Title:

Effect of Behavior-change Interventions on Daily Physical Activity in Patients with Intermittent Claudication: The OPTIMA Systematic Review with Meta-Analysis

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ABSTRACT

Aims: The study aimed to synthesize evidence of daily physical activity (PA) following Behavior-change technique (BCT)-based interventions compared to any control in individuals with peripheral arterial disease/intermittent claudication (PAD/IC); and examine the relationship between BCTs and daily PA.

Methods: Systematic search of 11 databases from inception to 30/11/2022 was conducted, plus weekly email alerts of new literature until 31/8/2023. Studies comparing BCT-based interventions with any control were included. Primary analysis involved a pairwise random-effects meta-analysis. Risk of bias was assessed using the Cochrane-RoB-2 and ROBINS-I tools. Certainty of evidence was evaluated with the GRADE system. The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guideline was followed. Outcome measures were short-term (<6 months) change in daily PA, and maintenance of the daily PA (6 months or longer) reported as standardized mean differences (SMDs) with 95% confidence intervals (95%CIs).

Results: Forty-one studies (4,339 patients; 26 RCTs/3,357 patients; 15 non-RCTs/982 patients; study mean age 60.3 to 73.8, 29.5% female) were included. Eleven RCTs (15 comparisons, 952 participants) suggested that BCT-based interventions increased daily PA in the short term compared to non-SET [increase of 0.20 SMD (95%CI: 0.07 to 0.33), ~473 steps/day] with high certainty. Evidence of maintenance of daily PA (≥6 months) is unclear [increase of 0.12 SMD (95%CI: -0.04 to 0.29); ~288 steps/day; 6RCTs, 8 comparisons, 899 participants], with moderate certainty. For daily PA, compared to SET it was inconclusive both for < 6months change [-0.13 SMD, 95%CI: -0.43 to 0.16); 3RCTs, 269 participants; low certainty] and ≥6months [-0.04 SMD, 95%CI: -0.55 to 0.47); 1 RCT, 89 participants; very low certainty]. It was unclear whether the number of BCTs or any BCT domain were independently related to an increase in PA.

Conclusion: BCT-based interventions improve short-term daily PA in people with PAD/IC compared to non-SET controls. Evidence for maintenance of the improved PA at 6 months or longer and comparison with SET is uncertain. BCT-based interventions are effective choices for enhancing daily PA in PAD/IC.

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Lay summary: This study evaluated the effect of behavior-change interventions on daily physical activity (PA) in people with intermittent claudication.

- In individuals with intermittent claudication, behavior-change interventions improve short-term physical activity compared to controls, but additional research is needed to ascertain their sustained benefits at 6-months or longer, as well as their benefit compared to SET.
- Behavior-change technique (BCT) based interventions may support patients to engage in daily physical activity.

Keywords: Peripheral arterial disease, Intermittent claudication, Behaviour change techniques, Behaviour change interventions, physical activity

Introduction

International guidelines recommend supervised exercise therapy (SET) as the primary treatment for intermittent claudication (IC) due to clinical and cost-effectiveness and lower rates of adverse events.[1] Availability of SET programs is limited by funding, staffing, and facilities,[2] whilst time, travel, pain-induced exercise intolerance, multimorbidity, low motivation, and limited disease understanding contribute to low enrolment and adherence.[3–5]

Optimum physical activity (PA) improves IC symptoms, cardiovascular risk factors, overall health, and quality of life.[6] Physical inactivity independently predicts disease outcomes and all-cause mortality in IC.[7] Individuals with PAD[8] and those with IC symptoms[9,10] are less physically active than peers without the disease. Increasing PA is crucial as engaging even in light-intensity PA is linked to 50% reduction in the risk of all-cause and cardiovascular mortality in patients with IC.[11]

Changing PA behavior is challenging.[12] Behavior change techniques are distinct, observable, and reproducible elements within interventions that aim to steer behavior.[13] Interventions utilising BCTs have been effective in promoting daily PA in various populations,[14,15] but their specific effectiveness in IC remains unclear. This paper aimed to report on the meta-analysis of the effectiveness of BCT-based interventions in enhancing and sustaining daily PA in people with IC, and the association between BCTs and daily PA.

Methods

The OPTIMA project was conceptualised and conducted with a Patient and Public Involvement and Engagement panel, including patients with IC, and prospectively registered on PROSPERO (CRD42020159869).[16] This paper reports on the primary outcome measure from the quantitative review. The secondary outcomes are reported in a companion paper. Our report follows PRISMA reporting guidelines.[17]

Information sources and search

Medline (OVID); Embase (OVID); CINAHL (EBSCO); Web of Science core collection (Clarivate); Psycinfo (OVID); NHS Economic Evaluation Database; Social Science Citation Index (Clarivate); Database of Abstracts of Reviews of Effects; CENTRAL (The Cochrane Library); PEDRO; Health Technology Assessment Database and trial registries (ClinicalTrials.gov and ICTRP (WHO)) were searched from inception to 30/11/2022. Additionally, we manually searched reference lists of included studies, and received weekly alerts about new literature until 31/8/2023. The search used a combination of controlled and free text vocabulary, using term sets for condition, (e.g. intermittent claudication), behavior-change interventions (e.g., home-based exercise), and outcomes (e.g. physical activity) (Supplementary material online, Table S1). No restrictions were used for language, publication year or publication status.

