The effect of structured patient education on physical activity in patients with peripheral arterial disease and intermittent claudication: a systematic review

Abaraogu, U.O.; Dall, P.M.; Seenan, C.A.

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Title: The effect of structured patient education on physical activity in patients with peripheral arterial disease and intermittent claudication: a systematic review.

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Authors: [a,b]Ukachukwu O Abaraogu, BMR, MSc PT; [a]Philippa M Dall, PhD; [a]Christopher Seenan, PhD PT.

Institutional Affiliations: [a]School of Health and Life Sciences, Glasgow Caledonian University, Glasgow, United Kingdom. [b]Department of Medical Rehabilitation, University of Nigeria Enugu Campus Enugu, Nigeria.

Corresponding author: Ukachukwu O Abaraogu │School of Health and Life Sciences, Glasgow Caledonian University, Glasgow, United Kingdom Email: Ukachukwu.Abaraogu@gcu.ac.uk; Department of Medical Rehabilitation University of Nigeria Enugu Campus Enugu 400006 Enugu Nigeria. Email: Ukachukwu.Abaraogu@unn.edu.ng

What does this review add to the existing literature and how will it influence future clinical practice: This article describes the first comprehensive systematic review of patient education interventions for physical activity (PA) improvement for individuals with intermittent claudication. The current evidence is inconclusive regarding the effect of patients' education on PA of individuals with IC. Further research is warranted to establish the effects and optimal design of education interventions.

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Abstract

Objectives: To review the components and effects of patient education interventions to improve PA in patients with PAD and IC, and patients' experiences of these interventions.

Data Sources: CINAHL, Cochrane Library, Ovid, ProQuest, AMED, MEDLINE, PsycINFO, *Web of Science Core Collection*, and PEDRO, and Trial registers and directory of Open-Access repository websites and Web of science conference proceedings were searched. Hand searching of reference lists of identified studies was also performed to identify studies that reported the effect of patient education interventions on daily PA and/or walking capacity in individuals with PAD and IC, or studies investigating patients' experiences of such interventions.

Review Methods: A systematic search was conducted in June 2016 (updated in March 2017). Primary outcomes were daily step count and self-reported PA; the secondary outcome was absolute claudication distance. There was substantial heterogeneity in terms of modalities of patient education in the included studies; hence a narrative synthesis was implemented.

Results: Six studies (1087 participants) were included in the review. Findings from a small number of high-quality trials demonstrated potential for PA improvement with structured education interventions. Nevertheless, evidence is currently inconclusive regarding the effect on daily PA and walking capacity of patients with IC. Patients reported that they valued the interventions studied, finding them acceptable and important in improving their PA, motivating and empowering them to self-manage their condition.

Conclusions: The evidence from the review is limited and inconclusive regarding the effectiveness of structured education for increasing PA in patients with PAD and IC. More rigorous trials are needed before recommendations can be made. Future interventions should

consider the key criteria for a structured patient education programme, and also report patients' experiences and perceptions.

Abstract word count: 274

Key words: Peripheral arterial disease, intermittent claudication, physical activity, patient education, systematic review.

Introduction

Peripheral arterial disease (PAD) is a growing public health burden. PAD leads to arterial stenosis and consequently inadequate blood flow to the peripheries.[1,2] This commonly presents as pain in the lower limb(s) precipitated by exercise and relieved by rest,[3] defined as intermittent claudication (IC). Patients with IC experience functional decline and limitation in physical activity (PA),[4] further raising the risk of a cardiovascular event in a vascular system already compromised by the underlying atherosclerosis.[1,3] Therefore, patients with PAD present with an increased risk of cardiovascular and cerebrovascular events similar to those with coronary heart disease.[5]

Lower daily PA levels have been recognised as a strong predictor of increased morbidity and mortality in this population.[6] Supervised exercise programmes (SEPs) are recommended as a primary therapy for this population,[7] and have been shown to improve treadmill walking distances of patients with IC.[8,9] However, most studies reporting such improvements did not investigate daily PA, and those that have, did not find improvements in daily PA.[9] Reduced self-efficacy, attributed to poor understanding of the disease and uncertainty regarding the importance of walking has been identified as a major barrier to exercise uptake in this population.[10,11] These findings suggest that a patient-centred self-management approach to improving PA, including structured patient education, may be beneficial in this population.

Although current literature supports educating patients with IC about their disease pathology and the importance of walking,[10,11] neither evidence of effectiveness nor patients' perceptions of interventions have been established. The aim of this review is to examine the effect of patient education for improving PA in individuals with PAD and IC and the experiences and perceptions of patients of these interventions.

