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Volume 29 • Issue 18 • May 2025

ISSN 2046-4924

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DOI 10.3310/ZBNG5240

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Extended Research Article

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

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Published May 2025
DOI: 10.3310/ZBNG5240

This report should be referenced as follows:

Abaraogu UO, Dall P, Seenan C, Rhodes S, Gorely T, McParland J, *et al.* Behaviour change interventions to promote physical activity in people with intermittent claudication: the OPTIMA systematic review. *Health Technol Assess* 2025;**29**(18). https://doi.org/10.3310/ZBNG5240

Health Technology Assessment

ISSN 2046-4924 (Online)

Impact factor: 3.5

A list of Journals Library editors can be found on the NIHR Journals Library website

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This article

The research reported in this issue of the journal was funded by the HTA programme as award number NIHR130664. The contractual start date was in August 2021. The draft manuscript began editorial review in June 2024 and was accepted for publication in October 2024. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

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Abstract

Background: People with intermittent claudication are significantly less active compared to their peers without intermittent claudication, worsening future health outcomes. Supervised exercise therapy is not commonly available, but behaviour change techniques in unsupervised interventions can improve physical activity. Specific behaviour change techniques, theoretical mechanisms and contextual features linked to effectiveness remain unclear.

Objectives: To conduct an integrative synthesis of: effectiveness of behaviour change technique-based interventions on daily physical activity and clinical-/patient-reported outcomes; behaviour change techniques and theoretical mechanisms within effective behaviour change technique-based interventions; feasibility and acceptability. Primary outcomes: short term (< 6 months) and maintenance (> 6 months) of daily physical activity. Secondary outcomes: clinical-/patient-reported outcomes.

Data sources: Seven primary studies databases; Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, Health Technology Assessment Database and Trial Registers to 31 August 2023.

Review methods: Systematic review 1: interventions incorporating ≥ 1 behaviour change technique (coded using Behaviour Change Technique Taxonomy version 1, and Theoretical Domains Framework). Systematic review 2: quantitative, qualitative, mixed-methods research on patient/provider experiences. Study quality assessed using revised Cochrane risk-of-bias tool for randomised trials; Risk Of Bias In Non-randomised Studies – of Interventions and Mixed Methods Appraisal Tool.

Results: Fifty-three articles (41 studies) were included in systematic review 1, and 28 articles (28 studies) in systematic review 2. Eleven randomised controlled trials demonstrated that behaviour change technique-based interventions increased daily physical activity in the short term [increase of 0.20 standardised mean difference (95% confidence interval 0.07 to 0.33), ~ 473 steps/day] with high certainty. Evidence of maintenance of daily physical activity is unclear (increase of 0.12 standardised mean difference; ~ 288 steps/day). Behaviour change techniques aimed at improving patients' intentions to engage in physical activity were most effective. Network analysis suggests that behaviour change technique-based interventions improved daily physical activity and may be better than supervised exercise therapy in maintaining daily physical activity. behaviour change technique-based interventions were acceptable and had short-medium-term benefits to initial/absolute claudication distance/time, walking impairment scores and disease-specific quality of life.

Conclusions: The behaviour change technique-based interventions are effective, targeting intention to engage in physical activity, in improving daily physical activity and functional outcomes in the short term, although evidence is limited for maintenance. There is a need for more randomised controlled trials examining daily physical activity and clinical outcomes, including longer-term follow-up, with detailed descriptions of behaviour change techniques, costs and provider views.

Study registration: This study is registered as PROSPERO CRD42020159869.

Funding: This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: NIHR130664) and is published in full in *Health Technology Assessment*; Vol. 29, No. 18. See the NIHR Funding and Awards website for further award information.

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Report Supplementary Material 3 Showing details of data extracted from the included studies, including data about the characteristics of included studies for review 2

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/ZBNG5240).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

6MWD	6-minute walk distance
6MWT	6-minute walk test
ABPI	ankle–brachial pressure index
ACD	absolute claudication distance
BASIC	Baltimore Activity Scale for Intermittent Claudication
BCT	behaviour change technique
BMI	body mass index
BP	blood pressure
CENTRAL	Cochrane Central Register of Controlled Trials
CINAHL	Cumulative Index to Nursing and Allied Health Literature
Cochrane-RoB 2	revised Cochrane risk-of-bias tool for randomised trials
CVD	cardiovascular disease
HRQoL	health-related quality of life
IC	intermittent claudication
ICD	initial claudication distance
ICTRP	International Clinical Trials Registry Platform
IPAQ	International Physical Activity Questionnaire
MD	mean difference
MET	metabolic equivalent
MMAT	Mixed Methods Appraisal Tool
MPA	moderate physical activity
MVPA	moderate to vigorous physical activity
NA	not applicable
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NMA	network meta-analysis
PA	physical activity
PAD	peripheral arterial disease
PEDro	Physiotherapy Evidence Database
PPI	patient and public involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROM	patient-reported outcome measure
QoL	quality of life
RCT	randomised controlled trial
RoB	risk of bias
ROBINS–I	Risk Of Bias In Non-randomised Studies – of Interventions
SET	supervised exercise therapy
SMD	standardised mean difference
SUCRA	surface under the cumulative ranking curve
TDF	Theoretical Domains Framework
TIDieR	Template for Intervention Description and Replication
TTM	transtheoretical model
VO_2	volume of oxygen consumption
VO_2 max	maximal volume of oxygen consumption
VPA	vigorous physical activity
WHO	World Health Organization
WIQ	Walking Impairment Questionnaire

Plain language summary

Around 3.2 million people in the United Kingdom have a condition called peripheral arterial disease, where the arteries in the legs become clogged, leading to fatigue, pain or cramps (known as intermittent claudication) when people walk, but going away with rest. Consequently, over time, people walk less and sit more, leading to further health deterioration. Walking for the recommended 30 minutes a day to maintain health can be challenging because of pain, so we need to know if supporting people to change their behaviour in unsupervised walking could help.

This project examined studies from other research teams who have looked into a variety of walking programmes, in terms of daily physical activity, how far people could walk without pain, self-reported walking difficulties, quality of life and ankle–brachial pressure index, which takes blood pressure readings from the ankles as an indication of any blockages. Finally, we aimed to understand the feasibility and acceptability of these programmes.

Eleven studies were included in the review and programmes which included strategies to support people's intentions to engage in physical activity showed an increase of around 473 more steps a day in the short term, compared to those that did not include that support. Over time, 6 months after the programmes finished, this dropped to 288 steps/day. These programmes also improved the distance people could walk before pain started or they had to rest, perceived walking difficulties and disease-specific quality of life. There were no changes in ankle–brachial pressure index. While supervised exercise ranks first in terms of short-term daily activity, behaviour-change-focused unsupervised walking programmes were better for medium-term outcomes and are feasible to set up and acceptable to the people taking part. They would be a suitable alternative or choice to supervised walking programmes.

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 (VO_2 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.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: NIHR130664) and is published in full in *Health Technology Assessment*; Vol. 29, No. 18. See the NIHR Funding and Awards website for further award information.

Chapter 1 Introduction

Peripheral arterial disease (PAD), a manifestation of cardiovascular disease (CVD), is a prevalent yet often undiagnosed condition that is frequently suboptimally treated.[1,2] PAD affects about one in five people aged 55–75 years with some degree of the disease.[3,4] In its early stages, PAD is characterised by intermittent claudication (IC), which manifests as pain, fatigue or cramping in the muscles of the lower limbs, typically in the calf, occurring during mild exertion like walking and relieved by short periods of rest.[5] About 40–75% of people with PAD experience the symptom of IC,[5] making it one of the main indications for referral to vascular surgeons in the UK. There is inequality in the prevalence of IC, as patients are more likely to have finished education on leaving school, have a below median income and be currently unemployed.[6] Similarly, people with IC have a greater comorbidity burden and are more likely to be obese, to currently smoke and currently consume alcohol.[7]

Intermittent claudication is a chronic condition where pain limits walking, which results in disability due to ambulatory dysfunction[8] and progressive impairment in physical function.[9,10] Without effective treatment, the natural progression is to chronic pain in the legs and eventually to non-healing wounds, gangrene and limb loss.[11] Due to the diffuse nature of atherosclerosis and the involvement of other arterial beds, people with IC have a 5.9 times greater risk of CVD mortality[12,13] and 3–4 times increased all-cause mortality risk compared to those without the disease.[13] Approximately, 25% of people with IC die from coronary or cerebrovascular events within 5 years of diagnosis,[14,15] and the overall 5-year mortality is about 33.2%.[16] Compared with people without the condition, people with IC have greater decrements in health-related quality of life (HRQoL).[13,17] People with IC have significantly lower health utilities and lower mental and physical component summary quality of life (QoL) scores.[7]

Intermittent claudication causes significant costs to patients and the UK NHS, in terms of reduced QoL, loss of healthy life-years, and medical and surgical treatment.[7,18] Progression of IC can result in worsening symptoms, including critical limb ischaemia. The yearly cost to the UK NHS to treat the 500–1000 new cases of critical limb ischaemia per million of the UK population diagnosed each year is estimated at £200M.[18] Compared to those without IC, people with IC who are employed report significantly greater levels of absenteeism, presenteeism and overall work impairment.[7] The number of physician visits, hospitalisations and number of emergency room visits within past 6 months are significantly higher in IC compared to age-matched controls.[7] Given the suboptimal treatment of IC and the ageing UK population, the burden of multimorbid IC patients with multiple significant vascular problems to the NHS is expected to rise over the next decades.[19]

Evidence, from a study which conducted a systematic review in addition to analysing two large cohort studies (N = 74,124), shows that individuals with PAD are generally less physically active than those without the disease.[20] People with symptoms of IC are 40–45% less physically active compared to age-matched individuals without IC.[21] Physical inactivity is an independent predictor of disease outcomes and all-cause mortality in people with IC.[22] Increasing and maintaining a physically active lifestyle provides improvement in claudication symptoms, cardiovascular risk factors, overall health and QoL in people with IC.[23]

Current guidelines from the National Institute for Health and Care Excellence (NICE) recommend supervised exercise therapy (SET) as the primary treatment for IC because it is more cost-effective, less risky/harmful and results in similar, if not greater, benefits compared to surgical intervention.[24] However, the widespread availability of SET in the UK is hindered by issues related to funding, staffing, facilities and expertise.[25] Even when available, challenges such as time and travel needed for regular attendance, pain-induced exercise intolerance, multimorbidity, patients' low motivation and limited disease understanding, all contribute to low enrolment and adherence rates to supervised exercise programmes.[26,27] Additionally, SET often prioritise clinically assessed walking distances, with less emphasis on promoting long-term habitual PA outside of the programme. Although SET remains the primary recommendation for IC, strategies are needed to support long-term habitual physical activity (PA) for all patients, regardless of their participation in SET.[28] Habitual PA is crucial for symptom improvement, reducing cardiovascular risks, increasing life expectancy and enhancing overall QoL.[24] Unfortunately, many patients revert to an inactive lifestyle after completing SET.[29]

Many studies have shown that patients with IC do better if they embrace lifestyle changes and increase PA.[30] Regardless of whether a patient is undergoing supervised, home-based exercise or is listed for surgery, increasing PA in people with IC is particularly important for symptom management, disease prognosis, cardiovascular outcomes and HRQoL. Where SET is not available, current NICE guidelines recommend suggesting unsupervised exercise and to advise patients to exercise for approximately 30 minutes three to five times per week, walking until the onset of symptoms.[24] However, in addition to challenges that are common to older adults or people with long-term conditions, claudication pain presents additional unique challenges to walking and exercise in people with IC.[27] This is because the claudication pain is specifically brought on by walking and exercising.

Efforts to encourage an active lifestyle in people with IC have been challenging because interventions targeting behaviour change, such as habitual PA, are complex and involve poorly described interacting components.[31] Behavioural change techniques (BCTs) have been effective in promoting habitual PA in various populations,[32,33] but there is limited understanding regarding which interventions may be more, or less, successful and for whom. Understanding about the specific effectiveness and applicability of BCTs for people with IC remains unclear. Although sharing some common barriers to PA with the general population of older adults and physically inactive adults with other long-term conditions, people with IC face unique barriers to PA, such as exercise-induced pain exacerbated by environmental factors.[27] Therefore, evidence about the effectiveness of BCTs and contextual factors that specifically support PA in people with IC cannot be automatically inferred from the wider population. There is no guidance from NICE on BCTs specific to IC, particularly informing strategy to encourage uptake and maintenance of PA either supervised or unsupervised. Identifying and specifying the fine-grain detail of the active components of interventions, and contextual features, in addition to user experiences, will be essential for implementing, replicating and synthesising successful approaches.[34] This project synthesises quantitative and qualitative evidence to shape implementable behaviour change strategies for enhancing PA in individuals with IC. Our multidisciplinary team, comprising co-applicants, collaborators, patient and public involvement (PPI) members, and an advisory group, collaboratively author the report.

The overarching objective of the project is to integrate the quantitative and qualitative evidence base for increasing and maintaining PA in IC with unsupervised interventions that have behaviour change embedded, researching concurrently to systematically review:

1. the effectiveness of interventions incorporating behaviour change in increasing and supporting maintenance of PA, clinical and patient-reported outcomes in people with IC
2. the association between different BCTs, mechanisms of action and contextual features of the interventions to increase and maintenance of postintervention change in PA in people with IC
3. the feasibility and acceptability of interventions containing behaviour change for improving/maintaining PA in people with IC
4. the feasibility of delivering services using interventions containing behaviour change for improving/maintaining PA in people with IC.

The project involved executing two separate systematic reviews – one quantitative looking at the effect of BCT-based interventions on PA and other clinical and patient-reported outcomes of interest, and another one looking at the feasibility and acceptability of BCT-based intervention through qualitative studies and mixed-methods studies. These two reviews were integrated in a synthesis to achieve the overall project aim.

In systematic review 1, we conducted a systematic review of the effectiveness of interventions incorporating behaviour change in increasing and supporting the maintenance of PA, clinical and patient-reported outcomes in people with IC. We also evaluated the association between different BCTs, mechanisms of action and contextual features of the interventions to increase and maintain postintervention change in PA in people with IC. To our knowledge, this is the first meta-analysis of behaviour change intervention for PA in people with IC. Methods and results are detailed in *Chapter 2*.

In systematic review 2, we systematically reviewed the feasibility and acceptability of interventions incorporating behaviour change to enhance/maintain PA in individuals with IC. Additionally, we assessed the feasibility of delivering services using such interventions. *Chapter 3* provides a detailed account of the methods and results.

In *Chapter 4*, we provide a comprehensive discussion synthesising the results of the two systematic reviews. Additionally, we address PPI involvement, equality, diversity and inclusion, as well as the impact and learning from the project. We also present the implications of the reviews for decision-makers, offer research recommendations and summarise the conclusions derived from the review results.

Chapter 2 Systematic review 1: systematic review of the effectiveness of interventions incorporating behaviour change in increasing and supporting maintenance of physical activity in people with intermittent claudication, and the association between behaviour change techniques, mechanisms of action and contextual features of the interventions to increases in, and long-term postintervention maintenance of, physical activity in people with intermittent claudication

Methods

Protocol

We created the protocol for the systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria[35] and registered it with PROSPERO [no. CRD42020159869; https://crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42020159869 (accessed 24 May 2024)]. The detailed protocol is also available via OSF Registries at https://osf.io/traf8 (accessed 24 May 2024).

Inclusion and exclusion criteria

Study design

We included reports of interventions using BCTs in individuals with IC, regardless of study design, as long as the study featured an intervention with either a separate comparator arm or a comparison of postintervention values to baseline. Service improvement evaluations were considered, in order to include and evaluate as much relevant research as possible.

Participants

We included studies with adults (≥ 18 years) diagnosed with PAD and IC. Clinical diagnosis was objective [.g. an ankle–brachial pressure index (ABPI) < 0.9], by questionnaire, or clinical diagnosis.

Interventions

We included interventions which contained at least one BCT and which aimed to assist people with IC to achieve increased and/or maintain habitual PA.[36–38] Our approach towards inclusion of intervention studies was pragmatic. We included both psychological/educational-based behavioural interventions and those which implemented active monitoring, for example, using a pedometer, so long as the components used in the intervention could be successfully coded as BCTs. Therefore, interventions in the form of, but not limited to, structured exercise/PA, lifestyle, motivational counselling, structured home-based exercises, comprehensive rehabilitation, structured patient education, mobile health intervention or combinations of any of these were considered for inclusion. Studies reporting on any mode of SET were eligible for inclusion if they included at least one BCT. We included studies which reported different approaches for delivering services, for example, web-based/e-mail/mobile phone support. Studies examining the type

of personnel, frequency of contact, mode of delivery (e.g. group vs. individual), use of incentives, or evaluation trials using hybrid implementation science approaches were also eligible for inclusion.

Comparator

We included studies with any comparator arm – active interventions, usual care, standard care or control interventions. We also considered for inclusion service improvement evaluations, as long as implementation evaluation is compared with a control group (including historical control) that has no intervention, as well as before–after studies comparing postintervention values to baseline values.

Outcomes

Our primary focus was interventions targeting PA improvement and reporting PA behaviour at postintervention and/or at follow-up. However, we also included studies reporting any walking or functional outcomes, whether or not they reported a PA behaviour outcome.

The definition of maintenance of PA varies in the literature, and various reviews of maintenance outcomes have not specified a minimum postintervention follow-up period.[36,37] However, maintenance is hypothesised to occur at a minimum of 6 months after initial behaviour change.[38] Therefore, in this review, we defined evaluation of maintenance of improvement as those assessed at least 6 months post intervention, and included any study with a follow-up of ≥ 6 months to maintenance of PA. However, the review aimed to assess both increase and maintenance of PA, and therefore we included studies with follow-up < 6 months in order to assess shorter-term increases in PA.

Our initial plan was to include only studies that assess change in habitual PA and/or maintenance of habitual PA either as primary or secondary outcome of the studies. However, our PPI members felt that if secondary outcomes of physical capacity, physical function and/or QoL have improved in behaviour change interventions, this is important for people with IC, not just whether PA was measured. We, therefore, broadened our inclusion to studies reporting physical capacity and functional outcomes.

Information sources and search strategy

We implemented the database search in September 2021, with supplementary searches run in November 2022, plus weekly e-mail alerts of new literature until 31 August 2023, using a comprehensive search strategy of index free text terms and synonyms located in the title or abstract and representing three broad concepts reflecting the disease (e.g. IC, PAD), behaviour change interventions (e.g. structured exercise, PA, lifestyle intervention, motivation, cognitive behavioural intervention) and outcome (e.g. PA, exercise) to search relevant electronic databases. The detailed search strategies implemented in different databases is provided in this report as a supplementary material (see *Table 1* in *Report Supplementary Material 1*). Databases searched were: MEDLINE (Ovid); EMBASE (Ovid); Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO); Web of Science – core collection (Clarivate); PsycInfo® (American Psychological Association, Washington, DC, USA) (Ovid); NHS Economic Evaluation Database; Social Science Citation Index (Clarivate); Database of Abstracts of Reviews of Effects; Cochrane Central Register of Controlled Trials (the Cochrane Library); Physiotherapy Evidence Database (PEDro) and Health Technology Assessment Database. The trial registries, including ClinicalTrials.gov and International Clinical Trials Registry Platform (ICTRP) [World Health Organization (WHO)], were also searched. No restrictions were used for language, publication year or publication status, and results were de-duplicated using EndNote [Clarivate Analytics (formerly Thomson Reuters), Philadelphia, PA, USA]. We also searched reference lists of included studied and contacted experts in the field to request information on relevant studies not already identified. Where required, we contacted authors of included studies by e-mail to request full intervention materials/protocols for active and comparator groups (including usual care, or their augmented version), to aid detailed BCT coding, Theoretical Domains Framework (TDF) and Template for Intervention Description and Replication (TIDieR) elements, qualitative and process outcomes, including written reports of any qualitative research and process evaluations.

Study selection and data extraction process

Titles identified in the electronic database searches were exported into Covidence (Melbourne, VIC, Australia; https://covidence.org/). Two researchers (from a pool of eight – Ukachukwu Abaraogu, Dawn Skelton, Ebuka Anieto, Trish Gorely, Cathy Gormal, Jeremy Dearling, Chidinma Ofodum, Philippa Dall) independently screened each title and

abstract of the search results followed by screening of full texts of potentially relevant studies against the inclusion criteria. Disagreements at any stage of the screening were resolved by discussion and reaching consensus or a third researcher mediated. Where there was insufficient information from published studies to complete data extraction, we contacted authors (two e-mails over 2 months) and excluded studies when we could not get adequate information to include studies.

To ensure comprehensive data capture, we developed, piloted and iteratively refined the data extraction forms ('Characteristics of included studies' as *Table 3*) to capture study details and outcome data. This included author/s, country of study, study design, sample size, population studied (e.g. newly diagnosed, prior to intervention, gender, age, comorbidities, ethnicity and level of education), intervention type, setting, study duration, attrition rate, outcomes, BCTs and intervention theories and TIDieR elements.

Assessment of measurement of habitual physical activity and selecting studies with physical activity outcome data

Defining habitual physical activity and use within the OPTIMA quantitative review

The OPTIMA quantitative review has a primary outcome measure of habitual PA which could be assessed by body-worn sensor (e.g. pedometer, accelerometer) or self-report measures (e.g. questionnaires). PA is defined as any bodily movement produced by skeletal muscles that results in energy expenditure.[39] Exercise is a subset of PA which is planned, structured and undertaken with the objective to maintain physical fitness.[39] For individuals with PAD and IC, exercise is often a main component of recommended intervention.[40] However, PA that is not part of a planned exercise may also contribute to physical fitness, and interventions that promote increased non-exercise PA as well as or instead of planned exercise are likely to be beneficial to health,[41] and therefore habitual PA was the primary outcome of this review. For the purposes of this review, we considered habitual PA to be all PA (not just exercise) that a person does during their daily life.

Whether habitual PA has been adequately measured depends on a combination of the tools used to collect information about PA (device-based or self-report), the specific protocol used to collect data in a study, and the way in which data from the tools are processed and reported. The measurement of habitual PA is multifaceted, and no criteria already existed to enable consistent identification of habitual PA. Led by the PA experts (PD, DS), our team extensively deliberated and developed, in consultation with our PPI members, the assessment criteria and methodology to determine the required components of each type of PA assessment to meet the threshold for measuring habitual PA (as opposed to other types of PA and/or exercise during the intervention itself). Having at least one habitual PA outcome measure meeting these threshold criteria was required for that study to be included in the assessment of the primary outcome measure in the quantitative systematic review.

We opted to use a traffic light system (*Table 1*) to provide a more nuanced quality assessment of the measure of habitual PA than a simple binary, where green represents a gold standard and fully acceptable measure of habitual PA, yellow represents a suboptimal but acceptable measure of habitual PA, and red represents an inadequate and unacceptable measure of habitual PA. The measures were judged against four criteria (see *Table 1*), and each criterion was graded according to the traffic light system. Any measure that had any (at least one) criteria judged to be not adequate (red) was judged to be not adequate (red). For a measure to be judged fully acceptable (green), all four criteria had to be judged to be fully acceptable (green). A measure with a mixture of green and yellow criteria was judged to be yellow overall. In the case where there was not sufficient information to make a full judgement on a criterion, the item was given a grading of unclear (blue). However, we made inferences from the information provided and reported that criteria as fully acceptable (green), partially acceptable (yellow) or not acceptable (red). When a criterion that was unclear (blue) was inferred to be fully acceptable (green), we downgraded that criterion to suboptimal (yellow) to account for the lack of clear reporting.

Studies using a green or yellow measure of habitual PA were included in the assessment of the primary outcome measure in the quantitative systematic review. Studies using a red measure of habitual PA were excluded from the assessment of the primary outcome measure in the quantitative systematic review. Studies excluded for assessment of the primary outcome measure may have been included in the review of secondary outcome measures.

TABLE 1 A four-item checklist to determine if the outcome measure reported habitual PA

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total period to represent habitual PA?	
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	
4	Does the measurement report outcomes, which represent habitual PA?	

Criteria for assessing habitual physical activity

As stated above, we defined habitual PA to be all PA (not just exercise) that a person does during their daily life. We identified four components that an assessment required to be considered to assess habitual PA:

1. the duration of assessment
2. the type of PA assessed
3. the intensity of PA assessed
4. the outcome metric that is reported.

Each component is discussed separately below. First, there is a general statement about what is required to measure habitual PA. Then situations that commonly occur during the assessment of PA and exercise are listed along with our decisions on whether they are adequate to measure habitual PA (green = fully acceptable; yellow = partially acceptable; red = not acceptable). This was then collated into a four-item checklist (see *Table 1*), which was used in the review to determine suitability of measures in studies that were screened as otherwise potentially suitable. Additionally, *Table 2* has been populated with examples of common measurement strategies that would be fully, partially, or not adequate to measure habitual PA.

Duration of assessment

Habitual PA represents any and all PA that is usually undertaken by an individual. As such, it is required that the duration of measurement be sufficiently wide to be considered to cover the majority of usual PA.

- Measurement should consider PA over an extended period, so that usual (or habitual) PA can be considered.
    - Self-report measurement could ask about a usual recall period (although for use as an outcome measure in an intervention study, the participant should be directed to think about usual activity within a specific time frame relevant to the study stage).
    - Self-report measurement could also ask about a recall period of a week or longer.
    - Self-report asking only about a single-day recall should be considered with caution.
        - If the single day is not anchored to the research visit but is referred to as a usual or typical day, this is acceptable, as it is assumed that a participant would self-select a day more closely representing their habitual PA.
        - If the single day is selected for the participant, and thus anchored to the research schedule (e.g. previous day), then this should be interpreted with caution, as the action of attending the research appointment (e.g.) may have influenced PA on the previous day. Even if the research schedule has not influenced habitual PA, there is no guarantee that the day provided to the participant will be reflective of habitual PA (i.e. it could have been an exceptional day).
    - Device-based measures should be conducted over a period longer than a single day, for example, a week. Even if monitors are provided for a suitable time period, there is an analytic decision about how to treat missing data, and the minimum number of days for inclusion in data analysis. It is this number of days which should form the decision point.

TABLE 2 Examples of measurement tools in the checklist

#	Criteria	Does the measure meet the criteria? Yes	Partial	No
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	***Device-based:*** At least 3 days of data included in analysis ***Self-report:*** Usual/typical recall period Longer recall period (e.g. 1 week, 4 weeks) Single day if recalling a typical or usual day	***Device-based:*** < 3 days of data included in analysis ***Self-report:*** Specified single-day recall period (e.g. previous day)	***Device-based:*** Very short periods of wear, for example, < 1 day ***Self-report:***
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	***Device-based:*** 24-hour wear protocols Waking wear protocols with adequate minimum wear time (e.g. 10 hours/day) ***Self-report:*** Assessment of whole day	***Device-based:*** Waking wear protocols with unreported minimum wear time ***Self-report:*** Assessment of only leisure-time PA	***Device-based:*** Waking wear protocols with inadequate minimum wear time Measurement only during specific exercise (including reporting adherence to intervention) ***Self-report:*** Assessment of only workplace PA Assessment of only exercise sessions
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	***Device-based and self-report:*** Assessment of all PA Assessment of only walking behaviour, for example, pedometers		***Device-based and self-report:*** Assessment limited to VPA only Assessment of only PA of at least moderate intensity (e.g. MVPA) Assessment of only exercise (assume limited to only reporting MVPA)
4	Does the measurement report outcomes which represent habitual PA?	***Measures of volume:*** Number of steps Device-based total volume metrics (e.g. total number of counts) Volume of intensity (e.g. MET/hours) ***Measurement of duration:*** Time spent in all PA Time spent in specific type/intensity of PA that is acceptable (e.g. time spent walking) ***Measurement of frequency*** ***Measurement of meeting thresholds***	***Measures of volume:*** Distance walked ***Measurement of duration:*** Time spent in specific type/intensity of PA that is partially acceptable ***Measurement of frequency:*** Combined frequency/volume metric (e.g. time spent walking derived from number of days walking and average time spent walking) ***Measurement of meeting thresholds:*** Number/percentage of people meeting PA guidelines Number/percentage of people meeting a volume/duration threshold	***Measures of volume*** ***Measurement of duration:*** Time spent in specific type/intensity of PA that is not acceptable (e.g. time spent in MVPA) ***Measurement of frequency:*** Number of days of doing exercise Number of exercise sessions in time period ***Measurement of meeting thresholds:*** Number/percentage of participants achieving a number of exercise sessions

    - Device-based measurement of at least 3 days of data can adequately represent habitual PA and will be considered adequate.[42]
    - Studies which include participants with fewer than 3 days of data in the analysis may represent habitual PA, but should be interpreted with caution.

- Measurement should consider PA undertaken during an entire 24-hour period:

    - Measurement only during waking hours (out of bedtime) is acceptable, as it can be assumed that most PA is conducted while awake.
    - For device-based measures using a waking wear protocol (i.e. where the monitor is removed overnight) – the minimum duration of wear for data inclusion should cover the majority of the waking day – for example, standard wear-time inclusion criteria of 10 hours per day would be acceptable.
    - Assessment of only leisure-time PA.
    - Measurement only during specific periods of exercise (e.g. monitoring adherence to an intervention) should not be considered to evaluate habitual PA.
    - Assessment of only workplace PA is not acceptable.
    - Assessment of only exercise is not acceptable.

Type of physical activity assessed

Ideally, habitual PA would measure any and all types of PA, including (but not limited to) walking, cycling, exercise, leisure activities, transportation activities and workplace PA.

- Although it is ideal to measure all types of PA, in reality many tools limit assessment to particular types.

    - Assessment of only walking (e.g. pedometer of self-reported walking) is acceptable, as this is the PA that most people do most. Additionally, this is a target of many interventions to increase PA and appropriate for inclusion.

Intensity of physical activity assessed

Habitual PA encompasses PA of any intensity, including incidental movement. Although it is ideal to measure all PA, in practice, truly incidental movement can only be captured by device-based measures. Self-report measures will ask questions which are likely to limit the type and intensity of PA reported but may include questions about light PA or walking, which would be considered more incidental.

- Assessment limited to vigorous physical activity (VPA) only should be excluded.
- Assessment limited to PA that is at least moderate intensity [e.g. moderate to vigorous physical activity (MVPA)] also does not adequately capture habitual PA and is not acceptable.
- Assessment of exercise only as a concept will be assumed to limit its reporting to MVPA and will be excluded.

Outcome metric

Habitual PA is an accumulation of PA throughout a period of time; therefore, it is best expressed as an aggregated measure:

- Measures of volume can encompass the aggregation of a number of aspects of PA.

    - Steps.
    - Device-based metrics such as counts.
    - Intensity, for example, metabolic equivalent (MET)/hours (a combination of time spent in an activity and its intensity).
    - Distance walked could be a suitable measure of volume but requires interpretation, especially if self-reported (as aggregating distance walked is a difficult thing to do, whereas recalling the maximum distance walked in one walk is easier to do).

- Measures of duration can encompass all PA or specific types of PA (so long as that type is acceptable).

  - Time spent in all PA.
  - Time spent in a specific type/intensity of PA that is acceptable (green) in terms of type/intensity of PA assessed.
  - Time spent in a specific type/intensity of PA that is suboptimal but acceptable (yellow) in terms of type/intensity of PA assessed.
  - Time spent in a specific type/intensity of PA that is not acceptable (red) in terms of type/intensity of PA assessed.

- Measures of frequency of PA are insufficient on their own, for example, the number of times that exercise was undertaken in a week would not be a suitable outcome measure unless you could combine it with a measure to provide a volume outcome.

  - Combined measure of frequency and volume/time, for example, time spent walking generated from number of days walking and average time spent walking in a day.
  - Number of days when exercise/PA was conducted.
  - Number of times exercise/PA was undertaken in a period of time (e.g. week).

- Measures of meeting a threshold (e.g. meeting PA guidelines). These may be appropriate, but caution is required in interpretation, the only improvement that can be recorded for an individual is if they were below the threshold at the start and over it at the end, any other improvement cannot be reported. Additionally, meeting a threshold of a measure that does not meet the criteria for habitual PA (e.g. number of exercise sessions) will not be appropriate.

  - Number/percentage of participants meeting PA guidelines.
  - Number/percentage of participants meeting a volume/duration threshold of PA.
  - Number/percentage of participants achieving a set number of exercise sessions in a week.

Identifying behaviour change techniques and mechanism of actions of interventions within the studies

All researchers involved in the BCT and TDF domain extraction and coding, first, completed the BCT-Taxonomy online training[43] before starting to code any study. Researchers first coded four studies independently using the 93-item BCT Taxonomy version 1[43] and the TDF domain version 2[44] and then discussed the outcomes and decision processes for the four studies to develop a uniform understanding of coding practice. One reviewer (LB), a health psychologist, then coded the remaining 37 studies using information within the published article/s, along with any associated published protocol papers and/or intervention manuals. Another reviewer (selected from a group of five: Ukachukwu Abaraogu, Dawn Skelton, Joanna McParl, Trish Gorely and Sarah Audsley) repeated this process independently for each study. Discrepancies for each study were resolved through discussion between the two reviewers. Study authors were contacted for full intervention details in all study arms where necessary.