Study Selection and Data Extraction

Reports of interventions that contained at least one BCT according to the BCT taxonomy v1,[13] in adults (≥18 years) with IC, any study design with a BCT intervention, with or without a comparator arm were

included. Two researchers (from UA, DS, EA, TG, CG, JD, CO) independently screened titles and abstracts, then full texts with disagreements discussed by a third reviewer. Authors were contacted (twice) when there was insufficient information. We extracted authors, year of publication, participants and intervention characteristics, and outcome data. Two trained reviewers (from LB, DS, TG, JM, SA) independently extracted BCTs, with discrepancies discussed by a third reviewer. The 93 BCTs were rated as present (clear evidence of inclusion) or absent, in both the intervention and comparison groups. If the same BCT was present in both intervention and comparison groups, the BCT was excluded from the total.[18]

Outcomes

This paper reports on daily PA, the primary outcome of the quantitative OPTIMA review. Measures (self-report or device-based) were included if they covered sufficient time (e.g. usual week), included a range of types and/or intensity of PA, and reported a suitable outcome (e.g. volume) to adequately report daily PA (screening tool in Supplementary material online, Table S2). Where PA was reported using more than one method, daily steps (the most common measure) were used. Data were synthesized at the following time points: less than 6-months: earliest change outcomes assessed within 6 months from baseline, and 6-months or longer: latest change outcomes assessed at 6 months or longer from baseline.

Risk of Bias Assessment

Two reviewers (from UA, EA, SR, LB) independently assessed the risk of bias in included studies and evaluated the overall review quality of evidence, using the Risk-of-Bias 2 (RoB 2) tool[19] for RCTs, and the Risk of Bias in Non-Randomized Studies-of Interventions (ROBINS-I)[20] for non-RCTs. The Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) method was applied to evaluate the certainty of evidence, considering bias, inconsistency, indirectness, imprecision, and publication bias[21](See table S12 - Supplementary material online). Differences were resolved through discussion and consensus.

Statistical analysis

RCTs with a measure of daily PA were combined in meta-analyses of pairwise comparisons using Stata v14 (College Station, TX). Pooled effect sizes with 95% confidence intervals were estimated using random-effects meta-analysis. Change from baseline and associated standard deviation (SD) was used in all analyses, where not reported we calculated using baseline and follow-up values and an imputed within-arm correlation of 0.5.[22] The rationale for using change scores is because an analysis based on changes from baseline is stated to be more effective as compared to using post-intervention values, as it removes an aspect of between-person variability from the analysis.[22] Standardized mean differences (SMD) were used to combine multiple measures used for the same outcome (e.g. total steps and PA duration).

Our primary analyses included robust evidence from RCTs comparing BCT-based interventions with any control. A control could be 'treatment as usual', attention control or an alternative intervention (without any BCTs or using fewer BCTs). We also separately analyzed studies that compared a BCT-based intervention to SET. When comparing BCT vs control, three-arm studies with two BCT interventions were included as two separate comparisons to a single control, halving the control group to avoid double counting. Data from some 3-arm studies were used twice: in analyses of BCT vs control and BCT vs supervised exercise. Data from non-RCTs were pooled separately.

Heterogeneity was assessed by visually inspecting forest plots and using the I^2, and Tau^2 statistics.[22] We conducted sensitivity analyses for the primary outcome to assess robustness, including:

- Fixed effects meta-analysis.
- Imputing a within-person correlation of 0.8.
- Excluding studies with estimated SDs.
- Removing one arm from 3-arm studies.
- Excluding supervised BCT interventions.
- Excluding studies at high risk of bias.
- Excluding studies using self-reported measures.
- Using only studies that reported 'steps/day'.

SMD-analysed data was converted back to steps/day (most common format) by multiplying the SMD with the median control group change-from-baseline. Network meta-analysis (NMA)[23] was used to compare types of BCT interventions, including post-hoc grouping by mode of delivery.

We used random-effects meta-regression to explore the relationship between individual BCTs, BCT domains, and effect size for daily PA. We analysed each BCT and BCT domain separately, comparing studies using BCTs within the domain to those that didn't. We couldn't combine multiple domains due to limited data. We conducted meta-regression to explore how the number of BCTs exclusive to intervention relates to the effect size. For each BCT appearing in ≥five interventions, meta-regression was conducted comparing the effect size in trials of an intervention that contained the BCT with those that didn't.

Results

Our search identified 6279 records, we screened 155 articles for full-text, and 41 studies (53 records) were included (Figure 1), 26 RCTs (3357 participants) and 15 non-RCTs (982 participants). An overview of included studies are in Table 1. Excluded records and the reason for their exclusion are documented in Supplementary material online, Table S3.

Description of the population

There were 4,339 participants in included studies (range 11 to 882, 29.5% female, mean age 68.7 [mean age range 60.3 to73.8] years). Study populations ranged from newly diagnosed individuals to those with longstanding disease and previous surgical interventions. When reported (29 studies did not), participants were predominantly white in 7 studies,[24–30] predominantly black or African American in 4 studies,[31–34] and a mix of white, black, and Hispanic in 1 study.[33]

Description of the Interventions

Interventions in the included studies encompassed structured and home-based walking programs, resistance training, activity monitoring, psychological interventions, group exercise sessions, and communication with healthcare providers. Interventions often included goal setting, motivational techniques, and offered exercise-related education for PAD.