Methods

The protocol for this review was registered with the International Prospective Register of Systematic Reviews (CRD42015027314), and has been published elsewhere.[12]

Eligibility Criteria

Studies reporting the effect of patient education interventions on daily PA and/or walking capacity in individuals with PAD and IC, or studies investigating patients' experiences of such interventions were included in this review. Diagnosis of PAD could be objective (eg, an ankle–brachial index (ABI) <0.9), by questionnaire or clinical diagnosis. Original English language research manuscripts in peer review journals and conference proceedings were included. Studies were included only if they reported on structured patient education interventions and/or components particularly related to PAD and IC. For the purposes of this review, the key criteria used to define structured education in diabetes were adopted.[13] To be included, a patient education intervention should: i) aim to empower and inform patients, and to support self-management of their PAD/IC by building sufficient knowledge and skills to do so; ii) include topics about the nature of PAD/IC, and day-to-day living and management of PAD/IC including importance of physical activity and walking; iii) have embedded quality assurance processes including having a structured curriculum, having trained educators, being quality assured, and being audited.

Outcomes

Daily PA (daily step count and self-reported change in daily PA) was the primary outcomes. Secondary outcomes included treadmill measured walking capacity (absolute claudication distance (ACD)), pain intensity, quality of life, and qualitative data regarding patients' experiences with interventions.

Information sources, search strategy, study records and data management

A systematic search was conducted in June 2016 (Updated in March 2017). Nine databases (CINAHL, Cochrane Library, Ovid, ProQuest, AMED, MEDLINE, PsycINFO, Web of Science Core Collection, and PEDRO), trial registers and directory of Open-Access repository websites were searched by the first author (UOA) using key words: patient education, lifestyle education, behaviour change intervention, peripheral arterial disease, intermittent claudication, physical activity and homebased exercise combined with specific search terms and strategies for each database.[12] Reference lists of identified studies were also searched. Titles, abstracts and full text of selected studies were independently screened by two authors from a pool of three (UOA, CS, PD) using previously defined eligibility criteria.[12] Differences of opinion regarding inclusion or exclusion were resolved by discussion between authors and reflection in consultation with the second author (PD).

Data collection Processes

The Cochrane Consumers and Communication Review Group Data Extraction Template,[14] and the Supplementary Guidance for Inclusion of Qualitative Research[15] were adapted to extract data from the included studies. The Cochrane Collaboration risk of bias tool was used to determine and summarise risk of the included studies.[16] Assessment was made in each of the included studies and graded as 'high risk' or 'low risk' following a well described procedure.[17] Studies were subsequently rated as low-quality trials (i.e. having high risk of bias) or high-quality' trials (i.e. having low to moderate risk of bias) if there were ≥3 or <3 identifiable sources of bias respectively (Table 2). Two reviewers (UOA, CS) performed the data extraction, and made judgements regarding the risk of bias independent of each other independently. Again any disagreement was resolved by discussion between the reviewers and consultation with the second author (PD).

Results

Study inclusion

The search initially identified a total of 5707 studies (Figure 1), of which six studies, contributing data on 1087 participants were included in the final analysis. Meta-analysis was not possible due to wide variations in interventions and substantial methodological and clinical heterogeneity in the included studies. The results of this review are reported using narrative synthesis.

Characteristics of included studies

Study design, participants and quality appraisal: Five of the included studies were RCTs,[18-22] and one was a pretest-postest design.[32] The number of participants in each study ranged from 23[19] to 882[20]. The basis for IC diagnosis in most (n=4) studies was post exercise ABI≤0.9.[18,20,22,30] Clinical characteristics between the intervention and control groups were similar at baseline for all included studies, except for one study[22] where the control group had a higher resting heart rate and weight (Table 1). Overall, four of the six trials were rated as high-quality[18-20,22] (Table 2). No study was assessed to have a risk of bias related to selective reporting. Sources of bias in included studies included lack of blinding of outcome assessment (n=5),[18--21,] lack of allocation concealment (n=3),[18,19,23] lack of participants and/or personnel blinding (n=3),[21-23] and not being powered to detect an effect size (n=4).[18,19,21,22]

Components of interventions in included studies

The included studies had wide variation in the intervention components used, but all included an education session, exercise prescription, and some behavioural change techniques (BCTs) (Table 1). Information provision, goal setting, action planning and feedback were reported in all included studies. Other reported BCTs included motivational interviewing (n=3), barrier identification/problem solving (n=5), feedback on performance (n=2), and prompting self-monitoring of behavioural outcome (n=4). Intervention duration ranged from 6 weeks[19] to 4 months.[18] Most studies (n=4) instructed patients to walk through moderate-to-severe leg pain.

