Disease management interventions for improving self-management in lower-limb peripheral arterial disease (Protocol)

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[Intervention Protocol]

Disease management interventions for improving self-management in lower-limb peripheral arterial disease

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this review is to systematically review, synthesise and quantify the effects of non-pharmacological and non-surgical chronic disease management interventions targeting self-management for people with lower-limb PAD.

BACKGROUND

Description of the condition

Peripheral arterial disease (PAD) is a chronic atherosclerotic cardiovascular disease impacting on quality of life and leading to adverse outcomes. The principal symptom of PAD is lower-limb pain or discomfort (known as intermittent claudication), which is typically brought on by walking and relieved by rest (Sutherland 2009). As PAD progresses, intermittent claudication may increase in severity and critical limb ischaemia may develop, which results in constant lower-limb pain at rest, leg ulceration, sepsis, and possibly gangrene and the need for amputation (Sutherland 2009). Several studies have indicated that the prevalence of PAD increases with age. A large study undertaken in San Diego, US identified a prevalence of 2.5% in people aged 60 years, 8.3% in those aged 60 to 69 years, and 18.8% in the study participants aged 70 years or older (Criqui 1985). Of 28,980 Scottish men and women screened using the ankle-brachial index (ABI), 10.9% of participants had an ABI which categorised them as 'at risk' (with an ABI < 0.9 indicating PAD and increased cardiovascular risk) (Price 2008). Another Scottish study identified that 4.6% of 2720 participants aged 55 to 74 years had intermittent claudication (lower-limb pain or discomfort brought on by walking and relieved by rest) and 8% had significant impairment of blood flow but were asymptomatic (Fowkes 1991).

Exercise, in particular regular walking, is a fundamental component of lower-limb PAD management (Hirsch 2005; Norgren 2007). Its effectiveness is proven by other Cochrane Reviews (Bendermacher 2006; Watson 2008). The latter showed that with exercise, including walking, skipping and running, the pain-free walking distance mean difference was 82.19 metres (95% confidence interval (CI) 71.73 to 92.65) and the maximum walking distance mean difference was 113.20 metres (95% CI 94.96 to 131.43) (Watson 2008). The benefits of exercise in PAD may be facilitated by the reversal of several pathological events that are common in PAD (for example arterial obstruction, endothelial dysfunction, altered skeletal muscle phenotype and inflammation) (Hamburg 2011). There are several important benefits of exercise for people with PAD. These are improved functional ability, cardiovascular fitness, physical mobility and psychological well being (Guidon 2010; Hamburg 2011). However, adhering to regular exercise can be problematic for people with PAD as the onset of intermittent claudication can act as a deterrent to exercise participation. A recent meta-analysis comparing endovascular treatment of intermittent claudication to supervised exercise reports that outcomes measured by treadmill walking were no different to the outcomes of endovascular treatment (Ahimastos 2011). The authors of the study concluded that "mechanisms that promote greater access to, uptake and sustainability of SVE (supervised exercise programs) would appear to be an important requirement to advance management of intermittent claudication given the favourable results" (Ahimastos 2011). Not only are access and uptake of such interventions important, but adherence is fundamental to the success of interventions such as exercise programs.

Smoking is a substantial risk factor for the development (odds ratio 5.09, 95% CI 2.97 to 8.72) (Leng 1995) and progression of lower-limb PAD and has significant implications for morbidity and mortality (Hirsch 2005; Norgren 2007). Quitting smoking is challenging and specialised support improves the success of attempts to quit (Fiore 2008). Like many other chronic diseases, people with PAD often experience poor health-related quality of life (Dumville 2004). There is evidence of socioeconomic disparity in the prevalence (Kroger 2009) and outcomes (Ferguson 2010) for people with PAD. Stigma and social marginalisation can be experienced by smokers (Stuber 2008).

