GP).

What happens when the research study stops?

The results of this study will be summarised and given to you. You will be given the opportunity to discuss the study with the researcher. The research will then be written up in a report that will form part of the researcher's PhD qualification. In addition the research may be published in an academic journal. You will not be identified in any report or publication.

This is a PhD research project and is being sponsored by The University of Stirling. The Fife and Forth Valley Research Ethics Committee, which has responsibility for scrutinising proposals for medical research on humans, has examined this proposal and has raised no objections from the point of view of medical ethics. If you require any more information about this study, please contact the researcher, Maggie Cunningham, on 01786 466 845. Alternatively, if you wish to speak to someone who is independent of the research, please contact Professor Ronan O'Carroll on 01786 467640.

Thank you for reading this Information Sheet and considering taking part in this study.