Control participants either received usual care,[18,19,22] an active control (7-minute video)[31] or no intervention.[20] One study did not include a control group.[23]

Outcomes reported in included studies

Five studies[18-20,22,30] reported walking capacity outcomes, and three[18,19,21] reported outcomes of daily PA. Walking capacity outcomes included treadmill walking distances and time, six minutes walking distance, WELCH score, walking impairment questionnaire speed, distance and stair climbing scores. Daily PA was assessed objectively in two studies: daily step counts using a pedometer[18] and accelerometer.[19] Three studies[18,19,23] reported outcomes on patients' experiences to interventions. Other outcomes reported included pain intensity,[23] self-efficacy and self-esteem,[19] and quality of life.[19-20,22,23]

Effect of interventions in included studies

Except where specified otherwise, effects of intervention are reported as comparison of the intervention versus the control**.**

Daily physical activity outcomes

Self-report daily physical activity outcome. Two studies provided data on self-report of daily PA.[20,21] A high-quality trial,[20] showed no difference between percentage of participants who engaged in walking for recreation ≥3 times per week (36.8 vs 31.4%; p=0.14), engaged in more than usual activity (10.2 vs 9.0%; p=0.73), or belonged to an exercise group (14.0 vs 10.1%) at 2-months. However, at 12 months follow up, a greater percentage were walking ≥ 3x/week (33.8 vs 25.0%; p=0.01), engaged in more activity than usual (11.1 vs 5.9%; p=0.03), or belonged to an exercise group (16.5 vs 1.8%; p<0.001). The other trial was of low-quality[31] and reported no change in time spent in various levels of activity.

Objectively measured daily physical activity outcome. Data on daily step counts were available from two high-quality trials.[18,19] At 4 months, Cunningham et al[18] reported a greater

184 increase in daily step count (1575; 95% CI 732 to 2419; p<0.001). In contrast, Tew et al.,[19]
185 did not find improvement in daily step count of their patients after a six-week intervention
186 (440; 95% CI -827 to1708; p>0.05).

187 ***Walking capacity***

188 Five studies[18-20,22,23] reported outcomes on walking capacity. One pretest-posttest study[23]
189 reported significant improvement in ACD: increases of 63% at 3 months, and 84% at 6
190 months compared to baseline. Similarly, one high-quality pilot RCT[19] reported a significant
191 increase in ACD at 6 weeks (173; 95% Cl 23-332) Another high-quality trial[20] found no
192 change in the number of people whose ACD improved, remained same or deteriorated at 2-
193 month follow up. However, a significantly greater number of patients were found to have
194 improved their maximum walking distance (p=0.003) at 12 months.

195 ***Quality of life and other outcomes***

196 Five trials,[18-20,22,23] reported outcomes related to quality of life (QoL). Generally, outcomes of
197 both general and disease specific QoL were mixed. One high quality trial showed
198 improvement in SF-36 (0.40 vs -0.30; p=0.002) but no change in ICQ score (p>0.05) at 4
199 months.[18] In contrast, another high quality pilot trial[19] reported improvement in ICQ (-10.6;
200 95% CI -18.9 to -2.3) but not general QoL (EQ-5D utility score 0.05; 95% CI -0.09 to 0.19).
201 Two high-quality trials reported no change in health related QoL at two months (0.83 vs 085;
202 p=0.33), and at 12-months follow-up (0.83 vs 0.84; p=0.13)[20] or in general QoL at 14
203 weeks.[22] A low quality trial however, reported post-intervention improvement in the physical
204 component of SF-36 score at both 3 months (40.8 vs 36.0; p<0.01) and at 12-month follow-
205 up (42.3 vs 36.0; p<0.01) compared to baseline.[33] For this trial, there was also an
206 improvement in the mental composite score at 3 months (45.2 vs 41.6; p<0.05) but not at 12
207 months (44.2 vs 41.6; p>0.05).

208

A high-quality trial reported an improved walking performance self-efficacy (mean adjusted difference 29.5; 95% CI 12.6-46.4) and perceived control over illness (mean adjusted difference 2.4 95% CI 0.0-4.7).[19] A low-quality trial[23] reported a decrease in pain intensity at 3 months compared to baseline (5.89 vs 4.73, $p<0.05$), which remained stable during the following 9 months (5.89 vs 4.53; $p<0.05$). Also, the time taken for claudication pain to disappear improved at 6 month from baseline (3.95 vs 2.01; $p<0.05$), and remained stable for the following 6 months (3.95 vs 2.83; $p<0.05$).

Patients experiences with interventions

Three studies[18,19,23] reported qualitative findings related to the experiences of patients with education interventions. Sixteen qualitative findings were extracted from the papers and grouped into eight categories. These categories were then merged to create three synthesised themes: Acquiring knowledge; Receiving pragmatic and tailored care; and Gaining confidence and self-monitoring (Tables 4 and 5). Although verbatim quotes were not available from the included papers, each synthesised theme is described below with some examples which reflect the patients' experiences, as reported in the included papers.