Fifteen studies included initial face-to-face structured walking/exercise sessions followed by telephone or mobile health follow-up for feedback, reinforcement, support, or monitoring.[24,25,27,28,30,31,33,35–42] Eight studies included an education component within a structured walking intervention without telephone or mobile health follow-up.[34,43–49] Seven studies used home-based structured walking programs without education or follow-up.[26,50–55] Six studies incorporated supervised exercise alongside education,

community-based walking, lifestyle coaching, and feedback.[29,56–60] Two studies employed a mobile health intervention with goal and progress review during follow-up visits.[42,61] Two studies used individual motivational interviews,[62,63] with 1 additionally following up via smartphone.[62] One study combined health coaching and walking training.[64]

Eleven studies did not have a comparator arm[34,36,47–49,53,53,55,56,59,64] and six were 3-arm trials with two active arms.[26,32,37,40,50,54] Comparator groups were described as: usual care (10 studies)[27,30,35,38,41,44,45,50,58,61], supervised exercise (6 studies)[28,39,42,43,51,52], walking advice (4 studies)[29,40,54,60], attention control (3 studies)[24–26,37], health education (3 studies)[31,32,63], and 'no intervention' (1 study).[62] Additional active controls were used in 5 of the studies that reported 3 arms, including supervised exercise in 4 studies [26,40,50,54] and high-intensity walking in 1 study.[32]

The duration of intervention sessions ranged from 30 minutes to 3 hours (not reported in 9 studies[27,34,36,37,42,44,51,53,64]). Intervention frequency was mostly 3 times/wk[25–29,31,32,34–37,39–42,45–52,54,55,57,59,60,64] but three studies had one-off sessions followed by telephone calls every two weeks.[33,38,63] Three interventions lasted between 1-2 months,[36,38,56] the rest were 3 months or greater. The follow up period was less than 6 months in 12 studies,[24,26,33,36,37,44,50,53,55,57,61,62] between 6 and 9 months in 6 studies,[25,28,30,41,43,59] 12 months in 11 studies,[31,32,40,42,45–47,49,52,58,60] and 2 years in 1 study.[65] Eleven studies did not report any follow up beyond the period of intervention.[27,29,34,38,39,48,51,54,56,63,64]

BCTs in included studies

Forty-six unique BCTs were identified across the 41 studies, implementing 47 unique interventions (Supplementary material online, Table S4). The mean (SD) number of BCTs coded per intervention was 7.60 (3.80), ranging from 2[28] to 17.[28,49] The most frequently occurring BCT was Goal setting (behavior), which was coded in 36 (78%) interventions. Other commonly used BCTs were 'Instruction on how to perform a behavior' (63%), 'Behavioral practice/rehearsal' (52%), 'Feedback on behavior' (52%), 'Social support(unspecified)' (50%), 'Self-Monitoring of behavior' (48%), 'Review behavior goals(s)' (43%), 'Problem solving' (35%) and 'Information about health consequences' (35%). Overall, 31 (67%) BCTs were used in fewer than five interventions.

Risk of bias in included studies

Risk of bias judgment for each the 26 RCTs and overall certainty are summarised in **Table 2**. Overall risk of bias was deemed low in 11 trials[26,29–32,35,38,40,40,41,50,65–71] (42%; 18 records), having some concerns in 10 trials[25,33,42,44,45,54,58,60,61,63,72–75] (39%; 14 records), and high in 5 trials[27,28,37,39,62] (19%; 5 records). Risk of bias arising from the randomization process was deemed low in 20 trials[25,26,29–33,35,38,40–42,50,54,58,60,61,63,65–77] (77%; 31 records). Bias due to missing outcome data was deemed low in 18 trials[24–38, 40–42, 44–47, 49–51, 56, 72, 77] (69%; 28 records). Risk of bias because of deviation from the intended interventions was low in 16 trials[24–26,29,30,30–32,35,38,40,41,45,50,54,58,60,65,67–70,72,73,75–77] (62%; 27 records). Fifteen trials were assessed low risk in terms of bias due to measurement of the outcome[24–27,29,30,30,31,35,38,40,41,50,54,61,65,67–70,74,76,77] (58%; 23 records), and bias arising from selection of the reported outcomes[24,26,30–32,35,38,41,41,42,50,58,60,61,65,67–75,77] (58%; 25 records). The items that contributed most to the assessment of high risk of bias for the RCTs were deviations from intended interventions and missing outcome data. Overall, we judged thirteen of the 15 non-RCT studies to have serious concern regarding risk of bias, and 2 to have moderate risk of bias

(Supplementary material online, Table S5). Bias due to confounding factors contributed most to assessment of serious risk of bias.

Meta-analysis

Physical activity volume

BCT-based interventions vs Controls

Evidence from 11 trials (15 comparisons, 952 patients) suggested that at <6months BCT-based interventions increase the volume of daily PA (Figure 2), with little evidence of heterogeneity (SMD, 0.20; 95%CI: 0.07-0.33; I^2=0%; Tau^2=0.00; high-certainty evidence). This improvement corresponded to an increase of 473 steps/day (95%CI: 165 steps/day to 780 steps/day)**.** This result was similar after conducting sensitivity analyses (Supplementary material online, Table S6) and there was no evidence of publication bias. Considering that some studies used subjective self-report measures of PA as opposed to objective device-based measures, a sensitivity analysis was conducted excluding such studies, however, the results were similar (Supplementary material online, Table S6). Combined data from three non-randomised studies (3 comparisons, 69 participants) suggested that BCT interventions increase daily PA by 786 steps/day (95%CI 198 steps/day to 1373 steps/day) which is consistent with the evidence from the RCTs (Supplementary material online, Figure S1). Evidence from 6 trials (8 comparisons, 899 patients; moderate-certainty evidence) leaves it unclear whether BCT-based interventions increase daily PA ≥6 months, with low heterogeneity (SMD, 0.12; 95%CI: -0.04-0.29; I^2=26.1%, Tau-squared=0.01). This corresponds to an increase of 288 steps/day (95%CI: -102 steps/day to 676 steps/day) (Figure 2).

BCT-based interventions vs SET

Low quality evidence from 3 trials (3 comparisons, 269 participants; low-certainty evidence) left it unclear whether BCT-based interventions increased daily PA in the short-term compared to SET (Figure 2), with little evidence of heterogeneity (SMD, 0.13; 95%CI: -0.43-0.16; I^2=0%, Tau-squared=0.00). Very low certainty evidence from one trial (1 comparison, 89 participants) left it unclear whether BCT-based interventions increase daily PA ≥6 months (SMD, -0.04 SMD; 95%CI: -0.55 to 0.47) compared to SET.