A BCT was only coded when there was clear evidence of its inclusion. The 93 BCTs were rated as present or absent, in the intervention and control or comparison groups separately. In cases where the same BCT was applied to the same target behaviour in both the intervention and control/comparison groups, resulting in overlapping BCTs, the BCT was excluded from the total number of BCTs used in that intervention. As a result, it was not considered as part of the BCT frequency count among the interventions. In other words, only the BCTs present in the intervention and absent in the control condition formed part of the BCT frequency count. This approach has been previously used in review of behaviour change interventions to explain the intergroup difference in effect between intervention and control arms.[45,46]

Similar to the BCT coding, two independent reviewers, systematically extracted the mechanisms of action from the included studies. The coding was guided by the 14 domains of the TDF.[44] A theoretical construct was coded as a mechanism of action if it: (1) was described as a pathway through which the PA behaviour change could occur; and (2) was clearly linked to a BCT identified in the intervention. To ensure accuracy, and following the coding guidelines, each BCT mechanism of action could be used to link to a theory only once per intervention description, with an emphasis on identifying the most specific connections.

Quality appraisal

Two researchers (UA and EA) independently assessed the RoB in the included studies using the Cochrane Collaboration's Risk Of Bias 2 (RoB 2) tool[47] for the randomised controlled trials (RCTs), and the Risk Of Bias In Non-randomised Studies – of Interventions (ROBINS–I)[48] for the non-RCTs. For the RCTs, we implemented a separate RoB assessment for PA, walking capacity and patient-reported outcome measures (PROMs). Each trial was evaluated for its outcome-level RoB based on the following criteria: if there were no concerns of bias in any of the domains, it was considered to have a low RoB; if there were concerns in at least one domain but not in domains that were deemed to have a high RoB, it was considered to have some concerns; and if there were high RoB in any domain or some concerns in multiple domains, it was considered to have a high RoB. Differences in opinion for all RoB assessment were resolved through discussion and reaching consensus.

Analysis/syntheses

Primary outcome: habitual physical activity

Volume of habitual PA was extracted from either self-report or from device-based measures, such as pedometers or accelerometers (e.g. step count per unit time, distance per unit time, time spent doing PA per unit time, activity score). Where PA was reported using more than one method, daily steps were used.

Secondary outcomes

We extracted data from secondary outcomes, including:

- clinically assessed maximum walking distance or time
- clinically assessed pain-free walking distance or time
- clinically assessed 6-minute walk distance (6MWD) (included post hoc)
- functional status (QoL domain)
- functional status assessed via Walking Impairment Questionnaire (WIQ)
- HRQoL
- disease-specific QoL
- psychological well-being (QoL domain)
- cardiovascular events
- disease progression outcomes
- mortality
- cost data
- process outcome data.

Time points

We carried out synthesis of data at the following time points:

- Short term: earliest change outcomes assessed within < 6 months post intervention.
- Maintenance of PA: latest change outcomes assessed from 6 months post intervention. In our original proposal, we have designated ≥ 6 months as long term, but during the course of our review and consultations, our PPI and advisory groups suggested that 6 months might not be adequate to capture the long-term effect of intervention. The research team agreed, but as there is no gold standard definition of 'long-term', we have changed our description of maintenance to medium-term outcome, but it is important to point out that many of the included studies assessed outcomes at 1–2 years post intervention.

Meta-analysis

Studies were considered clinically homogeneous for both the population (people with IC) and the interventions (PA with BCTs). RCTs with similar outcome data (e.g. a measure of habitual PA) were combined, and meta-analyses of pairwise comparisons for primary and secondary outcomes were carried out where direct evidence was available. Pooled effect sizes with 95% confidence intervals (CIs) were estimated using random-effects meta-analysis. Change from baseline was used in all analyses of continuous outcome measures. Mean differences (MDs) were used for continuous outcomes where all measures could be converted to the same scale [e.g. meters walked as part of the 6-minute walk

test (6MWT)], and standardised mean differences (SMDs) were used where multiple measures were used for the same outcome (e.g. different measures of volume of PA, such as steps per day and minutes of PA per day). Risk ratios (RRs) were used for binary outcomes. A forest plot was presented for each analysis. Stata v14 (College Station, TX) was used for meta-analyses.

Comparisons

Our primary analyses included robust evidence from RCTs comparing BCT interventions with any control. A control could be 'treatment as usual', attention control or an alternative intervention (without any BCTs or using fewer BCT components). We also separately analysed studies that compared a BCT intervention to SET because evidence already exists in this population of an effect of SET in improving clinical and functional outcomes in this population.[49,50]

When comparing BCT versus 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 three-arm studies were used twice: in analyses of BCT versus control and BCT versus SET.

Non-randomised studies have varying designs and a higher RoB; therefore, for the primary outcome only, we pooled data from non-randomised studies to allow comparison. The secondary outcome data from non-randomised studies were summarised in a table (effect size and 95% CI).

Missing data

For continuous measures, we used change from baseline and the associated standard deviation (SD). Where this was not reported, we calculated the mean change from baseline and the associated SD using baseline and follow-up values and an imputed within-arm correlation of 0.5, as per guidance in the Cochrane Handbook. Where SDs were not presented, we calculated them from 95% CIs or standard errors (SEs) or from other reported SDs of the same measure (e.g. using baseline SDs to estimate follow-up SDs). Where only medians and interquartile ranges were reported, we estimated the mean using the median and estimated the SD by dividing the interquartile range by 1.35. Sensitivity analyses of primary outcome data were conducted to test these assumptions.

Heterogeneity

Heterogeneity was assessed by visually inspecting forest plots and using the I^2 and T^2. The I^2 statistic quantifies inconsistency across trials and describes the percentage of variability in effect estimates that may be due to heterogeneity rather than sampling error. Heterogeneity was regarded as substantial, where T^2 is greater than 0 and I^2 is > 50%.

Sensitivity analyses

We performed the following sensitivity analyses for the primary outcome measure to test whether conclusions were robust:

- fixed-effects meta-analysis rather than random effects
- imputing an alternative estimate of within-person correlation for change-from-baseline of 0.8 (estimated from studies in the review that allowed calculation of this parameter)
- removing studies where SDs were estimates from interquartile ranges
- removing one arm from each three-arm study (due to correlation between results from the same study)
- removing comparisons with a supervised BCT intervention arm (these were not considered a pure test of a BCT intervention)
- excluding studies judged to be at high RoB for the primary outcome
- excluding studies that used a self-report measure for the primary outcome
- using steps per day rather than SMD of change scores (excluding studies which did not report steps per day).

Interpretation

To aid interpretation of data analysed as SMDs, we converted measured data back into original units of the most commonly occurring format by multiplying the SMD by the median control group change-from-baseline SD (e.g. steps per day for volume of PA).

Exploratory network meta-analysis

We conducted network meta-analysis (NMA) to allow comparison of multiple types of BCT intervention, and to allow indirect effect estimates to be estimated. Groups of interventions by mode of delivery (e.g. BCT implemented with technologies) were created post hoc after examination of the data. Network plots were created to summarise direct evidence. We combined direct and indirect evidence using frequentist NMA[51] to estimate treatment effects between multiple types of intervention simultaneously. Interventions were ranked in order of the probability of being the most effective treatment using surface under the cumulative ranking curves (SUCRAs).[51]

Exploratory metaregression

We conducted random-effects metaregression to explore the relationship between BCT domains and effect size for the primary outcome measure PA. We analysed each BCT domain separately, comparing studies that used BCTs within that domain to those that did not. There were insufficient data to combine multiple domains in the same analysis. In addition, we conducted metaregression exploring the relationship between the number of BCTs (exclusive to the intervention) and effect size.

Subgroup analyses

If data were available, we planned to explore whether the effectiveness of interventions differed according to whether all/majority of participants are selected on the basis of a new diagnosis of or long-standing IC (with or without previous revascularisation surgery). We also planned to explore the effect of body mass index (BMI) category, comorbidities related to IC, sex, deprivation, age and ethnicity.

Results

Outcomes of searches and study selection processes

The electronic searches identified 6279 unique articles. After removing duplicates and screening title and abstracts, 155 articles remained for full-text screening (*Figure 1*), 102 were further excluded after full-text screening. Of the articles excluded at this stage, 31 articles were not studies of behaviour change interventions and/or were not reporting on studies designed to target PA;[52–81] 30 were ongoing study protocols[82–108] or protocols of studies terminated early for some reason without results;[109–111] 4 were articles not reporting on primary studies or peer-reviewed journal publications;[112–115] 4 were articles of studies which included a patient population without IC;[116–119] 10 were conference abstracts without full studies reports;[120–129] 15 reported on studies not designed to evaluate or report the effect of behaviour change intervention;[70,72,130–142] there were no clear inclusion of BCT techniques in 3 articles;[81,143,144] 3 articles had the wrong outcomes;[140,145,146] and 2 were dissertation/thesis (not peer-review publication).[147,148] Hand-searching of included studies yielded no additional potential articles for inclusion. The process from article identification through to final inclusion is presented in a PRISMA diagram as *Figure 1*.

Overview of included studies

In total, 53 articles[115,149–200] from 41 unique studies, published over a 41-year period (from 1981 to 2022), were included (see *Table 3*). Henceforth, except where specified in this review, for studies reported in multiple articles, the main article reporting the primary outcome measure(s) at first follow-up is referenced in the text and tables. Included studies involved a total number of 4339 participants (range 11–882), including 1280 (29.5%) female participants. Twenty-two of the studies (12 RCTs and 10 non-RCTs) included fewer than 50 participants,[115,149,159–161,164–166,168,169,171–174,176,179–183,189,190] 4 between 50 and 100 participants,[151,158,175,186] 12 between 100 and 200 participants,[150,153,162,163,167,170,178,185,187,188,195] and 4 over 200.[157,177,184,192]

Twenty-six (with a total of 3357 participants) of the included studies were RCTs, and 15 (with a total of 982 participants) were non-RCTs. The studies were performed in 10 different countries, with the largest representation from the USA (n = 16), UK (n = 9) and the Netherlands (n = 4).

The mean age of participants in included studies was 67.2 (range 60.3–73.8) years. Except for one study which did not describe the study population,[166] populations of people with IC within the included studies vary across newly diagnosed, to those with long-standing disease, including those who have previously undergone surgical intervention. Most of the

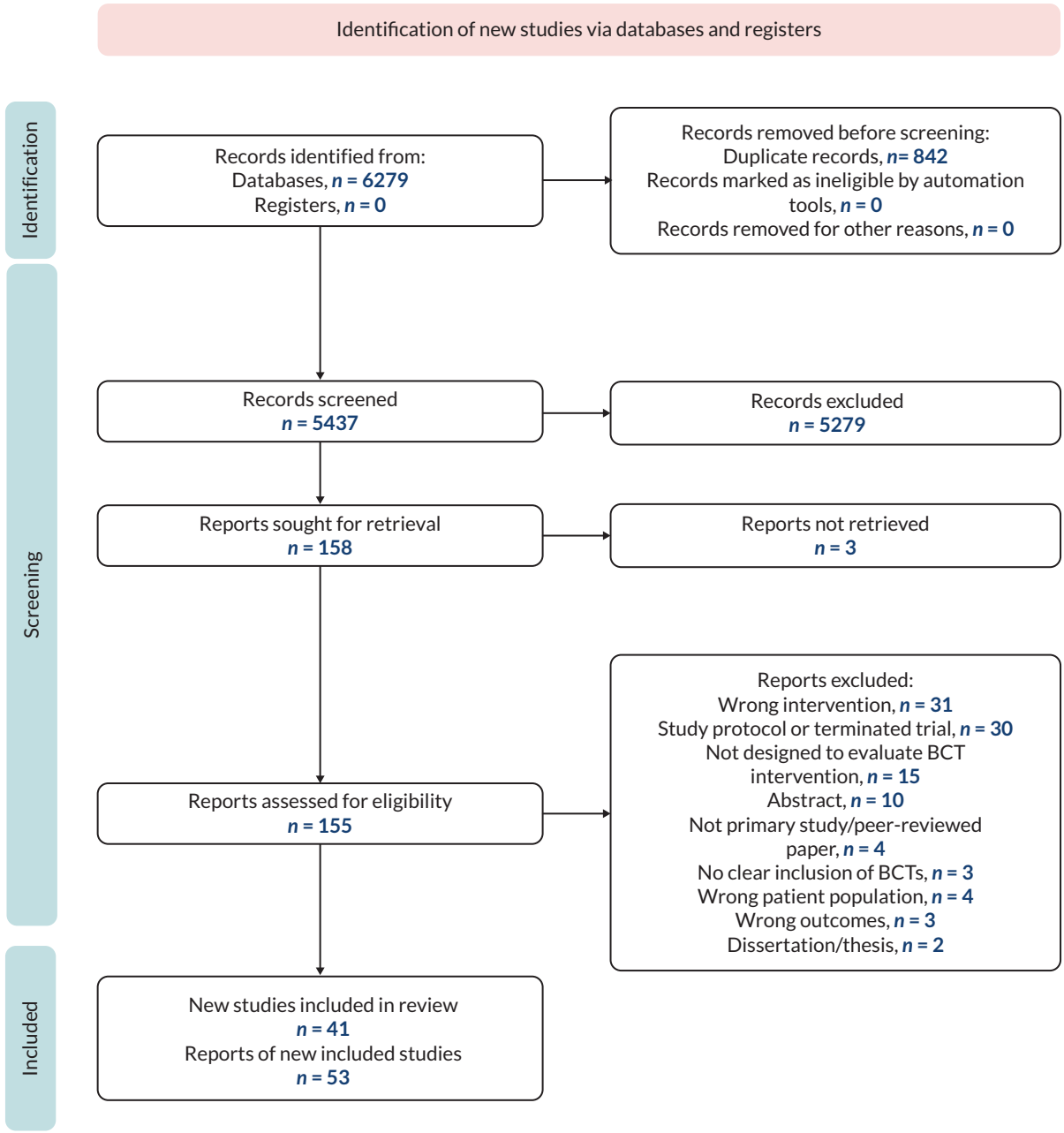

FIGURE 1 The PRISMA diagram for systematic review of effects of behaviour change intervention in people with IC.

included studies (*n* = 29) did not report the ethnicity of their participants. For the remaining 12 studies, the majority of the study participants were white in 7 studies (range 57–90% white),[149,150,163,166,176,183,195] black or African Americans in 4 studies,[153,157,158,160] and distributed among white, black and Hispanic ethnic groups in 1 study.[158]

The interventions described in the included studies varied but were all focused on increasing exercise and PA in individuals with PAD and IC. The interventions included structured walking programmes, home-based walking programmes, resistance training, wearing activity monitors to track exercise, psychological interventions, group-based exercise sessions, and communication interventions with healthcare providers. Many of the interventions involved setting specific exercise goals, incorporating motivational techniques and providing education on the benefits of exercise for PAD. Some interventions also included follow-up phone calls or meetings to provide ongoing support and encouragement for exercise adherence.

TABLE 3 Characteristics of included studies

Source and design	Sample/age (years)		Intervention	Control	Duration (weeks)		Outcomes reported					
							PA		QoL			
	n	Mean (SD)			Intervention	Follow-up	Behaviour	Capacity	Generic	Health	PAD	Others
Galea *et al.* 2019[a] (MOSAIC feasibility trial)[149] RCT	24	66.8 (9.4)	Motivational intervention + structured walking	Attention	12	16	Steps/day	6MWT		X		BASIC
Collins *et al.* 2011[150] RCT	145	66.5 (10.1)	Walking programme + telephone support	Attention	24	24		ACD, ICD, WIQ	X	X		Depression
Cunningham *et al.* 2012[151,152] RCT	58	65.3 (8.5)	Patient education + motivational interviewing	Usual care	16	104	Steps/day	ICD	X	X	X	Disease progression
GOALS Trial 2012[153–156,199] RCT	194	69.3 (9.5)[a]	Walking programme	Health education	24	52	Activity units	ACD, ICD, 6MWT, WIQ		X		Self-efficacy
LITE Trial 2021[157,191] RCT	305	69.3 (9.5)	1. Low-intensity walking programme 2. High-intensity walking programme	Health education	52	52	Activity score	ACD, 6MWT, WIQ		X		
Paldan *et al.* (TrackPAD study) 2019–2021[190,200] RCT	39	64.6 (9.8)	Mobile phone intervention + structured exercise	Usual care	12	12		6MWT		X	X	
Collins *et al.* 2009[158] RCT	51	67.4 (8.9)	Communication intervention	Education video	12	12		WIQ				
Fowler *et al.* 2002[184] RCT	882	73.1	Education + walking advice + structured exercise	Usual care	8	52	Self-report PA	ACD		X		
Fukaya *et al.* 2021[161] RCT	41	66.1 (9.4)	1. Walking programme + feedback + behavioural monitoring + motivational updates 2. Walking programme + feedback + behavioural monitoring + motivational updates + financial incentive	Attention	12	12	Steps/day	6MWT, WIQ		X		

continued

TABLE 3 Characteristics of included studies (*continued*)

	Sample/age (years)				Duration (weeks)		Outcomes reported					
							PA		QoL			
Source and design	*n*	Mean (SD)	Intervention	Control	Intervention	Follow-up	Behaviour	Capacity	Generic	Health	PAD	Others
Gardner *et al.* 2014[163] RCT	180	65.7	1. Walking programme 2. SET	Attention	12	12	Strides/day, total activity time	ACD, ICD, 6MWT, WIQ		X		Peak VO_2
Mays *et al.* 2015[183] RCT	39	67.6 (11.8)	Community-based walking exercise structured training, monitoring, and coaching	Usual care	14			ACD, ICD, WIQ		X		Physical fitness, peak VO_2
HONOR Trial[187] RCT	200	70.2 (10.4)	Walking programme + wearable activity monitor + telephone coaching	Usual care	36	36	Activity outcome, distance walked, exercise frequency	6MWT, WIQ		X		
Quirk *et al.* 2012[182] RCT	19	73.2 (8.0)	Motivational interviewing	Usual care	12	12	MET minute/week			X	X	
CIPIC Rehab Study 2020[167,197] RCT	118	70.3 (7.2)	Walking programme + health education + text messages	Usual care	12	12		ACD, ICD			X	Anxiety, depression
Tew *et al.* 2015[168] RCT	23	71 (8)	Education + follow-up telephone support	Usual care	6		Steps/day	ACD, ICD, 6MWT, WIQ		X	X	
Gardner *et al.* 2011[162] RCT	119	65 (11)	1. Home-based exercise walking programme 2. SET	Usual care	12	12	Total strides/day, total Activity time/day	WIQ		X		BASIC, peak VO_2
Duscha *et al.* 2018[166] RCT	19	69.4 (8.4)	Walking programme	Usual care	12		Steps/day, distance/week, distance/day, total active minute/day	ACD, ICD				Peak VO_2
MOSAIC trial 2019[195,198] RCT	190	68	Walking programme + telephone support	Usual care	12	24	MET minute/week	ACD, 6MWT			X	WELCH score, NEADL, BIPQ score
Pochstein and Wegner 2010[175] RCT	90	65.48 (7.07)	Strengthening of volitional competence	Usual care	6	12		ACD, ICD, WIQ		X		

TABLE 3 Characteristics of included studies (*continued*)

Source and design	Sample/age (years)		Intervention	Control	Duration (weeks)		Outcomes reported					
							PA		QoL			
	n	Mean (SD)			Intervention	Follow-up	Behaviour	Capacity	Generic	Health	PAD	Others
EXITPAD study 2010[192–194] 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[179] RCT	44	65	1. Home-based walking programme + telephone support 2. SET	Walking advice	12			ACD				Pain intensity, peak VO_2, heart rate
Spronk 2003[178] pretest–post-test non-RCT	104	68	Walking programme	NA	16	16		Corridor/ outdoor test				BIPQ score
Normahani 2018[189] RCT	37	69.1 (10.4)	Walking programme + routine SET	SET	12	52		ACD, ICD			X	
Regensteiner 1997[172] RCT	20	64 (7)	Walking programme + patient education	SET	12			ACD, ICD WIQ		X		ABPI, peak VO_2, heart rate
Savage 2001[176] RCT	21	66.3 (8.8)	Walking programme	SET	24	24		ACD, ICD		X		ABPI, peak VO_2
SUNFIT trial 2022 [185,201] RCT	166	72	1. Home-based structured exercise 2. Supervised exercise	Walking advice	52	52	Active steps/ day	6MWT, WIQ		X	X	ABPI, disease progression, cardiovascular events
Collins 2022[202] RCT	29	66.0 (8.12)	Motivational interviewing + telephone support	Education and walking plan via app	12			6MWT			X	BMI, systolic BP, diastolic BP
Cornelis 2021[159] pretest–post-test non-RCT	20	64.6 (10.6)	Walking programme + resistance training	NA	4	12	Steps/day	ACD, ICD, WIQ		X	X	Physical fitness, self-efficacy
Endicott 2018[160] pretest–post-test non-RCT	49	67.4 (7.8)	Education + ongoing counselling	NA	24		Steps/day					
Prevost 2015[171] pretest–post-test non-RCT	48	60.3 (8)	Educational workshop + walking programme	NA	52	52		ACD, ICD		X		Pain intensity, ABPI

continued

TABLE 3 Characteristics of included studies (*continued*)

	Sample/age (years)				Duration (weeks)		Outcomes reported					
							PA		QoL			
Source and design	*n*	Mean (SD)	Intervention	Control	Intervention	Follow-up	Behaviour	Capacity	Generic	Health	PAD	Others
Roberts 2008[180] pretest–post-test non-RCT	47	67.7 (7)	Walking programme + telephone support	NA	12	12		ACD				Pain intensity
Matthews 2021[164] pretest–post-test non-RCT	11	70	SET + cardiovascular education	NA	8			6MWT, WIQ		X		Anxiety, depression, systolic BP
Racodon 2018[186] pretest–post-test non-RCT	68	62.7 (9.7)	Therapeutic education + vascular rehabilitation	NA	52	52		ACD, corridor/ outdoor test				BMI
Fakhry 2011[177] Non-RCT	217	67.5	Structured walking programme	SET	24	52		ACD, ICD	X	X	X	ABPI
Jacobsen 2022[169] pretest–post-test non-RCT	35	71.5 (7.7)	Lifestyle counselling + SET	NA	12	24		ACD, ICD, 6MWT			X	
Mouser 2009[170] pretest–post-test non-RCT	120	67.4 (10.3)	Education + walking programme	NA	24			ACD, ICD				
Aalami 2022[188] pretest–post-test non-RCT	139	65	SEP	NA	12	52		WIQ				
Wullink 2001[181] pretest–post-test non-RCT	31	66 (14)	Home-based walking programme	NA	24			ACD, ICD, WIQ, corridor/ outdoor test				
Jonason 1981[173] Non-RCT	17	66	Education + home-based walking programme	SET (same participants)	12	24	Walking activity	ACD, ICD				
Otsuka 2021[165] Non-RCT	30	73.8	Home-based exercise with Triaxial accelerometer + telephone instruction	Attention control with Triaxial accelerometer	12	12	Activity, steps/day	6MWT, WIQ		X	X	Self-efficacy
Leslie 2022[174] Non-RCT	46	69 (11)	Walking programme	SET	12			ACD, ICD				ABPI

ACD, absolute claudication distance; BASIC, Baltimore Activity Scale for Intermittent Claudication; BIPQ, Brief Illness Perception Questionnaire; BP, blood pressure; ICD, initial claudication distance; NEADL, Nottingham Extended Activities of Daily Living; VO_2, volume of oxygen consumption; WELCH, Walking Estimated-Limitation Calculated by History.
a Additional information obtained from authors.

Specifically, 15 studies implemented initial face-to-face delivery of structured walking/exercise, followed by telephone or mobile health follow-up for feedback, re-enforcement, support or monitoring.[149–151,153,158,159,161,166,168,172,176,185,187,189,195] Eight studies incorporated an education component within a structured walking intervention, but no telephone or mobile health follow-up.[160,170,171,173,175,184,186,188] A home-based structured walking programme without an education or telephone/mobile health follow-up component was used in seven studies,[162,163,174,177–180] whereas six others implemented a supervised exercise in addition to education, and/or community-based walking, lifestyle coaching, feedback.[164,165,167,169,183,192] Two studies used a completely mobile health intervention with participants' goals and progress reviewed during follow-up visits,[189,190] while another two implemented individual motivational interviews,[115,182] with one of them additionally following participants up via smartphone.[182] Finally, one study used health coaching and walking training.[181] *Table 3* provides further information on included studies.

Owing to the study designs (pretest–post-test design), 11 studies did not have a comparator arm[159,160,164,169,170,178,180,181,186,188] and 7 were three-arm trials with two active arms.[157,161–163,179,185,192] However, one of the three-arm trials merged outcomes in two of the study arms to one, so we report this study as a two-arm trial.[161] There were several types of comparator group across the 30 studies. This was described as usual care in 10 studies,[151,162,166–168,175,184,187,190,195] supervised exercise in 6 studies;[172–174,176,177,189] walking advice in 4 studies,[179,183,185,192] attention control in 4 studies,[149,150,161,163] health education in 3 studies,[115,153,157] and 1 study did not implement any intervention in the control group.[182] Additional active controls were used in the five studies that reported three arms. These included supervised exercise in four studies[162,163,179,185] and high-intensity walking in one study.[157] This brings a total number of supervised exercise groups across studies to 10.[162,163,172–174,176,177,179,185,189]

Study settings varied across included studies. Interventions were started and/or finished off at hospital/clinic, park and participants' homes in 20 of the studies,[115,149,150,157,159,160,163,165,166,171–174,176,178,179,185,189,195] 10 were delivered mainly at hospital/clinics,[158,164,167,169,170,175,182,184,186,190] 8 were entirely home-based.[151,153,161,162,177,180,187,188] Three studies were delivered in multiple settings, one in hospital and community settings,[183] one in home-based and community settings[168] and one in a movement science laboratory and home-based.[181]

The duration of intervention session was not reported in nine studies.[159–161,166,174,175,178,181,189] For the remaining 32 studies, sessions range from 30 minutes to 3 hours. Intervention frequency was mostly three times/week,[150,151,153,157,159–163,165,166,169–172,174,176,177,179–181,183–189,192] but there were also studies in which one-off sessions were followed with telephone calls every 2 weeks.[115,158,168] With the exception of three interventions which lasted between 4 and 8 weeks,[159,164,168] intervention duration was 12 weeks or greater in the included studies. Eleven studies did not report any follow-up beyond the period of intervention.[115,160,164,166,168,170,172,174,179,181,183] For the remaining 30 studies, the follow-up period was < 6 months in 12 studies,[149,158,159,161–163,165,175,178,180,182,190] between 6 and 9 months in 6 studies,[150,169,173,176,187,195] up to 12 months in 11 studies,[153,157,167,171,177,184–186,188,189,192] and 2 years in 1 study.[152]

Behaviour change techniques in included studies

A total of 46 unique BCTs were identified across the 41 studies implementing 47 unique interventions (see *Sheet 1* in *Report Supplementary Material 2*). The mean (SD) number of BCTs coded per intervention was 7.60 (3.80), with a range of 2[176] to 17.[153,195] The most frequently occurring BCT was '*Goal-setting (behaviour)*', which was coded in 36 (78%) interventions. Other commonly used BCTs were '*Instruction on how to perform a behaviour*' (coded in 29; 63% interventions), '*Behavioural practice/rehearsal*' and '*Feedback on behaviour*' (each coded in 24; 52% interventions), '*Social support (unspecified)*' (coded in 23; 50% interventions), '*Self-monitoring of behaviour*' (coded in 22; 48% interventions); '*Review behaviour goals(s)*' (coded in 20; 41% intervention), '*Problem-solving*' (coded in 16; 35% intervention) and '*Information about health consequences*' (coded in 16; 35% intervention). Overall, 31 (67%) BCTs were used in fewer than five interventions.

The BCT domain that was most commonly used was '*Goals and planning*', with 42 (89%) of all interventions and 100% of interventions within our primary analysis using at least one BCT from within this domain. Other commonly used domains were '*Feedback and monitoring*' (89% of all interventions), '*Repetition and substitution*' (64% of all interventions), '*Shaping knowledge*' (62% of all interventions) and '*Social support*' (53% of all interventions). See details in *Tables 4* and *5*.

TABLE 4 Frequency of BCT usage – *n* (%) of interventions using at least one BCT and median number of BCTs used for each BCT domain (BCTs exclusive to intervention only)

BCT domain	*n* (%) of behaviour change interventions *N* = 47	Median (range) of individual BCTs within this domain that were used
1 Goals and planning	42 (89)	2 (0–6)
2 Feedback and monitoring	33 (70)	1 (0–4)
3 Social support	25 (53)	1 (0–3)
4 Shaping knowledge	29 (62)	1 (0–1)
5 Natural consequences	20 (42)	0 (0–1)
6 Comparison of behaviour	10 (21)	0 (0–0)
7 Associations	5 (11)	0 (0–1)
8 Repetition and substitution	30 (64)	1 (0–3)
9 Comparison of outcome	18 (38)	0 (0–1)
10 Reward and treat	2 (4)	0 (0–2)
11 Regulation	2 (4)	0 (0–1)
12 Antecedent	16 (34)	0 (0–1)
13 Identity	4 (9)	0 (0–1)
14 Scheduled consequences	0 (0)	0 (0–0)
15 Self-belief	5 (11)	0 (0–1)
16 Covert learning	1 (2)	0 (0–1)

Theoretical mechanism of actions for included studies

Table 6 shows the results for each of the TDF domains targeted by the 47 included interventions (41 studies). The details of the coding process and results are included as Supplementary Material (see *Sheet 2* of *Report Supplementary Material 2*). The included interventions addressed at least one of the 14 TDF domains, with most targeting multiple domains. Included interventions targeted around 3.8 (average) TDF domains, but slightly more than 21% (10/47) of the interventions targeted at least 50% (7–9) of the 14 TDF domains. The most targeted TDF domains in the included studies were *Goals* (41/47 interventions), *Skills* (31/47 interventions), *Behaviour regulation* (31/47 interventions) *Knowledge* (28/47 interventions), and *Environmental context and resources* (28/47 interventions). The least targeted TDF domains were *Social/professional roles and identity* (1/47 interventions), *Optimism* (1/47 interventions), *Emotion* (3/47 interventions) and *Memory, attention and decision processes* (5/47 interventions).

Measurement of habitual physical activity in studies screened at full text for inclusion in the quantitative review

All studies that were screened at full text and considered acceptable for inclusion on all other criteria were then screened to determine whether they had a suitable measure of habitual PA. A summary of the results of the screening are displayed in *Table 7*. The overall decision column records the final decision on inclusion or exclusion of the study (based on measure of habitual PA). Studies identified with fully adequate or partially adequate measures were included in the analysis of PA in review; studies identified with not adequate measures were excluded from the PA analysis in the review. Note *Table 7* only reports on a single outcome measure per study (the one selected for use in the review). The GOALS trial[199] reported both device-based and self-report measures of habitual PA that were partially adequate, and the device-based measure was used in the review.

Five studies were identified that used fully adequate measures of habitual PA, all of which used device-based measures. A further 13 studies were identified reporting partially adequate measures of habitual PA. Nine of those studies

TABLE 5 Frequency of BCT usage among interventions used in primary analysis (RCTs with data on volume of PA)

BCT domain	*n* (%) of behaviour change interventions using this domain out of those that report short-term volume of PA data *N* = 15	*n* (%) of behaviour change interventions using this domain out of those that report maintenance volume of PA data *N* = 8
1. Goals and planning	15 (100)	8 (100)
2. Feedback and monitoring	11 (73)	7 (88)
3. Social support	7 (50)	6 (75)
4. Shaping knowledge	11 (73)	6 (75)
5. Natural consequences	7 (47)	3 (37)
6. Comparison of behaviour	2 (13)	3 (38)
7. Associations	1 (7)	0 (0)
8. Repetition and substitution	12 (80)	5 (63)
9. Comparison of outcome	4 (27)	0 (0)
10. Reward and treat	1 (7)	0 (0)
11. Regulation	1 (7)	2 (25)
12. Antecedent	9 (60)	3 (38)
13. Identity	3 (20)	2 (25)
14. Scheduled consequences	0 (0)	0 (0)
15. Self-belief	3 (20)	2 (25)
16. Covert learning	0 (0)	0 (0)

reported on device-based measures, and in all these cases, it was the lack of clear reporting as to the wear protocol and minimum duration for days to be included in analysis that led to this assessment. It is possible that these measures were fully adequate, but the lack of information did not allow us to be sure. Eight studies were excluded from the review at this stage, as they did not report an adequate measure of habitual PA. Four studies used self-report measures that only asked about a limited subset of activity types and/or intensity, one study used a self-report measure that only reported on continuous activity that was longer than 30 minutes, and three studies used measures to assess adherence of the exercise component of intervention (two device-based and one self-report measures).

Additional detail of the grading of device-based are provided in the following sections, while additional detail of the grading of self-report measures is provided in *Appendix 9*.

Grading of device-based tools for assessment of habitual physical activity

The device-based measures from studies which otherwise met the criteria for inclusion in the quantitative review were checked to decide whether they adequately assessed habitual PA. Studies which used device-based measures to check adherence to intervention are not included in the following information. Data to make this assessment were initially derived from the text of the article. Additional information was also sought to aid the decision, including literature referenced in the article, and e-mail requests for additional information to authors.