Acquiring knowledge: Acquiring knowledge entails patients being provided information about their pathology and the systemic nature of IC, being informed of the importance of secondary prevention and risk factor modification including the importance of PA. Tew et al.[19] reported that patients valued a 6-week programme of pragmatic group-based structured patient education because it provided them with greater understanding of their condition, and empowered them to walk more.

Receiving pragmatic and tailored care: Patients valued the idea of a group-based intervention which also gave opportunity for individual attention. Prevost et al.[23] reported that 97% of the participants were satisfied with the quality, duration, topics discussed as well as

the group nature of the session. Similarly, 95% reported that they were satisfied with the scope, quality, and benefit of individual discussion.

Gaining confidence and self-monitoring: Gaining confidence encompassed developing a positive self-attitude, overcoming uncertainties, and feeling empowered. Gaining confidence to self-monitor their daily step counts with a pedometer: patients were presented with the opportunity to self-monitor their progress and they considered this an important component for meeting their physical activity goal. Prevost et al.[23] reported that their participants were very satisfied with the improvement in their attitude toward walking with claudication and their physical self-confidence and valued the use of pedometer as a tool for motivation, self-monitoring, and goal setting.

Discussion

Six trials evaluating a range of patient education interventions for improving PA in patients with PAD and IC were reviewed. The included studies were mostly of high methodological quality. The major sources of risks of bias were lack of blinding of outcome assessment, performance bias and lack of allocation concealment. Combined evidence from four studies indicated that structured patient education intervention increased maximal walking capacity[19,23] and improved daily PA,[18, 20] however, similar number of studies demonstrated no change in maximal walking capacity,[20,22] and free-living PA.[19,20] Generally, while daily step count tended to improve only after longer period of follow up (4 months upwards), there was no such trend for the outcomes related to maximal walking distance. Evidence from five trials[18-20,22,23] showed marked variability regarding quality of life measures. Useful interventions from the patients' perspective included those that provided them with information about their condition, were designed to enhance group interaction while maintaining individual discussion, and that provided them with confidence and self-monitoring.

Related reviews have been conducted on behaviour change techniques[24] and home-based exercise programmes[25] for PA improvement in this population. Galea et al.[24] reported limited evidence from one high-quality RCT to support BCTs for improving maximal and pain free walking capacities, and for increasing daily PA among people with IC. Similarly, Al-Jundi et al.[25] reported that there is "low-level" evidence that home-based exercise programmes can improve walking capacity and quality of life in patients with IC. However, the reviews were limited to RCTs of BCT,[24] or primarily reported outcomes related to walking capacity rather than daily PA.[24,25] No review has considered the qualitative experiences of patients with these interventions. Further, although these reviews include studies with patient education modalities, study eligibility did not specifically consider the key criteria for a structured patient education.[13]

Possible explanations for the contrasting findings in the current review may be related to the heterogeneity of study design. One[23] of the studies employed a prepost-posttest design therefore lacked a control group, and had high risk of bias including selection, detection, and performance bias. In another trial,[21] it was difficult to completely rule out possible contamination of the control group as both groups received some form of patient education. One study[22] included patients who underwent vascular intervention in the weeks prior to the intervention, and one patient who did not report claudication pain during treadmill testing. Furthermore, the large variations in patient education modalities and components warranted different contact time, duration of intervention, time point of outcome assessment, and intervention components, possibly resulting in wider outcome variability.

The high-quality pilot trial by Tew al al.,[19] which applied a 6-week structured education intervention demonstrated potential for increasing PA early in the programme, was particularly rigorous with blinded outcome assessment demonstrating improvement in walking capacity at 6 weeks. Although no change in daily step count was observed, it is

possible that the effect of behaviour change interventions takes longer to be noticeable. There could be other factors that mediate a slow response to adapting PA change in patients with PAD and IC even when the disease pathology is understood. One possible barrier is the claudication pain which these patients experience even when they are motivated to walk. Current NICE guidelines recommend "encouraging claudicants to exercise to the point of maximal pain."[7] Perhaps for patients with IC to gain the benefit of secondary prevention, concomitant pain management may be desirable to delay the onset and reduce the intensity of pain. By delaying peak maximal pain and empowering patients through education the potential therapeutic value of walking not only could be realised early in the programme, but may be sustained.