Exploratory network meta-analysis comparing interventions by mode of delivery both <6months and ≥6months left it unclear whether any intervention modality was better than any other (Supplementary material online, Table S7). Pairwise comparisons combining both direct and indirect evidence produced wide confidence intervals that did not rule out 'no difference'. Ranking and SUCRA estimates [23] suggested that supervised exercise was likely to offer the most benefit in terms of PA <6months, and that other BCT interventions or BCT interventions with technology were likely to offer the most benefit ≥6 months (Supplementary material online, Table S8).

Association between BCTs and intervention effects

Meta-regression on the outcome of daily PA did not suggest a relationship between the number of BCTs and the magnitude of the effect size either <6 months (effect -0.01: 95%CI -0.04 to 0.02) or ≥6 months (effect 0.00: 95%CI -0.04 to 0.04) (Supplementary material online, Table S9). After comparing interventions that did and did not use individual BCT domains, it was unclear whether any domain was independently related to increased PA (Supplementary material online, Table S10). For each commonly

occurring BCT, we saw no evidence to suggest that interventions containing that BCT were associated with a larger effect size than interventions that did not (Supplementary material online, Table S11).

Discussion

The primary finding was that BCT-based interventions lead to a significant increase in daily PA (approximately 473 steps/day) for individuals with IC at <6 months, outperforming non-supervised exercise controls. The impact becomes less definitive at ≥ 6 months, resulting in a modest increase in daily PA (approximately 288 steps/day), with much uncertainty due to participant attrition, fewer trials and increased heterogeneity. When compared to SET, the effects of BCT-based interventions on daily PA are uncertain. Pairwise meta-analysis found no statistically significant difference, but exploratory network meta-analysis showed that SET was most effective <6months, while BCT-based interventions were most effective ≥6 months.

The increase of 473 steps/day found in this review represents 13% of the average daily steps (3586) of typical adults with IC.[78] Guidelines recommend 150 minutes per week (22 minutes/day) of moderate-to-vigorous aerobic PA.[79] In public health messaging this is often simplified as 3000 steps in 30 minutes.[80] At that rate, the 473 steps observed in our review would represent an additional 4.7 min of walking, approximately 20% of the PA daily guidelines. Many of the comparator arms in the included studies had active BCTs and also increased PA, meaning that the true effect of the BCT-based interventions may have been underestimated. International PA guidelines also recommend that any increase of PA among previously inactive individuals can improve overall health.[81,82] Individuals with IC face unique barriers to PA,[3,4] with low PA compared to peers,[9,10] and therefore any increase in daily PA represents an important health behavior-change with the potential to positively impact their clinical outcomes.[7,11,83–85] Indeed, members of our Patients and Public Involvement (PPI) group (CG, JD) believed that 400 steps/day was a meaningful improvement.

Investigating the maintenance of behavior changes over time, especially in the absence of intervention contact, is essential to understand whether positive changes can be maintained. There was a small increase in daily PA of BCT-based intervention over the non-SET sustained at ≥6 months, but the margins of the confidence intervals were wide and we could neither confirm nor rule out benefit. However, this small increase may be important given that IC is a progressive long-term condition, and the natural course of the disease would expect patients to reduce PA over time. The success in sustaining the gained PA benefit beyond 6 months needs further investigation.

Our meta-analysis did not confirm or rule out a superior outcome for daily PA for BCT-based interventions compared to SET, but our exploratory network meta-analysis suggested that BCT-based interventions were more beneficial than SET for daily PA beyond 6 months . Current guidelines recommend SET as the first line treatment in people with IC.[1] However, given that IC is a long-term condition and patients need to maintain long-term optimal PA to continue to derive positive disease outcomes, BCT-based interventions may represent a promising alternative for long-term maintenance of PA. However, further research would be needed to establish the evidence base.

The BCTs linked to improved daily PA can vary across different populations. For example, BCTs 'goal setting' and 'feedback' for cancer survivors[86], and 'action planning', 'graded tasks,' and 'unspecified social support' in hospitalized patients were associated with interventions that increased PA.[87] This review did not identify any specific connections between individual BCTs or BCT domains and daily PA

for people with IC. This does not conclusively rule out the existence of an association, but it highlights the challenge in establishing one due to the consistent use of a limited set of BCTs and BCT domains in the relatively small number of studies included. Further exploration in this area is warranted.

Limitations

Data were combined from different BCT-based interventions and comparisons. Including studies from single and multicomponent interventions delivered across different settings via different modes potentially increases clinical heterogeneity, which could limit the chances of drawing accurate inferences from the findings. Despite that the analysis showed little evidence of heterogeneity when estimated with the I^2 test, sensitivity analyses including a fixed effect meta-analysis were conducted to ensure robustness. The sensitivity analyses showed similar results, however, it is important for future research to include a broader set of BCTs in the intervention and ensure that the control groups are devoid of BCTs to help for more homogeneity across studies. The BCTs in the included studies were identified through coding of various indicative sentences by trained reviewers, as most of the studies did not specifically name the BCTs they used. Future research should use a comprehensive classification system such as the BCT ontology in describing and reporting of the BCTs implemented in interventions to facilitate identification and coding of the BCTs and subsequently linking intervention effectiveness to the specific BCTs used. It is important to approach the exploratory network meta-analysis results with caution due to the limited direct evidence, affecting the reliability of the inferred summary effect, and the imprecision that impacts the overall quality of evidence in the comparisons.