The devices used, attachment and protocol and aspects of programming and data processing are reported in *Table 8*. Details of the outcome measures reported, and information provided on reliability and validity of the device are reported in *Table 9*.

A range of devices were used in studies, including pedometers (two studies); research-grade accelerometers (nine studies), one of which also included physiological measures; and commercial wearables (three studies). Wear locations

TABLE 6 Theoretical Domains Framework domains targeted by included interventions

			Domains of the TDF														
	Study ID	Interventions	Knowledge	Skills	Social/ professional role and identity	Beliefs about capabilities	Optimism	Beliefs about consequences	Reinforcement	Intentions	Goals	Memory, attention and decision processes	Environmental context and resources	Social influences	Emotion	Behavioural regulation	Total
1	Collins *et al.*[150]	Home-based walking		1				1	1	1	1		1			1	7
2	Fowler *et al.*[184]	Community-based behaviour change	1	1							1						3
3	Fukaya *et al.*[161]	Behaviour change no financial incentive				1					1		1			1	4
		Behaviour change with financial Incentive				1			1		1		1			1	5
4	Gardner *et al.*[163]	Home-based exercise									1		1			1	3
		Supervised exercise		1							1		1				3
5	Matthews *et al.*[164]	Structured exercise	1	1		1					1			1			5
6	Sierke *et al.*[167]	Behaviour change + supervised exercise	1	1		1					1		1	1		1	7
7	McDermott *et al.* (LITE Trial)[157]	Low-intensity walking exercise	1							1			1		1		5
		High-intensity walking exercise	1							1			1		1		5
8	Tew *et al.*[168]	Structured education	1	1		1		1			1		1	1		1	8

TABLE 6 Theoretical Domains Framework domains targeted by included interventions (*continued*)

			Domains of the TDF													
	Study ID	Interventions	Knowledge	Skills	Social/ professional role and identity	Beliefs about capabilities	Optimism	Beliefs about consequences	Reinforcement	Intentions	Goals	Memory, attention and decision processes	Environmental context and resources	Social influences	Emotion	Behavioural regulation	Total
9	Gardner.[162]	Supervised exercise		1							1		1				3
		Home-based exercise		1							1		1			1	4
10	Duscha *et al.*[166]	MHealth programme	1	1							1		1	1		1	6
11	Wullink *et al.*[181]	Walking exercise programme	1	1				1	1	1				1		1	7
12	Cornelis *et al.*[159]	Tele-monitored home-based exercise	1	1							1		1			1	5
13	Endicott *et al.*[160]	Fitbit self- monitored walking programme	1					1			1		1			1	5
14	Paldan *et al.* (TrackPAD study)[190]	Supervised exercise with mobile phone–based self-tracking app		1					1		1		1	1			6
15	Otsuka *et al.*[165]	Home-based exercise									1					1	2
16	Mays *et al.*[183]	Community-based exercise	1	1							1		1	1		1	6
17	Quirk *et al.*[182]	Motivational interviewing				1				1	1					1	4
18	McDermott *et al.* (HONOR Trial)[187]	Home-based exercise	1	1							1		1	1		1	6
19	Cunningham *et al.*[151,152]	Psychological intervention	1			1		1		1	1					1	6

continued

TABLE 6 Theoretical Domains Framework domains targeted by included interventions (*continued*)

			Domains of the TDF														
	Study ID	Interventions	Knowledge	Skills	Social/ professional role and identity	Beliefs about capabilities	Optimism	Beliefs about consequences	Reinforcement	Intentions	Goals	Memory, attention and decision processes	Environmental context and resources	Social influences	Emotion	Behavioural regulation	Total
20	Collins *et al.*[158]	Face-to-face communication intervention	1	1				1			1						4
21	Bearne *et al.* (MOSAIC Trial)[195]	Home-based walking exercise behaviour change intervention	1			1					1					1	4
22	Galea *et al.*[a] (MOSAIC feasibility trial)[149]	Home-based walking exercise behaviour change intervention	1								1					1	3
23	McDermott *et al.* (GOALS Trial)[153–156,199]	Home-based walking		1	1		1				1			1	1		7
24	Aalami *et al.*[188]	App-based exercise with BCTs	1	1				1	1	1	1		1	1		1	9
25	Spronk *et al.*[178]	Personalised home-based exercise	1											1			2
26	Fakhry *et al.*[177]	Structured home-based exercise programme	1	1					1		1		1	1		1	7
27	Jacobsen *et al.*[169]	SET combined plus lifestyle counselling	1	1					1		1		1	1		1	7
28	Leslie *et al.*[174]	Home-based exercise	1	1							1		1			1	5
29	Sandberg *et al.* (SUNFIT trial)[185]	Home-based structured exercise programme		1							1		1				3
		Supervised exercise		1							1		1				3

TABLE 6 Theoretical Domains Framework domains targeted by included interventions (*continued*)

			Domains of the TDF													
	Study ID	Interventions	Knowledge	Skills	Social/ professional role and identity	Beliefs about capabilities	Optimism	Beliefs about consequences	Reinforcement	Intentions	Goals	Memory, attention and decision processes	Environmental context and resources	Social influences	Emotion	Behavioural regulation	Total
30	Nicholai *et al.*[192]	Supervised exercise with or without feedback	1	1							1		1			1	5
31	Normahani *et al.*[189]	SEP plus activity monitor		1									1	1			3
32	Roberts *et al.*[180]	Home exercise programme									1			1		1	3
33	Sandercock *et al.*[179]	Supervised walking sessions		1							1					1	3
		Home walking sessions		1							1			1		1	4
34	Mouser *et al.*[170]	Structured home-based exercise	1	1					1		1		1	1		1	7
35	Prévost *et al.*[171]	Therapeutic education and home-based exercise	1	1		1					1			1		1	7
36	Racodon *et al.*[186]	Therapeutic education	1	1				1									3
37	Regenstein-er *et al.*[183]	Home-based unsupervised exercise	1	1							1			1		1	5
38	Savage *et al.*[176]	Supervised exercise plus at-home exercise	1	1							1		1				4
39	Collins *et al.*[202]	In-person motivation interview plus telephone counselling	1	1					1	1	1					1	6

continued

TABLE 6 Theoretical Domains Framework domains targeted by included interventions (*continued*)

			Domains of the TDF														
	Study ID	Interventions	Knowledge	Skills	Social/ professional role and identity	Beliefs about capabilities	Optimism	Beliefs about consequences	Reinforcement	Intentions	Goals	Memory, attention and decision processes	Environmental context and resources	Social influences	Emotion	Behavioural regulation	Total
40	Jonason *et al.*[173]	Structured exercise						1	1		1						3
41	Pochstein and Wegner[175]	Psychological intervention	1							1	1			1		1	5
	Total			28	31	1	9	1	9	10	9	41	5	28	19	3	32

a Additional information obtained from authors.

TABLE 7 Summary table of measures of habitual PA in screened studies

Study	Tool used to measure PA or exercise	Measurement of habitual PA checklist				
		Suitable time frame	Adequate part of day	Suitable types/intensity	Reported outcomes	Overall decision
Bearne *et al.* (MOSAIC trial)[195]	**Self-report** IPAQ short	Yes: last 7 days	Partial: only asks about activities of at least 10 minutes' duration	Yes: time spent in VPA, MPA and walking	Yes: volume of activity total MET minute/week	Partially adequate
Collins *et al.*[158]	**Self-report** NHIS part B	Yes: 2 weeks	Yes: asks about all activities in that period	No: limited to MVPA, stretching or strengthening exercises	No: time spent in specific type/intensity of PA that is not acceptable	Not adequate
Collins *et al.*[150]	**Self-report** Stanford Patient Education Exercise Behaviour Questionnaire	Yes: previous week	Yes: asks about all time in the week	No: only assesses time spent in exercise	No: converts time spent in exercise into a score	Not adequate
Collins *et al.*[202]	**Self-report** Stanford Patient Education Exercise Behaviour Questionnaire	Yes: previous week	Yes: asks about all time in the week	No: only assesses time spent in exercise	No: converts time spent in exercise into a score	Not adequate
Cornelis *et al.*[159]	**Device** SenseWear Armband Mini	Yes: 7 days wear, at least 3 weeks and 2 weekend days for inclusion in analysis	Yes: 24-hour protocol; worn for minimum 90% of day for inclusion in data analysis	Yes: assesses light, moderate and vigorous activity and walking	Yes: number of steps	Fully adequate
Cunningh-am *et al.*[151]	**Device** Omron HJ-113 pedometer	Yes: 6 days	Partial: duration of day worn was not reported	Yes: assesses all walking	Yes: number of steps	Partially adequate
Duscha *et al.*[166]	**Device** Fitbit Charge	Yes: 14 days	Yes: waking wear protocol	Yes: assesses all movement	Yes: number of steps, time spent in total activity	Fully adequate
Endicott *et al.*[160]	**Device** Fitbit One	Yes: at least a month	Partial: duration of day worn was not reported	Yes: assesses all movement	Yes: number of steps	Partially adequate
Fowler *et al.*[184]	**Self-report** unnamed questionnaire	Unclear: Implies yes as reported 'weekly frequency'	Partial: excludes work-time VPA	Yes: covers vigorous activity, non-vigorous activity, walking for fitness and walking for recreation	Partial: percentage of people undertaking walking for recreation at least 3 times per week	Partially adequate
Fukaya *et al.*[161]	**Device** Fitbit Flex	Yes: 7 days	Partial: duration of day worn was not reported	Yes: assesses all movement	Yes: number of steps	Partially adequate

continued

TABLE 7 Summary table of measures of habitual PA in screened studies (*continued*)

Study	Tool used to measure PA or exercise	Measurement of habitual PA checklist				
		Suitable time frame	Adequate part of day	Suitable types/intensity	Reported outcomes	Overall decision
Gardner *et al.*[162]	**Device** StepWatch 3 accelerometer	Yes: 7 days	Partial: duration of day worn was not reported	Yes: assesses all movement	Yes: number of strides, time spent in activity	Partially adequate
Gardner *et al.*[163]	**Device** StepWatch 3 accelerometer	Yes: 7 days	Partial: duration of day worn was not reported	Yes: assesses all movement	Yes: number of strides, time spent in activity	Partially adequate
Galea *et al.*[a] (MOSAIC feasibility trial)[149]	**Device** Omron Walking Style Pro pedometer	Yes: 6 days' wear, minimum 3 days for inclusion in analysis	Partial: waking day wear protocol, criteria for a missing day is zero steps/day, no assessment for minimum wear time during a day	Yes: assesses all walking	Yes: number of steps	Partially adequate
Jonason *et al.*[173]	**Self-report** unnamed questionnaire	Unclear: implies yes as reported 'per week'	Unclear: no information provided	Yes: assessed all walking and additionally one type of exercise	Partial: distance walked	Partially adequate
Mays *et al.*[183]	**Device** accelerometer manufactured by OrthoCare Innovations	Yes: 14 weeks of intervention	No: only worn during exercise sessions	No: only worn during exercise sessions	No: reported compliance with exercise sessions	Not adequate
GOALS study[153–156,199]	**Device** Caltrac accelerometer	Yes: 7 days	Partial: duration of day worn was not reported	Yes: assesses all movement	Yes: total volume of activity in proprietary units	Partially adequate
	Self-report City Blocks Walked in Last Week	Yes: previous week	Yes: asks about all time walking	Yes: asks about walking and stair climbing	Partial: distance walked	Partially adequate
McDermott *et al.* (HONOR trial)[187]	**Device** ActiGraph accelerometer	Yes: 7 days	Partial: Waking wear protocol, removed for bathing, minimum wear criteria not reported	Yes: assesses all movement	Yes: total volume of activity in proprietary units	Partially adequate
McDermott *et al.* (LITE trial)[157]	**Device** ActiGraph accelerometer	Unclear: communication with author implies 1 week	Partial: duration of day worn was not reported	Yes: assesses all movement	Yes: total volume of activity in proprietary units	Partially adequate
Otsuka *et al.*[165]	**Device** Omron Active style Pro accelerometer	Yes: worn for 3 months	Yes: waking wear protocol, not worn while bathing	Yes: assesses all movement	Yes: number of steps	Fully adequate

TABLE 7 Summary table of measures of habitual PA in screened studies (*continued*)

Study	Tool used to measure PA or exercise	Measurement of habitual PA checklist				
		Suitable time frame	Adequate part of day	Suitable types/intensity	Reported outcomes	Overall decision
Paldan *et al.* (TrackPAD study)[190,200]	**Device** TrackPAD mobile phone app	Yes: used across entire intervention	No: only used during exercise sessions	No: only assesses during exercise sessions	No: reported as adherence	Not adequate
	Self-report Unnamed Questionnaire	Unclear: no information	Unclear: no information	Unclear: implies not as reported as number of days on which there is PA	Unclear: measure of frequency: number of days on which there is PA	Not adequate
Pochstien *et al.*[175]	**Self-report** modified Kaiser Physical Activity Survey	Yes: last 4 weeks	No: only asked about exercise	No: only asked about 5 types of exercise	No: time spent in specific type/intensity of PA that is not acceptable	Not adequate
Quirk *et al.*[182]	**Self-report** IPAQ-Short	Yes: last 7 days	Partial: only asks about activities of at least 10 minutes' duration	Yes: time spent in VPA, MPA and walking	Yes: volume of activity total MET minute/week	Partially adequate
Sandberg *et al.* (SUNFIT trial)[185]	**Device** activPAL3 accelerometer	Yes: 7 days; minimum of 4 days to be included in analysis	Yes: 24-hour wear protocol, water-proof, minimum of 10-hour non-wear allowed in valid day	Yes: assesses all movement	Yes: number of steps	Fully adequate
(CIPIC Rehab Study) Siercke *et al.*[167]	**Self-report** Self-reported time walking	Yes: reported for a week	No: only asks about activities undertaken for at least 30 minutes in a day	Yes: covers walking and PA	No: number of days of at least 30 minutes walking/exercise	Not adequate
Tew *et al.*[168]	**Device** ActiGraph GT3X + accelerometer	Yes: 7 days; minimum of 3 days required for inclusion in analysis	Yes: Waking wear protocol, water-proof, minimum wear time 10 hours per day	Yes: assesses all movement	Yes: number of steps	Fully adequate
Wullink *et al.*[181]	**Self-report** Walking Diary	Yes: completed for entire intervention, diary from first 7 days and last 7 days used for outcomes	No: only asks for a record of walking exercise undertaken as part of the intervention	No: only asks for a record of walking exercise undertaken as part of the intervention	No: Number of walks for exercise per day, maximum walking duration of an exercise session	Not adequate

IPAQ, International Physical Activity Questionnaire; MPA, moderate physical activity.
a Additional information obtained from authors.

TABLE 8 Device-based measures of habitual PA, Part 1: device, attachment and protocol, programming and data processing

	Device	Attachment and protocol			Programming and data processing	
Author	Make and model/type of device	Wear location/ attachment method	Who attached/how returned/instructions	Number of days worn/ any specifics of those days/wear protocol/ when removed	Software used/ programming information/ download information	Process to identify non-wear/criteria for wear time for valid day/criteria for inclusion in data analysis
Cornelis *et al.* 2021[159,a]	**SenseWear Armband Mini**/ accelerometer + physiological measures	Right upper arm, mid-triceps/ proprietary elastic strap	Attached by researcher/returned by participant/--	7 days/5 weeks + 2 weekend days/24-hour wear protocol/removed for water-based activities	SenseWear 8.1/researcher added personal data (age; smoking status; weight; height; preferred hand) to device/--	Monitor reported off-body time/90% daily wear time/ worn for at least 3 weeks and 2 weekend days
Cunningham *et al.* 2012[151]	**Omron HJ-113**/pedometer	--/--	Attached by participant/ device collected, not clear by who/use demonstrated, walked 50 steps to check recording walking accurately/	6 days data/worn 7 days/--/--	--/--/--	--/--/--
Duscha *et al.* 2018[166,a]	**Fitbit Charge**/commercial wearable	Non-dominant wrist/proprietary wristband and clasp	Attached by participants/--/--	2 weeks/--/24-hour wear protocol/not worn when showering or charging	--/--/Participants synchronised with phone regularly, then downloaded weekly by researchers, contacted participants if gaps	--/--/Authors reported all data were analysed, because participants were closely monitored and there was little missing data
Endicott *et al.* 2018[160]	**Fitbit One**/commercial wearable	--/--	--/--/--	6 months/--/--/--	--/--/Data storage on device for 30 days, downloaded every 4 weeks	--/--/--
Fukaya *et al.* 2020[161]	**Fitbit Flex**/commercial wearable	Wrist/wristband	--/--/--	7 days/--/--/--	Fitbit app + website/--/ data stored in the tracker synchronised to smartphone and transferred app or website	--/--/--
Gardner *et al.* 2011[162]	**StepWatch3**/accelerometer	Right ankle above the lateral malleolus/elastic Velcro straps	--/--/--	7 days/consecutive/ waking wear protocol/--	StepWatch3 analysis software/programmed using USB docking station/downloaded using proprietary software	--/--/--
Gardner *et al.* 2014[163]	**StepWatch3**/accelerometer	Right ankle above the lateral malleolus/elastic Velcro straps	--/--/--	7 days/consecutive/ waking wear protocol/--	StepWatch3 analysis software/programmed using USB docking station/downloaded using proprietary software	--/--/--

TABLE 8 Device-based measures of habitual PA, Part 1: device, attachment and protocol, programming and data processing (*continued*)

	Device	Attachment and protocol			Programming and data processing	
Author	Make and model/type of device	Wear location/ attachment method	Who attached/how returned/instructions	Number of days worn/ any specifics of those days/wear protocol/ when removed	Software used/ programming information/ download information	Process to identify non-wear/criteria for wear time for valid day/criteria for inclusion in data analysis
Galea *et al.* 2018[a] (MOSAIC feasibility trial)[149]	**Omron Walking Style Pro 2.0 HJ-322U-E**/pedometer	Hip/belt clip	Attached by participants/collected by researcher/detailed instructions provided/	6 days/includes weeks and weekend days/ waking wear protocol/--	--/Individual data (height, weight, stride length) input to the activity monitor. Stride length determined at research appointment walking along corridor/--	Number of steps per day, or data lost when monitor returned late/days with 0 steps not included/ minimum 3 days
McDermott *et al.* (GOALS Trial)[153–156,199]	**Caltrac**/accelerometer	Waist/belt clip	--/Value from accelerometer reported by participant over phone, then posted back	7 days/--/waking wear protocol/removed for bathing	--/Accelerometers were programmed using identical age, weight and sex for each participant/--	--/--/--
McDermott *et al.* 2018 (HONOR Trial)[187]	**ActiGraph**/accelerometer	Right hip/--	--/--/--	7 days/--/waking wear protocol/removed for bathing	--/--/--	--/--/--
McDermott *et al.* 2021 (The LITE Trial)[a,157]	**ActiGraph**/accelerometer	Hip/--	--/--/--	--/--/--	--/--/--	--/--/--
Otsuka *et al.* 2021[165]	**Omron Active style Pro HJA-750C**/accelerometer	Lower back/--	--/--/--	Up to 3 months/worn daily/waking wear protocol/removed for bathing	--/--/--	--/Excluded days with < 480 minutes/day wear time/--
Sandberg *et al.* 2022[a] (SUNFIT trial)[185]	**activPAL3**/accelerometer	Right thigh midline/placed in waterproof sleeve and attached with Tegaderm waterproof dressing	--/Removed by participant and returned by post/no specific instructions about PA or required behaviour	7 days/worn 9 days/24-hour protocol/ waterproof	PALbatch software suite version 8.10.12.57, CREA version 1.2/used default settings/downloaded using proprietary software	Proprietary algorithm (CREA) identified non-wear and sleep/excluded days with > 10-hour non-wear time, processed data in time awake/minimum 4 days
Tew *et al.* 2015[168,a]	**ActiGraph GT3X+**/accelerometer	Hip/elastic belt	Attached by participants/returned by participant/researcher provided verbal instructions	7 days/including days put on and off/ waking wear protocol/ waterproof	--/--/--	--/Excluded if < 10 hours of accelerometer movement data/minimum 3 days

a Additional information obtained from authors.

TABLE 9 Device-based measures of habitual PA, Part 2: outcome measures, reliability and validity

Author	Device	PA outcome measures		Reliability and validity
	Make and model/type of device	Measure of habitual PA used in review/ other measures of habitual PA/*other measures related to PA and exercise*	Derivation of outcome measure from data. Reported timescale/calculation of measure/other relevant information	
Cornelis *et al.*[159,a]	**SenseWear Armband Mini**/ accelerometer + physiological measures	**Number of steps**/ time spent in LIPA; time spent in MPA; time spent in VPA (if summed)/*time in spent SB*	Reported per day/daily average calculated across valid days/used proprietary software to apply MET thresholds to distinguish time in SB, LIPA, MPA and VPA	--
Cunningham *et al.*[151]	**Omron HJ-113**/pedometer	**Number of steps**	Reported per day/--/--	Reported 'demonstrated good reliability and validity in sedentary older adults' referring to[203]
Duscha *et al.*[166,a]	**Fitbit Charge**/commercial wearable	**Number of steps**/ distance walked, time spent in total activity/*time spent in low activity/moderate-low activity/moderate-high activity, number of flights of stairs*	Reported per day and per week/--/low activity uses the Fitbit light activity category, moderate-low activity uses the Fitbit fairly active category, moderate-high activity uses the Fitbit very active category. Total activity is sum of all intensities	--
Endicott *et al.*[160]	**Fitbit One**/commercial wearable	**Number of steps**/distance walked/*number of days with steps greater than zero*	Reported per day, per month and total values/average and total values used/distance walked calculated from number of steps, using a standard table (included in appendix of article) providing number of steps per mile based on participant height	Reported 'has been validated in a recent systematic review as a reliable step counter' referring to[204]
Fukaya *et al.*[161]	**Fitbit Flex**/commercial wearable	**Number of steps**	Reported per day/baseline average of 7 days, follow-up '3-month average', unclear exactly how many days included in average/--	--
Gardner *et al.*[162]	**StepWatch3**/accelerometer	**Number of strides**[b]/ total activity time/*average cadence, maximum cadence for 60, 30, 20, 5 continuous minutes of ambulation*	Reported per day/average for the 7-day monitoring period/used average strides per minute of the maximum number of strides taken over a sliding window of 60, 30, 20 and 5 continuous minutes each day; also used maximum stride rate obtained during single highest minute	
Gardner *et al.*[163]	**StepWatch3**/accelerometer	**Number of strides**[b]/ total activity time/*average cadence, maximum cadence for 60, 30, 20, 5 continuous minutes of ambulation*	Reported per day/average for the 7-day monitoring period/used average strides per minute of the maximum number of strides taken over a sliding window of 60, 30, 20 and 5 continuous minutes each day; also used maximum stride rate obtained during single highest minute	Reported 'The Step-activity monitor is accurate and reliable' referring to[205] and 'accurately record the duration and cadence of ambulation' referring to[162]

TABLE 9 Device-based measures of habitual PA. Part 2: outcome measures, reliability and validity (*continued*)

Author	Device	PA outcome measures		Reliability and validity
	Make and model/type of device	Measure of habitual PA used in review/ other measures of habitual PA/*other measures related to PA and exercise*	Derivation of outcome measure from data. Reported timescale/calculation of measure/other relevant information	
Galea *et al.* (MOSAIC feasibility study)[149,a]	**Omron Walking Style Pro 2.0 HJ-322U-E**/pedometer	**Number of steps**	Reported per day/mean steps over 6 measurement days/--	Test–retest reliability provided as substudy in thesis. Twelve participants walked around a 70 m circuit at 'a brisk pace' against visual step count; two circuits with 2-minute rest between. Test–retest good (ICC 0.95), agreement with visual count good (ICC 0.97)
McDermott *et al.* (GOALS Trial)[153–156,199]	**Caltrac**/accelerometer	**Total activity in proprietary 'activity units'**	--/--/--	--
McDermott *et al.* (HONOR Trial)[187]	**ActiGraph**/accelerometer	**Total activity in ActiGraph counts**	Reported per day/--/--	--
McDermott *et al.* (LITE Trial)[157,a]	**ActiGraph**/accelerometer	**Total activity in ActiGraph counts**	--/--/--	--
Otsuka *et al.*[165]	**Omron Active style Pro HJA-750C**/accelerometer	**Number of steps**	Reported per day/average value/ monitor was worn continuously for 3 months; it was not clear in article which days were used to form the baseline and which the follow-up assessment period	--
Sandberg *et al.* (SUNFIT trial)[185,a]	**activPAL3**/accelerometer	**Number of steps**	Reported per day/calculated as daily average of waking day/--	--
Tew *et al.*[168,a]	**ActiGraph GT3X+**/accelerometer	**Number of steps**	Reported per day/mean value of valid days/--	--

ICC, intraclass correlation coefficient; LIPA, light-intensity physical activity; MPA, moderate physical activity; SB, sedentary behaviour.
a Additional information obtained from authors.
b Multiply by 2 to get steps.

included wrist, upper arm, waist/hip, thigh and ankle. However, there was a general lack of reporting of details about the device-based measures used in these studies. Even such basic details as wear location of the device are missing for several studies. In particular, lack of information on wear protocol, anticipated removal of the device (e.g. overnight), and details of when data were considered valid for inclusion in analysis, hindered the ability to fully determine whether a measure was adequate for habitual PA. There was generally also very limited information on the suitability of the devices used. Three studies stated in the text that the device was reliable or valid referring to other published work. On contact with authors, reliability information about the device for one other study was obtained from an associated thesis.

Summary of all physical activity measures and measurement in included studies

Overall, 26 studies reported some data on PA.[149–151,157–163,165–168,173,175,181–185,187,190,195,199,202] However, we judged that eight of these did not apply PA measurement in a manner that met our criteria for measurement of habitual PA in this review.[150,158,167,175,181,183,190,202] Of these eight studies, four used a self-report measure which asked about and reported on a limited subset of PA [exercise generally, specific types of exercise, or only vigorous and moderate PA (MPA)] which was not broad enough to meet our criteria for habitual PA.[150,158,175,202] One study[190] provided no information about the

questions asked in their questionnaire, while another study[167] only reported on exercise and walking for 30 minutes per day, potentially neglecting lower levels of habitual PA. Finally, three studies only recorded exercise during intervention sessions without measuring habitual PA as an outcome.[181,183,190] These studies were removed from the PA analysis implemented in this review. Therefore, only 18 studies were included for outcome analysis and reporting related to PA. For these 18 studies, device-based measures of PA were used in 14 (77.8%), and self-report was used in 5 (27.8%), 1 of which also used a device-based measure. Five studies were identified that used a fully adequate measure of PA, all of which used a device-based measure.[159,165,166,168,185] In all of the remaining nine studies using device-based measures, it was the lack of clear reporting, specifically of the wear protocol and minimum duration of days included in the analysis, which meant there was insufficient information provided to make a judgement.

Out of the 14 studies that evaluated PA using device-based measures, the majority (78.6%) used accelerometers,[157,160–163,165,166,168,185,187,199] 2 (14.3%) used pedometers,[149,151] and 1 study used a multisensor device, which included an accelerometer along with other sensors (SenseWear Mini).[159] Various accelerometer devices were used, such as Fitbit (used in three studies),[160,161,166] ActiGraph (used in three studies)[157,168,187] and StepWatch (used in two studies).[162,163] One study each used the activPAL,[185] Caltrac[199] and Omron Active Style Pro[165] accelerometer devices. The placement of devices was only reported in 10 (71.3%) studies, and participants were mainly instructed to wear devices on the hip,[149,157,187,199] ankle,[162,163] lower back,[165] upper arm[159] or wrist.[161]

For the four studies which only assessed PA through self-report, two used the short version of the International Physical Activity Questionnaire (IPAQ) questionnaire,[182,195] and two used unnamed questionnaires.[173,184] The reliability and validity of measures were often based on prior research. Seven (38.9%) studies that assessed PA using devi ces[151,160,162,163,165,187,199] provided details on the validity of the measures based on prior research,[41,203–209] while all studies noted the validity assessments of self-report measures by providing information from previously published studies.

Secondary outcome measures and measurements in included studies

Thirty-four studies reported outcomes on walking capacity (distance or time).[115,149–151,159,161,163–174,176–181,183,185–187,189,190,192,195,199] One of these studies exclusively used a self-report measure to evaluate initial claudication distance (ICD),[151] whereas objective measurements of walking capacity were assessed in 33 studies,[115,149,150,159,161,163–174,176–181,183,185–187,189,190,192,195,199] including 2 studies which additionally assessed absolute claudication distance (ACD) with self-report measures.[192,195] Of the 33 studies that objectively measured walking capacity, 17 studies used the treadmill test,[150,159,162,166,167,170–174,176,177,179,180,183,189,192] 7 others used the treadmill test in addition to the 6MWT[157,163,168,169,199] or a corridor/outdoor test,[181,186] and 1 used a corridor test.[178] The remaining eight studies solely relied on the 6MWT to measure walking capacity.[115,149,161,164,165,185,187,190]

Twenty-nine studies report outcome on QoL using a range of generic,[177,199] health- related[149,150,157,161–164,168,169,171,172,176,182–185,187,193,199] and vascular/PAD-specific[115,151,159,165,167–169,177,180,182,185,189,190,195] QoL measures, while 18 studies reported outcome on walking impairment.[150,157–159,161–165,168,172,181,183,185,187,188,193,199]

Outcomes on cardiovascular risk factors reported included peak volume of oxygen consumption (VO2) (seven studies),[162,163,166,170,172,179,183] ABPI (seven studies),[171,172,174,176,177,180,185] BMI (three studies),[115,180,186] heart rate (three studies),[172,179,180] systolic blood pressure (BP) (three studies)[115,164,180] and diastolic BP (two studies).[115,180] Two studies reported outcomes on disease progress.[151,185]

Risk of bias in included studies

Randomised controlled trials

For the RCTs, we completed RoB assessment at the outcome levels and, where possible, aggregating RoB assessment for outcomes with similarity in measurement and risk level. This gave rise to four different RoB assessments:

At the level of *PA outcomes*, 10 of the 14 RCTs were assessed as having a low RoB for all items.[149,151,157,162,163,168,185,187,195,199] One was rated to have 'some concerns' on two items but did not have any items assessed as being of high RoB.[184] Three were assessed as high RoB.[161,166,182] The item that contributed most to the assessment of high RoB were deviations from intended interventions and missing PA outcome data. See details of RoB assessment at the outcome level of PA in *Figure 2*.

For *walking capacity/ability outcomes*, 11 of the 23 RCTs were assessed as having a low RoB for all items,[149,151,157,162,163,168,183,185,187,195,199] and 6 studies were rated to have 'some concerns' on 1 to 3 items but did not have any items assessed as being of high RoB.[150,167,179,184,190,192] Six were assessed as high RoB.[161,165,166,172,176,189] The item that contributed most to the assessment of high RoB were deviations from intended interventions and missing outcome data related to walking capacity. See details of RoB assessment at the outcome level of walking capacity outcomes in *Figure 3*.

We assessed eight RCTs for RoB at the *outcome level of cardiovascular risk factors*, including peak VO_2, heart rate, BP and ABPI. Three of these were assessed as having low RoB in all domains,[162,163,185] two were rated to have 'some concerns'

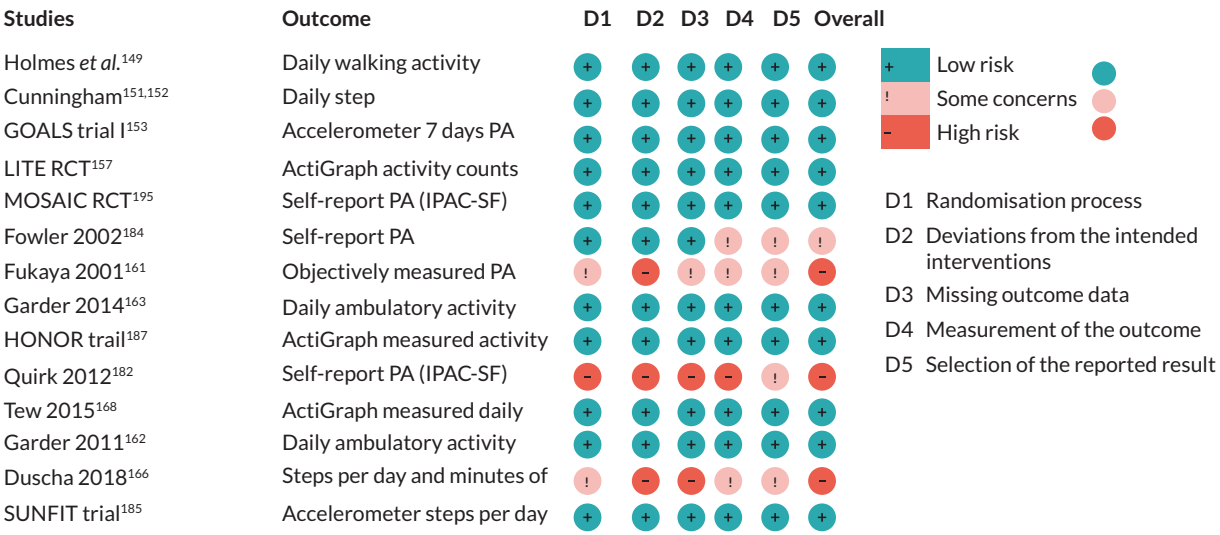

FIGURE 2 Risk-of-bias assessment for PA outcomes assessed in RCTs.