Structured Exercise Programmes are the recommended exercise therapy for IC, however, based on the small number of included trials, most exercise programmes either do not incorporate patient education, or do not typically comply with criteria definitions of a structured education programme.[12] While 'usual care' patient education is included in the NICE SEPs recommendations for secondary preventions in IC, the development and implementation of the education components in SEPs interventions are not sufficiently reported to allow a judgement of their fidelity. Therefore, it is often not known how education was delivered, whether educators were sufficiently trained, whether education interventions were delivered as intended, and/or whether sufficient topics are included to enhance patient self-management skills. These elements are important as not only do they underpin the potential effectiveness of education programmes, they may be crucial in translating gains in a hospital based SEPs intervention to sustained improvement in daily physical activity at the end of the 3 months SEP duration, which is crucial in managing chronic diseases such as PAD/IC.

Only three of the included papers reported patient experience with interventions. In these trials, patients reported that they valued interventions that improved their understanding of the diseases pathology of PAD and IC, and provided them with information of the importance of walking and how walking helped. For these patients, gaining confidence, self-monitoring ability and skills were key to their accepting and perhaps adhering to interventions. Other important components according to the patients were the benefits from socialising in a group session without losing the opportunity for individualise care. The interventions that included these components demonstrated improvement in both maximal walking capacity,[19,23] and free-living PA.[17]

Several limitations are recognised regarding the conclusions in this review. First, the planned meta-analysis could not be implemented due to heterogeneity in the included studies. Secondly, although four of the six included papers were of high quality, three were pilot trials assessing outcomes after a relatively short time point. For instance, Tew et al.[19] only had 13 or 9 participants in each group and assessed outcomes after just a 6-week intervention. This means that an inadequate sample and early assessment of outcome could limit the statistical power. Thirdly, the time point of outcome assessments were so varied that it was difficult to establish a reference time point to assess outcome performance even in a narrative synthesis. Fourthly, lack of a control group or use of an active control group meant that the specific efficacy of the intervention versus the usual care or nothing could not be clearly ascertained. In addition, the review design itself has inherent limitations; non-English language literature and unpublished literature was not searched or reviewed.

Limited evidence from four trials is inconclusive regarding the effect of structured patient education to improve daily PA, and walking capacityof patients with IC. Interventions that provided patients with information about their disease pathology and walking, provided motivation and empowered patients were valued, acceptable and seen by patients as

important in improving their PA. Structured education programmes may prove to be an essential part of exercise programmes for patients with IC but, rigorous trials are required before this can be recommended. Future interventions should consider the key criteria for a structured patient education programme. In addition, reporting on patients constructs of their experiences and perceptions to the interventions should always be factored in and reported so that holistic evaluation of effective components from the patients' perspective can be undertaken.

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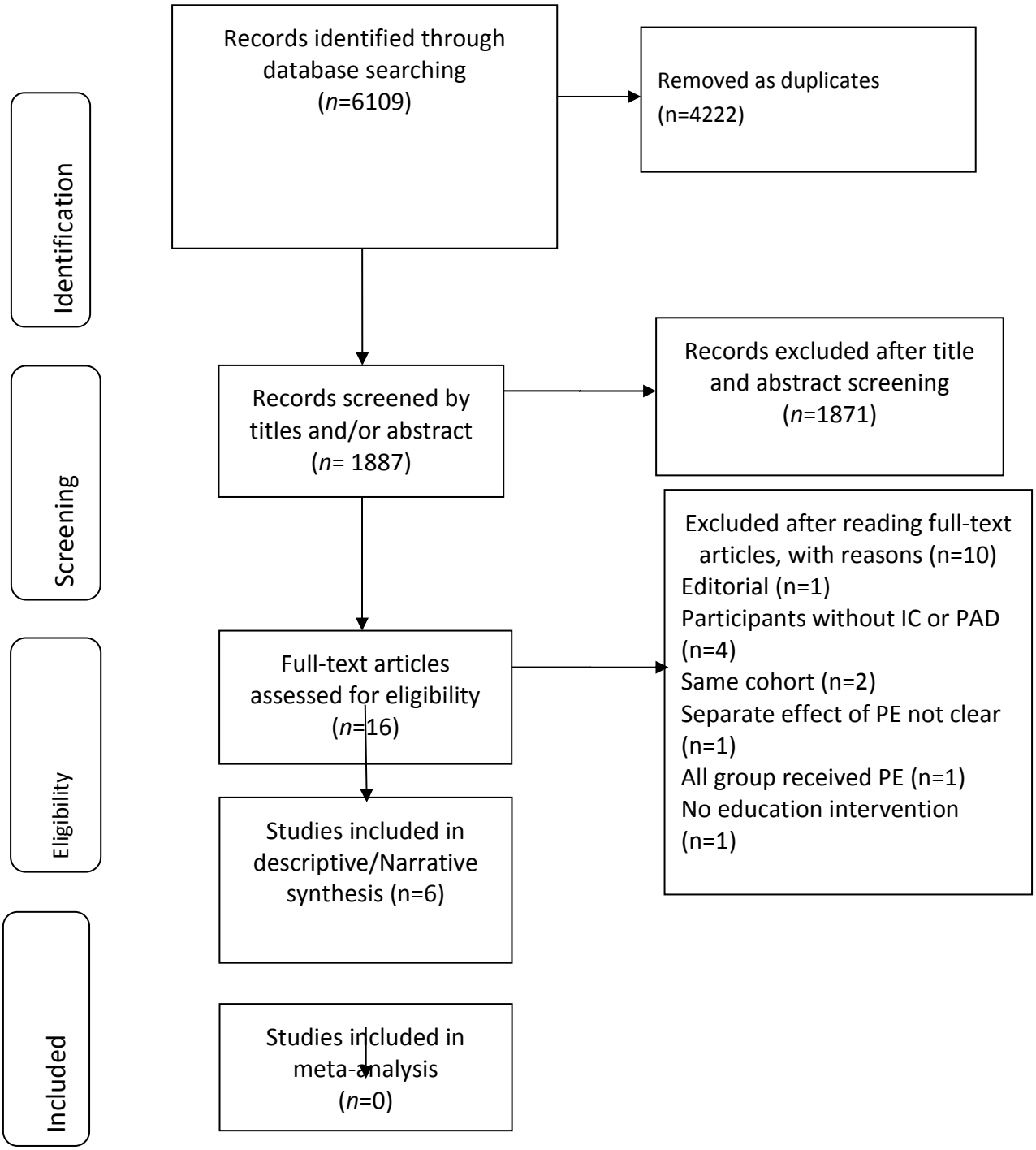

