

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

3 **Short title:** patient education in intermittent claudication

4 **Category:** Review

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

26

27 **Manuscript word count** (Including title page, review highlights, abstract text, and
28 references): 4516

29

30

31 Abstract

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

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

41 **Review Methods:** A systematic search was conducted in June 2016 (updated in March
42 2017). Primary outcomes were daily step count and self-reported PA; the secondary outcome
43 was absolute claudication distance. There was substantial heterogeneity in terms of
44 modalities of patient education in the included studies; hence a narrative synthesis
45 was implemented.

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

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

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

57 **Abstract word count:** 274

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

60

61

62 **Introduction**

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

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

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

85

86 **Methods**

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

89 ***Eligibility Criteria***

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

104 ***Outcomes***

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

109 ***Information sources, search strategy, study records and data management***

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

121 *Data collection Processes*

122 The Cochrane Consumers and Communication Review Group Data Extraction Template,¹⁴
123 and the Supplementary Guidance for Inclusion of Qualitative Research¹⁵ were adapted to
124 extract data from the included studies. The Cochrane Collaboration risk of bias tool was used
125 to determine and summarise risk of the included studies.¹⁶ Assessment was made in each of
126 the included studies and graded as ‘high risk’ or ‘low risk’ following a well described
127 procedure.¹⁷ Studies were subsequently rated as low-quality trials (i.e. having high risk of
128 bias) or high-quality’ trials (i.e. having low to moderate risk of bias) if there were ≥ 3 or < 3
129 identifiable sources of bias respectively (Table 2). Two reviewers (UOA, CS) performed the
130 data extraction, and made judgements regarding the risk of bias independent of each other
131 independently. Again any disagreement was resolved by discussion between the reviewers
132 and consultation with the second author (PD).

133 **Results**

134 ***Study inclusion***

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

140 ***Characteristics of included studies***

141 ***Study design, participants and quality appraisal:*** Five of the included studies were RCTs,¹⁸⁻
142 ²² and one was a pretest-posttest design.³² The number of participants in each study ranged
143 from 23¹⁹ to 882²⁰. The basis for IC diagnosis in most (n=4) studies was post exercise
144 ABI \leq 0.9.^{18,20,22,30} Clinical characteristics between the intervention and control groups were
145 similar at baseline for all included studies, except for one study²² where the control group had
146 a higher resting heart rate and weight (Table 1). Overall, four of the six trials were rated as
147 high-quality^{18-20,22} (Table 2). No study was assessed to have a risk of bias related to selective
148 reporting. Sources of bias in included studies included lack of blinding of outcome
149 assessment (n=5),¹⁸⁻²¹ lack of allocation concealment (n=3),^{18,19,23} lack of participants and/or
150 personnel blinding (n=3),²¹⁻²³ and not being powered to detect an effect size (n=4).^{18,19,21,22}

151 ***Components of interventions in included studies***

152 The included studies had wide variation in the intervention components used, but all included
153 an education session, exercise prescription, and some behavioural change techniques (BCTs)
154 (Table 1). Information provision, goal setting, action planning and feedback were reported in
155 all included studies. Other reported BCTs included motivational interviewing (n=3), barrier
156 identification/problem solving (n=5), feedback on performance (n=2), and prompting self-
157 monitoring of behavioural outcome (n=4). Intervention duration ranged from 6 weeks¹⁹ to 4
158 months.¹⁸ Most studies (n=4) instructed patients to walk through moderate-to-severe leg pain.