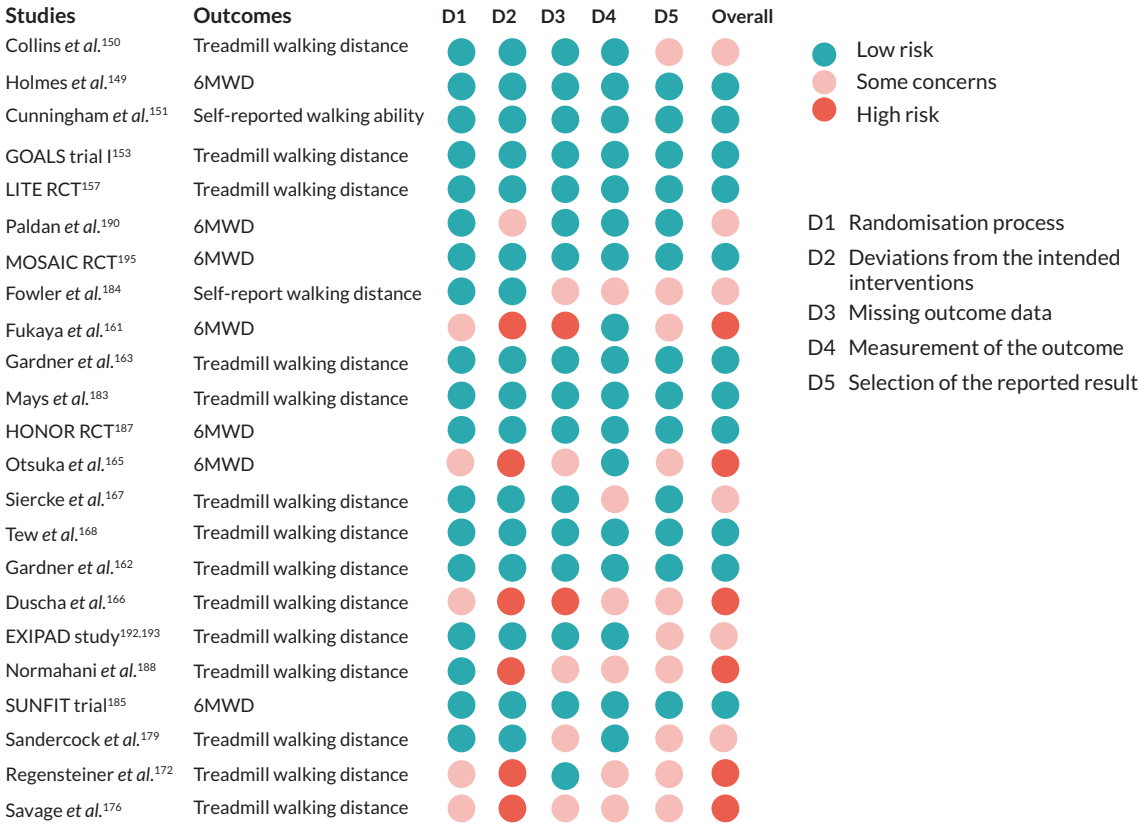

FIGURE 3 Figure of the RoB assessment for walking capacity outcomes.

on two domains but no domain assessed as being of high RoB.[179] Three were assessed as having high RoB.[166,172,176] The items that contributed to the assessment of high RoB were deviations from intended interventions and missing outcome data. See details of RoB assessment at the outcome level of cardiovascular risk factors in *Figure 4*.

We assessed 24 RCTs for RoB at the outcome level of PROMs, including QoL, walking impairment, pain intensity rating and/or depressive symptoms in a combined risk of assessment for patient-reported outcomes (*Figure 5*). Eight studies were assessed as having low RoB in all domains,[151,157,162,163,185,187,195,199] 10 were rated to have 'some concerns' in 1 to 3 domains but no domain assessed as being of high RoB.[115,149,150,158,167,168,183,184,189,192] Six were assessed as having high RoB.[161,172,176,179,182,190] The items that contributed most to the assessment of high RoB were deviations from intended interventions and missing outcome data. See details of RoB assessment at the outcome level of cardiovascular risk factors in *Figure 5*.

Non-randomised controlled trials

We implemented RoB assessment for the 15 included non-RCTs at the studies level using ROBINS–I tool. Overall, we judged 13 of the studies to have serious concern regarding RoB, and the remaining 2 were judged to have moderate RoB. The item that contributed most to the assessment of serious RoB was bias due to confounding (*Table 10*).

Effectiveness outcomes

Volume of physical activity (primary outcome)

Behaviour change interventions versus controls

Evidence from 11 RCTs (15 comparisons, 952 patients) suggests that BCT interventions increase the volume of PA by an average of 0.20 SMD (95% CI 0.07 to 0.33) in the short term (< 6 months) when compared to non-supervised controls. There was little evidence of heterogeneity (I^2 = 0%, T^2 = 0.00) (*Figure 6*). This improvement corresponds to an increase of 473 steps/ day (95% CI 165 steps to 780 steps). Several sensitivity analyses for this effect were robust, and results did not change the effect estimate (see *Table 1* in *Report Supplementary Material 1*).

Evidence from 6 RCTs (8 comparisons, 899 patients) left it unclear whether or not BCT interventions lead to maintenance of increased PA (medium term). Average increase in volume of PA was 0.12 SMD (95% CI −0.04 SMD to 0.29 SMD). Heterogeneity was low (I^2 = 26.1%, T^2 = 0.01) (see *Figure 6*). This corresponds to an increase of 288 steps/ day (95% CI: from a 102 step reduction to a 676 step increase). Several sensitivity analyses for this effect were robust, and results did not change the effect estimate (see *Table 1* in *Report Supplementary Material 1*).

Combined data from 3 studies that were not randomised (3 comparisons, 69 participants) on steps per day suggested that BCT interventions increase the steps per day by 786 steps (95% CI 198 steps to 1373 steps), in the short term, which is consistent with the randomised evidence (see *Appendix 3* and *Appendix 4*).

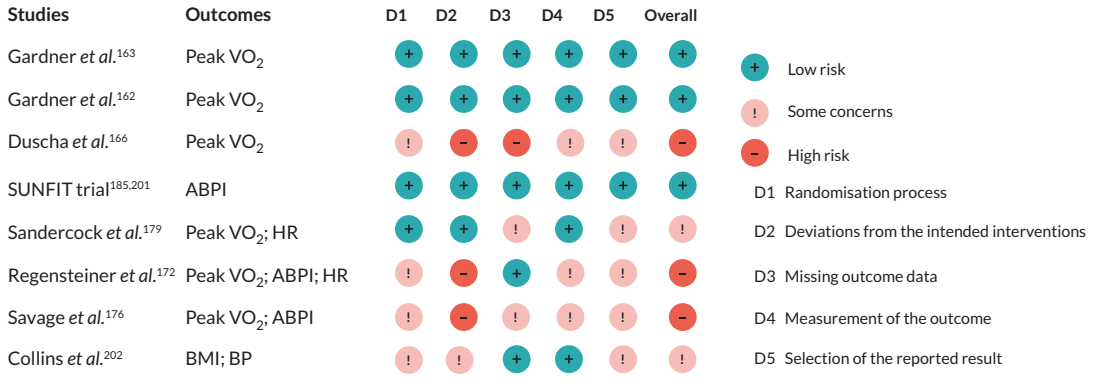

FIGURE 4 Figure of the RoB assessment for cardiovascular risk outcomes.

FIGURE 5 Figure of the RoB assessment for patient-reported outcomes. BIPQ, Brief Illness Perception Questionnaire.

Exploratory NMA comparing interventions by modality of delivery of BCT interventions, in terms of volume of PA both in the short term and medium term, left it unclear whether or not any intervention modality was better than any other (see *Appendices 5–8*. Also see *Figure 1* in *Report Supplementary Material 1*).

Behaviour change interventions versus supervised exercise

Evidence from 3 RCTs (3 comparisons, 269 participants) left it unclear whether or not BCT interventions increase the volume of PA in the short term (< 6 months) when compared to SET: −0.13 SMD (95% CI −0.43 to 0.16). There was little evidence of heterogeneity (I^2 = 0%, T^2 = 0.00) (see *Figure 1*).

Evidence from 1 RCT (1 comparison, 89 participants) left it unclear whether or not BCT interventions increase the volume of PA in the medium term when compared to SET: −0.04 SMD (95% CI −0.55 to 0.47) (see *Figure 6*).

Exploratory NMA comparing interventions by modality of delivery in terms of volume of PA both for the short term and medium term left it unclear whether or not any intervention modality was better than any other. Pairwise comparisons combining both direct and indirect evidence (see *Appendix 5* and *Appendix 7*) produced wide CIs that did not rule out 'no difference'. However, ranking and SUCRA estimates suggested that SET was likely to offer the most benefit in terms

TABLE 10 Risk of bias assessment for non-RCTs

Reference	Domain 1: bias due to confounding	Domain 2: bias in selection of participants into the study	Domain 3: bias in classification of interventions	Domain 4: bias due to deviation from intended interventions	Domain 5: bias due to missing data	Domain 6: bias in measurement of outcomes	Domain 7: bias in selection of the reported result	Overall bias
Cornelis *et al.*[159]	Serious	Low	Low	Low	Low	Moderate	Moderate	Serious
Endicott *et al.*[160]	Moderate	Low	Low	Low	Moderate	Moderate	Moderate	Moderate
Otsuka *et al.*[165]	Serious	Low	Low	Low	Moderate	Moderate	Moderate	Serious
Matthews *et al.*[164]	Serious	Low	Low	Low	Low	Moderate	Moderate	Serious
Wullink *et al.*[181]	Serious	Low	Low	Low	Moderate	Moderate	Moderate	Serious
Aalami *et al.*[188]	Serious	Low	Low	Low	Moderate	Serious	Moderate	Serious
Racodon *et al.*[186]	Serious	Low	Low	Low	low	Moderate	Moderate	Serious
Roberts *et al.*[180]	Serious	Low	Low	Low	Low	Moderate	Moderate	Serious
Spronk *et al.*[178]	Serious	Low	Low	Low	Moderate	Moderate	Moderate	Serious
Fakhry *et al.*[177]	Moderate	Low	Low	Low	Low	Moderate	Moderate	Moderate
Jacobsen *et al.*[169]	Serious	Low	Low	Low	Low	Moderate	Moderate	Serious
Mouser *et al.*[170]	Serious	Low	Low	Low	Moderate	Moderate	Moderate	Serious
Prevost *et al.*[171]	Serious	Low	Low	Low	Low	Moderate	Moderate	Serious
Jonason *et al.*[173]	Serious	Low	Low	Low	Moderate	Moderate	Moderate	Serious
Leslie *et al.*[174]	Serious	Low	Low	Low	Low	Moderate	Moderate	Serious

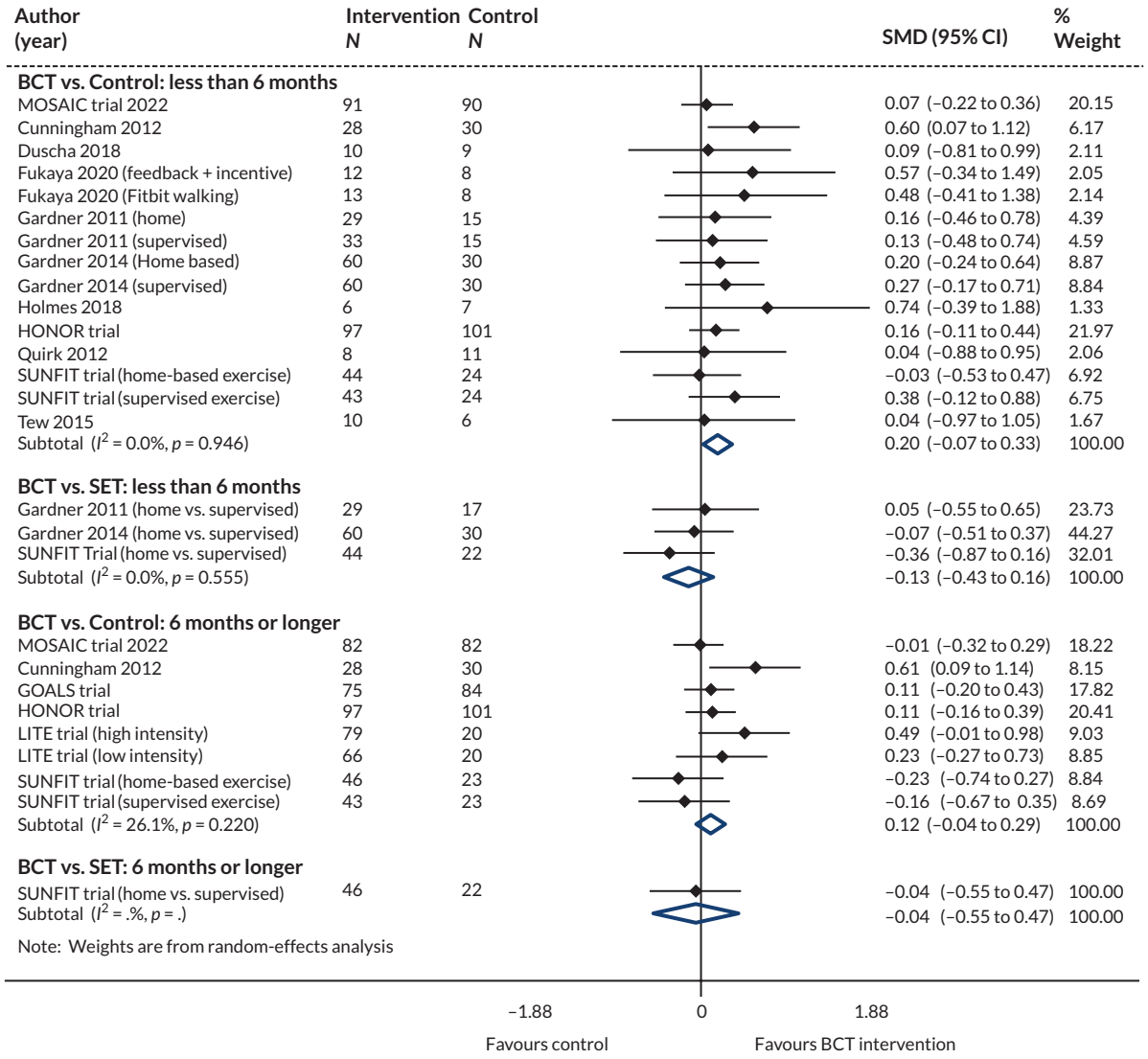

FIGURE 6 Meta-analysis of the effect of behaviour change interventions vs. controls on volume of PA. Note: Daily PA combined using SMD, using 'change from baseline'. Daily PA uses steps/day, distance per day or a total activity count. Where multiple measures of daily PA were reported, the steps or distance 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 RCTs only. Source: Reproduced with permission from Abaraogu *et al.*[210] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

of PA in the short term, and that other BCT interventions or BCT interventions with technology were likely to offer the most benefit in the medium term (see *Appendix 6* and *Appendix 8*). Also see *Figure 3* in *Report Supplementary Material 1*. The results of the NMA should be interpreted cautiously due to imprecision.

Clinically assessed absolute claudication distance or time

Behaviour change interventions versus controls

Evidence from 9 RCTs (13 comparisons, 693 participants) suggests that behaviour change interventions increase ACD in the short term by 0.42 SMD (95% CI 0.22 to 0.61). There was low heterogeneity (I^2 = 26.5%, τ^2 = 0.040) (*Figure 7*). This improvement corresponds to an average increase of 39 m (95% CI 21 m to 58 m) or 1.6 minutes (95% CI 0.8 minute to 2.1 minutes).

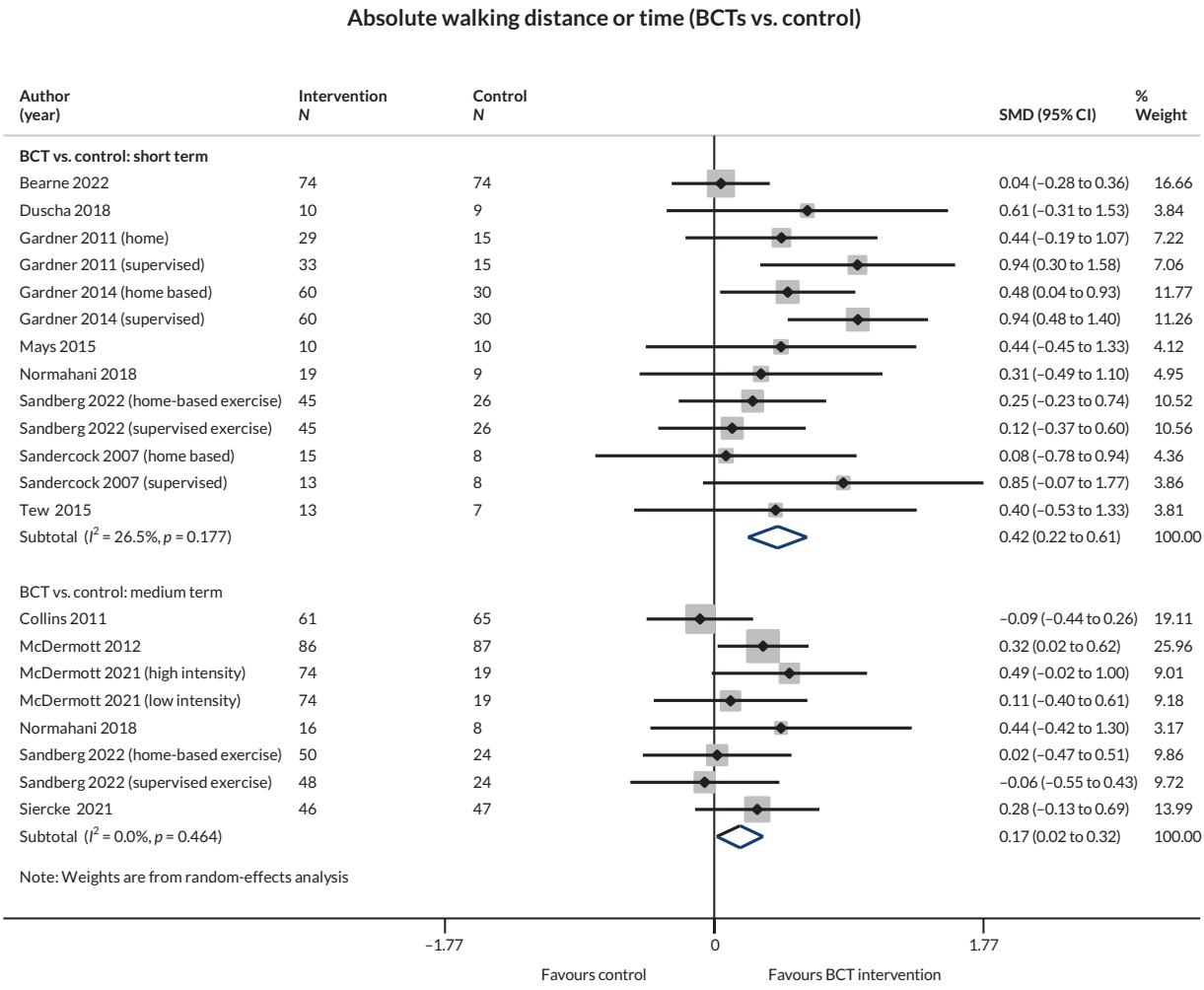

FIGURE 7 Meta-analysis of effect on absolute walking distance of BCT-based interventions vs. controls. Note: Absolute walking distance/ACD or time measured on a treadmill using 'change from baseline' combined using SMD. Comparison between BCT intervention and control using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

Evidence from 6 RCTs (8 comparisons, 748 participants) suggests that behaviour change interventions increase ACD in the medium term by 0.17 SMD (95% CI 0.02 to 0.32) (see *Figure 7*). This corresponds to an increase of 16 m (95% CI 2 m to 30 m) or 0.6 minutes (95% CI 0.07 minute to 1.12 minute) extra walking. There was low heterogeneity (I^2 = 0.0%, T^2 = 0.018).

Behaviour change interventions versus supervised exercise

Data from 6 RCTs (6 comparisons, 341 participants) suggest that behaviour change interventions are less effective than SET at increasing ACD in the short term by −0.43 SMD (95% CI −0.82 to −0.03) (*Figure 8*).

Data from 2 RCTs (2 comparisons, 119 participants) left it unclear whether or not behaviour change interventions are as effective as SET in the medium term: −0.03 SMD (95% CI −0.39 to 0.46) (see *Figure 8*).

Clinically assessed initial claudication distance or time

Behaviour change interventions versus controls

Data from 9 RCTs (11 comparisons, 634 participants) suggest that behaviour change interventions increase ICD in the short term by 0.54 SMD (95% CI 0.36 to 0.72) (*Figure 9*). This roughly corresponds to an extra 73 m (95% CI 49 m to 98 m).

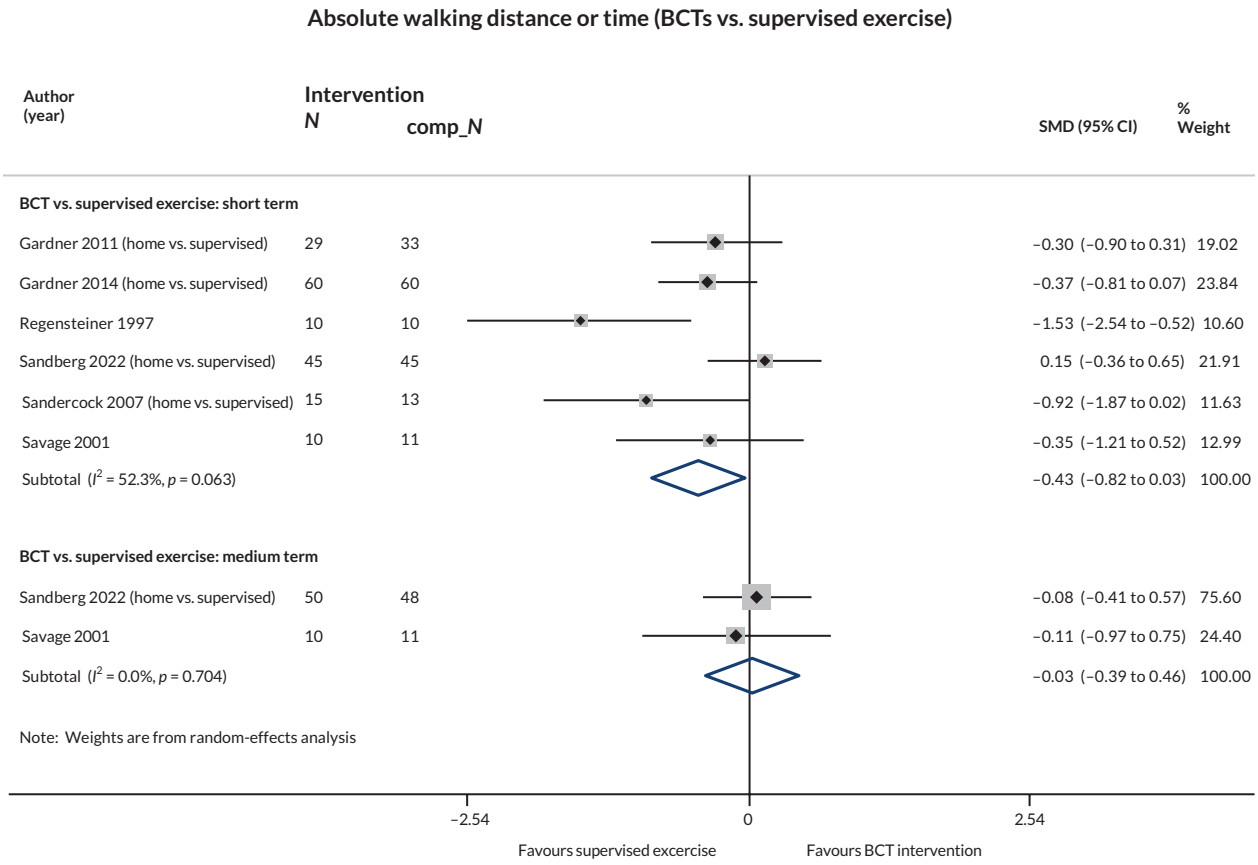

FIGURE 8 Meta-analysis of effect on absolute walking distance of BCT-based interventions vs. supervised exercise. Note: Absolute walking distance/ACD measured on a treadmill using 'change from baseline' combined using SMD. Comparison between BCT interventions and SET using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

Data from 5 RCTs (6 comparisons, 534 participants) suggest that behaviour change interventions increase ICD in the medium term by 0.24 SMD (95% CI 0.07 to 0.42) (see *Figure 9*). This roughly corresponds to an extra 32 m (95% CI 9 m to 57 m).

Behaviour change interventions versus supervised exercise

Data from 5 RCTs (5 comparisons, 313 participants) left it unclear whether or not behaviour change interventions are as effective as SET in the short-term effect for ICD: −0.29 SMD (95% CI −0.66 to 0.08) (*Figure 10*).

Data from 2 RCTs (2 comparisons, 119 participants) left it unclear whether or not behaviour change interventions are as effective as SET in the medium-term effect for ICD: −0.30 SMD (95% CI −1.30 to 0.69) (see *Figure 10*).

6-minute walk test distance

Behaviour change intervention versus control

Data from 9 RCTs (12 comparisons, 815 patients) provided evidence that behaviour change interventions increase 6MWD in the short term by 26 m on average (95% CI 6 m to 46 m) (*Figure 11*).

Data from 4 RCTs (6 comparisons, 757 participants) left it unclear whether or not behaviour change interventions increase 6MWD in the medium term: average increase of 15 m (95% CI 5-m reduction to 35-m increase) (see *Figure 11*).

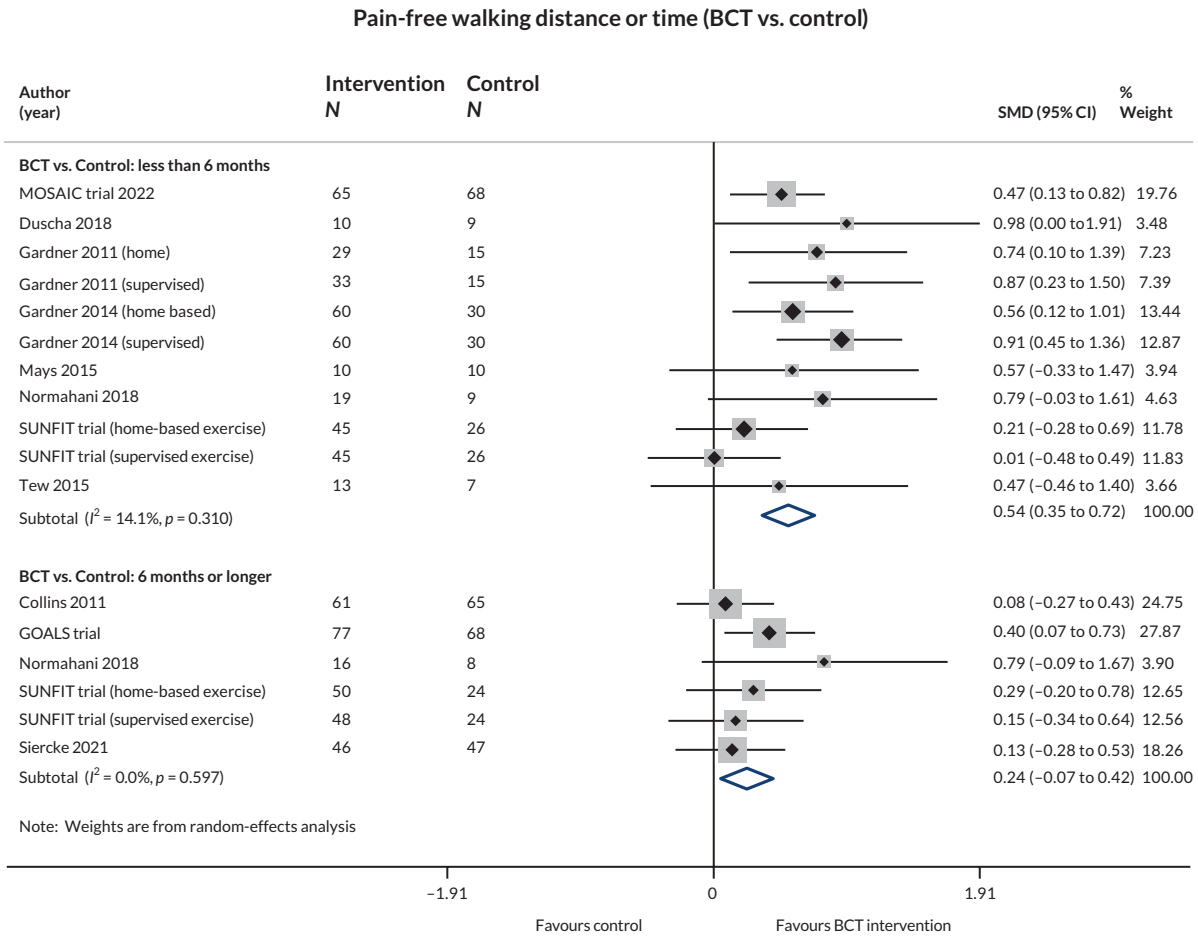

FIGURE 9 Meta-analysis of effect on pain-free walking distance of BCT-based interventions vs. controls. Note: Pain-free walking distance/ICD or time measured on a treadmill using 'change from baseline' combined using SMD. Comparison between BCT intervention and control using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

Behaviour change intervention versus supervised exercise

Data from 2 RCTs (2 comparisons, 210 participants) left it unclear whether or not behaviour change interventions differ from SET in changes to 6MWD in the short term: 24-m increase on average (95% CI: 4-m reduction to 51-m increase) (*Figure 12*).

Data from 1 RCT (1 comparison,98 participants) left it unclear whether or not behaviour change interventions differ from SET in changes to 6MWD in the medium term: average increase of 8 m (95% CI 41-m reduction to 57-m increase) (see *Figure 12*).

Walking impairment assessed via Walking Impairment Questionnaire

Behaviour change intervention versus control

Data from 3 RCTs (3 comparisons, 471 participants) provided evidence that behaviour change interventions increase WIQ score in the short term by 16 points (95% CI 9 to 24) (*Figure 13*).

Data from 2 RCTs (3 comparisons, 287 patients) provided evidence that behaviour change interventions increase WIQ score in the medium term by 10 points (95% CI 6 to 14) (see *Figure 13*).

Behaviour change intervention versus supervised exercise

No study reported data comparing WIQ in behaviour change interventions versus SET in the short term.

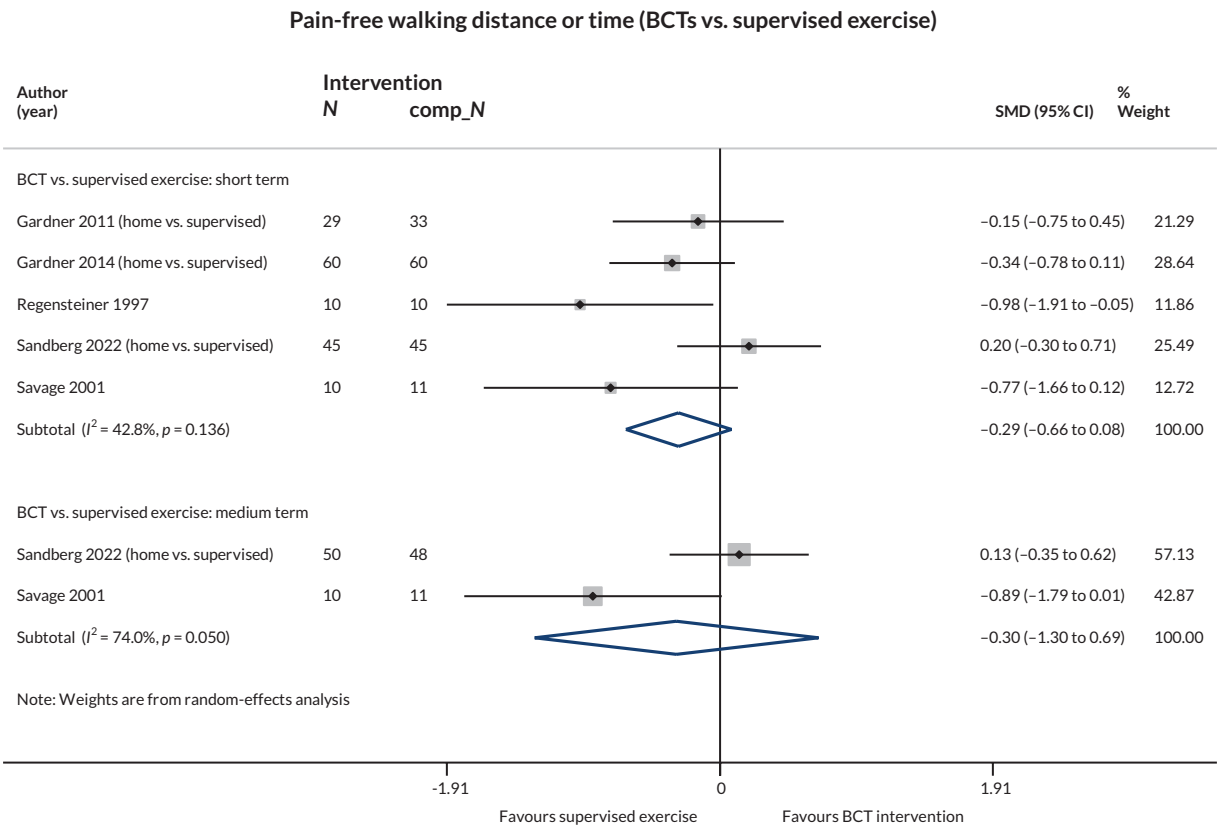

FIGURE 10 Meta-analysis of effect on pain-free walking distance/time of BCT-based interventions vs. supervised exercise. Note: Pain-free walking distance/ICD measured on a treadmill using 'change from baseline' combined using SMD. Comparison between BCT intervention and supervised exercise using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

Data from 1 RCT (97 participants) left it unclear whether or not behaviour change interventions increase WIQ score compared to SET in the MD: mean difference = −2.5 points (95% CI −18 to 13). No figure included.

