



Extended Research Article

Behaviour change interventions to promote physical activity in people with intermittent claudication: the OPTIMA systematic review

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Scientific summary

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Scientific summary

Background

People with intermittent claudication (IC) are significantly less active, by 40–45% compared to their peers without the condition. Supervised exercise therapy (SET) is recommended as the primary treatment, but access and adherence are low; traditional SET programmes are short-lived and do not improve daily activity levels. Incorporating behaviour change components boosts exercise intervention effectiveness, aiding in physical activity (PA) maintenance. However, the specific behaviour change techniques (BCTs), theoretical mechanisms and contextual features linked to effectiveness in individuals with IC remain unclear.

Objectives

To integrate the quantitative and qualitative evidence base for increasing and maintaining PA in IC by behaviour change interventions, researching concurrently to systematically review evidence about: (1) The effectiveness of behaviour change interventions in increasing and maintaining PA in people with IC; (2) the relationship between BCTs, intervention mechanisms and contextual factors in promoting PA in people with IC; (3) the feasibility and acceptance of behaviour change interventions for PA improvement in people with IC; and (4) the feasibility of delivering PA improvement services through behaviour change interventions for individuals with IC. Primary outcome measures were *short-term* (< 6 months) change in daily PA, and maintenance (6 months or longer, *medium term*) of daily PA reported as standardised mean differences (SMDs) with 95% confidence intervals (CIs). Secondary outcomes considered patient-reported and clinical outcomes, such as initial and absolute claudication distance (ACD) and time, 6-minute walk test, Walking Impairment Questionnaire (WIQ), generic health-related and disease-specific quality of life (QoL), maximal volume of oxygen consumption (VO₂ max), blood pressure (BP), ankle-brachial pressure index (ABPI), revascularisation, cardiovascular events and mortality.

Data sources

MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature (EBSCO), Physiotherapy Evidence Database, Web of Science, PsycInfo® (American Psychological Association, Washington, DC, USA), Social Science Citation Index for primary studies. We also searched the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, the Health Technology Assessment Database, Trial Registers (International Standard Randomised Controlled Trial Number, EU Clinical Trial Register, <https://clinicaltrials.gov/>). Databases were searched from inception to 30 November 2022; plus, we reviewed weekly e-mail alerts of new literature until 31 August 2023. We also searched reference lists of included articles.

Study selection

Systematic review 1 – included randomised (RCT) and non-randomised controlled studies of adults diagnosed with IC, which assess an intervention incorporating at least one BCT.

Systematic review 2 – included studies reporting on feasibility and acceptability of intervention to improve PA in people with IC, including quantitative, qualitative and mixed-methods research on patient/provider experiences with interventions.

Data extraction/risk of bias assessment

Data relating to study design, quality, sample characteristics, interventions and comparators, and primary and secondary outcomes were extracted in a table. Study quality was assessed using the revised Cochrane risk-of-bias tool for randomised trials and Risk Of Bias In Non-randomised Studies – of Interventions tools, as well the Mixed Methods

Appraisal Tool tools. Intervention content was coded using the BCT Taxonomy version 1, and the Theoretical Domains Framework (TDF). Data extraction, risk of bias assessment and intervention coding were completed by two independent reviewers. Any disagreements were resolved through consensus or, if necessary, by referral to a third reviewer.

Data synthesis

Data were summarised in a narrative review and, when appropriate, meta-analysis was carried out. Interventions were examined using the BCT Taxonomy and the TDF. Integrative synthesis was employed to combine the findings of the two reviews.

Results

In total, 53 articles from 41 unique studies, published over a 41-year period, were included. Overall, RCTs included in this review ($n = 11$, 15 comparisons, 952 participants) demonstrated that BCT-based interventions increased daily PA in the *short term* (< 6 months) compared to control groups [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, *medium term*) is unclear [increase of 0.12 SMD (95% CI -0.04 to 0.29); ~ 288 steps/day; 6 RCTs, 8 comparisons, 899 participants], with moderate certainty. We found that compared to SET, the effects of BCT-based interventions on daily PA are uncertain for *short-term* change [-0.13 SMD, 95% CI -0.43 to 0.16]; 3 RCTs, 269 participants; low certainty] and *medium term* [-0.04 SMD, 95% CI -0.55 to 0.47]; 1 RCT, 89 participants]. Interventions aimed at improving patients' intentions to engage in PA were more effective in enhancing PA behaviour than those that did not focus on this theoretical domain. However, it remains unclear if the number or type of BCTs independently influenced the increase in PA.