Considering the psychological burden (Smolderen 2009), poor quality of life (Dumville 2004), risk of acute events (Criqui 2008) leading to increased morbidity and mortality, and management strategies requiring behavioural change and long-term adherence, chronic disease management interventions that aim to improve self-management may improve outcomes for people with PAD. Performance measures for management of PAD underscore the importance of risk assessment, patient education (in particular on the importance of exercise and smoking cessation), self-management (especially adherence to exercise and smoking cessation) and monitoring of disease status (Olin 2010). Based on this guideline, non-pharmacological, non-surgical disease management interventions for PAD should incorporate risk assessment, patient education, self-management strategies and monitoring of disease status.

Description of the intervention

Surgical and pharmacological interventions can provide symptom relief and reduce the risk of adverse outcomes for people with lower-limb PAD. However, benefits to quality of life and other outcomes can also be gained through non-surgical and non-pharmacological strategies, in particular, smoking cessation and exercise. However, adhering to exercise programmes and quitting smoking can be very challenging and interventions which promote and support the change of health behaviours and adherence to prescribed treatments may assist people with PAD to improve their own health. Health professionals typically refer to this concept as self-management. There is currently a lack of consensus on the definition of self-management (Gardetto 2011) and self-care is also often used as an interchangeable term. In this review, we will use the term self-management for consistency. Self-management is a core component of disease management interventions (Lovell 2011), which are organised programmes or services often led by a nurse or allied health professional. They aim to increase self-efficacy (a person's belief that they can achieve a given task) and knowledge about the disease, treatment and outcomes (health literacy) so that the person is better informed and capable of engaging in activities which protect or promote their own health

(for example exercise participation and quitting smoking), manage their symptoms (for example managing intermittent claudication through medications and pain management strategies), the impact which lower-limb PAD has on their life, and also adhere to any prescribed therapies (such as a prescribed exercise regime or risk-reducing medications). These interventions may be delivered face-to-face (in a group or one-on-one session), via telephone or other information communication technologies, such as Internet, short message service (SMS) or e-mail, and will often involve a combination of delivery modes. Increasingly the role of disease management is emphasised to address the burden of chronic conditions, and self-management is a core component of disease management. Lorig 1993 defines self-management approaches as helping individuals "to make informed choices, to adapt new perspectives and generic skills that can be applied to new problems as they arise, to practise new health behaviours, and to maintain or regain emotional stability". Gardetto 2011 has combined definitions of self-management by Lorig 2003 and Barlow 2002, defining self-management as "the individual's ability (problem solving, decision making, resource utilization, formation of patient-provider partnerships, action planning, and tailoring of daily activities) to undertake and manage day-to-day tasks, inherent lifestyle changes, physical symptoms, and psychosocial consequences of health and well-being over the lifetime of an illness". These definitions emphasise the importance of a patient-provider partnership where information is tailored and targeted to the needs of an individual and action planning and self-monitoring are integral to achieving optimal health outcomes. Like in many other chronic conditions, the role of disease management interventions in PAD is to reduce symptoms and improve clinical outcomes (Lovell 2011).

How the intervention might work

For many chronic conditions, adhering to both pharmacological and non-pharmacological interventions is important to improve survival, functional status and health-related quality of life. Adherence with these recommendations also improves organisational outcomes such as decreasing admissions to hospital. Promoting and enhancing self-management strategies is an integral element of chronic disease management programs which have a strong evidence base across many conditions, such as heart failure (Inglis 2010), chronic obstructive respiratory disease (Effing 2007), osteoarthritis and diabetes (Deakin 2005). These approaches recognise the need to shift the focus on purely acute events to a focus on supporting the individual living with a chronic condition. Incorporating critical elements such as patient empowerment, increasing adherence to evidence-based recommendations and promoting care coordination can improve health outcomes (Tsai 2005). Increasingly, health providers recognise that information alone is not sufficient to promote adherence and drive behaviour change. This has led to multiple interventions to assist individuals in adopting favourable health behaviours and to engage in self-management strategies. Systematic reviews of integrated disease management strategies have shown that coordinated strategies and promoting self-management can improve health outcomes, yet identifying the key components of interventions is less clear (Coster 2009). Chronic disease management interventions which are designed to improve self-management typically focus on increasing self-efficacy, health literacy, symptom monitoring and management, and adherence. By addressing these important aspects of managing and living with a chronic disease, these interventions can also improve outcomes and health-related quality of life. Adherence to exercise regimes, smoking cessation and risk reducing pharmacotherapies is important for managing PAD. Making a change to health behaviours can be very challenging, especially if this involves a lifetime habit such as smoking or exercise which causes pain and discomfort. These interventions might work by engaging people with PAD in decisions regarding their own health as well as by using behavioural change strategies to promote smoking cessation, exercise participation and other lifestyle modifications.