Quality-of-life outcomes: generic health-related quality of life

Behaviour change interventions versus controls

Data from 8 RCTs (9 comparisons, 1134 participants) left it unclear whether or not behaviour change interventions increase HRQoL in the short term: 0.17 SMD (95% CI −0.05 to 0.39) (*Figure 14*).

Data from 8 RCTs (9 comparisons, 1527 participants) left it unclear whether or not behaviour change interventions increase HRQoL in the medium term: 0.08 SMD (95% CI −0.03 to 0.19) (see *Figure 14*).

Behaviour change interventions versus supervised exercise

Data from 2 RCTs (2 comparisons, 110 participants) left it unclear whether or not behaviour change interventions effects HRQoL differently to SET in the short term: −0.11 SMD (95% CI −0.75 to 0.54) (*Figure 15*).

Data from 2 RCTs (2 comparisons, 118 participants) left it unclear whether or not behaviour change interventions increase HRQoL differently to SET in the medium term: 0.20 SMD (95% CI −0.22 to 0.62) (see *Figure 15*).

Physical function domain of quality of life

Behaviour change interventions versus controls

Data from 5 RCTs (7 comparisons, 471 participants) left it unclear whether or not behaviour change interventions increase physical function in the short term: −0.03 SMD (95% CI −0.35 to 0.29) (*Figure 16*).

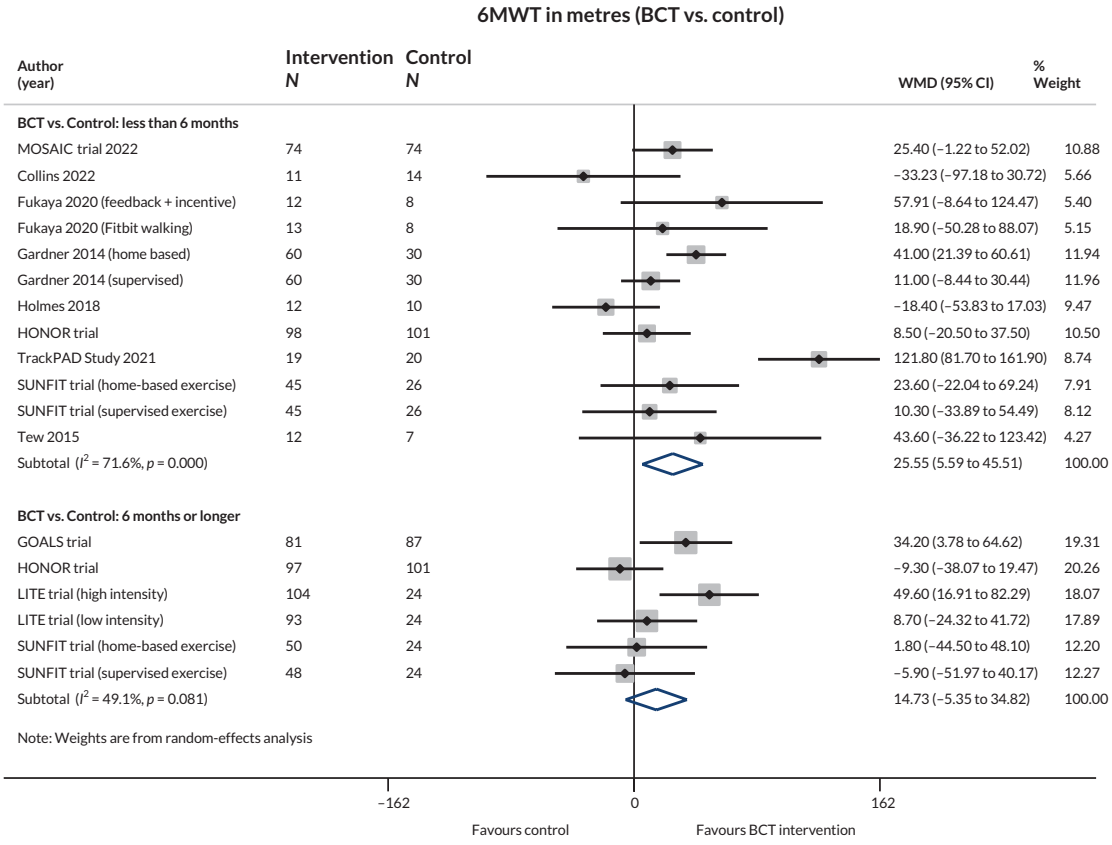

FIGURE 11 Meta-analysis of effect on 6MWT of BCT-based interventions vs. controls. Note: 6MWT using 'change from baseline' in m. Comparison between BCT intervention and control using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

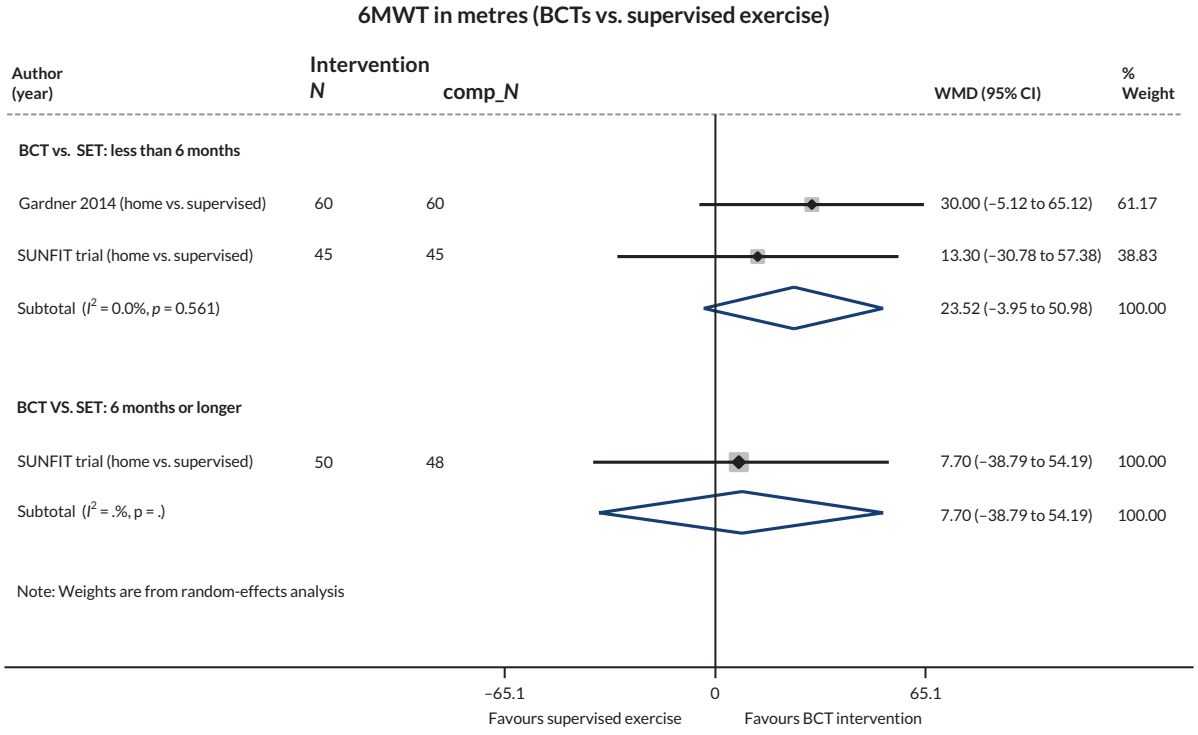

FIGURE 12 Meta-analysis of effect on 6MWT of BCT-based interventions vs. supervised exercise. Note: 6MWT using 'change from baseline' in m. Comparison between BCT intervention and supervised exercise using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

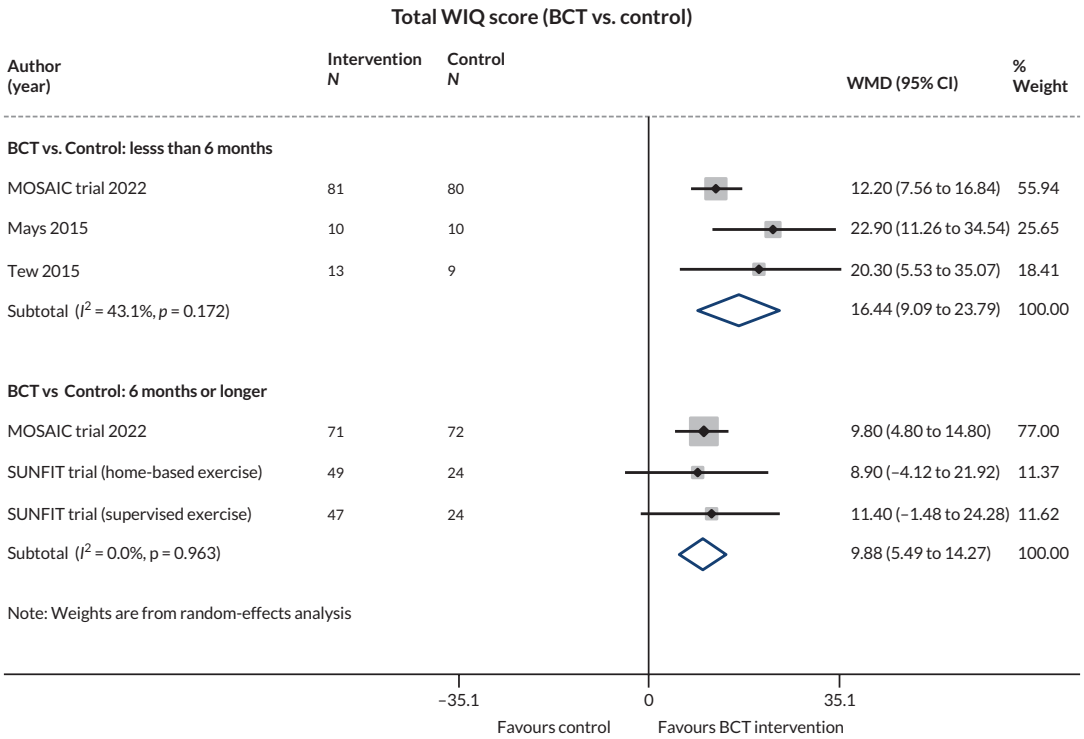

FIGURE 13 Meta-analysis of effect on walking impairment of BCT-based interventions vs. controls. Note: Total WIQ score using 'change from baseline'. Comparison between BCT intervention and control using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

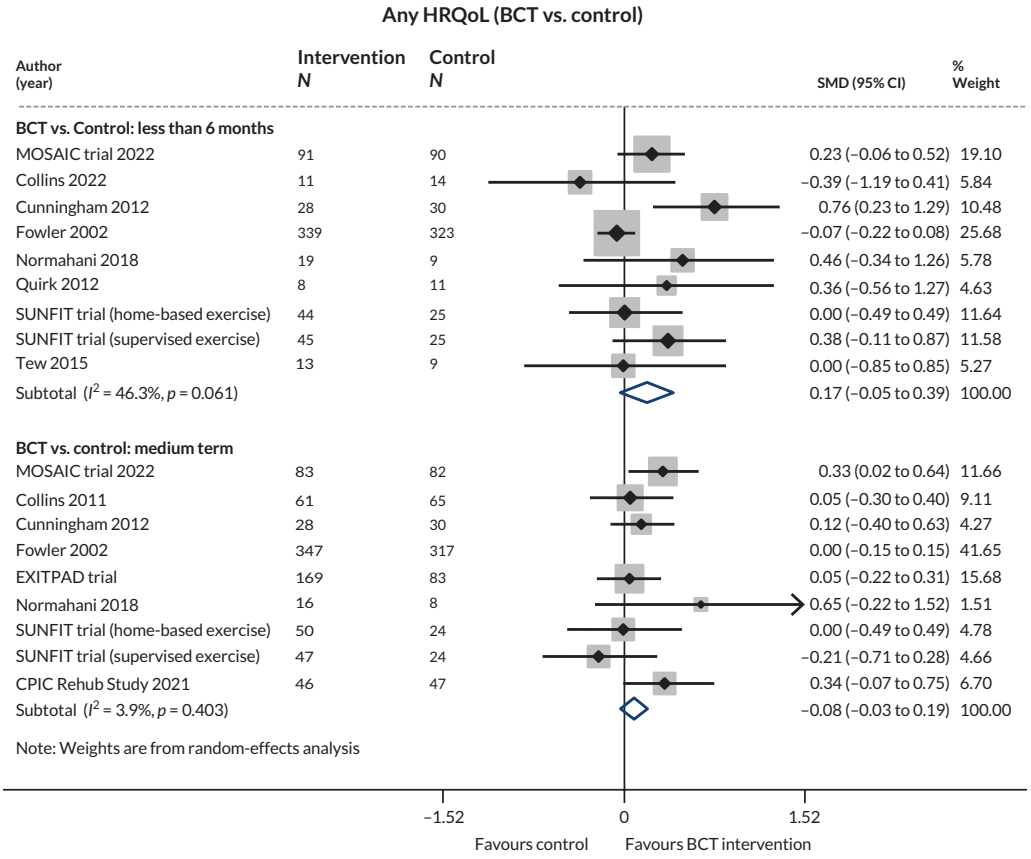

FIGURE 14 Meta-analysis of effect on any HRQoL of BCT-based interventions vs. controls. Note: Any HRQoL using 'change from baseline' combined using SMD. Comparison between BCT intervention and control using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

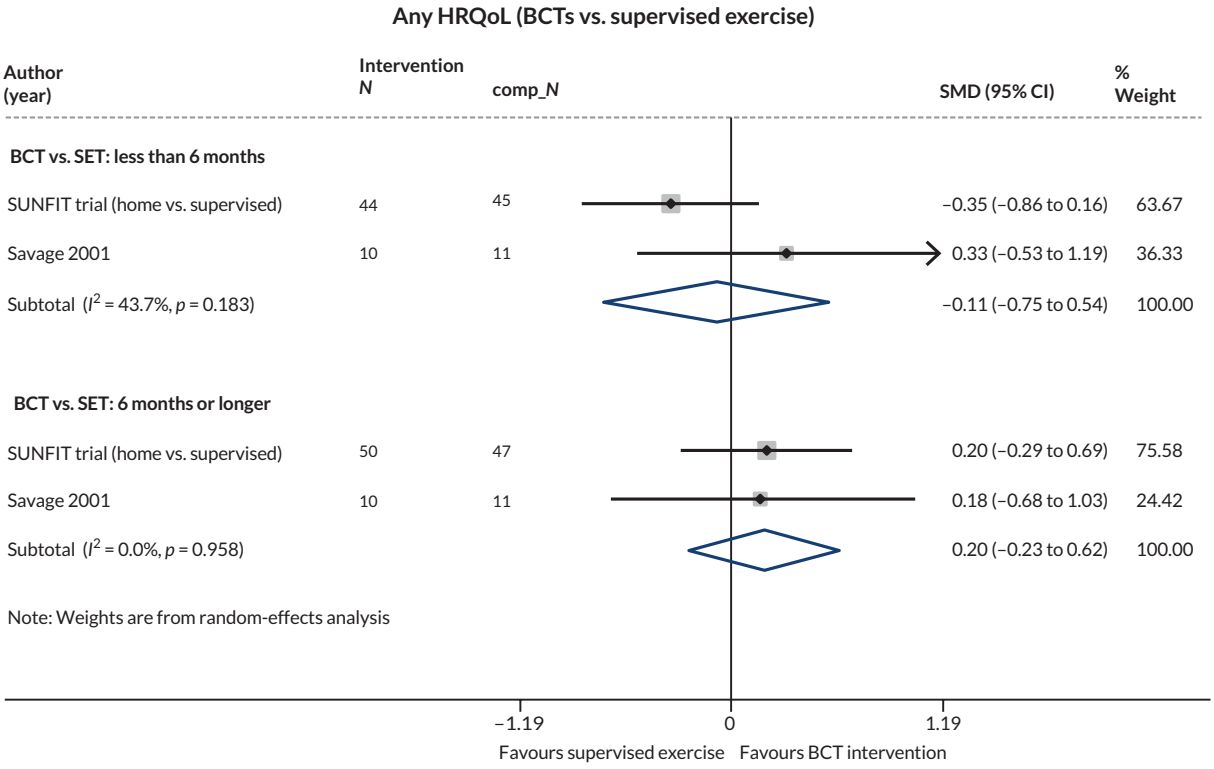

FIGURE 15 Meta-analysis of effect on any HRQoL of BCT-based interventions vs. supervised exercise. Note: Any HRQoL using 'change from baseline' combined using SMD. Comparison between BCT intervention and supervised exercise using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

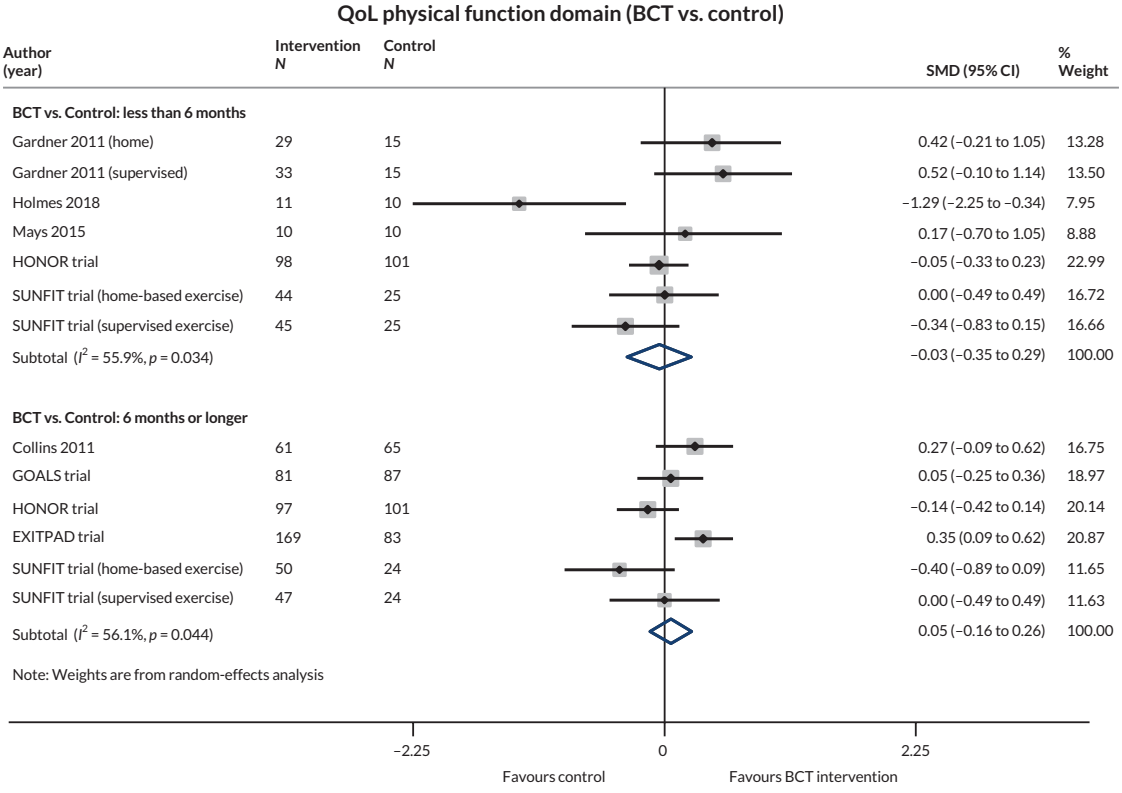

FIGURE 16 Meta-analysis of effect on physical function domain QoL of BCT-based interventions vs. controls. Note: QoL physical function domain using 'change from baseline' combined using SMDs. Comparison between BCT intervention and control using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

Data from 4 RCTs (6 comparisons, 889 participants) left it unclear whether or not behaviour change interventions increase physical function in the medium term: 0.05 SMD (95% CI −0.16 to 0.26) (see *Figure 16*).

Behaviour change interventions versus supervised exercise

Data from 3 RCTs (3 comparisons, 172 participants) left it unclear whether or not behaviour change interventions increase physical function compared to SET in the short term: 0.31 SMD (95% CI −0.07 to 0.69) (*Figure 17*).

Data from 2 RCTs (2 comparisons, 118 participants) left it unclear whether or not behaviour change interventions increase physical function compared to SET in the medium term: −0.09 SMD (95% CI −0.79 to 0.60) (see *Figure 17*).

Psychological well-being domain of quality of life

Behaviour change interventions versus controls

Data from 5 RCTs (6 comparisons, 224 participants) left it unclear whether or not behaviour change interventions change psychological well-being in the short term: 0.07 SMD (95% CI −0.19 to 0.35) (*Figure 18*).

Data from 3 RCTs (4 comparisons, 565 participants) left it unclear whether or not behaviour change interventions change psychological well-being in the medium term: 0.00 SMD (95% CI −0.17 to 0.17) (see *Figure 18*).

Behaviour change interventions versus supervised exercise

Data from 2 RCTs (2 comparisons, 110 participants) left it unclear whether or not behaviour change interventions differ from SET in terms of psychological well-being outcomes in the short term: −0.30 SMD (95% CI −1.23 to 0.63) (*Figure 19*).

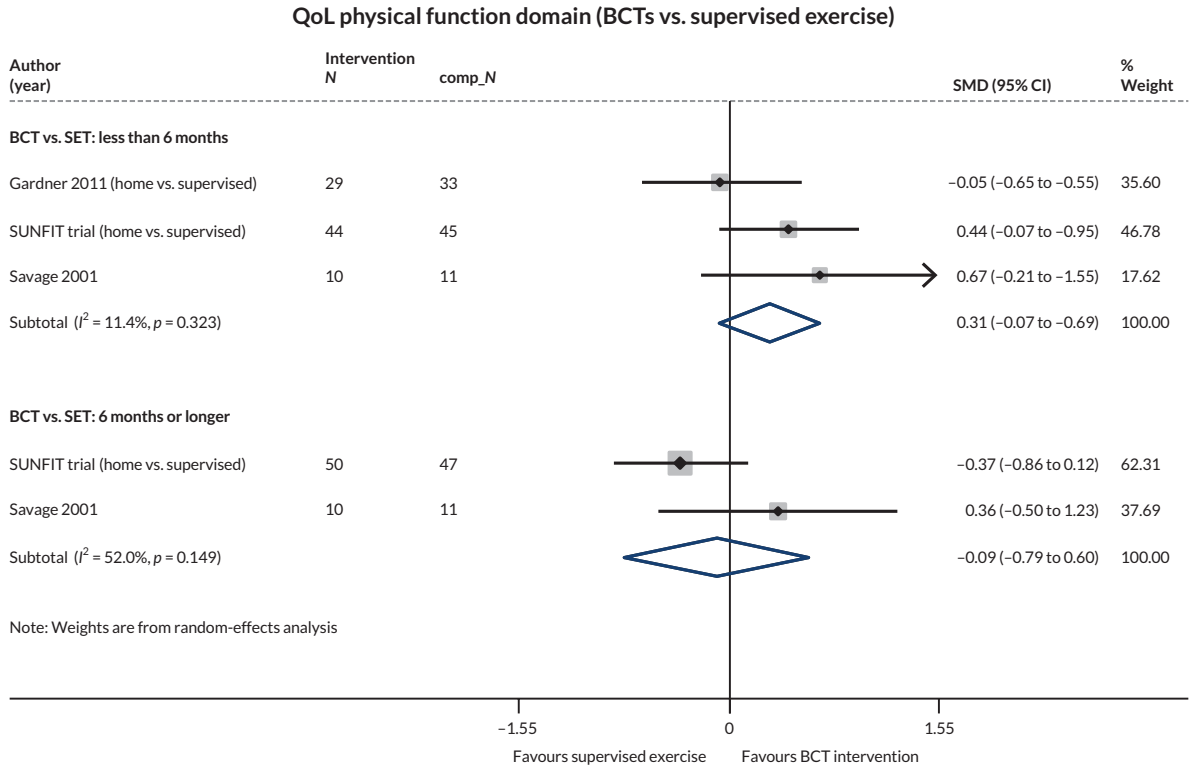

FIGURE 17 Meta-analysis of effect on physical function domain QoL of BCT-based interventions vs. supervised exercise. Note: QoL physical function domain using 'change from baseline' combined using SMDs. Comparison between BCT intervention and supervised exercise using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

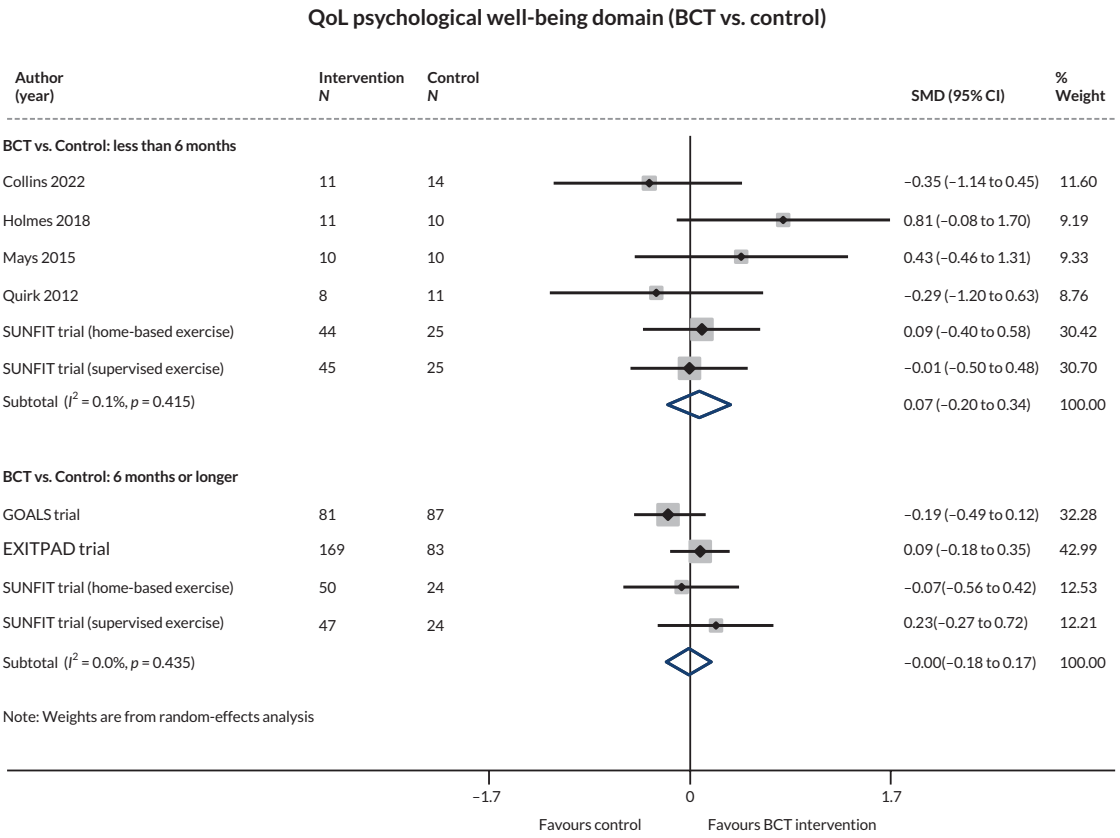

FIGURE 18 Meta-analysis of effect on psychological well-being domain QoL of BCT-based interventions vs. controls. Note: QoL psychological well-being domain using 'change from baseline' combined using SMDs. Comparison between BCT intervention and control using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

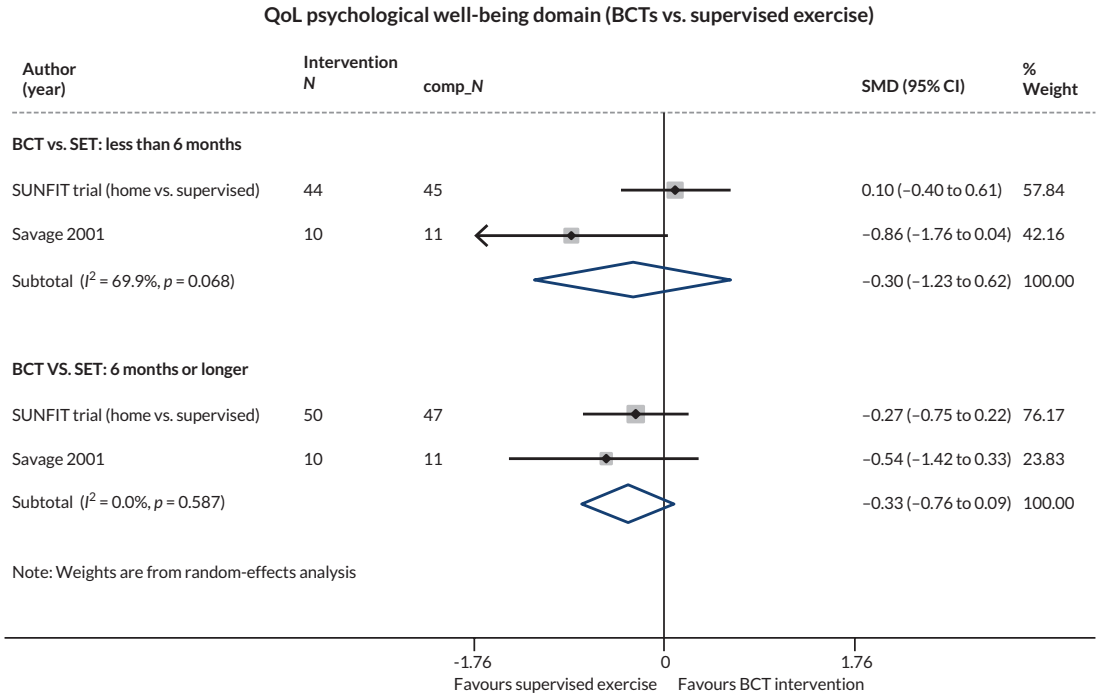

FIGURE 19 Meta-analysis of effect on psychological well-being domain QoL of BCT-based interventions vs. supervised exercise. Note: QoL psychological well-being domain using 'change from baseline' combined using SMDs. Comparison between BCT intervention and supervised exercise using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

Data from 2 RCTs (2 comparisons, 118 participants) left it unclear whether or not behaviour change interventions differ from SET in terms of psychological well-being outcomes in the medium term: −0.33 SMD (95% CI −0.76 to 0.10) (see *Figure 19*).

Disease-specific quality of life

Behaviour change interventions versus controls

Data from 7 RCTs (8 comparisons, 472 participants) provided evidence that behaviour change interventions increase disease-specific QoL in the short term by 0.31 SMD (95% CI 0.13 to 0.50) (*Figure 20*).

Data from 5 RCTs (6 comparisons, 485 participants) provided evidence that behaviour change interventions increase disease-specific QoL in the medium term by 0.32 SMD (95% CI 0.14 to 0.50) (see *Figure 20*).

Behaviour change interventions versus supervised exercise

Data from 1 RCT (89 participants) left it unclear whether or not there was any difference between a behaviour change intervention or SET in change in disease-specific QoL in the short term: −0.06 SMD (95% CI −0.57 to 0.44). No figure provided.

Data from 1 RCT (97 participants) left it unclear whether or not there was any difference between a behaviour change intervention or SET in change in increase disease-specific QoL in the medium term: −0.33 SMD (95% CI −0.82 to 0.16). No figure provided.