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

161 ***Outcomes reported in included studies***

162 Five studies^{18-20,22,30} reported walking capacity outcomes, and three^{18,19,21} reported outcomes
163 of daily PA. Walking capacity outcomes included treadmill walking distances and time, six
164 minutes walking distance, WELCH score, walking impairment questionnaire speed, distance
165 and stair climbing scores. Daily PA was assessed objectively in two studies: daily step counts
166 using a pedometer¹⁸ and accelerometer.¹⁹ Three studies^{18,19,23} reported outcomes on patients'
167 experiences to interventions. Other outcomes reported included pain intensity,²³ self-efficacy
168 and self-esteem,¹⁹ and quality of life.^{19-20,22,23}

169

170 **Effect of interventions in included studies**

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

173 ***Daily physical activity outcomes***

174 ***Self-report daily physical activity outcome.*** Two studies provided data on self-report of daily
175 PA.^{20,21} A high-quality trial,²⁰ showed no difference between percentage of participants who
176 engaged in walking for recreation ≥ 3 times per week (36.8 vs 31.4%; $p=0.14$), engaged in
177 more than usual activity (10.2 vs 9.0%; $p=0.73$), or belonged to an exercise group (14.0 vs
178 10.1%) at 2-months. However, at 12 months follow up, a greater percentage were walking \geq
179 3x/week (33.8 vs 25.0%; $p=0.01$), engaged in more activity than usual (11.1 vs 5.9%;
180 $p=0.03$), or belonged to an exercise group (16.5 vs 1.8%; $p<0.001$). The other trial was of
181 low-quality³¹ and reported no change in time spent in various levels of activity.

182 ***Objectively measured daily physical activity outcome.*** Data on daily step counts were
183 available from two high-quality trials.^{18,19} At 4 months, Cunningham et al¹⁸ 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 to 1708; $p > 0.05$).

187 *Walking capacity*

188 Five studies^{18-20,22,23} reported outcomes on walking capacity. One pretest-posttest study²³
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 RCT¹⁹ reported a significant
191 increase in ACD at 6 weeks (173; 95% CI 23-332). Another high-quality trial²⁰ 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 trial¹⁹ 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 0.85;
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

209 A high-quality trial reported an improved walking performance self-efficacy (mean adjusted
210 difference 29.5; 95% CI 12.6-46.4) and perceived control over illness (mean adjusted
211 difference 2.4 95% CI 0.0-4.7).¹⁹ A low-quality trial²³ reported a decrease in pain intensity at
212 3 months compared to baseline (5.89 vs 4.73, $p<0.05$), which remained stable during the
213 following 9 months (5.89 vs 4.53; $p<0.05$). Also, the time taken for claudication pain to
214 disappear improved at 6 month from baseline (3.95 vs 2.01; $p<0.05$), and remained stable for
215 the following 6 months (3.95 vs 2.83; $p<0.05$).

216 *Patients experiences with interventions*

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

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

230 ***Receiving pragmatic and tailored care:*** Patients valued the idea of a group-based
231 intervention which also gave opportunity for individual attention. Prevost et al.²³ reported that
232 97% of the participants were satisfied with the quality, duration, topics discussed as well as

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

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

243 **Discussion**

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

258 Related reviews have been conducted on behaviour change techniques²⁴ and home-based
259 exercise programmes²⁵ for PA improvement in this population. Galea et al.²⁴ reported limited
260 evidence from one high-quality RCT to support BCTs for improving maximal and pain free
261 walking capacities, and for increasing daily PA among people with IC. Similarly, Al-Jundi et
262 al.²⁵ reported that there is “low-level” evidence that home-based exercise programmes can
263 improve walking capacity and quality of life in patients with IC. However, the reviews were
264 limited to RCTs of BCT,²⁴ or primarily reported outcomes related to walking capacity rather
265 than daily PA.^{24,25} No review has considered the qualitative experiences of patients with these
266 interventions. Further, although these reviews include studies with patient education
267 modalities, study eligibility did not specifically consider the key criteria for a structured
268 patient education.¹³

269 Possible explanations for the contrasting findings in the current review may be related to the
270 heterogeneity of study design. One²³ of the studies employed a prepost-posttest design
271 therefore lacked a control group, and had high risk of bias including selection, detection, and
272 performance bias. In another trial,²¹ it was difficult to completely rule out possible
273 contamination of the control group as both groups received some form of patient education.
274 One study²² included patients who underwent vascular intervention in the weeks prior to the
275 intervention, and one patient who did not report claudication pain during treadmill testing.
276 Furthermore, the large variations in patient education modalities and components warranted
277 different contact time, duration of intervention, time point of outcome assessment, and
278 intervention components, possibly resulting in wider outcome variability.