Conclusions

There is high-quality evidence that BCT-based interventions compared to controls improve daily PA, in the short term. Evidence for the maintenance of this benefit beyond 6 months or the benefit of BCT-based interventions compared with SET is unclear and necessitates further primary research. Our findings support BCT-based intervention for improving daily PA in people with IC. Clinicians could consider recommending BCT-based interventions to patients with IC as a strategy towards improving the PA uptake in the population group.

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Conflict of interest

None declared.

Authors contributions

U.O.A. P.D., C.S., T.G., J.D., C.G., J.M., C.F., D.A.S. contributed to the conception and design of the systematic review and meta-analysis. U.O.A., L.B., E.M.A., S.R., P.D., C.S., T.G., J.M., J.D., S.A., C.F., D.A.S.

were involved in the acquisition and analysis of the data. U.O.A., S.R., P.D., C.S., T.G., J.M., J.D., S.A., C.F., L.B., J.B., K.F., S.R. were involved in the interpretation of the results. U.O.A. drafted this manuscript. All authors provided critical revisions of the protocol and approved the submission of the final manuscript.

Data availability

There is no data linked to this manuscript.

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1 **Table 1: Characteristics of the Included Studies**

Source and Design	Sample / Age (years)		Intervention	Control	Duration (weeks)		Outcomes reported					
							Physical Activity		Quality of Life			Others
	n	Mean (SD)			Intervention	Follow-up	Behavior	Capacity	Generic	Health	PAD	
Holmes et al, 2018[24] RCT	24	66.8 (9.4)	Motivational intervention + structured walking	Attention	12	16	Steps /day	6MW		X		BASIC
Collins et al, 2011[25] RCT	145	66.5 (10.1)	Walking program+ Telephone support	Attention	24	24		ACD, ICD, WIQ	X	X		Depression
Cunningham et al, 2012[35,65] RCT	58	65.3 (8.5)	Patient education + motivational interviewing	Usual care	16	104	Steps /day	ICD	X	X	X	Disease progression
GOALS Trial[31,67–70] RCT	194	69.3 (9.5) *	Walking program	Health education	24	52	Activity units	ACD, ICD, 6MW, WIQ		X		Self-efficacy
LITE Trial[32,77] RCT	305	69.3 (9.5)	1. Low intensity walking program 2. High intensity walking program	Health education	52	52	Activity score	ACD, 6MW, WIQ		X		
TrackPAD study[61,74] RCT	39	64.6 (9.8)	Mobile phone intervention + Structured exercise	Usual care	12	12		6MW		X	X	
Collins et al, 2009[33] RCT	51	67.4 (8.9)	Communication intervention	Education video	12	12		WIQ				
Fowler et al, 2002[45] RCT	882	73.1	Education + Walking Advice +	Usual care	8	52	Self-report PA	ACD		X		

			Structured exercise									
Fukaya et al, 2021[37] RCT	41	66.1 (9.4)	Walking program + Feedback + Behavioral monitoring + Motivational updates	Attention	12	12	Steps/day	6MW, WIQ		X		
Gardner et al, 2014[26] RCT	180	65.7	Walking program	Attention	12	12	Strides/day, Total activity time	ACD, ICD, 6MW, WIQ		X		Peak VO_2
Mays et al, 2015[29] RCT	39	67.6 (11.8)	Community based walking exercise structured training, monitoring, and coaching (TMC)	Usual care	14			ACD, ICD, WIQ		X		Physical fitness, Peak VO_2
HONOR Trial[41] RCT	200	70.2 (10.4)	Walking program + wearable activity monitor +Telephone coaching	Usual care	36	36	Activity outcome, Distance walked, Exercise frequency	6MW, WIQ		X		
Quirk et al, 2012[62] RCT	19	73.2 (8.0)	Motivational interviewing	Usual care	12	12	MET mins/week			X	X	
CIPIC Rehab Study[58,75] RCT	118	70.3 (7.2)	Walking program + Health education + Text messages	Usual care	12	12		ACD, ICD			X	Anxiety, Depression,

Tew et al, 2015[38] RCT	23	71 (8)	Education + Follow-up telephone support	Usual care	6		Steps /day	ACD, ICD, 6MW, WIQ		X	X	
Gardner et al, 2011[50] RCT	119	65 (11)	Walking program	Usual care	12	12	Total strides/day, Total Activity time/day	WIQ		X		BASIC, Peak VO_2
Duscha et al, 2018[27] RCT	19	69.4 (8.4)	Walking program	Usual care	12		Steps/day, Distance/week, Distance/day, Total active min/day	ACD, ICD				Peak VO_2
MOSAIC Trial[30,71] RCT	190	68	Walking program + Telephone support	Usual care	12	24	MET min/week	ACD, 6MW			X	WELCH score, NEADL, BIPQ score
Pochstein & Wegner 2010[44]	90	65.48 (7.07)	Strengthening of volitional competence	Usual care	6	12		ACD, ICD, WIQ		X		
EXITPAD Study[60,72,73] RCT	304	66.2	1. SET + Feedback 2. SET alone	Verbal walking advice	52	52		ACD			X	ABPI, BMI, Heart rate, Systolic BP, Diastolic BP
Sandercock 2007[54] RCT	44	65	Walking program + Telephone support	Walking advice	12			ACD				Pain intensity, Peak VO_2, Heart rate