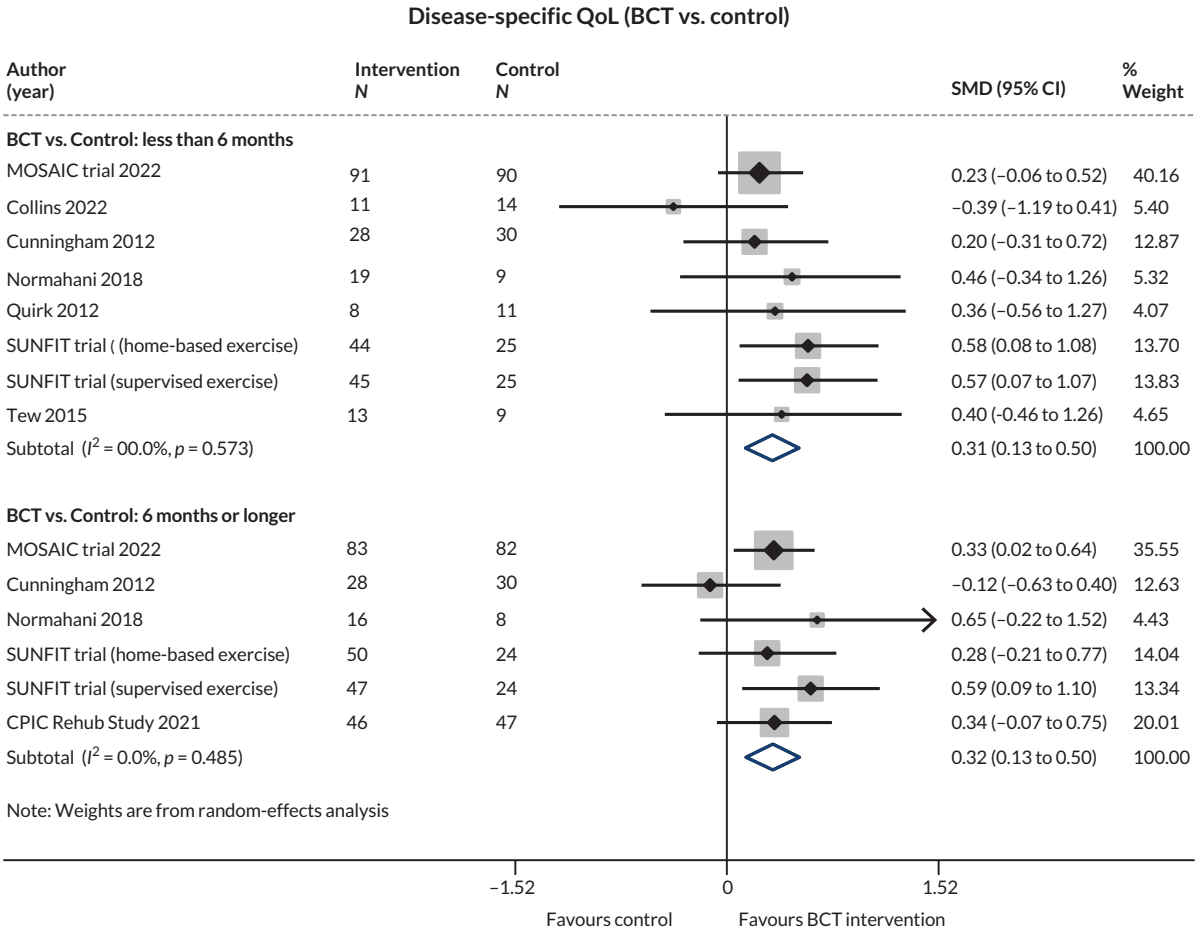

FIGURE 20 Meta-analysis of effect on disease-specific QoL of BCT-based interventions vs. controls. Note: Disease-specific QoL using 'change from baseline' combined using SMD. Comparison between BCT intervention and control using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

Cardiovascular risk factors: Peak Oxygen Uptake (maximal volume of oxygen consumption)

Behaviour change interventions versus controls

Data from 3 RCTs (4 comparisons, 131 participants) left it unclear whether or not behaviour change interventions increase VO_2 max in the short term: MD 0.87 ml/kg/minute (95% CI −0.03 to 1.76) (*Figure 21*).

No trials reported VO_2 max in the medium term.

Behaviour change interventions versus supervised exercises

Data from 3 RCTs (3 comparisons, 113 participants) left it unclear whether or not there was any difference between a behaviour change intervention or SET in change in VO_2 max in the short term: MD −0.02 ml/kg/minute (95% CI −1.35 ml/kg/minute to 1.32 ml/kg/minute) (*Figure 22*).

Data from 1 RCT (21 participants) left it unclear whether or not there was any difference between a behaviour change intervention or SET in change in VO_2 max in the medium term: MD −0.10 ml/kg/minute (95% CI −2.83 ml/kg/minute to 3.03 ml/kg/minute) (see *Figure 22*).

Systolic blood pressure

Behaviour change interventions versus controls

Data from 1 RCT (1 comparison, 25 participants) left it unclear whether or not behaviour change interventions change systolic BP in the short term: MD 3.66 mmHg (95% CI −11.4 mmHg to 18.7 mmHg). No trials reported data on systolic BP in the medium term.

Behaviour change interventions versus supervised exercises

No trials reported on systolic BP.

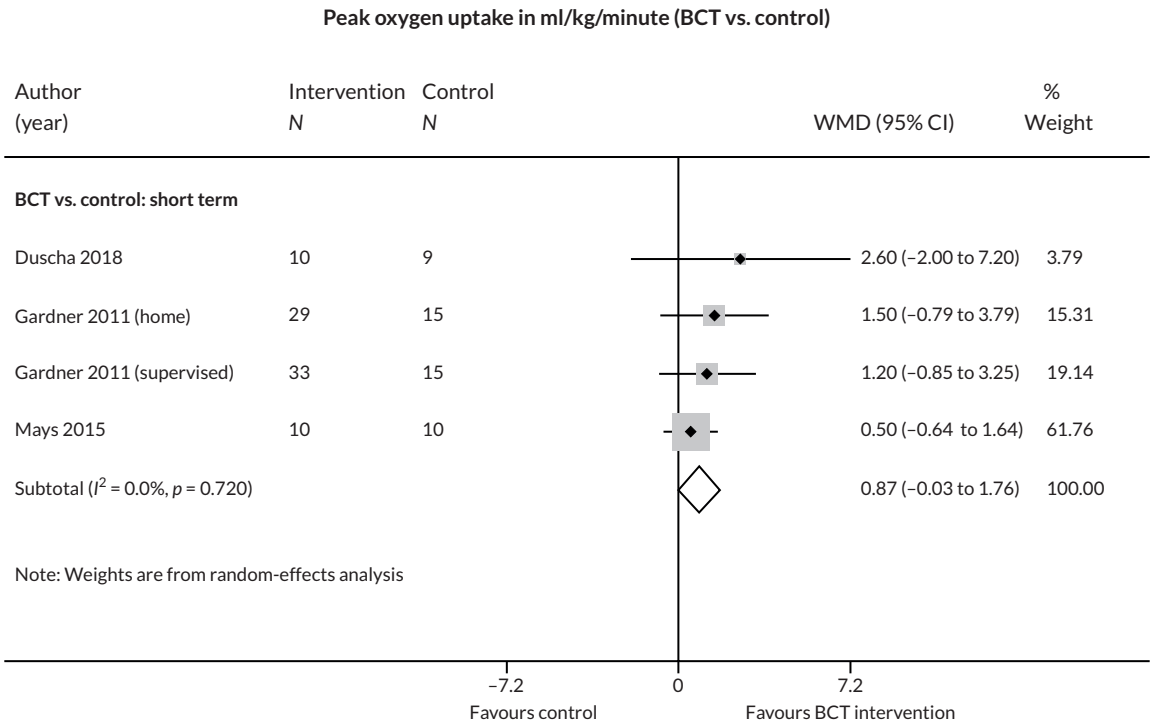

FIGURE 21 Meta-analysis of effect on peak oxygen uptake of BCT-based interventions vs. controls. Note: Peak oxygen uptake (VO_2 max) in ml/kg/minute using 'change from baseline'. Comparison between BCT intervention and control using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

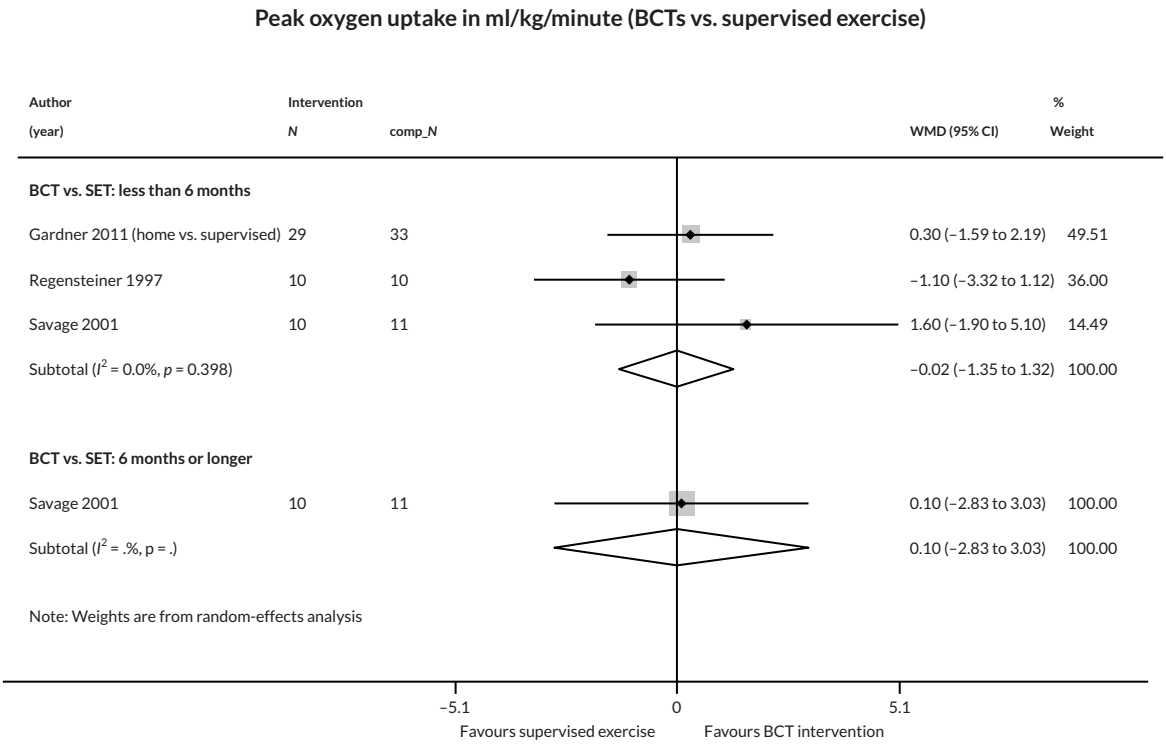

FIGURE 22 Meta-analysis of effect on peak oxygen uptake of BCT-based interventions vs. supervised exercise. Note: Peak oxygen uptake (VO_2 max) in ml/kg/minute using 'change from baseline'. Comparison between BCT intervention and supervised exercise using random-effects meta-analysis. Short term is outcome data < 6 months from baseline.

Diastolic blood pressure

Behaviour change interventions versus controls

Data from 1 RCT (1 comparison, 25 participants) left it unclear whether or not behaviour change interventions change diastolic BP in the short term: MD 3.34 mmHg (95% CI −4.34 mmHg to 11.0 mmHg). No trials reported data on diastolic BP in the medium term.

Behaviour change interventions versus supervised exercises

No trials reported on diastolic BP.

Disease progression: cardiovascular events

Behaviour change interventions versus controls

Only one trial[185] reported cardiovascular events. They reported zero adverse events in any group.

Behaviour change interventions versus supervised exercises

Only one trial[185] reported cardiovascular events. They reported zero adverse events in any group.

Revascularisation

Behaviour change interventions versus controls

Data from 1 RCT (58 participants) left it unclear whether or not that behaviour change interventions reduce the risk of revascularisation in the short term: RR 0.59 (95% CI 0.29 to 1.21) (*Figure 23*).

Data from 2 RCTs (3 comparisons, 249 participants) left it unclear whether or not behaviour change interventions reduce the rate of revascularisation in the medium term: RR 2.47 (95% CI 0.31 to 19.8) (see *Figure 23*).

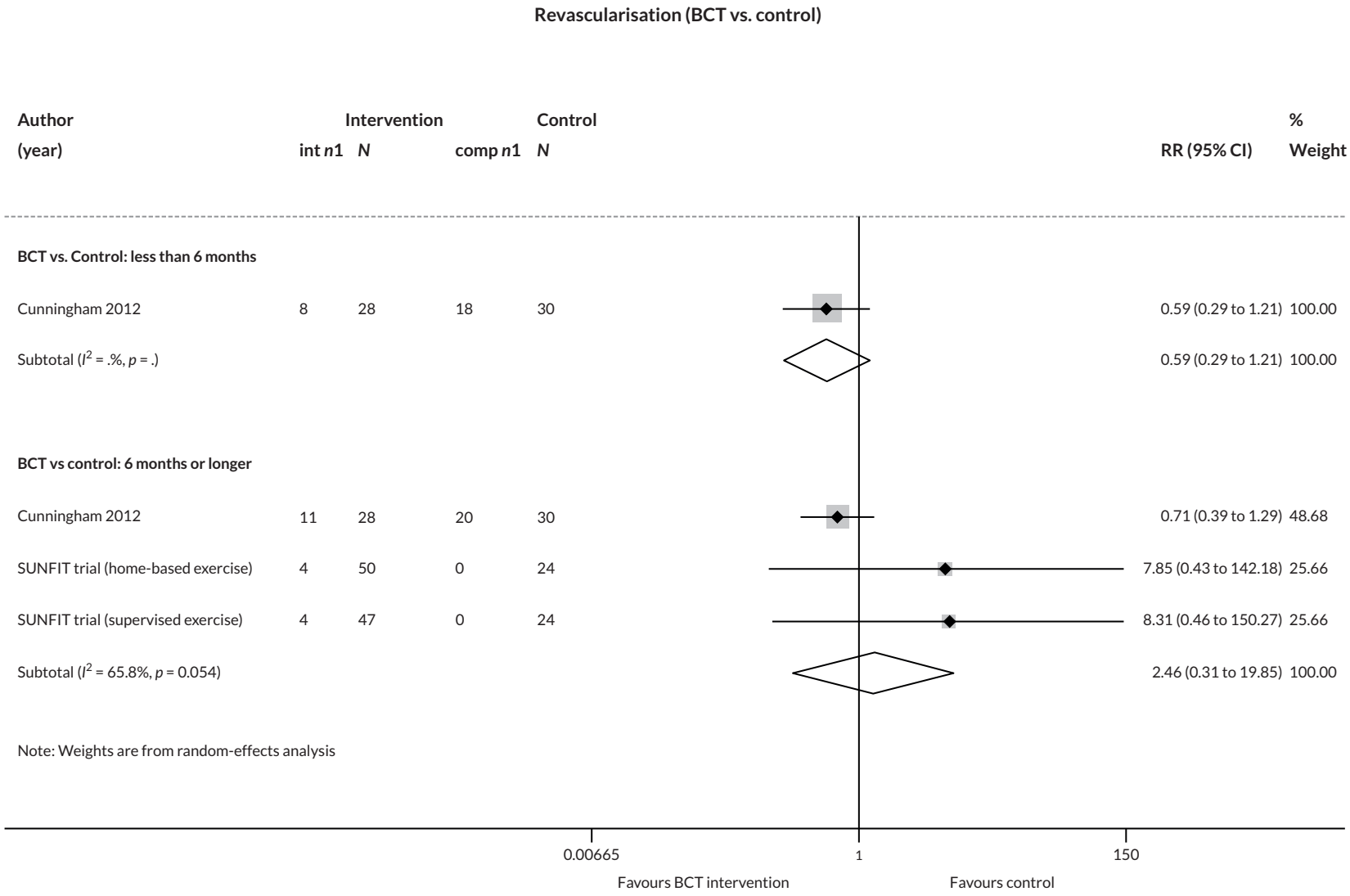

FIGURE 23 Meta-analysis of effect on revascularisation of BCT-based interventions vs. controls. Note: Revascularisation combined using relative risks (RRs). Comparison between BCT intervention and control using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

Behaviour change interventions versus supervised exercises

No trials compared revascularisation in behaviour change interventions versus SET in the short term.

Data from 1 RCT (110 participants) left it unclear whether or not behaviour change interventions differed from SET in the rate of revascularisation in the medium term: RR 0.94 (95% CI 0.22 to 3.98). No figure shown.

Mortality

No studies reported data on mortality.

Ankle–brachial pressure index

Behaviour change interventions versus controls

No trials comparing behaviour change interventions with control reported data on ABPI.

Behaviour change interventions versus supervised exercises

Data from 2 RCTs (2 comparisons, 41 participants) left it unclear whether behaviour change interventions differed from SET in change in ABPI in the short term: MD 0.00 units (95% CI −0.08 to 0.09) (*Figure 24*).

Data from 1 RCT (21 participants) left it unclear whether behaviour change interventions differed from SET in change in ABPI in the medium term: MD −0.14 units (95% CI −0.28 to 0.00) (see *Figure 24*).

Association between behaviour change techniques and intervention effects on physical activity

After entering each BCT domain separately into a metaregression, comparing interventions that used this domain with those that did not, it was unclear whether or not there was a relationship with any individual BCT domain in the short or medium term (*Table 11*). It was also unclear whether or not there was a relationship between the number of BCTs and the magnitude of the effect size in either the short term (effect: −0.01, 95% CI −0.04 to 0.02) or the medium term (effect: 0.00, 95% CI −0.04 to 0.04) (*Table 12*).

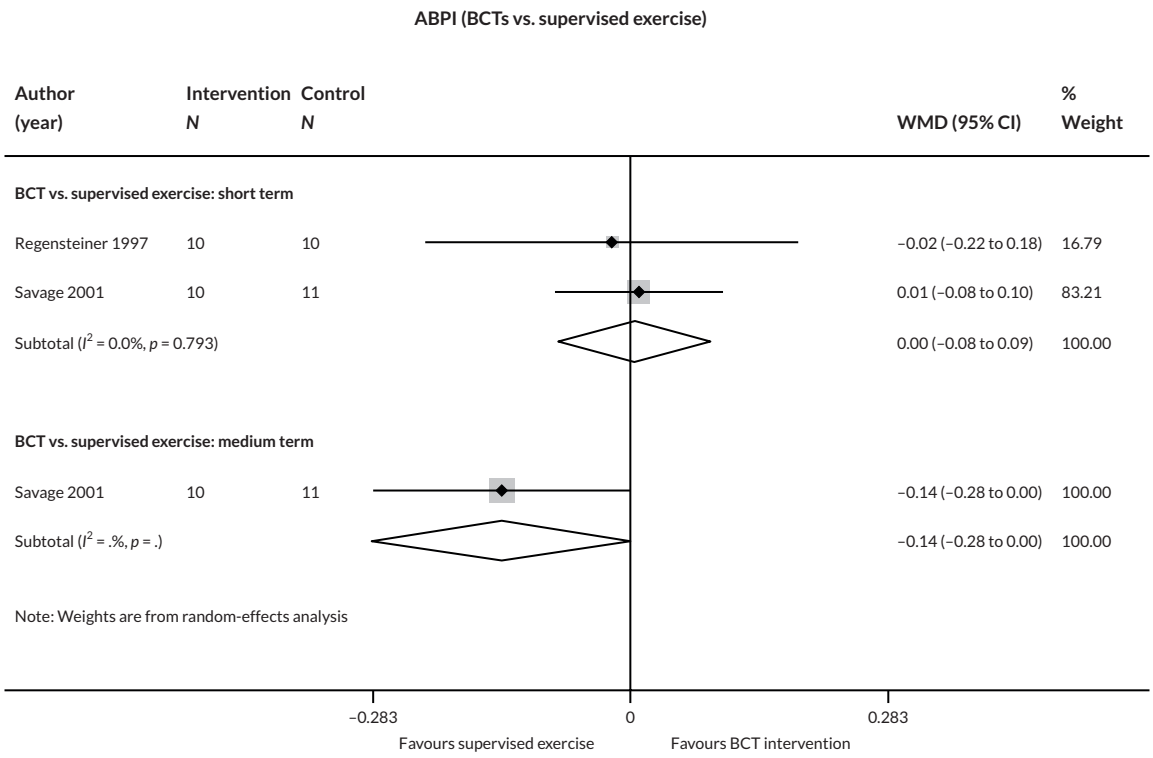

FIGURE 24 Meta-analysis of effect on ABPI of BCT-based interventions vs. supervised exercise. Note: ABPI using 'change from baseline'. Comparison between BCT intervention and supervised exercise using random-effects meta-analysis. Short term is outcome data < 6 months from baseline. Medium term is outcome data 6 months or more from baseline.

TABLE 11 Results of exploratory metaregression looking at the independent effect of the use of each BCT domain on volume of PA

BCT domain	Short-term effect of BCT domain (95% CI) *N* = 15	Medium-term effect of BCT domain (95% CI) *N* = 8
1. Goals and Planning	–	–
2. Feedback and monitoring	−0.14 (−0.49 to 0.21)	−0.53 (−1.21 to 0.15)
3. Social support	−0.05 (−0.34 to 0.24)	0.37 (−0.12 to 0.85)
4. Shaping knowledge	0.00 (−0.38 to 0.38)	0.37 (−0.12 to 0.85)
5. Natural consequences	0.06 (−0.24 to 0.36)	0.06 (−0.41 to 0.53)
6. Comparison of behaviour	0.02 (−0.30 to 0.34)	−0.11 (−0.57 to 0.34)
7. Associations	0.38 (−0.64 to 1.40)	–
8. Repetition and substitution	−0.33 (−0.82 to 0.16)	−0.42 (−0.83 to 0.00)
9. Comparison of outcome	0.09 (−0.38 to 0.56)	–
10. Reward and treat	0.38 (−0.64 to 1.40)	–
11. Regulation	−0.16 (−0.52 to 0.19)	−0.10 (−0.56 to 0.34)
12. Antecedent	−0.11 (−0.42 to 0.20)	−0.11 (−0.54 to 0.32)
13. Identity	−0.03 (−0.35 to 0.29)	0.09 (−0.44 to 0.62)
14. Scheduled consequences	–	–
15. Self-belief	−0.07 (−0.41 to 0.27)	−0.11 (−0.56 to 0.34)
16. Covert learning	–	–

TABLE 12 Total number of individual BCTs used within each intervention (BCTs exclusive to intervention only), and results of metaregression exploring the relationship between number of BCTs and effect size

	Total number of BCTs		Increase in effect per additional BCT (95% CI) from metaregression
	Mean (SD)	Median (range)	
Studies reporting short-term volume of PA	8.5 (4.0)	9 (3–17)	−0.01 (−0.04 to 0.02)
Studies reporting medium-term volume of PA	8.8 (5.6)	7 (3–17)	0.00 (−0.04 to 0.04)
All interventions	7.6 (3.8)	7 (2–17)	-

Association between Theoretical Domains Framework/mechanism of action of behaviour change techniques and intervention effects on physical activity

For each of the theoretical domains, metaregression was performed comparing the effect size for the primary outcome (volume of daily PA) in trials of an intervention that targeted the domain with those that did not. Metaregression looking at the effect of 'number of domains' was also performed (*Table 13*). In the short term, there was no evidence of differences in effect sizes for trials with interventions that targeted each domain and trials with interventions that did not (see *Table 13* and *Figure 25*). In the medium term (≥ 6 months), there was some evidence that trials of interventions targeting the domain of 'Intentions' had larger effect sizes on average than trials of interventions that did not (difference in effect sizes: 0.42, 95% CI 0.00 to 0.83) (see *Table 13* and *Figure 26*). There was no evidence that the number of theoretical domains targeted in an intervention was related to the trial effect size [*short-term* increase per domain: 0.01 (95% CI −0.10 to 0.12); *medium-term* increase per domain: 0.08 (95% CI −0.05 to 0.22)].

TABLE 13 Results of exploratory metaregression looking at the independent effect of each commonly targeted TDF domain (RCTs with volume of PA outcome data)

TDF	< 6 months Effect of domain (95% CI) *N* = 15	≥ 6 months Effect of domain (95% CI) *N* = 8
Knowledge	−0.03 (−0.32 to 0.26)	0.25 (−0.18 to 0.67)
Skills	−0.06 (−0.36 to 0.23)	−0.24 (−0.65 to 0.18)
Social/professional role and identity	[a]	−0.01 (−0.63 to 0.61)
Beliefs about capabilities	0.02 (−0.28 to 0.33)	0.09 (−0.44 to 0.62)
Optimism	[a]	−0.01 (−0.63 to 0.61)
Beliefs about consequences	0.30 (−0.24 to 0.84)	0.53 (−0.15 to 1.21)
Reinforcement	0.29 (−0.71 to 1.28)	[a]
Intentions	0.28 (−0.25 to 0.80)	0.42 (0.00 to 0.83)
Goals	[b]	−0.29 (−0.82 to 0.23)
Memory, attention and decision processes	[a]	[a]
Environmental context and resources	−0.01 (−0.32 to 0.31)	−0.06 (−0.53 to 0.41)
Social influences	−0.07 (−0.40 to 0.26)	−0.01 (−0.50 to 0.47)
Emotion	[a]	0.17 (−0.26 to 0.59)
Behavioural regulation	0.00 (−0.32 to 0.33)	0.06 (−0.41 to 0.53)
Number of domains	0.01 (−0.10 to 0.12)	0.08 (−0.05 to 0.22)

N, number of studies.
a No interventions contributing to this analysis targeted this domain.
b All interventions contributing to this analysis targeted this domain.

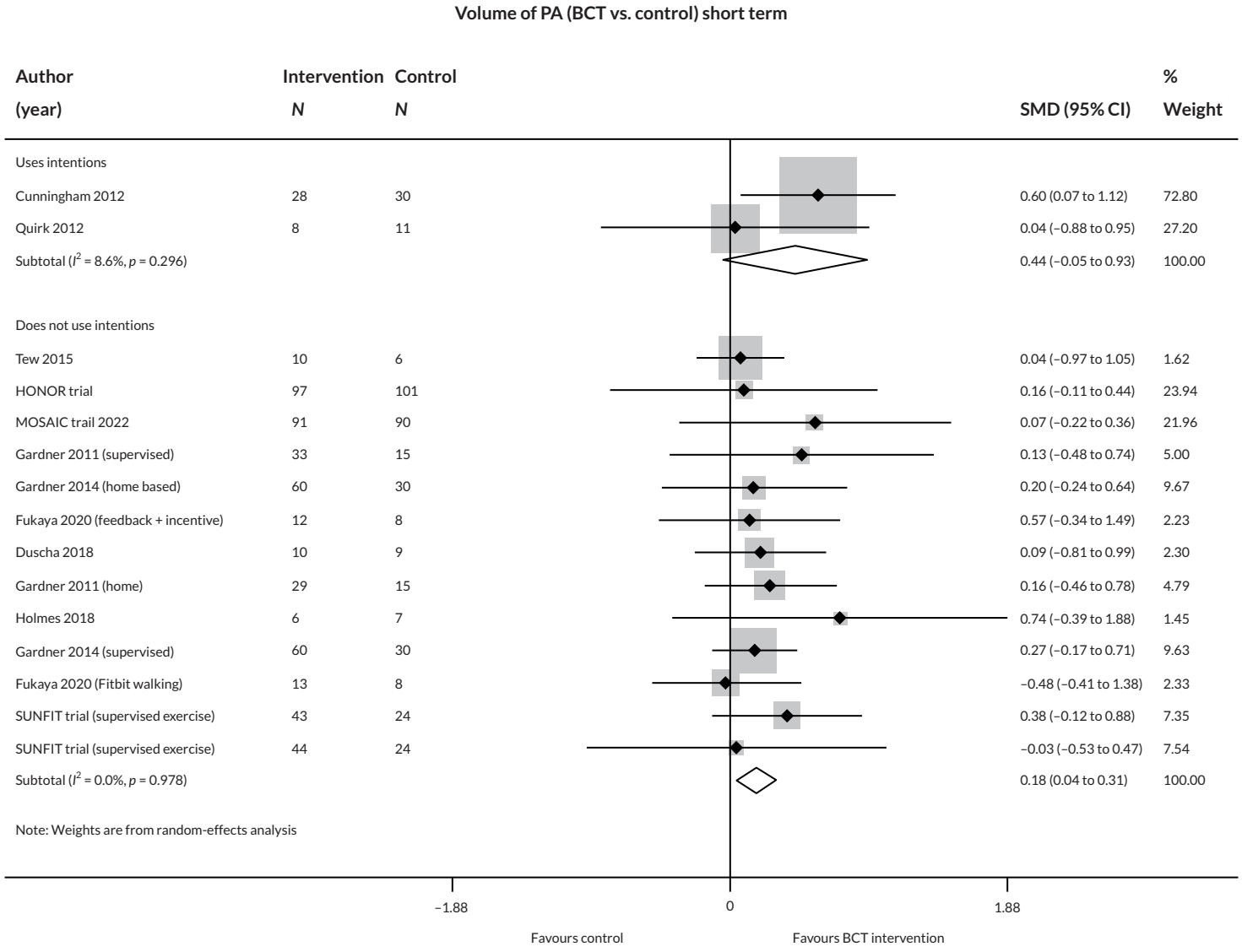

FIGURE 25 Exploratory subgroup analyses comparing short-term effect on PA of trials of 'interventions' that target the domain of 'Intentions' vs. trials of interventions that did not.

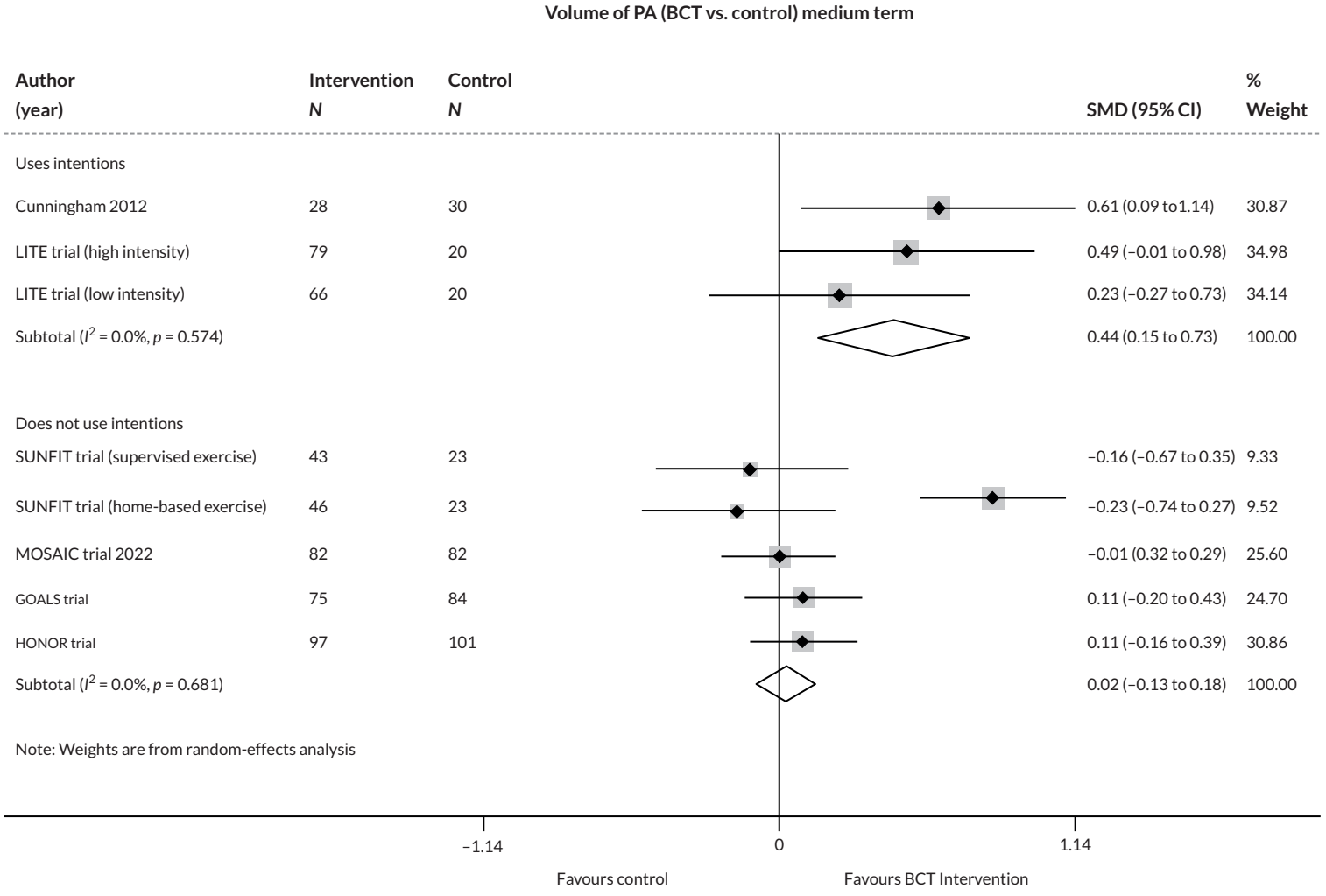

FIGURE 26 Exploratory subgroup analyses comparing medium-term effect on PA of trials of 'interventions' that target the domain of 'Intentions' vs. trials of interventions that did not.