Why it is important to do this review

Evidence supports the use of chronic disease management interventions to improve self-management in chronic diseases other than PAD (Deakin 2005; Effing 2007; Inglis 2010), however it is unclear what benefits these interventions offer for people with PAD. To our knowledge, there are no other systematic reviews of the evidence for chronic disease management interventions to improve self-management for lower-limb PAD.

OBJECTIVES

The objective of this review is to systematically review, synthesise and quantify the effects of non-pharmacological and non-surgical chronic disease management interventions targeting self-management for people with lower-limb PAD.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) of chronic disease management interventions to support self-management for people with lower-limb PAD.

Types of participants

Adults (aged ≥ 16 years) of either sex, any age or ethnic group with a diagnosis of lower-limb PAD, ideally defined by the ankle-brachial index (ABI) measurement (ABI < 0.9) or diagnostic equivalent. We will include studies which do not report an ABI or diagnostic equivalent to confirm diagnosis of PAD but state that participants were patients with PAD or had intermittent claudication. Study participants may be from hospital or community cohorts. We will exclude studies dealing with general cardiac or vascular disorders rather than specifically with PAD unless the intervention is tailored to individual patient needs (that is addresses the needs specific to people with PAD and involves the key characteristics of self-management) and data are available for participants with PAD separate from participants with other cardiac or vascular disorders.

Types of interventions

We will include chronic disease management interventions designed to engage people with lower-limb PAD in activities that protect and promote their own health (for example smoking cessation, diet, exercise). These interventions must have a component that supports people in understanding, monitoring and managing symptoms of lower-limb PAD and the impact of lower-limb PAD has on their life (intermittent claudication) as well as maintaining lifestyle modifications that are recommended to people with PAD and adherence to prescribed therapies.

Interventions which involve exercise or everyday physical activity, or both, will be considered for inclusion. However, in addition to prescribing or facilitating an exercise regime, the intervention must be multifaceted and include additional components such as support in understanding, monitoring and managing symptoms of lower-limb PAD and the impact lower-limb PAD has on their life (intermittent claudication), as well as maintaining lifestyle modifications that are recommended to people with PAD and adherence to prescribed therapies. Interventions with no self-management component will be excluded. These interventions will include an active component of support or interaction with the patient as opposed to the mere provision of recommendations about therapies to patients. Education interventions should include some form of assessment of understanding and follow-up.

These interventions could take the form of, but are not limited to, interactive education, telemonitoring, self-monitoring, a peer-support group, coaching and motivational interviewing (Lai 2010). Modifiable risk factors such as smoking and adherence to exercise can be addressed with behaviour change strategies that consider the individuals' beliefs, values and motivation to change. We will not exclude studies based on the personnel delivering the intervention and our review may include programmes delivered by lay personnel (Foster 2007).

We will compare these interventions with usual care, defined as no specialist chronic disease management intervention aimed at improving self-management. For example, usual care could involve a patient receiving instructions from a clinician to stop smoking and commence an exercise programme, but the patient is not enrolled in a programme which addresses self-management specifically and there is no ongoing follow-up of the patient to encourage or support self-management. Interventions will not be performed as part of a trial of surgical or pharmacological interventions and at the same time. The only difference between the intervention and control arms in terms of care received should be the chronic disease management intervention to support self-management.