Figure 1: Patient Education review PRISMA Flow Diagram

Table 1: Characteristics of included studies

Study (country), Design, Quality, Attrition	**Participants**	**Descriptions of Interventions**	**Outcomes, follow-up**	Conclusion
Cunningham et al.[18] (UK) RCT High quality 3%	Total *n* = 58 , IC in at least one leg Post-exercise ABI<0.7	Intervention: Usual care + Information on PAD and walking, motivational interviewing, PA goal setting, action planning, self-monitoring and feedback, barrier identification with problem solving. Delivered at patients' homes by via a trainee health psychologist 2 x 1-hr sessions Control: Usual care (walking advice + consultation with vascular surgeon)	Daily steps (pedometer) Walking ability (patient report) ICQ (disease-specific quality of life) Medical Outcome Study Short-Form (generic health-related quality of life) Outcomes assessed at baseline and 4 months	Brief psychological intervention significantly improved walking behaviour in patients with IC in comparison with usual care.
Tew et al[19] (UK) Pilot RCT High quality 4.35%	Total *n* = 23 Stable Rutherford IC Classification 1-3 for ≥3months.	Intervention: Usual care plus one off 3-hr session of group patient centred structured education including patient story, PAD/IC and walking information provision, PA feedback, barrier identification with problem solving, goal setting, action planning, and self-monitoring. Delivered at in clinical research facility followed by twice-weekly phone calls for 6 weeks. Control: Usual care	Daily step (accelerometer) ICD, 6-minute walk test WELCH questionnaire ICQ (disease-specific quality of life) EQ-5D (generic health-related quality of life) Self-efficacy Acceptability (exit	Education programme is feasible, acceptable, and potentially useful for improving walking capacity and quality of life

			interview) Outcomes assessed at baseline and 6 weeks	
Fowler et al.[20] (Australia) RCT High quality 15%	Total *n* = 882 ABI ≤0.9 Clinical diagnosis of PAD Definite IC or atypical IC on Edinburgh Claudication Questionnaire	Intervention: Educational package + mobility program (supervised or home-based) + smoking cessation where applicable Control: No intervention	ICD PA pattern (Patient report) Medical Outcome Study Short-Form (generic health-related quality of life) Outcomes assessed at baseline, 2 months, and 12 months	Intervention for early PAD based on increased PA &Smoking cessation results in a greater max walking distance 12 months later.
Collins et al.[21] (USA) Pilot RCT Low quality 13.7%	Total *n* = 51, Diagnosis of PAD ABI >0.5 & ≤0.955.	Intervention: Communication intervention beginning with completion of guide and followed by 15-20 minutes of motivational interviewing, provision of information related to PAD/IC and walking, barrier identification and problem solving strategies, patient tailored walking prescription. Delivered by medical student. Control: Video Intervention	PA pattern and time (patients report) ICD and ACD WIQ Outcomes assessed at baseline, and 12 weeks.	-Patients watching video on the use of PA in PAD improved participants walking speed
Prevost et al.[23] (France) Pretest-posttest design Low quality	Total *n* = 48 Level II Leriche and Fontaine IC Atypical symptom ABI<0.9;	Intervention: Educational classes, implementation of secondary prevention, and a personalised program of reconditioning exercises. Control: No intervention	ICD and ACD Medical Outcome Study Short-Form (generic health-related quality of life)	Educational therapeutic program results in a significant improvement in functional and QoL parameters during the first 3months in patients with IC and persists even patients are no longer coached.