Chapter 3 Systematic review 2: feasibility and acceptability of behaviour change intervention for physical activity in people with intermittent claudication

Introduction

Studies examining the feasibility and acceptability of interventions have a key role in understanding how factors facilitate or hinder the effectiveness of health interventions and how intervention processes are perceived and implemented. The focus of review 2 is to understand the feasibility and acceptability of interventions containing BCTs for people with IC and intervention providers.

Universally accepted definitions of feasibility and acceptability in behaviour change interventions are lacking, and previous reviews have failed to establish a clear threshold for participant withdrawals, leaving the criteria for deeming an intervention unacceptable undefined.[211,212] For this review, feasibility generally concerns the successful implementation of the behaviour change intervention as initially intended, including the effective execution of research methods, such as assessment protocols by the researchers.[213] On the other hand, acceptability relates to how well the behaviour change intervention and associated methods align with the perceptions and preferences of the intended users, such as individuals living with IC, or those tasked with implementing the intervention, such as healthcare providers delivering the intervention, or research staff responsible for participant recruitment and/or outcome assessment.[213]

Research questions

The initial broad research questions for the review of qualitative evidence were:

1. What is the experience of engaging with (or being a provider for) interventions containing BCTs for PA for people with IC?
2. What is it about behaviour change interventions to increase and/or maintain PA in people with IC that make interventions beneficial or not beneficial?

Given that the analysis was conducted iteratively, these questions were refined after including studies as follows:

1. What is the evidence for the feasibility and acceptability of behaviour change interventions for increasing long-term PA in people with IC?
2. What are the factors associated with feasibility and acceptability outcomes?

Methods

Information sources and search strategy

A comprehensive search strategy of index-free text terms and synonyms located in the title or abstract, representing three broad concepts reflecting the disease (e.g. IC, PAD), behaviour change interventions (e.g. structured exercise, PA, lifestyle intervention, motivation, cognitive behavioural intervention) and outcome (e.g. PA, exercise) was used to search electronic databases. Searches were created and run in September 2021, with supplementary searches run in November 2022 (plus weekly e-mail alerts of new literature until 31 August 2023). Databases searched were: 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; Cochrane Central Register of Controlled Trials (the Cochrane Library); PEDro; and Health Technology Assessment Database.

The trial registries ClinicalTrials.gov and ICTRP (WHO) were also searched. No restrictions were used for language, publication year or publication status, and results were de-duplicated using EndNote. Copies of the full searches can be seen in *Table 3* in *Report Supplementary Material 1*. Reference lists of the included studies were searched for additional studies.

Inclusion and exclusion criteria

All studies had to include adults with PAD (and/or the views of providers involved in their care) and consider issues relating to PA. Given the focus of this review was to understand the feasibility and acceptability of interventions containing BCTs for people with IC and intervention providers, instead of purely qualitative or mixed-methods studies, we initially adopted a pragmatic approach to the inclusion of studies. Specifically, we considered for the inclusion of primary research of any study design (qualitative, quantitative or mixed methods), including information on the feasibility and/or acceptability of interventions containing BCTs for people with IC and intervention providers. We then re-grouped the identified studies into two categories;

a. **Category A** studies were studies linked to RCTs and non-randomised behaviour change interventions reporting feasibility and/or acceptability outcomes, including any qualitative data reported as part of papers reporting quantitative outcomes.
b. **Category B** studies were studies not linked to any specific behaviour change intervention but which drew on the experiences and perceptions of people with IC (and/or providers involved in their care) and improving PA.

To gather the most relevant data for this review (while also ensuring we generated a manageable amount of data for analysis within the timescale of the project), we initially planned to focus on only those studies that explicitly included the views of people with IC (or providers) on interventions containing BCTs for PA for people with IC (Category A studies). We had also planned to include studies from the broader literature that had explored patients' experiences and perceptions of PAD, provided they reported data specifically relating to views/experiences about behaviour change in the context of PA (Category B), only if we found that only a few studies in Category A were specific about included participants' IC status and/or interventions with behaviour change elements. We did not have to implement this as there were sufficient papers in Category A exploring this (see *Deviation from the review protocol*).

Study population/participants

Studies involving adults (≥ 18 years) clinically diagnosed with PAD and IC and/or healthcare providers involved in the care of adults with PAD and IC were included.

Eligible studies

Both intervention and non-intervention-focused studies were considered for inclusion and were grouped as described earlier. For intervention studies, studies that examined interventions that contained at least one BCT and which aimed to assist people with IC to increase and/or maintain habitual PA or other clinical outcomes and PROMs, including walking distances, QoL outcomes, cardiovascular events, were included. A pragmatic approach towards inclusion was used. Interventions that were psychologically based (e.g. patient psycho-education, motivational interviewing) behavioural interventions and those that implemented active monitoring (e.g. using a pedometer) were included, so long as the components used in the intervention could be successfully coded as BCTs, or were overtly reported as BCTs. Therefore, interventions in the form of, but not limited to, structured exercise/PA, lifestyle, motivational interviewing, counselling, structured home-based exercises, comprehensive rehabilitation, structured patient education or combinations of any of these were included. Studies reporting on any mode of SET were considered if they included at least one BCT.

Setting

All settings for interventions were considered, including hospital, primary care, community settings, home-based voluntary sector, leisure centres or gyms, and digital domains (e.g. mobile telephone apps).

Outcomes

Studies that contained any quantitative and/or qualitative data from participants or intervention providers describing the feasibility and/or acceptability of interventions containing behaviour change elements that were either overtly

reported or could be coded for at least one BCT were included. Examples of the feasibility outcomes were: recruitment rate, retention rate, intervention adherence/compliance rate, cost of implementation/cost-effectiveness, and record of adverse events. Acceptability outcomes included patient satisfaction, likelihood of recommending the intervention, motives and barriers, usefulness, reasons for declining, reasons for non-adherence, and reasons for dropout.

Study selection and data extraction process

Titles identified in the electronic database searches were exported into Covidence, an electronic tool for managing references identified in a systematic review. Duplicates were automatically removed using Covidence. Two reviewers (from a pool of eight – Ukachukwu Abaraogu, Dawn Skelton, Ebuka Anieto, Trish Gorely, Cathy Gormal, Jeremy Dearling, CO, Philippa Dall), including two trained PPI members, independently screened the titles and abstracts of the identified studies, and disagreements were resolved by reaching consensus. The full text of the studies that emerged after title and abstract screening were further screened by two independent reviewers (from a pool of seven – Ukachukwu Abaraogu, Dawn Skelton, Ebuka Anieto, Trish Gorely, Cathy Gormal, Jeremy Dearling, CO), and disagreements were resolved by reaching consensus, including further discussions at research team meetings when required. Where required, the authors of included studies were contacted by e-mail (maximum of two e-mails) to request necessary information not provided in the study but needed to make a decision about study eligibility.

For each included study, information about the aims, methods, populations involved, among others, were extracted into a standardised data extraction form in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). Two independent reviewers (from a pool of seven – Ukachukwu Abaraogu, Dawn Skelton, Ebuka Anieto, Trish Gorely, Cathy Gormal, Jeremy Dearling, CO) conducted the data extraction. Discrepancies in the extracted data were resolved by discussions or consultations with a third reviewer.

Quality appraisal

Two researchers independently assessed the RoB in included studies using the Mixed Methods Appraisal Tool (MMAT), which was designed for the quality appraisal of quantitative, qualitative and mixed-methods studies included in systematic reviews.[214] It is not advisable to use an overall numerical scoring for the MMAT because it is less informative and does not show the aspects (quantitative vs. qualitative) of the studies that have quality issues.[214] Rather, it is recommended that the quality of each aspect (quantitative, qualitative, mixed component) should be reported, and each study rated as either a low or high MMAT studies.[214] For this review, a component (quantitative vs. qualitative) was rated as high quality if > 60% (i.e. more than 3 out of the 5) questions were 'yes', and low quality if ≤ 60% (i.e. ≤ 3 out of the 5) questions were 'yes'; these ratings have been used in previous reviews.[215,216] Disagreements on the results of the quality assessment were resolved by discussion or additional consultation with a third review author.

Methods of analysis and synthesis

We appreciate there are many approaches to synthesising feasibility and acceptability data, with differing philosophical stances underlying each approach.[217] Given that we aimed to synthesise data that are relevant to informing policy, practice and research, and that included studies ranged across different study designs we adopted a pragmatic approach to synthesis. Our pragmatic approach was informed by the 'realist' philosophy,[218] the aim of which was to find out not only 'what works' in terms of behaviour change interventions for people with IC and intervention providers, but also 'for whom, and under what circumstances'. Data were grouped together to provide a tabular summary for narrative synthesis of the included studies, and the quantitative data were analysed using descriptive statistics of frequencies and percentages. The feasibility data analysed included recruitment rate, retention rate, intervention adherence rate/compliance rate, cost of implementation/cost-effectiveness and records of adverse events. The acceptability data analysed were patient satisfaction and the likelihood to recommend the intervention, motives and barriers, usefulness, reasons for declining, reasons for non-adherence and reasons for dropout.

For this review, recruitment rate was defined as the percentage of the participants recruited out of the total number of eligible participants that were invited. The retention rate was estimated as the percentage of the participants that completed the intervention programme/follow-up testing out of the total number that were recruited; the adherence rate was described as the percentage of the recruited participants that adhered to the intervention criteria or the percentage of the intervention sessions completed by the recruited participants.

Deviation from the review protocol

The systematic review had some deviations from the stipulations in the registered protocol in PROSPERO. These are highlighted and described below:

Database search strategy

A search filter for qualitative and mixed-methods studies was not applied for databases searches contrary to the original plan. The review team and information specialist agreed that applying qualitative and mixed-methods studies filters might make it impossible to retrieve studies that reported on some feasibility and acceptability outcomes but did not employ traditional qualitative or mixed methods in their study design. This consideration is further justified in that most of the included studies were not traditional qualitative or mixed-methods studies.

Inclusion criteria

The aim to include mostly qualitative studies was not achieved as most of the existing studies that were relevant to addressing the feasibility and acceptability research questions did not use exclusively qualitative designs. The review included mostly quantitative and mixed-methods studies that reported feasibility and acceptability data. Similarly, we excluded studies that were not directly related to behaviour change interventions (Category B studies). We found 28 studies that provided feasibility and/or acceptability outcomes, including qualitative data within papers reporting quantitative outcomes (Category A studies).

Quality appraisal

In our original protocol, we planned to use the Toye *et al.* criteria for quality appraisal qualitative appraisal of included studies.[219] However, given that included studies were mostly quantitative and mixed-methods studies, the MMAT[214] was used.

Results

Outcomes of searches and study selection processes

A total of 14,493 studies were identified from the database searches. After de-duplication and title and abstract screening, 173 full texts of the remaining studies were retrieved and screened against the review's eligibility criteria, leading to the exclusion of 122 additional studies (*Figure 27*). True to our original protocol, we separated the remaining 51 studies into Category A (*n* = 28, studies linked to a behaviour change intervention) and Category B (*n* = 23, studies looking at broad area of living with PAD). Since our primary focus was synthesising evidence for the feasibility and acceptability of behaviour change interventions, we included only studies from Category A (*n* = 28). Furthermore, most of the studies in Category A did not use purely qualitative designs; however, they contained data on feasibility and acceptability of behaviour change interventions, which were relevant to the review.

Overview of included studies

None of the studies reported on feasibility from the health professional point of view. Details of data extracted from the included studies, including data about the characteristics of included studies, are included as *Report Supplementary Material 3*. A total of 28 studies representing data from 2476 patients with PAD (range 17–305 per study) with a mean age < 68 years (range 65–69.4 years) were included in the review.[149,151,157–163,166,168,169,171–173,178,180–183,185,187–189,192,195,196,200] Most studies (*n* = 25, 89.2%) had samples comprising < 50% females.[149,151,157–161,163,166,168,169,171,173,178,180–183,185,188,189,192,195,196,200] Most studies (*n* = 19, 67.9%) included participants with ongoing versus newly diagnosed IC.[149,157,158,160–162,168,169,171–173,178,180,182,185,187–189,200] The majority of the studies (*n* = 18) did not report the ethnicity of the included participants. Out of the 10 studies (35.7%) that reported ethnicity/race, most (60%) had samples comprising > 50% white participants.[149,162,163,166,183,195]

Most of the interventions (*n* = 20, 71.4%) involved walking programmes, which lasted for an average of 5 months (1–12 months).[149,157,159–163,166,171–173,178,180,181,183,187–189,195,196] A total of 13 studies (46.4%) used activity monitor devices to track the participants' daily walking performance,[149,151,157,160–163,166,168,185,187,189,196] 4 studies used Fitbit devices,[160,161,166,187] 3 studies used pedometer devices,[149,151,196] 3 studies used accelerometers,[157,168,185] 2 studies used StepWatch3 devices[162,163] and 1 study used a NikeFuel band device.[189] The settings of the interventions

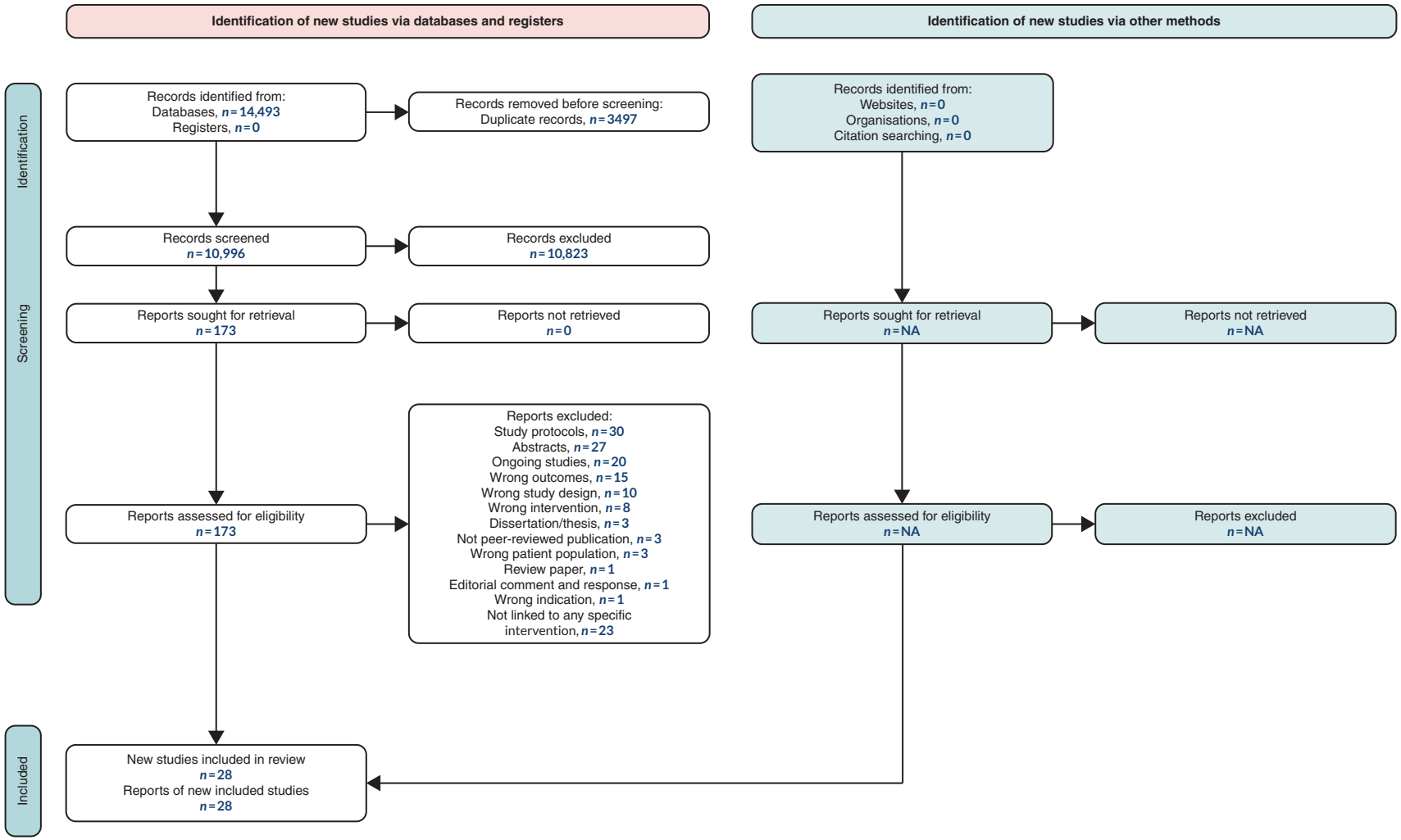

FIGURE 27 The PRISMA diagram for systematic review of feasibility and acceptability of behaviour change intervention for people with IC.

were home-based in ten studies,[149,151,158–161,166,168,181,188] home-based plus hospital/clinic/medical centre in 15 studies,[157,162,163,169,171–173,178,180,185,187,189,190,195,196] hospital/clinic-based in 2 studies,[182,192] and hospital-based + community in 1 study.[149,151,157–163,166,168,169,171–173,178,180–183,185,187–190,192,195,196]

Most of the studies (*n* = 23, 82.1%) reported the workforce that delivered the intervention, which included physiotherapists in four studies,[149,159,192,195] a trainee health psychologist,[151] general practitioners or practice nurse,[181] study staff,[166] researcher,[161] exercise physiologist,[162] exercise coach,[157,187] physician-trained exercise technician,[190] trained psychologist,[182] vascular nurse, experienced cardiac physiotherapist and dietitian,[196] vascular surgeons, vascular nurse, exercise scientist, and general practitioner,[168] clinicians (medical students),[158] a physician and a physiotherapist,[173] vascular surgeons, a vascular nurse, physiotherapists, and research nurses,[185] multilingual health coaches,[188] vascular nurse only,[178] a technician, and a cardiovascular rehabilitation nurse,[172] a physiotherapist, and a training assistant,[169] a physiotherapist and a vascular nurse specialist.[189]

Only 10 studies[149,151,158,168,169,182,185,190,192,195] reported training (in behaviour change) of the workforce that delivered the interventions, and most of the included studies (*n* = 25, 89.2%) reported supervision of the participants receiving the intervention.

Feasibility and acceptability data analysis

The feasibility data that were analysed included recruitment rate, retention rate, intervention adherence rate/compliance rate, cost of implementation/cost-effectiveness and records of adverse events. The acceptability data analysed included patient satisfaction and likelihood to recommend to others, motives and barriers, usefulness, reasons for declining, reasons for non-adherence and reasons for dropout. Adopting the criteria from previous studies,[220–222] we set the cut-off points for acceptable recruitment rate, retention rate and adherence rates as 40%, 70% and 77%, respectively.

Feasibility and acceptability results

Recruitment rate

For this review, the recruitment rate was defined as the percentage of the participants recruited out of the total number of eligible participants that were invited. Out of the 28 included studies, 6[160,161,166,172,173,189] did not report their recruitment rates. The recruitment rate in the remaining 22 studies ranged from 9% to 100% (average 69%). Only 3 studies[149,157,187] stated their recruitment target, and they all reported meeting the target. Based on the review cut-off point of 40%, two studies[168,181] did not attain an acceptable recruitment rate (*Table 14*). Only two studies reported reasons given for participants declining to take part.[149,189] One study reported 11% (*n* = 7) of those contacted being not interested, 10% (*n* = 6) being unavailable to take part and 3% (*n* = 2) not providing a reason.[151] Normahani *et al.* reported that 24% (*n* = 21) declined to take part due to travel distance or time constraints.[189]

Retention rate

For this study, the retention rate was defined as the percentage of the participants that completed the intervention programme or follow-up testing out of the total number that were recruited. Based on the cut-off point, all the included studies attained the acceptable retention rate of 70%. The average retention rate in the included studies was 88% (ranging from 71% to 100%) (see *Table 14*). Eight studies reported reasons for participant dropout.[151,162,163,166,181,189,190] The highest dropout in any one study was due to disinterest in continuing (20% dropout). Health issues were the most common reason for dropout across the studies (*Table 15*).

Adherence

The adherence rate was described as the percentage of the recruited participants that adhered to the intervention criteria, or the percentage of the intervention sessions completed by the recruited participants. Five studies[158,166,178,182,189] did not report adherence rates. The average adherence rate in the remaining 23 studies was 76%. Based on the cut-off point, 10 (35.7%) of the included studies[149,159,160,168,180,185,190,192,195,196] did not attain the acceptable adherence rate of 77%. Four studies reported reasons for non-adherence.[149,160,181,190] The reasons included practical issues with technologies used,[160,190] unable to deliver intervention due to participants being unavailable,[149] personal reasons[190] and accompanying diseases interfering with the intervention[181] (see *Table 14*).

TABLE 14 Feasibility of the behaviour change interventions in the included studies

Study	Sample size *N*	Recruitment	Retention rate	Cost of implementation	Adherence rate	Adverse events
Galea *et al.*[a] (MOSAIC feasibility trial)[149]	24	25%	92%	NR	67%	None
Cunningham et al.[151]	58	81%	97%	NR	85%	Three events – unrelated Intervention group: one participant received angioplasty. Control group: two participants received angioplasty
Cornelis *et al.*[159]	20	50%	95%	NR	55%	Three events – unrelated Two participants had revascularisation, one hospitalisation
Wullink *et al.*[181]	31	39%	77%	NR	77%	Five events – unrelated Two participants had vascular surgery, one participant had depression, one participant had CVA, one participant died due to CVD
Duscha *et al.*[166]		NR	95%	NR	NR	Two events – unrelated Control group: development and complications of a new diabetic foot ulcer in one participant, one participant was claustrophobic and could not wear headgear for peak VO_2 analysis
Endicott *et al.*[160]	49	NR	80%	$119.95 (£94.78) (cost of Fitbit device)	57%	NR
Fukaya *et al.*[161]	41	NR	100%	NR	88%	NR
Gardner *et al.*[162]	119	77%	87%	NR	81%	14 events – unrelated Described only the four events that led to withdrawal from the study; Intervention groups: one participant had leg revascularisation, one participant had stroke Control group: one participant had stroke, one participant had myocardial infarction
Gardner *et al.*[163]	180	95%	77%	NR	83%	11 events – unrelated Described only the six events that led to withdrawal from the study; Intervention groups: one participant had leg revascularisation, one participant had stroke, one participant had myocardial infarction, one participant had hernia surgery Control group: one participant had stroke, one participant had leg revascularisation
Mays *et al.* [183]	39	100%	80%	NR	82%	One event – unrelated Intervention group: one participant was diagnosed with advanced metastatic cancer

TABLE 14 Feasibility of the behaviour change interventions in the included studies (*continued*)

Study	Sample size *N*	Recruitment	Retention rate	Cost of implementation	Adherence rate	Adverse events
McDermott *et al.* (HONOR Trial)[187]	200	77%	91%	NR	79%	Intervention group: related; • 16 participants reported chest discomfort during activity/exercise • 39 participants reported dizziness or generalised weakness during activity or exercise • 43 participants experienced more difficulty than usual during exercise • 45 participants reported shortness of breath during activity or exercise • 55 serious adverse events among 23 participants: 1 abdominal pain, 2 anaemia, 2 calciphylaxis, 1 cancer, 1 cardiac arrhythmia, 1 myocardial infarction, 1 carotid revascularisation, 1 chest pain, 1 compression fracture, 2 deaths, 1 dehydration, 1 dizziness, 2 elective surgeries, 1 fall, 1 foot ulcer, 1 gout, 4 heart failure, 1 hypoglycaemia, 4 infection, 5 lower extremity revascularisation, 2 metabolic problems, 3 non-cardiac chest pain, 3 pancreatitis, 1 pericardial disease, 1 pericardial effusion, 2 pulmonary disease, 1 severe constipation, 2 severe hypertension, 2 stroke, 2 syncope, 1 unknown (hospitalisation) Control group: related; • 27 participants reported chest discomfort during activity/exercise • 39 participants reported dizziness or generalised weakness during activity or exercise • 51 participants experienced more difficulty than usual during exercise • 48 participants reported shortness of breath during activity or exercise • 23 serious adverse events among 15 participants: 1 acute limb ischemia, 1 anaemia, 1 anaemia and acute kidney failure, 1 cardiac arrhythmia, 1 complication from revascularisation, 1 dehydration, 1 elective surgery, 2 gastroenteritis, 2 gastrointestinal bleeding, 1 hypoglycaemia, 3 infection, 4 non-cardiac chest pain, 1 PAD progression, 1 pneumonia, 2 severe hypertension
McDermott *et al.* (The LITE Trial)[157]	305	82%	82%	NR	90%	Intervention group: 74 serious adverse events in low-intensity group and 80 in high-intensity group Adverse event related to the study; • One participant developed a transient supraventricular arrhythmia after the baseline stress test, one participant developed chest discomfort while exercising No details provided on the other adverse events Control group: 30 serious adverse advents No details provided on the type of adverse events
Paldan *et al.* (TrackPAD study)[200]	46	76%	85%	NR	75%	Two events Intervention group: None Control group: one worsening of non-study-related disease, one death
Quirk *et al.*[182]	19	50%	83%	NR	NR	NR
Siercke *et al.* (CIPIC Rehab Study)[167,196]	118	53%	83%	€600 (£499.38) per patient	70%	Four events – unrelated Intervention group: one participant had surgery Control group: three participants had surgery

continued

TABLE 14 Feasibility of the behaviour change interventions in the included studies (*continued*)

Study	Sample size *N*	Recruitment	Retention rate	Cost of implementation	Adherence rate	Adverse events
Tew *et al.*[168]	23	9%	96%	NR	54%	One event – unrelated to study participation Intervention group: one participant suffered a non-fatal stroke
MOSAIC Trial[195]	190	57%	78%	NR	66%	37 events Intervention group: 25 adverse events; not related/unlikely – one lower extremity pain, 4 falls, 1 foot or ankle injury/problem, 1 renal failure, 1 lower extremity muscle strain, 1 chest pain, 1 TIA Possibly related – 1 chest pain, 1 walking difficulty secondary to hypertension Serious events leading to hospitalisation; not related/unlikely – 1 chest infection, 1 post spinal injection infection, 1 atrial fibrillation, 1 anaemia, 1 investigations for blackouts, 1 prostate surgery, 1 perforated abdominal ulcer, 1 road traffic accident, 1 lower extremity wound debridement, 1 investigation for dizziness, 1 chest pain, 2 investigations for severe lower extremity pain Control group: 12 adverse events; not related/unlikely – 1 leg cellulitis, 1 lower extremity pain, 1 low mood, 3 falls, 2 foot or ankle injuries/problems, 1 leukaemia Serious events leading to hospitalisation; not related – one TIA, one diabetic eye haemorrhage, one chest infection
Jonason *et al.*[173]	17	NR	82%	NR	93%	One event – one malignant ventricular arrhythmia
Regensteiner *et al.*[172]	20	NR	100%	NR	100%	NR
Normahani *et al.*[189]	37	64%	76%	£30 (Cost of wearable activity monitors)	NR	Six events – no information on if the events were related to the study Intervention group: one participant had worsening COPD and heart failure, one participant had worsening claudication symptoms and underwent an angioplasty Control group: one participant had stroke, one lung cancer, one septic arthritis, one surgery for worsening symptoms and critical limb ischemia
Collins *et al.*[158]	29	100%	86%	NR	NR	NR
SUNFIT trial *et al.*[185,201]	166	46%	92%	NR	24%	15 events – unrelated Intervention groups: – eight participants underwent lower limb revascularisation, three critical ischemia, and two surgeries. Control group: – one participant died, one atrial flutter
Aalami *et al.*[188]	139	91%	96%	NR	86%	NR
Spronk *et al.*[178]	104	100%	71%	NR	NR	18 events – unrelated – five participants had angina pectoris, seven incidental rest pain, and six diabetes mellitus
Roberts *et al.*[180]	47	94%	100%	NR	71%	NR
Prevost *et al.*[171]	48	86%	96%	NR	93%	Two events – no information on if the events were related to the study – two participants had major depressive disorder

TABLE 14 Feasibility of the behaviour change interventions in the included studies (*continued*)

Study	Sample size *N*	Recruitment	Retention rate	Cost of implementation	Adherence rate	Adverse events
Jacobsen *et al.*[169]	35	56%	100%	NR	91%	NR
EXIPAD study *et al.*[192,193]	304	NR	83%	NR	71%	33 events Intervention group: two progression of PAD, one coronary heart disease, two orthopaedic diseases, one diabetic foot, three other concomitant diseases, four deaths, one complication lower-extremity bypass surgery, one lung carcinoma, one ruptured abdominal aortic aneurysm, one pancreatic cancer, one amputation, two coronary heart diseases, three other concomitant diseases

COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident (stroke); NR, not reported; TIA, transient ischaemic attack. Conversion rate: 1 US$ = 0.7918 GBP and 1 EUR = 0.8323 GBP. Date of conversion: 16 December 2024.
a Additional information obtained from authors.

TABLE 15 Reasons for dropout reported in the included studies

Study	Personal reasons/decision	Health issues	Other	No reason given
Wullink *et al.*[181]		*N* = **5 (16%)** Two patients had to undergo vascular surgery 3.5 months after the start of the programme. One patient appeared to suffer from depression, one patient had experienced a CVA, and one patient died of CVD	*N* = **2 (6%)** The counsellor did not succeed in motivating two patients with the health counselling model	
Duscha *et al.*[166]		*N* = 1 (5%) One patient randomised to usual care dropped out due to the development and complications of a new diabetic foot ulcer		
Paldan *et al.* (TrackPAD study)[190,200]	*N* = **3 (14%)** No further information			
Gardner *et al.*[163]	*N* = **7 (12%)**[a] *N* = **6 (10%)**[b]	*N* = **1 (2%)** stroke[a] *N* = **1 (2%)** leg revascularisation[b]		
Gardner *et al.*[162]		*N* = **1 (2.5%)** stroke[a] *N* = **3 (7.5%)** 1 × myocardial infarction[b]; 1 × leg revascularisation; 1 × hernia surgery	*N* = **7 (15%)** disinterest in continuing[a] *N* = **8 (20%)** disinterest in continuing[b]	
Cunningham *et al.*[151,152]				*N* = **1 (3.5%)**
Normahani *et al.*[189]	*N* = **2 (10%)** 2 × due to family bereavement.	*N* = **2 (10%)** 1 × worsening COPD and heart failure, 1 × worsening claudication symptoms and underwent an angioplasty		
Jonason *et al.*[173]	*N* = **1 (1.7%)** **1 ×** work commitments.	*N* = **1 (1.7%)** **1 ×** malignant ventricular arrhythmia		

COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident (stroke); *N*, number of participants.
a Supervised exercise intervention.
b Home-based exercise.

Cost of implementation

There was no robust analysis or reporting of cost of implementation in the any of the included studies. Costs reported varied among three studies: one study[160] cited $119.95 (£94.78) (exchange rate of 1 US$ = 0.7918 GBP, as of 16 December 2024) for the Fitbit activity device, another[167] mentioned a potential €600 (£499.38) (exchange rate of 1 EUR = 0.8323 GBP, as of 16 December 2024) per patient for the cardiac rehabilitation programme and a third[189] indicated a £30 expense for wearable activity monitors (see *Table 14*).

Adverse events

Among the studies (*n* = 20, 71.4%) that reported on whether there were adverse events during the interventions, only three of the studies[157,187,195] reported that some of the adverse events were related or possibly related to the study participation. The adverse events related or possibly related to the study participation included: transient supraventricular arrhythmia after baseline exercise stress test,[157] chest discomfort/pain while exercising,[157,187,195] walking difficulty secondary to hypertension,[195] dizziness or generalised weakness during activity or exercise,[187] experiencing more difficulty than usual during exercise,[187] and shortness of breath during activity or exercise[187] (see *Table 14*).

Satisfaction and likelihood to recommend

Five studies reported on intervention satisfaction and/or likelihood to recommend the intervention to others.[149,159,161,182,190] There was no universal measure of satisfaction and likelihood to recommend used among the five studies. Two studies gathered data using a survey method,[159,190] another two used interview methods[149,182] and the remaining study did not state the method used. All of the three studies which reported on satisfaction stated levels of satisfaction were high.[159,161,190] Two of the four studies that reported on likelihood to recommend to others indicated that between 83% and 88% of participants would recommend the intervention to others.[182,190] One study stated that recommendation likelihood scores ranged between 4 and 5 on a scale of 1 to 5, with 5 being most likely to recommend to peers.[187] The remaining study only stated that participants would recommend to others.[149]

Motivators and barriers

Eight studies reported on participant motivators and barriers to the interventions.[149,151,160,161,167,168,181,182] The most important motivator was a supportive environment (*Table 16*), whether that be safe space and sufficient time to communicate[182] or encouragement from others,[161,182] including social support.[196] This argument is supported by another study, which stated that participants were not motivated because several aspects of the intervention passed too quickly.[187] Other important motivators included the use of pedometers[160,168,196] and perceived improvements in symptoms and walking ability.[151,161] One study reported that participants stated that financial incentives were not motives; however, this conflicts with the quantifiable data, which suggested that financial incentives did appear to motivate participants to adhere to the intervention.[187] Barriers to the intervention were reported in two of the eight studies,[149,151] which included uncertainty,[149] weather, lack of social support and health problems[151] (see *Table 16*).