Spronk 2003[53] Non-RCT	104	68	Walking program	NA	16	16		Corridor/ Outdoor test				BIPQ score
Normahani 2018[42] RCT	37	69.1 (10.4)	Walking program + Routine SEP	SEP	12	52		ACD, ICD			X	
Regensteiner[39] 1997 RCT	20	64 (7)	Walking program + Patient Education	SEP	12			ACD, ICD WIQ		X		ABPI, Peak VO_2, Heart rate
Savage 2001[28] RCT	21	66.3 (8.8)	Walking program	SEP	24	24		ACD, ICD		X		ABPI, Peak VO_2
SUNFIT Trial RCT[40,76]	166	72	1.Home-based structured exercise 2.Supervised exercise	Walking advice	52	52	Active steps /day	6MW, WIQ		X	X	ABPI, Disease progression, Cardiovascular events
Collins 2022[88] RCT	29	66.0 (8.12)	Motivational interviewing + Telephone support	Education and walking plan via app	12			6MW			X	BMI, Systolic BP, Diastolic BP
Cornelis 2021[36] Non-RCT	20	64.6 (10.6)	Walking program + resistance training	NA	4	12	Steps /day	ACD, ICD, WIQ		X	X	Physical fitness, Self-efficacy
Endicott 2018[34] Non-RCT	49	67.4 (7.8)	Education + Ongoing counselling	NA	24		Steps /day					
Prevost 2015[46] Non-RCT	48	60.3 (8)	Educational workshop + Walking program	NA	52	52		ACD, ICD		X		Pain intensity, ABPI
Roberts 2008[55] Non-RCT	47	67.7 (7)	Walking program + Telephone support	NA	12	12		ACD				Pain intensity
Matthews 2021[56] Non-RCT	11	70	SEP + Cardiovascular education	NA	8			6MW, WIQ		X		Anxiety, Depression,

												Systolic BP
Racodon 2018[47] Non-RCT	68	62.7 (9.7)	Therapeutic education + Vascular Rehabilitation	NA	52	52		ACD, Corridor/outdoor test				BMI
Fakhry 2011[52] Non-RCT	217	67.5	Structured walking program	SEP	24	52		ACD, ICD	X	X	X	ABPI
Jacobsen 2022[59] Non-RCT	35	71.5 (7.7)	Lifestyle counselling + SEP	NA	12	24		ACD, ICD, 6MW			X	
Mouser 2009[48] Non-RCT	120	67.4 (10.3)	Education + Walking program	NA	24			ACD, ICD				
Aalami 2022[49] Non-RCT	139	65	SEP	NA	12	52		WIQ				
Wullink 2001[64] Non-RCT	31	66 (14)	Home-based walking program	NA	24			ACD, ICD, WIQ, Corridor/ Outdoor test				
Jonason 1981[43] Non-RCT	17	66	Education + Home-based walking program	SET (Same participants)	12	24	Walking activity	ACD, ICD				
Otsuka 2021[57] Non-RCT	30	73.8	Home-based exercise with Triaxial accelerometer + telephone instruction	Attention control with Triaxial accelerometer	12	12	Activity, Steps/day	6MW, WIQ		X	X	Self-efficacy
Leslie 2022[51] Non-RCT	46	69 (11)	Walking program	SET	12			ACD, ICD				ABPI

Key/ abbreviations: ACD (Absolute claudication distance), ICD (Initial claudication distance), WIQ (Walking impairment questionnaire), 6MWD (6 minutes walking distance), ABPI (Ankle brachial pressure index).