4.17%			Pain intensity Patients experiences via exit questionnaire (12months only) Outcomes assessed at baseline, 3 months and 12 months.	
Mays et al.[22] (USA) Pilot RCT High quality 20%	Total *n* = 25 Patients without walking limiting comorbidities except IC Severe cardiac ischemia ≤3months previous myocardia infarction TIA or stroke < 1month treatment with cilostazol or penthoxifylline Endovascular therapy 4-6wks prior baseline Or stable IC without revascularisation in the last 4-6weeks (ABI ≤0.9)	Intervention: Initial in-hospital walking exercise (2 weeks, 3 days/week) followed by community-based walking exercise (12 weeks) with training, monitoring and coaching (TMC) components. Control: Usual care (standard advice to walk)	ICD and ACD WIQ Medical Outcome Study Short-Form (generic health-related quality of life) Outcomes assessed at baseline and 14 weeks	Community-based walking exercise with TMC improves ICD and walking performances other than ACD.

Key: IC = intermittent claudication; ABI = Ankle brachial index; RCT; Randomised control trial; ACD = Absolute claudication distance; ICD = Initial claudication distance; NS = not significant, PA= Physical activity, WIQ =walking impairment questionnaire; ICQ = Intermittent claudication questionnaire, EQ-5D = EuroQoL EQ-5D-5L, WELCH = Walking Estimated- Limitation Calculated by History questionnaire

Table 2: Risk of bias in individual studies

	[*]Sources/ Potential sources of bias								
	Selection bias		Performance bias	Detection bias	Bias due to attrition	Reporting bias	Other bias		
Authors	**Random sequence generation**	**Allocation concealment**	**Participants and personnel blinding**	**Blinding of outcome assessments**	**Incomplete outcome data**	**Selective reporting**		**Summary of risk of bias**	**[†]Quality index**
Cunningham et al.[18]	No	Yes	No	Yes	No	No	Trial was not powered	Low	High
Tew et al.[19]	No	No	No	No	Yes	No	Pilot study	Low	High
Fowler et al.[20]	No	No	No	Yes	No	No	NA	Low	High
Collins et al.[21]	No	Yes	Yes	Yes	No	No	Pilot study	High	Low
Prevost et al.[23]	Yes	Yes	Yes	Yes	No	No	NA	High	Low
Mays et al.[22]	No	No	Yes	Yes	No	No	Pilot study	Low	High

[#]The Cochrane Collaboration tool for assessing risk of bias was used to determine and summarise possible sources of risk of bias in included studies (Cochrane 2011) ([*]Yes indicates the presence or potential presence of a source of bias). [*]Summary risk of bias in included studies was presented. [†]Studies were subsequently rated as low-quality trials (i.e. having high risk of bias) or high-quality' trials (i.e. having low to moderate risk of bias)if there was ≥3 or <3 identifiable sources of bias respectively

Table 3: Data extraction of finding from included studies (Except where specified, results are presented as intervention group compared to control group)