The analysis of secondary outcomes for BCT-based interventions versus control groups revealed significant improvements in ACD, absolute claudication time, initial claudication distance, initial claudication time, WIQ score, and disease-specific QoL in the short term {ACD [increase of 0.42 SMD (95% CI 0.22 to 0.61), 9 RCTs, 693 participants]; ICD [increase of 0.54 SMD (95% CI 0.36 to 0.72), 9 RCTs 634 participants]; WIQ [increase of 16 points; (95% CI 9 to 24), 3 RCTs, 471 participants] and disease-specific QoL [increase of 0.31 SMD (95% CI 0.13 to 0.50), 7 RCTs, 8 comparisons, 472 participants]}. There were also improvements in the medium term {ACD [increase of 0.17 SMD (95% CI 0.02 to 0.32), 6 RCTs 748 participants], ICD [increase of 0.24 SMD (95% CI 0.07 to 0.42), 5 RCTs, 543 participants], WIQ [increase of 10 points (95% CI 6 to 14); 2 RCTs, 3 comparisons, 287 participants], and disease-specific QoL [increase of 0.32 SMD (95% CI 0.14 to 0.50), 5 RCTs, 6 comparisons, 485 participants]}. The 6-minute walk distance (6MWD) test improved significantly in the short term (increase of 26 m 95% CI 6 m to 46 m) but not in the medium term, while generic health-related QoL and the risk of revascularisation showed no significant improvements. Evidence about cardiovascular events and short-term effects on VO_2 max, systolic and diastolic BP was unclear, and there were no available data on the medium-term effects on these measures or on mortality or ABPI.

We found that compared to SET, the effects of BCT-based interventions on daily PA were uncertain. In our pairwise meta-analysis, no statistically significant difference was found, but our exploratory network meta-analysis (NMA) showed that SET ranked first for short-term daily PA improvement, while BCT-based interventions were the most effective at ≥ 6 months. When comparing BCT-based interventions with SET, we found no significant differences in changes in short-term ACD, ICD, 6MWD, VO_2 max, generic QoL, disease-specific QoL or ABPI. Medium-term outcomes also showed no difference in these measures, as well as in WIQ and the risk of revascularisation. There were no studies reporting on BP, mortality or the short-term impact on WIQ and the risk of revascularisation.

Evidence from systematic review 2 highlighted the overall feasibility and acceptability of behaviour change interventions to patients, but no evidence could be found regarding the health professionals. Only 2 (out of 22 studies) did not achieve acceptable recruitment rates (40%). Average retention rate was 88%, and average adherence rate was 76%. Twenty studies reported adverse events, with three suggesting 'non-serious' adverse events due to the intervention. Only five studies reported on intervention satisfaction, which was good. Our patient and public involvement and advisory group suggested key strategies to optimise these interventions for better implementation in the UK.

Limitations

The limited number of primary studies hindered our ability to analyse the influence of contextual factors on intervention effectiveness. Included studies displayed significant methodological differences, although we managed to combine them for a meta-analysis. The control/comparison groups in the included studies also used BCTs, so our results reflect the intervention's effects beyond those of the BCTs in the control/comparison groups. Furthermore, the lack of detailed intervention manuals and study protocols limited our assessment of the content and delivery, including BCTs and TDF domains. Many studies did not report recruitment rates or reasons for not taking part, reasons for dropout, adherence rate or reasons for non-adherence. Although some costs were presented, no studies considered the cost of implementation. We are not able to identify evidence about the feasibility and acceptability from the viewpoint of health professionals.

Conclusions

The evidence regarding the effectiveness of behaviour change interventions suggests they are effective in improving daily PA and might be better than SET in maintaining daily PA in the longer term. Effectiveness is likely to be enhanced when behavioural interventions target the theory domain of patients' intention to engage in daily PA. There are general uncertainties around the longer-term effects as well as uncertainties around independent influence of number or type of BCTs and contextual factors on PA outcome. However, behaviour change interventions are generally feasible and acceptable to patients.

Future work

There is a need for well-designed, UK-based trials of behaviour change interventions that clearly articulate intervention content in both the active and control/comparison arms. Questions that still need to be addressed include the longer-term effects of BCTs, effectiveness and cost-effectiveness against SET as well as other aspects of use/implementation which may influence provision.

Study registration

This study is registered as PROSPERO CRD42020159869.

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This article

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