Table 2: Risk of Bias Assessment in Randomised Control Trials

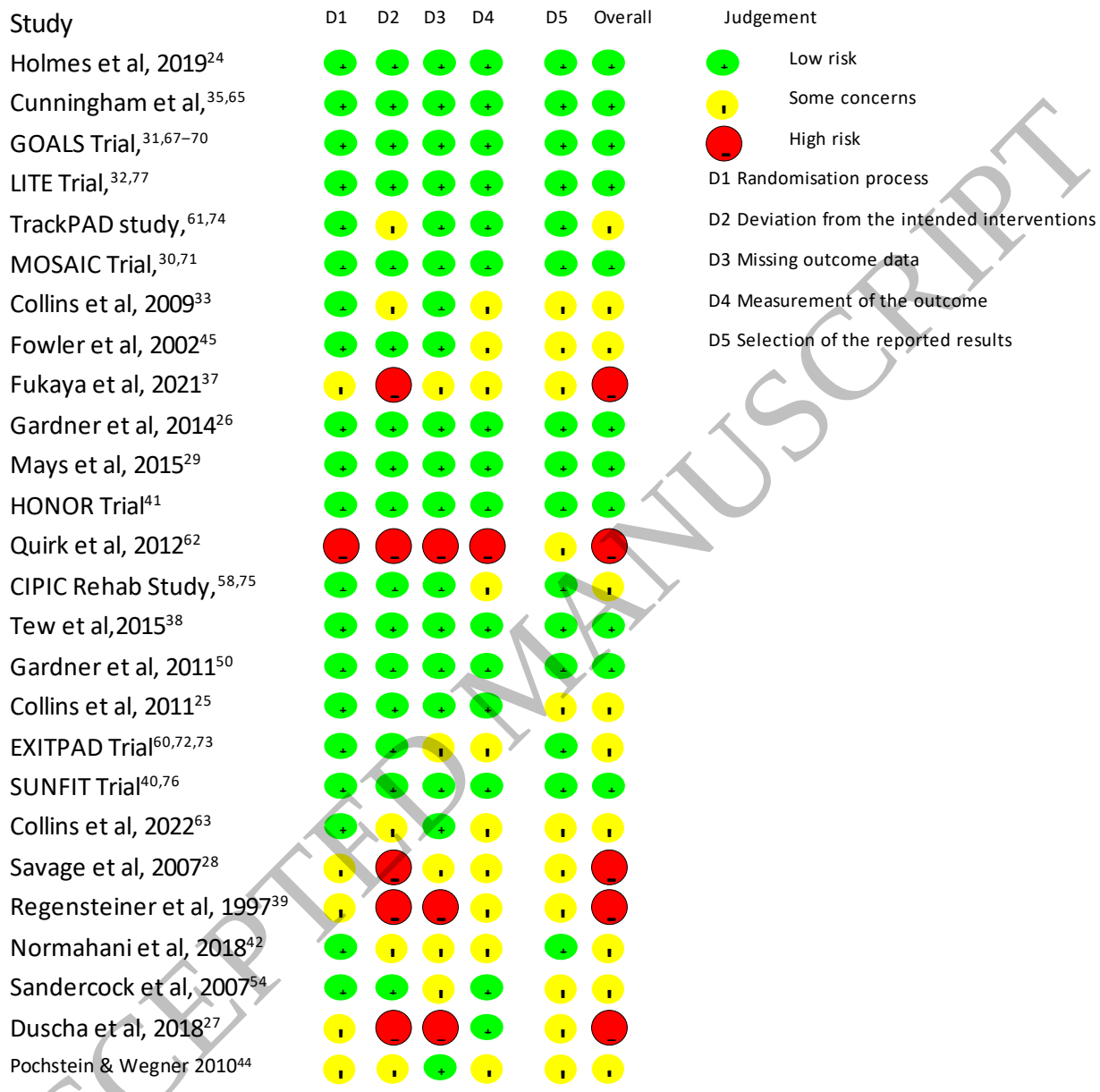


Figure 1: PRISMA diagram for systematic review of effects of behavior-change intervention in people with intermittent claudication.