Types of outcome measures

We will not exclude studies based on the outcomes reported. We will examine immediate outcomes (up to six weeks from the commencement of the intervention), intermediate (up to and including one year from the commencement of the intervention), and longer-term outcomes (measured more than one year after the intervention).

Primary outcomes

We will examine the following as our primary outcomes.

- Functional status will be examined in separate meta-analyses according to the individual measures of distance, such as:
    - absolute claudication distance;
    - initial claudication distance;
    - the six-minute walk test.
- Functional status will also be examined according to the individual questionnaires, such as:
    - Summary Lower Extremity Performance Score (Vogt 1994);
    - Walking Impairment Questionnaire (Regensteiner 1990);
    - Baltimore Activity Scale (Gardner 2006).
- Health-related quality of life measured using PAD-specific validated questionnaires, such as the Intermittent Claudication Questionnaire (Chong 2002), the Claudication Scale (CLAU-S) (Spengel 1997); or generic health-related quality of life measures such as the Medical Outcomes Short-Form (SF) 36 (Ware 1992) and its related instruments or the EuroQoL (EQ-5D) (The EuroQol Group 1990).

Secondary outcomes

We will examine the following as our secondary outcomes:

- all-cause mortality;
- revascularisation or amputation;
- acute events (stroke or myocardial infarction);
- self-efficacy for exercise (using validated measures such as Bandura's Self-Efficacy for Exercise Scale (Bandura 1994));
- modifiable risk factors (smoking, obesity, blood pressure, lipids);

- adherence to prescribed therapies (exercise, medications, diet);
- patient acceptance and satisfaction with the intervention;
- adverse events.

Adverse events are not a commonly reported outcome in non-pharmacological, non-surgical chronic disease management studies, however improved adherence to pharmacological interventions may lead to increases in adverse event rates and hence these will be examined, if reported.

Search methods for identification of studies

We will not apply date limits to database searches. We will search all databases from commencement of the database up to the search date. Language restrictions will not apply to any of the searches.

Electronic searches

The Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator (TSC) will search the Specialised Register and the Cochrane Central Register of Controlled Trials (CENTRAL), part of *The Cochrane Library* (www.the cochranelibrary.com). See Appendix 1 for details of the search strategy which will be used to search CENTRAL. The Specialised Register is maintained by the TSC and is constructed from weekly electronic searches of MEDLINE, EMBASE, CINAHL, AMED, and through handsearching relevant journals. The full list of the databases, journals and conference proceedings which have been searched, as well as the search strategies used, are described in the Specialised Register section of the Cochrane Peripheral Vascular Diseases Group module in *The Cochrane Library* (www.thecochranelibrary.com).
In addition, the authors will search the following databases using search strategies based on the CENTRAL search strategy.

- PsycINFO.
- Web of Science.
- ProQuest Dissertations & Theses Database.
- ANU Digital Theses Collection.
- Index to Theses.

Searching other resources

We will review bibliographies of retrieved studies to identify other relevant studies. We will use citation tracking to identify other publications related to the included studies or other relevant references.
In addition, we will search our personal literature collections for relevant studies.
We will handsearch conference abstracts to identify relevant abstracts of randomised controlled trials of self-management interventions for people with PAD. Due to resource constraints, we will handsearch abstracts for the following conferences for the past five to 10 years if we are able to obtain copies of abstract books or access to online resources:

- American Heart Association Annual Scientific Sessions;
- Society for Vascular Surgery Annual Meetings;
- Society for Vascular Nursing Annual Conventions;
- European Society for Vascular Surgery Annual Meetings.

Data collection and analysis

Two review authors will review all identified abstracts and results from database searches for relevance to the review topic. If the reference appears relevant, we will obtain a full copy of the reference for detailed review to determine the inclusion in the review or exclusion of the study.

Selection of studies

Two review authors will independently review the results of each search according to the exclusion and inclusion criteria. A third review author will adjudicate in the instance of disagreement between the first two review authors.