Authors	**Change in Daily PA behaviour**	**PA Capacity/Ability measures**	**Pain, Self-efficacy, and Perceived control over illness.**	**Quality of life**
Mays et al.[22]		At 14 weeks: Pain free walking time (p= NS); Greater increase in caudication onset time (5.8±1.5min to 7.4±1.6min vs 4.7±1.4min → 4.1±1.5min; p=0.045); Greater improvement in walking impairment (42.3±7.7min → 60.6±7.2% vs 49.1±7.7 → 44.6±7.2%; p=0.001).		At 14 weeks: General QoL (p=NS)
Prevost et al.[23]		Significant % increase in ICD from baseline (277% at 3months, 203% @ 6months, 141% @ 12months; p<0.001) Significant % increase in ACD from baseline (63% @ 3months; 84% @ 6months; 65% @ 12month; p <0.01).	Decrease in pain intensity at 3, 6, 12months from baseline (5.89→ 4.73* → 4.34$^{\alpha}$ → 4.53*) Improved from baseline in Time of release of pain at 6 months, and 12months(3.95 →2.01$^{\alpha}$ → 2.83$^{\alpha}$)	Improvement from baseline in physical composite score of SF-36 at 3, 6, & 12months (36.0→ 40.8→ 41.9→ 42.9; p<0.01) Improvement from baseline in the mental composite of SF-36 at 3 and 6 months (41.6→ 45.5→ 44.7→ 44.2; p<0.05)
Cunningham et al.[18]	At 4 months: Greater increase in daily steps (1358 vs -227; p<0.001)	At 4 months: *Greater pain-free walking distance (1.00 vs 0.00; p=0.008)		At 4 months: Improvement in general QoL (0.40 vs -0.30; p=0.002) Disease specific QoL (*p=NS*)
Tew et al., 2015	At six weeks : Daily steps (*p=NS)*	At six weeks: Improvement in Six-minute walk distance (44.9; CI 6.9 to 82.9); Greater increase in ACD (173; CI 23 to 322); ICD *p=NS* Greater improvement in self-reported walking ability WELCH score (21.8; CI 8.6 to 35.0); WIQ Speed (21.0; CI 3.8 to 38.1), WIQ distance (30.7; CI 6.4 to 55.0), WIQ stair climbing (30.7; CI 6.4 to 55.0).	At six weeks: Improvement in walking performance efficacy (29.5; CI 12.6 to 46.4) Greater improvement in perceive control over illness (2.4; CI 0.0 to 4.7)	At six weeks: Greater improvement in disease specific QoL (-10.6; CI -18.9 to -2.3) General QoL (p=NS)
Fowler et	**At 2nd months:** % of patients walking for	**At 2nd month:** Self-report maximum		At 2nd month: HQoL(NS)

al., 2002	recreation ≥3/wk (*p=NS*); % of patients engaging in vigorous PA (*p=NS*); % of patient belonging to exercise group (*p=NS*) **At 12th month:** Greater % of patient walking for recreation ≥3/wk (33.8 vs25; p=0.01); % of patients engaging in vigorous PA (p=NS); Greater % of belonging to exercise group (16.5 vs 1.8, p<0.001)	walking distance before the onset of pain (p=NS) **At 12th month:** Improvement in self-report maximum walking distance before the onset of pain (p=0.04)		At 12th month HQoL(NS)
Collins et al 2009	At 12weeks: Activity patterns in various levels of physical activity (*p=NS*)			

Keys: PWD = Peak walking distance; WIQ = Walking impairment questionnaire; QoL = Quality of life; COT = Claudication onset time; Int = Intervention; Cont = Control; grp = Group; NS = No significance; Δ = Change; HQoL = Health related quality of life; MWD = Maximum walking distance; ACD = Absolute claudication distance; PA = Physical activity; ICD = Initial claudication distance; FCD = Functional claudication distance.
*Results adjusted for co-founding variables
$^{\#}p<0.05$, $^{\alpha}p<0.01$

Table 4: Categories: Label and description of patients experiences with intervention

Category label	Category description
Receiving information about disease	Participants valued participation in the intervention because it provided them with greater understanding of their condition (T); Patient valued intervention because it provided them with extra information about their illness(C). 97% were very satisfied with the topic discussed (P)
Receiving information about walking	Patients reported that they valued the intervention because it provided them with understanding of the importance of walking(C); Patients reported that they valued the intervention because it provided them with understanding of how walking will help(C); Patient said intervention were worthwhile and that they valued it because it provided them with extra information about walking(C)
Being motivation and empowered	Patients reported being satisfied with their improvement in attitude towards walking with their claudication and their physical self-confidence (P); Patients reported being satisfied with their improvement in their physical self-confidence (P); Participants valued participation because it enabled them to walk more (T); Patients said they valued intervention because it provided them with extra encouragement and motivation(C).
Benefit of group education session	97% reported that they were very satisfied with the benefit of group education session (P)
Self-monitoring	The use of pedometer was valued as it was seen as useful tool for self-monitoring (T)
Goal setting	Patient reported that intervention were worthwhile because it provided them clarity on what to do(C);
Pedometer as useful tool	Patients valued the pedometer and seen as a valuable tool for motivation, self-monitoring and goal setting (T)
Receiving personalised care	95.5% reported very satisfied with the scope, quality, and benefit of individual discussion(P); Patients valued the intervention because it provided personalised plan(C)

Key: T: Tew et al.[19]; C: Cunningham et al.[18]; P: Prevost et al.[23]

Table 5: Developing synthesis findings from the categories

Synthesised finding	Category
Acquiring knowledge	Receiving information about disease; Receiving information about for walking; Goal setting; Pedometer as useful tool
Pragmatic and tailored care	Benefit of group education session; Receiving personalised care
Gaining confidence and self-monitoring	Being motivation and empowered; Pedometer as useful tool; Self-monitoring; Pedometer as useful tool