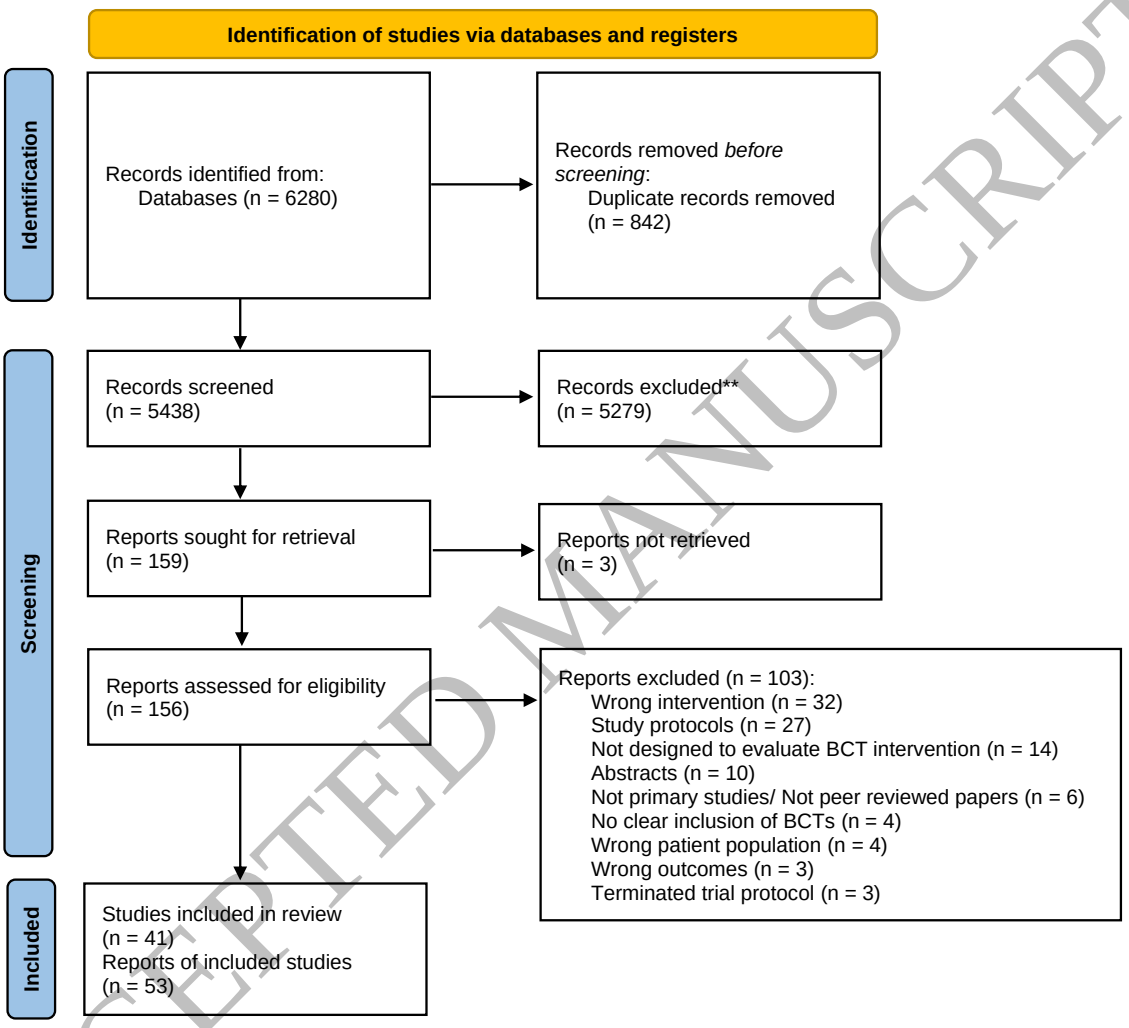
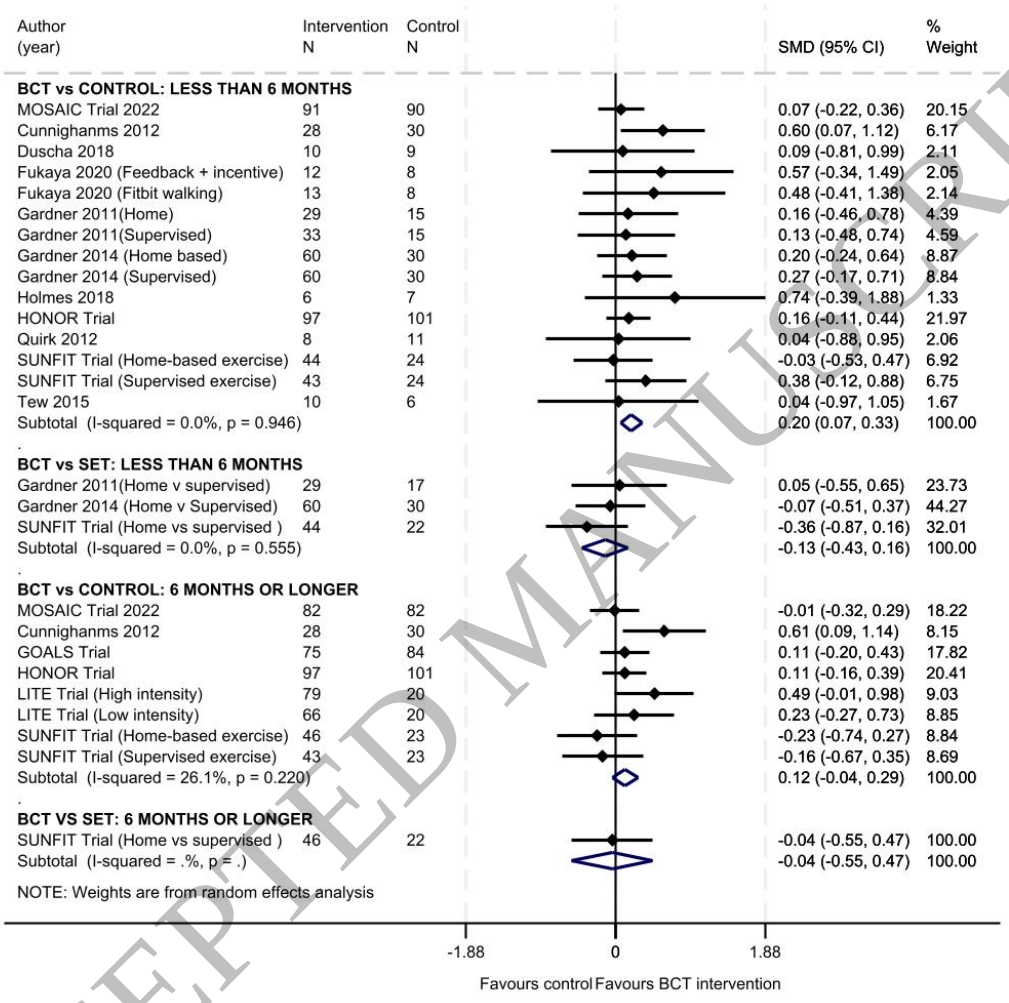
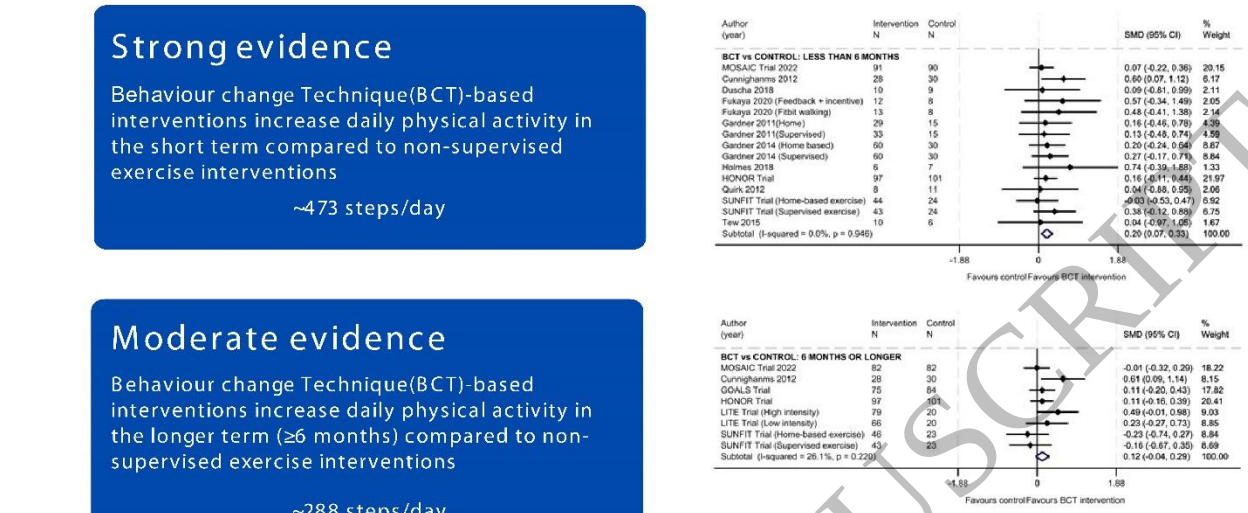


Figure 2: Meta-analysis of effect on volume of PA of BCT-based interventions vs Controls or SET



Daily PA combined using standardised mean differences (SMD), using 'change from baseline'. Daily PA uses steps/day, distance per day or a total activity count. Where multiple measures of daily PA were reported, the steps or distance per day was chosen in preference. Comparison between BCT intervention and any non-SET control (e.g. attention control or usual care) or SET using random effects meta-analysis. Data from randomised controlled trials only.

Graphical abstract: Effect of Behavior-change Interventions on Daily Physical Activity in Patients with Intermittent Claudication: The OPTIMA Systematic Review with Meta-Analysis



Graphical Abstract
494x274 mm (DPI)