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

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

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

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

316 Several limitations are recognised regarding the conclusions in this review. First, the planned
317 meta-analysis could not be implemented due to heterogeneity in the included studies.

318 Secondly, although four of the six included papers were of high quality, three were pilot trials
319 assessing outcomes after a relatively short time point. For instance, Tew et al.¹⁹ only had 13
320 or 9 participants in each group and assessed outcomes after just a 6-week intervention. This
321 means that an inadequate sample and early assessment of outcome could limit the statistical
322 power. Thirdly, the time point of outcome assessments were so varied that it was difficult to
323 establish a reference time point to assess outcome performance even in a narrative synthesis.

324 Fourthly, lack of a control group or use of an active control group meant that the specific
325 efficacy of the intervention versus the usual care or nothing could not be clearly ascertained.

326 In addition, the review design itself has inherent limitations; non-English language literature
327 and unpublished literature was not searched or reviewed.

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

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

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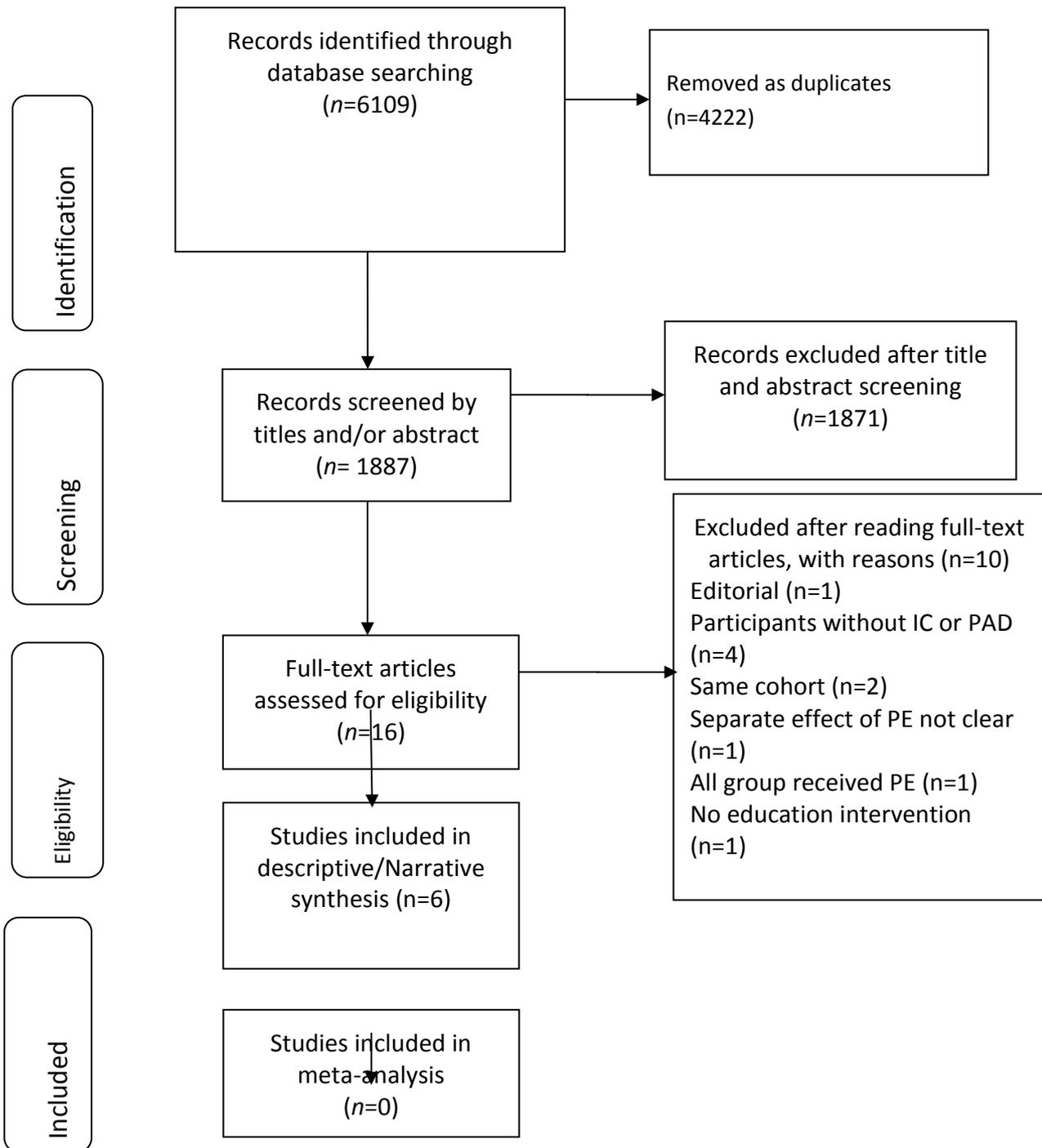