Data extraction and management

Two review authors will extract data from the included studies in a blinded manner and a third review author will check all extracted data for accuracy and consistency. We will use a customised electronic data extraction form to record all extracted data.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias (methodological quality). A third review author will adjudicate in the instance of disagreement between the first two review authors. We will assess the risk of bias in the following domains using the Cochrane Collaboration tool (Higgins 2011):

- sequence generation;
- allocation concealment;
- blinding;
- incomplete outcome data;
- selective outcome reporting;
- other sources of bias.

We will rate the assessment of risk of bias as 'unclear risk of bias', 'low risk of bias' and 'high risk of bias' according to the Cochrane Collaboration tool (Higgins 2011) for assessing risk of bias; examples from the text will be provided to support this classification.

Measures of treatment effect

We will analyse outcomes which are continuous variables using difference in means and the 95% confidence intervals (CI) for studies using the same outcome measurement scale. In the instance of

studies reporting the same outcome (for example quality of life or measures of functional status) but using different measurements, we will use the standardised mean difference and 95% confidence interval to report these data.
We will report risk ratios (RR) for outcomes which are dichotomous variables (that is all-cause mortality, revascularisation or amputation, and acute events).

Unit of analysis issues

If the included trials report outcomes at more than one time point, we will report the primary outcome data. That is, the main time point used in the analysis in the primary publication of the study.

Dealing with missing data

We will contact study authors via e-mail in the instance of missing or unclear data in order to maximise data synthesis. Where possible, we will perform all analyses using intention-to-treat analysis, that is, we will analyse all participants and their outcomes in the groups to which they were allocated regardless of whether they received the intervention or whether or not they were assessed for the outcome. In the event of dropouts, we will adjust the denominator for the number of participants followed up for each outcome if these data are available.

Assessment of heterogeneity

We will assess statistical heterogeneity for the outcomes meta-analysed using the I^2 statistic, which describes the percentage of variability in effect estimates due to heterogeneity (Deeks 2011).

Assessment of reporting biases

Funnel plots allow review authors to make a visual assessment of whether small-study effects may be present in a meta-analysis (Sterne 2011). Small-study effects, when the intervention effect is more beneficial in smaller studies, is considered to be possibly caused by publication bias. We will explore this potential for small-study effects in the primary outcomes of the review further using funnel plots if at least 10 studies are included in the meta-analysis of the primary outcomes (Sterne 2011).

Data synthesis

We will quantitatively meta-analyse primary outcomes and some secondary outcomes (all-cause mortality, revascularisation, amputation, stroke or myocardial infarction, smoking status) depending on the availability of suitable data from high-quality studies. Considering the likely heterogeneity in participant populations, intervention characteristics, length of follow-up and outcome measurement, we will perform a random-effects meta-analysis.
We will tabulate and describe other outcomes such as adherence, self-efficacy for exercise, modifiable risk factors (obesity, blood pressure, lipids) and patient acceptance and satisfaction with the intervention.
We will include the following outcomes in the summary of findings table: functional status, health-related quality of life, all-cause mortality, revascularisation, amputation and smoking status.

Subgroup analysis and investigation of heterogeneity

If the number of included studies permits, we will perform subgroup analyses and investigations of heterogeneity for each outcome meta-analysed by considering each particular type of intervention. For example, some studies may use a face-to-face in a group or one-on-one format, other studies may include an Internet, e-mail, telephone-based or SMS delivered intervention. We will also consider the elements of interventions, that is clinician delivered, theoretically derived, and the intensity of the intervention, if the number of included studies permits. If the number of studies permits, we will also perform subgroup analyses to examine the clinical characteristics of the study participants, such as history of revascularisation.