Figure 1: Patient Education review PRISMA Flow Diagram

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 ≥ 3 months.	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)	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)	Intervention for early PAD based on increased PA & Smoking cessation results in a greater max walking distance 12 months later.
RCT				
High quality				
15%				
			Outcomes assessed at baseline, 2 months, and 12 months	
Collins et al. ²¹ (USA)	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	-Patients watching video on the use of PA in PAD improved participants walking speed
Pilot RCT				
Low quality				
13.7%			Outcomes assessed at baseline, and 12 weeks.	
Prevost et al. ²³ (France)	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 3 months in patients with IC and persists even patients are no longer coached.
Pretest- posttest design				
Low quality				

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)	Total $n = 25$	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.	ICD and ACD	Community-based walking exercise with TMC improves ICD and walking performances other than ACD.
Pilot RCT	Patients without walking limiting comorbidities except IC		WIQ	
High quality	Severe cardiac ischemia ≤ 3 months previous myocardia infarction TIA or stroke	Control: Usual care (standard advice to walk)	Medical Outcome Study Short-Form (generic health-related quality of life)	
20%	< 1month treatment with cilostazol or pentoxifylline Endovascular therapy 4-6wks prior baseline Or stable IC without revascularisation in the last 4-6weeks (ABI ≤ 0.9)		Outcomes assessed at baseline and 14 weeks	

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

Authors	*Sources/ Potential sources of bias						Summary of risk of bias	†Quality index	
	Selection bias		Performance bias	Detection bias	Bias due to attrition	Reporting bias			Other bias
	Random sequence generation	Allocation concealment	Participants and personnel blinding	Blinding of outcome assessments	Incomplete outcome data	Selective reporting			
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 ^a → 4.53*) Improved from baseline in Time of release of pain at 6 months, and 12months(3.95 → 2.01 ^a → 2.83 ^a)	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	<p>recreation ≥ 3/wk ($p=NS$); % of patients engaging in vigorous PA ($p=NS$); % of patient belonging to exercise group ($p=NS$)</p> <p>At 12th month: Greater % of patient walking for recreation ≥ 3/wk (33.8 vs 25; $p=0.01$); % of patients engaging in vigorous PA ($p=NS$); Greater % of belonging to exercise group (16.5 vs 1.8, $p<0.001$)</p>	<p>walking distance before the onset of pain ($p=NS$)</p> <p>At 12th month: Improvement in self-report maximum walking distance before the onset of pain ($p=0.04$)</p>		<p>At 12th month HQoL(NS)</p>
Collins et al 2009	<p>At 12weeks: Activity patterns in various levels of physical activity ($p=NS$)</p>			

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

[#] $p<0.05$, ^u $p<0.01$

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