Sensitivity analysis

We will perform sensitivity analyses if issues with methodological quality of the included studies are identified. Additionally, we will perform a sensitivity analysis to assess the influence of publication type (full peer-reviewed publication versus abstract or thesis) on reported outcomes. We will perform further sensitivity analyses to assess the effect of dropouts on outcomes, that is, in the event of dropouts we will not adjust the denominator for the number of participants followed up for each outcome and the denominator will be the total number of participants randomised to each arm irrespective of whether or not they were followed up for the outcome. If a sensitivity analysis indicates the results are influenced by particular methodological or publication factors, we will discuss the findings of the review within this context.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor Arteriosclerosis, this term only
#2 MeSH descriptor Arteriolosclerosis, this term only
#3 MeSH descriptor Arteriosclerosis Obliterans, this term only
#4 MeSH descriptor Atherosclerosis, this term only
#5 MeSH descriptor Arterial Occlusive Diseases, this term only
#6 MeSH descriptor Intermittent Claudication, this term only
#7 MeSH descriptor Ischemia, this term only
#8 MeSH descriptor Peripheral Vascular Diseases explode all trees
#9 (arter* or vascular or vein* or veno* or peripher*) near (occlus* or reocclus* or re-occlus* or steno* or obstuct* or lesio* or block* or harden* or stiffen*)
#10 (peripheral near3 dis*)
#11 claudic* or IC
#12 (isch* or CLI)
#13 (leg or limb) near4 (obstruct* or occlus* or steno*)
#14 dysvascular*
#15 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14)
#16 MeSH descriptor Self Care explode all trees
#17 self near3 (care or help or manag* or directed or monitor* or efficacy or admin*)
#18 symptom near3 (care or help or manag* or directed or monitor* or efficacy or admin*)
#19 MeSH descriptor Patient Education as Topic, this term only
#20 (patient near3 (education or promot*))
#21 (patient near3 (information or care or manage*))

#22 (health near3 (education or promot*))
#23 health near3 information
#24 empower*
#25 MeSH descriptor Adaptation, Psychological explode all trees
#26 psychologic* near3 adjust*
#27 psychologic* near3 adapt*
#28 cope or copes or coping
#29 adapt* near4 behav*
#30 behav* near4 therap*
#31 behav* near4 intervent*
#32 MeSH descriptor Counseling explode all trees
#33 counsel* or feedback
#34 MeSH descriptor Health Education explode all trees
#35 health near3 literacy
#36 health near3 educt*
#37 MeSH descriptor Motivation, this term only
#38 motivat*
#39 MeSH descriptor Cognitive Therapy, this term only
#40 MeSH descriptor Psychotherapy explode all trees
#41 psychoeducation
#42 psycho-education
#43 psychotherap*
#44 psycho-therap*
#45 MeSH descriptor Attitude to Health explode all trees
#46 MeSH descriptor Disease Management, this term only
#47 (disease near3 manag*):ti,ab,kw
#48 MeSH descriptor Managed Care Programs, this term only
#49 (manage* near3 care):ti,ab,kw
#50 MeSH descriptor Patient Care Planning explode all trees
#51 (care near3 (patient or nursing or goal)):ti,ab,kw
#52 MeSH descriptor Delivery of Health Care, Integrated explode all trees
#53 (integrated near3 (health or care* or system or delivery)):ti,ab,kw
#54 ((interdisciplin* or multidisciplin*) near3 (care or health or deliver* or system)):ti,ab,kw
#55 MeSH descriptor Patient Care Management, this term only
#56 MeSH descriptor Patient-Centered Care, this term only
#57 MeSH descriptor Reminder Systems, this term only
#58 (reminder near3 system*):ti,ab,kw
#59 (peer near3 support):ti,ab,kw
#60 (coach*):ti,ab,kw
#61 MeSH descriptor Telemedicine, this term only
#62 (telemedicine or telemonitor*):ti,ab,kw
#63 (self near3 (care or monitor*)):ti,ab,kw
#64 (care near3 plan):ti,ab,kw
#65 (#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64)
#66 (#15 AND #65)

HISTORY

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Sally C Inglis: responsible for conception and design of this review. Responsible for writing the protocol. Reviewed and revised the protocol for intellectual content.

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None known

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