Usefulness

Eight studies reported on the usefulness of the interventions.[149,151,161,168,181,182,190,196] Six of the eight studies stated that the interventions were useful by providing information[149,151,168,182,190,196] which increased understanding of the participants' disease[151,168,190] and self-awareness (*Table 17*). Five of the eight studies reported that participants found the interventions motivated them to adhere to and/or continue with the behaviour change.[151,161,168,181,190]

Quality of studies

A full description of the quality appraisal using the MMAT[214] is presented in *Table 18*. Only three studies (10.7%) were rated high on the mixed-methods/integration domain of the MMAT tool.[149,151,196] The reason for the low rating in the mixed-methods domain of the majority of the studies (*n* = 25, 89.2%) is that most did not use a robust qualitative approach to determine the acceptability of the behaviour change interventions. Hence, the five items that made up the qualitative domain (appropriate qualitative approach, adequate qualitative data collection methods, adequate derivation of the findings from the data, substantiation of the results by data, and coherence between the interpretation and qualitative data sources, collection and analysis) could not be evaluated in most of the studies.

TABLE 16 Descriptions of motivators and barriers to behaviour change interventions

Study	Motivators	Barriers
Galea *et al.*[a] (MOSAIC feasibility trial)[149]	Participants appreciated home visits and supportive telephone calls. Ample time with the physiotherapist was central to the experience and therapeutic relationship	Challenges to behaviour change were reported in both groups, including those who increased healthy behaviours Participants had limited expectations of the study and expressed uncertainty. This was alleviated upon taking part Despite uncertainty, positive experiences were reported overall
Cunningham *et al.*[151]	'Several participants reported that as they increased walking they could see their leg symptoms were reducing, and this provided them with a strong motivation to stick to the action plan'	Participants reported barriers that they had to overcome in order to follow their action plans, including the weather, family members not wanting to walk, and other health problems such as back pain and arthritis
Wullink *et al.*[181]	Some patients were not motivated sufficiently to complete the programme. Apparently, stages 1–3 of the Health Counseling Model (awakening, weighing, decision-making) may have passed too fast (p. 1632)	
Endicott *et al.*[160]	There was a strong and significant correlation between total distance walked and feeling the tracker encouraged activity (Spearman $r = 0.73$). . . . In those that used the device, our patients reported the Fitbit to encourage walking which was reflected in increased walking distance over the study time period	
Fukaya *et al.*[161]	All patients in the study group noted high satisfaction, improvement in perceived walking ability and expressed personalised feedback or encouragement was a large motivation for them to be active . . . . Eleven out of 12 patients reported that financial incentives did not influence their engagement and activity levels. However, the results showed that the patients who received financial incentives had a larger increase in their activity levels	
Quirk *et al.* [182]	38% said they had made changes to their behaviour (e.g. further walking) . . . . Participants in the motivational interviewing group also reported that the benefits of the intervention for them included 'enjoyed having a non-judgmental space to talk which wasn't dictatorial'; 'opportunity to discuss things'; 'communication/company'; and some motivational interviewing group participants reported that they 'felt really good coming out of sessions and motivated to exercise', 'felt that coming was worthwhile' and some indicated they were now 'going further each time in walking before planning to sit down' and were 'more inclined to improve exercise'	
Sierke *et al.* [196]	Participants experienced social support from other patients, which motivated them to exercise. The intervention encouraged the patients' management of leg pain, while a local setting and a pedometer were important motivational factors to keep adherence to the programme	
Tew *et al.* [168]	The pedometer was valued, and seen as a useful tool for motivation, self-monitoring and goal-setting	

a Additional information obtained from authors.

TABLE 17 Report of patients' descriptions of usefulness of behaviour change intervention

Study	Usefulness
Galea *et al.*[a] (MOSAIC feasibility trial)[149]	Positive and useful information and support were gained from the interventions
Cunningham *et al.*[151]	All participants in the intervention group reported that the experience had been worthwhile; reasons given included the extra encouragement and motivation from the intervention, receiving extra information about their illness and about walking, having a personalised plan, being clear on what they needed to do, understanding why walking was important and how it would help
Wullink *et al.*[181]	At the beginning of the programme, the meeting with the counsellor every 3 weeks (preceded by a telephone call 1 week before to make the appointment) was considered very supportive for the participants to help them integrate the walking exercises into their daily life. Later, when walking was already a part of daily life, the contact between counsellor and patient was reported to be an important stimulus to continue (not clear how these data were collected/reported)
Fukaya *et al.*[161]	All patients in the study group noted high satisfaction, improvement in perceived walking ability and expressed personalised feedback, or encouragement was a large motivation for them to be active
Paldan *et al.* (TrackPAD study)[190]	The vast number of questions regarding functionality, aesthetics and informational content of TrackPAD (a smartphone app to support SET) were reported as positive to extremely positive (4 or 5 stars out of 5) . . . The users' feedback also included questions regarding the perceived impact of the TrackPAD with respect to their PAD disease. Only one (6%) user disagreed, stating the app had not changed their awareness of SET. The other participants reported that the app had significantly increased their motivation to perform SET and their compliance to SET. They also stated that using the app changed their attitude regarding SET and increased their knowledge about SET
Quirk *et al.*[182]	In the follow-up interview participants in the motivational interviewing group reported re-appraisal of their health condition following the intervention, as evidenced by comments such as 'made me self-aware' and . . . felt that coming was worthwhile
Sierke *et al.* (CIPIC Rehab Study)[196]	The participants found the components in the rehabilitation programme meaningful, but encountered difficulties in continuing on their own after completion of the programme
Tew *et al.*[168]	The exit interviews indicated that participants valued attending the programme, that it gave them a greater understanding of their condition, and that they had been walking more for exercise since attending

TABLE 18 Quality assessment in the included studies using MMAT

Study	Qualitative component score (%)/ rating	Quantitative component score (%)/ rating	Mixed methods/integration					
			Rating	Justification	Integration	Interpretation	Disagreements addressed	Adherence
Galea *et al.*[a] (MOSAIC feasibility trial)[149]	60/Low	60/Low	High	Yes	Yes	Yes	Yes	No
Cunningham *et al.*[151]	40/Low	100/High	High	Yes	Yes	Yes	Yes	Cannot tell
Cornelis *et al.*[159]	20/Low	60/Low	Low	No	Yes	Yes	Yes	No
Wullink *et al.*[181]	0/Low	40/Low	Low	No	Cannot tell	No	Yes	No
Duscha *et al.*[166]	0/Low	60/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Endicott *et al.*[160]	0/Low	40/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Fukaya *et al.*[161]	0/Low	40/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Gardner *et al.*[163]	0/Low	60/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Gardner *et al.*[162]	0/Low	60/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Mays *et al.*[183]	0/Low	40/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
McDermott *et al.* (HONOR trial)[187]	0/Low	80/High	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
McDermott *et al.* (the LITE trial)[157]	0/Low	60/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Paldan *et al.* (TrackPAD study)[190]	0/Low	60/Low	Low	Yes	Cannot tell	Yes	Yes	No
Quirk *et al.*[182]	80/High	20/Low	Low	No	Yes	Yes	Yes	No
Sierke *et al.*[196]	100/High	60/Low	High	Yes	Yes	Yes	Yes	No
Tew *et al.*[168]	60/Low	40/Low	Low	No	Cannot tell	Yes	Yes	No
Bearne *et al.* (MOSAIC study)[195]	40/Low	60/Low	Low	Yes	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Jonason *et al.*[173]	60/Low	40/Low	Low	No	Yes	Yes	Yes	No
Regensteiner *et al.*[172]	0/Low	60/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Normahani *et al.*[189]	0/Low	40/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Collins *et al.*[158]	0/Low	40/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Sandberg *et al.* (SUNFIT trial)[185]	0/Low	40/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Aalami *et al.*[188]	60/Low	40/Low	Low	Yes	No	No	Yes	No

TABLE 18 Quality assessment in the included studies using MMAT (*continued*)

Study	Qualitative component score (%)/ rating	Quantitative component score (%)/ rating	Mixed methods/integration					
			Rating	Justification	Integration	Interpretation	Disagreements addressed	Adherence
Spronk *et al.*[178]	0/Low	40/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Roberts *et al.*[180]	0/Low	60/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Prevost *et al.*[171]	60/Low	60/Low	Low	No	No	No	Yes	No
Jacobsen *et al.*[169]	0/Low	60/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell
Nicholai *et al.*[192]	0/Low	60/Low	Low	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Cannot tell

a Additional information obtained from authors.

Chapter 4 Integrative discussion on the two systematic reviews

Main findings

We analysed data from 41 studies, consisting of 26 RCTs and 15 non-RCTs, which investigated the effectiveness of BCT-based interventions for people with IC. The primary finding of this review was that BCT-based interventions led to a substantial increase in average daily PA (approximately, 473 steps/day) for patients in the short term (< 6 months), outperforming non-supervised exercise controls. However, the impact became less definitive at ≥ 6 months (medium term), resulting in only a modest average increase in daily PA (approximately, 288 steps/day), although there is uncertainty in this estimate due to dropout, fewer trials and increased heterogeneity.

The analysis of secondary outcomes for BCT-based interventions versus non-supervised exercise controls reveals significant improvements in ACD, ICD, WIQ and disease-specific QoL both in the short and medium terms. The 6MWD improved significantly in the short term but not in the medium term, while generic HRQoL 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 and ABPI.

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

The qualitative review found that BCTs are generally feasible and acceptable to people with PAD and IC, but no evidence could be found regarding health professionals. Only 2 (out of 22 studies that reported) failed to achieve acceptable recruitment rates (40%). The average retention rate was 88%, and the 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, but for those studies, satisfaction was good.

Meaning and wider consideration of the evidence

The average increase of 473 steps/day found in this review translates to an additional 13.2% of the daily average steps (3586) of a typical adult with IC.[223] International guidelines recommend at least 150 minutes per week (22 minutes per day) of at least moderate aerobic PA,[224] often equated to 3000 steps per 30 minutes or 100 steps/minute in public health messaging.[225] Therefore, the 473 steps observed in our review represents an additional 4.7 minutes of walking, potentially equating to 20% of the PA guidelines of 22-minute MVPA per day. In addition, many of the comparator arms in the included studies had active BCTs and increased PA, meaning that the true effect of the BCT-based interventions will have been underestimated. National and international PA guidelines recommend, based on a large body of evidence, that any increment in PA among individuals who were previously inactive can improve overall health.[226,227] Individuals with IC face unique barriers to PA,[26,27] leading to a substantial reduction in their activity levels compared to their peers,[21,228] and any increase in daily PA represents an important health behaviour change with the potential to positively impact their clinical outcomes.[22,41,206,229,230] Indeed, the patient members of our PPI group (including author CG) believe that 400 extra steps in a day is a meaningful improvement.

Although there was a small increase in daily steps, our review could not confirm or rule out the benefit of BCT-based interventions over non-SET interventions in sustaining improved daily PA at 6 months or longer, as the margins of the CI were wide. Given that IC is a long-term condition, it is important to ensure that initial PA increases are maintained in the long term and to mitigate relapse. Investigating the maintenance of behaviour changes over time, especially in the absence of intervention contact, is essential to understand whether positive changes gained from initiating interventions can be maintained. Our findings suggest that BCT-based interventions have the potential to enhance daily PA when compared to non-SET controls, although success in sustaining the gained benefit at 6 months or longer needs further investigation.

Our meta-analysis did not reveal a superior outcome in daily PA between BCT-based interventions and SET. Our exploratory NMA suggested that SET ranked first for short-term daily PA improvement, and BCT-based interventions appeared more beneficial in maintaining improved daily PA at 6 months or longer. It is important to approach the NMA results with caution due to the limited direct evidence (two trials comprising three comparisons for the short term, one trial for the maintenance), which affects the reliability of the inferred summary effect, and the imprecision that impacts the overall quality of evidence in these comparisons. Current guidelines recommend SET as the first-line treatment in people with IC. There are many issues with availability of SET perhaps due to cost, and adherence is low due to multiple barriers.[25–27] One study showed that a BCT-based intervention was more cost-effective compared to SET, without any loss of efficacy,[201] and our exploratory meta-analysis suggests the potential for a better maintenance effect in the longer term. There is a lack of cost-effectiveness studies, but we propose that BCT-based interventions, as they are feasible and acceptable, may provide a wider reach for enhancing daily PA, but further research would be needed to establish the evidence base. Certainly, the barriers to BCT interventions are different to those that face participants recommended to SET programmes. and the potential motivators include no need for specific travel and timings for appointments for the intervention. Specific barriers to unsupervised BCT interventions included the weather and family members not wanting to walk; SET may provide a social (peer supported) element and may provide a weather environment if indoors, but then lacks the involvement of family members or the potential enjoyment of nature.

We did not identify any specific connections between individual BCTs or BCT domains and daily PA for people with IC. Research has shown that BCTs that are linked to improved daily PA can vary across different populations and across the different phases of the behaviour change process.[231,232] For example, BCTs like ‘goal-setting’ and ‘feedback’ were associated with increased PA in cancer survivors,[231] while interventions failing to yield PA benefits in hospitalised patients were less likely to include elements, such as ‘action planning’, ‘graded tasks’ and ‘unspecified social support’.[232] Similarly, evidence in other patient population has shown that BCTs effective in prompting individuals to initiate change may not necessarily be effective in maintaining that behaviour change over the long term.[233] Our findings do not conclusively rule out the existence of an association between individual BCTs and intervention effect, but they do highlight the challenge in establishing one due to the consistent use of a limited set of BCTs. Therefore, further targeted exploration in this area in people with PAD and IC is warranted.

It may also be important to note that many of the comparator arms in the included studies had active BCTs and that participants in those arms increased their PA; meaning that the true effect of the BCT-based intervention is likely to have been underestimated due to the positive gain in the non-SET control groups. In addition, conclusions were robust to several sensitivity analyses. Therefore, notwithstanding the modest effect size of the result, it is imperative to consider the body of evidence, suggesting that any increment in PA among individuals who were previously inactive holds significance for their overall health.[226,227] Our review could not establish any benefit of BCT-based interventions over non-SET interventions in the medium term, a finding that is consistent with a previous review demonstrating a decline in PA levels following the conclusion of behaviour change interventions.[234] Unfortunately, we could not examine maintenance effects, as studies in our review did not report on maintenance interventions beyond the initial period of intervention. Nevertheless, to ensure the longevity of the initial progress to increase PA and to mitigate relapse, it may be imperative to transition towards a more sustainable approach in BCT-based interventions, as opposed to the conventional short-term interventionist model without a long-term maintenance strategy. Considering the increasing recognition of daily PA as a crucial assessment criterion in the management of PAD and IC,[235] our findings introduce a novel meta-analysis that suggests BCT-based interventions indeed have the potential to enhance daily PA when compared to non-SET controls, although their success over an extended duration necessitates further investigation.

We found that interventions which targeted the domain of 'intention' outperformed in terms of PA outcome at ≥ 6 months compared with interventions that did not target this domain. This suggests that when people with IC are intentionally motivated to change behaviour, meaning they have made a conscious decision to increase their PA, they are more likely to maintain these changes over. The 'intention' domain of the TDF is strongly linked to the transtheoretical model (TTM), which outlines stages that individuals go through when changing behaviour, such as precontemplation, contemplation, preparation, action and maintenance.[38,236] Future BCT-based interventions for people with IC may need to explicitly target and enhance patients' intentions to engage in PA. This could involve strategies like goal-setting, action planning, and motivation interviewing, all designed to solidify a patient's resolve to increase their PA. Similarly, BCT-based interventions could be more effective if they are tailored to the specific stage of change an individual with IC is in, according to the TTM. For example, those in the contemplation stage may benefit from interventions focused on increasing awareness of the disease and importance of PA and resolving ambivalence regarding barriers to and the safety of walking with pain; whereas those in the preparation stage may need support in planning and executing their walking intentions. Since the findings highlight the effectiveness of intention-based interventions over a longer period (≥ 6 months), future interventions should be designed with long-term perspective, incorporating follow-up strategies to sustain the walking behaviour change. Incorporating methods to regularly monitor and provide feedback to patients to support their intentions can help maintain their motivation and maintenance of PA over time.

Limitations and strengths

Despite an inclusive selection criterion for behaviour change interventions, very few trials met the criteria for long-term benefits or comparison to SET. The limited number of primary studies hindered our ability to analyse the influence of contextual factors on intervention effectiveness. Although we combined data for some meta-analyses, the diversity of interventions, ranging from single to multicomponent and delivered across various settings and modes, increased methodological, clinical and statistical heterogeneity. The exploratory NMA relied on limited direct evidence, affecting the reliability and precision of the inferred summary effect, which impacts the overall quality of evidence. Additionally, many of the control/comparison groups also used BCTs, meaning our results reflect the interventions' effects beyond those of the BCTs in those comparison groups. The lack of detailed intervention manuals and study protocols further limited our assessment of content and delivery, including coding BCTs and TDF domains. Inadequate description, measurement and reporting of PA also prevented the inclusion of some studies in our primary analysis. Furthermore, studies assessing the feasibility and acceptability of interventions did not set prior criteria and often did not report on all recruitment, retention and adherence outcomes.

Despite the limitations of the included studies in the reviews, we conducted a rigorous systematic review and meta-analysis, including exploratory NMAs. For the first time, we investigated BCT-based PA interventions versus any control for people with PAD/IC. This study includes RoB assessments [revised Cochrane risk-of-bias tool for randomised trials (Cochrane-RoB 2) for all the outcomes, and ROBINS–I for the primary outcomes]. Both RCT and non-RCT evidence has been collected and presented separately. The strengths of this review also lie in its detailed appraisal of intervention content and mechanisms of action using the BCT Taxonomy version 1 and the TDF. The review provides detailed descriptions of the intervention content in terms of BCTs, and theoretical mechanisms of action employed. This approach demonstrates the feasibility of assessing evidence at this level of detail, while highlighting areas for improvement. Additionally, we developed a preliminary framework for assessing daily (habitual) PA measurement and reporting in systematic reviews. Once further developed, this framework has the potential to enhance the reporting of PA measurement and standardise selection and data extraction of PA data and outcomes in systematic reviews. We also evaluated the feasibility and acceptability of these interventions based on previous literature. The small number of intervention-related adverse events, none of which were serious, also provide evidence on the safety of BCT interventions.

Patient and public involvement

Patient and the public involvement in developing the research proposal

This review was informed by discussions with patients with IC during the course of the PrEPAID feasibility trial.[237] Some authors of this review conducted the trial between 2018 and 2020 to test efficacy and feasibility of a non-invasive

pain management intervention with and without patient education to improve PA in individuals with PAD and IC. The intervention in the PrEPAID trial, lasting 6 weeks with followed up assessment at 3 months, proved highly valuable in kick-starting patients' engagement in PA. Yet, many participants expressed a desire to sustain their progress over time. They actively engaged with our research team, emphasising the need for evidence-based interventions to maintain their increased PA levels. Therefore, prior to applying for this grant, patients with IC participated in discussions about the proposed review project and explored with us the potential impact of deriving evidence that will enable the development of scalable interventions to help them become and remain active. These discussions involved a mixed group of patients who had participated within NHS Greater Glasgow and Clyde to promote PA and also those who had volunteered to participate but were excluded at baseline assessment due to wide variations in their treadmill distances. In preparing the application for the OPTIMA review, three of the patients provided useful feedback that helped refine our reviews objectives and scope and informed our decision to include one patient PPI member (CG) as a coinvestigator and one public adviser (JD) in our team. Both contributed to the development of the application, including input on research questions, choice of outcomes, dissemination strategy, writing the lay summary and agreement to be part of our advisory group.

To develop this application, we set up a preliminary advisory group to provide advice from a broad range of views. The advisory group was made up of the principal applicants, Dr Chris Seenan, and Professor Julie Brittenden, a vascular consultant and director of Research and Development NHS Greater Glasgow and Clyde. The advisory group had the mandate to advise on the activities patients might undertake during the systematic review, and how best to provide patients with support and information to undertake the tasks. During the first meeting which took place in September 2019, the advisory group developed the terms of reference, strategies for recruiting patients and other PPI members and role descriptions for their involvement. In addition, the advisory group recommended directly approaching individuals within our clinical and research contacts as the best approach to recruiting patients. Based on this recommendation, four patients with IC were subsequently recruited (October 2019), from our network of patients with IC within the NHS Greater Glasgow and Clyde vascular clinics. One of the patients later dropped out due to illness in their family. We met with the three patients (November and December 2019) to familiarise them with the objectives and rationale for the review, and provided them with the opportunity to provide input into refining the scope of the review and to give feedback on the draft review protocol. Given the interest and involvement as well as prior skill of one of the patients (CG) as an information scientist, she later became a co-applicant. We also sought input from a public representative (JD) with experience of a long-term conditions and involvement with PPI, who also contributed to the public summary and as well the overall application. We consulted with clinical vascular physiotherapists and vascular nurses across Scotland (including NHS Greater Glasgow and Clyde and NHS Lanarkshire) and England (such as Oxford University Hospitals NHS Foundation Trust and Central Manchester University Hospitals NHS Foundation Trust). Two notable contributors from this group were Fairer Kimberley, vascular physiotherapy lead at Oxford NHS, and Suzanne Austerberry, vascular nurse specialist at Manchester NHS. Both actively participated in shaping the application and agreed to be members of our advisory group.

Patient and public involvement in conducting the research proposal

We used the months between August and October 2021 for preparatory work, including recruiting of the patient PPI and external members of the project advisory board. We had a total of three people with IC (Cathy Gormal, Neeru Bhatnagar and Graham Fisher) and one member of the public (Jeremy Dearling) as PPI members involved in our project. Two of these people were members of the advisory group. The advisory group identified, discussed and agreed on all processes of PPI involvement, including the training and support requirements of individual patient PPI members. We provided induction for the two PPI members (CG and JD) at our first advisory group meeting. With their help, we developed training material, which was refined following feedback from the project team and the advisory group, and further edited based on suggestions of the PPI members throughout the course of their involvement. Following this, we had a first training session with the PPI members, where we covered the basic principles of clinical trials, qualitative research and systematic reviews, and familiarised them with the review process, including the use of Covidence for title and abstract screening. One of the PPI co-applicants was less comfortable with research terms and methodology, and the other has been involved in 'jargon-busting' such terms, so time was spent with them both ensuring that all terms in the protocol were fully understandable. In two subsequent 2-hour online meetings with Dawn Skelton (co-Principal Investigator), the systematic review processes and review design for OPTIMA specifically were clarified.

Over the month of October 2021, we developed (with the help of the information specialist on the project and one of the PPI co-applicants who was previously a librarian) and piloted our search strategies. We implemented searches in the identified databases. In November 2021, we spent some focused time with the PPI co-applicants in one-to-one practical sessions where each of the two PPI members were involved in title and abstract screening using Covidence, alongside Dawn Skelton, until they were confident to continue on their own. They were fully involved in this process, and they regularly communicated with Ukachukwu Abaraogu and Dawn Skelton when they had any queries related to abstract/title screening. Between November 2021 and January 2022, the titles and abstracts of the two reviews were screened independently by a pool of seven co-applicants (including these two PPI members) and a third independently reviewed any discrepancies (where one person included a study and another excluded that study). This was not a common occurrence suggesting close adherence to the criteria and understanding of the main aims of the review. There was further training and mentoring of the wider three PPI members (one man, two women) conducted in April 2022 and November 2022 to familiarise them with the principles of clinical trials, qualitative research, systematic reviews, study interpretation, and dissemination strategies, and to assist them effectively contribute to the project. The two PPI members on the advisory panel (Jeremy Dearling and Cathy Gormal) led on this with oversight from Ukachukwu Abaraogu and Dawn Skelton. We then asked our PPI members for their input at various stages of conducting the review projects, including feedback on data extraction, analysis plan and data analysis, results interpretation, dissemination strategy and writing the lay summary of this report.

In our original proposal, we planned to include only papers that have our primary outcome (PA behaviour) for review 1 (the quantitative review). However, in implementing the search for review 1, we deliberately set our search strategy broadly to capture both primary and secondary outcomes. We kept aside the papers without the primary outcome measure, but which included the secondary outcome measures. Following the completion of screening, we engaged our PPI members regarding further inclusion criteria and what they thought about the papers without the primary outcomes. The PPI members felt these studies were valuable information to keep and wanted the research team to extract to data on these as well. The PPI members felt that if secondary outcomes of physical capacity had improved this was important for people with IC, not just whether habitual PA was measured. These changes to the workplan for this project led to our application for extension and funding to analyse the secondary outcomes in review 1.

We presented the extracted data and initial analysis plan to our PPI members and requested their input and feedback on both. For the data extraction, we specifically asked our PPI members for clarity and comprehensiveness feedback, as well as any suggestions to include, exclude, emphasise or de-emphasise certain data. PPI members were happy with our data collection and analysis plan and suggested we extract data on the range of individuals delivering interventions, as this may impact comparability and cost implications. They also highlighted the potential of underutilised peer support as a valuable resource for improving outcomes sustainability. Between April and October 2023, we carried out various analyses for the reviews, including meta-analysis of effectiveness outcomes for primary and secondary outcomes, and metaregression of BCT domains to explore their potential association with outcome effectiveness. Between October 2023 and March 2024, we again sought input and feedback from our PPI members and advisory group committee to refine the analyses, interpretation of the results and dissemination strategies. We sought feedback on how they perceived the data analysis and the implications of the results for them. We received valuable feedback from the PPI members, which included the following points:

- Their preference for personalised and targeted walking programmes catering to the specific needs of PAD patients, rather than generic exercise programmes, considering the variation in services provided by different individuals based on their discipline and funding reasons.
- They noted the wide variation in training provided to intervention deliverers; and they stressed the need for an economically sustainable training model to ensure personalised care availability and prevent individuals from seeking information from alternative sources when facing unmet needs in traditional healthcare settings.
- They emphasised the role of self-motivation in intervention success, and how individuals more interested in their health and open to advice are likely to benefit from guided exercise programmes for PAD patients.
- They highlighted the impact of daily pain on motivation, suggesting personalised approaches and potential referrals to approved websites as viable options to start interventions.

- They acknowledged that environmental conditions, especially weather, can significantly influence exercise participation, and for PAD patients, factors like pain and the need to plan walks carefully can impact motivation, suggesting indoor sessions in controlled environments might be more suitable for some patients.
- They noted the potential for patients to be trained to deliver support, and how wearable technology can offer opportunities for self-monitoring and timely feedback.
- They stressed the importance of cocreation, involving patients from the beginning of the process to ensure active participation throughout the studies, rather than passive involvement at the end.
- They highlighted the underused resource of peer support, which could yield long-term benefits, as suggested by the willingness of participants to recommend exercise programmes to others.
- They recognised the value of personalised walking programmes in addressing individual needs alongside generalised exercise programmes and considering the use of apps like the 'new 2 type 2' app for people with diabetes to aid in setting personalised goals.

Challenges with patient and public involvement recruitment and diversification/inability to recruit a commissioner

We originally had a group of five patient PPI members, but only one was female, and there was no one from any ethnic minority group. We advertised via National Institute for Health and Care Research (NIHR) Involve and contacted several underrepresented ethnic communities. Additionally, our PPI members introduced us to African Families UK, through which we recruited a person from an underrepresented ethnic group with IC. Despite having symptoms similar to PAD and IC, and being diagnosed by her general practitioner, this person was later confirmed by a vascular consultant not to have PAD or IC. Nevertheless, she made significant contributions to our project, reflecting the long journey to diagnosis experienced by this patient group. We were unable to recruit a vascular service commissioner to our advisory group. We e-mailed several vascular service commissioners across the UK and received only one response, which declined our invitation, indicating that the individual was the lead commissioner for specialised vascular services and that this area is commissioned by Commissioning Care Groups in England. Following the advisory group's advice, the project team continued efforts to recruit a commissioner throughout the project, but ultimately did not succeed.

Equality, diversity and inclusion

The project teams prioritised equality, diversity, and inclusion by incorporating diverse ethnic, cultural and disciplinary representation in the research team, as well as among PPI and advisory group members. The research team includes a black early-career male principal investigator, mentored by an experienced senior white female coprincipal investigator. This review project is the product of ongoing, productive relationships and collaboration with patients with IC.

Our project benefited significantly from partnerships with two of the largest NHS boards in Scotland (NHS Greater Glasgow and Clyde and NHS Lanarkshire vascular clinics) and collaborations with clinical and public health colleagues across the UK. Key contributors include Fairer Kimberley, Advanced Practice Vascular Physiotherapist at Oxford University Hospitals NHS Foundation Trust; Suzanne Austerberry, Vascular Specialist Nurse at Manchester University Hospital NHS Foundation Trust; and Julie Brittenden, Professor of Vascular Surgery at Queen Elizabeth University Hospital Glasgow and Director of NHS Greater Glasgow and Clyde Research and Development, Elizabeth Orton Professor of Public Health, Director of Lifespan and Population Health, Faculty of Medicine and Health Sciences The University of Nottingham, Lindsay Bearne Professor of Physiotherapy and Rehabilitation St George's, University of London and Senior Research Fellow in knowledge mobilisation and implementation science at the NIHR. These professionals contributed to the protocol and/or served on our advisory group, ensuring the review was informed by a broad range of clinical experience and interdisciplinary insights, leading to treatments and services that better reflect patients' needs.

Our approach to including studies in the reviews was inclusive and pragmatic. For review 1, we included studies of any design that used BCTs aimed at increasing PA in people with IC, irrespective of study setting. This encompassed studies with varied patient populations (e.g. newly diagnosed, prior intervention), gender, age, comorbidities, ethnicity and education levels. We also considered feedback from our PPI members to analyse secondary outcomes, such as physical capacity, QoL and other patient-centred outcomes. Our PPI members emphasised the importance of these

outcomes for people with IC, beyond merely measuring PA in the interventions. This approach ensures that findings are generalisable across a range of patient groups. For review 2, we considered any studies reporting on the feasibility and acceptability of behaviour change interventions to improve PA in people with IC, regardless of study design. This further ensured that the evidence generated is feasible and acceptable to a broad range of patients with IC, aligning with the goals of our research.

To ensure inclusive opportunities for patient involvement, we sought input from a diverse group of patients with IC within the NHS Greater Glasgow and Clyde vascular clinics. We also engaged patients and the public across the UK via the NIHR *people in research* website. Three patients (one female, two males) provided written input into the objectives and scope of the protocol, with two of them leading the writing of the lay summary. Following the award, we intentionally recruited a demographically balanced group of patients for our PPI, including a patient with IC from a South Asian ethnic minority community.

We communicated the summary of our review proposal in plain English language and provided a lay summary of this report to ensure that patients and the public could understand the work undertaken, the findings and the implications for patients with IC. Our PPI advisory group members, Cathy Gormal and Jeremy Dearling, led the writing of this summary as part of their involvement activities. As part of our dissemination strategy, we worked with our steering group to identify relevant stakeholders – patients, health professionals and policy-makers – for targeted infographic summaries of our review. We are tailoring the content of these infographics to suit each audience, and once completed, hard copies will be distributed to NHS authorities and charitable groups. Infographics and podcasts will be posted on YouTube, with links sent to relevant stakeholders.

We trained, mentored and supported our PPI members in their involvement in this project. This included training on general research design, systematic reviews and specific training for active participation in the current review project, aiming to build their confidence and skills for public involvement. Further details are available in the *Patient and public involvement* section.

Impact and learning

From the review we now know that BCT interventions in the short term (< 6 months) improve PA and important clinical outcomes, including walking capacity and disease-related QoL. There is not enough research evidence to clearly evaluate the effects in the longer term (≥ 6 months). We do not know which BCT ingredients work to increase and/or sustain PA in people with PAD and IC, but interventions which aim at increasing PA by focusing on enhancing patients' intention to engage in PA on average lead to greater improvement in patients' PA compared to interventions that do not target intention to engage in PA. We found no evidence that in the short term, behaviour change interventions are less effective than SET.

We presented the results of the primary outcome of review 1 to the Scottish Physical Activity Research Connections Conference on 8 November 2023. The full manuscript on the primary outcome has been published in the *European Journal of Preventive Cardiology*.[210] The screening tool to standardise decision-making on measurement of habitual PA was presented at the International Conference for the Measurement of Physical Activity and Movement (20 June 2024), the conference of the International Society for the Measurement of Physical Behaviour; therefore, it was disseminated to a wide audience of PA measurement specialists. We are planning to submit two more manuscripts – one reporting the secondary outcomes from review 1 (to the *European Journal of Preventive Cardiology*), and the second one reporting on the review 2 (to the *Implementation Science* Journal).

As part of our dissemination strategy, we worked with our steering group to identify relevant stakeholders – patients, health professionals and policy-makers – for targeted infographic summaries of our review. We are tailoring the content of these infographics to suit each audience, and once completed, hard copies will be distributed to NHS authorities and charitable groups. In addition, we are planning to produce a podcast highlighting the finding of the reviews and implication for patients with IC. The infographics and podcasts will be posted on YouTube (YouTube, LLC, San Bruno, CA, USA), with links sent to relevant stakeholders.

There are the key learnings from this review, and they support future intervention design, programme policy and implementation planning. In terms of designing BCT-based interventions, numerous issues need to be addressed in future studies. To date, the use of BCTs to design and implement behaviour change interventions for people with IC seems too homogenous for researchers to isolate the impact of individual BCTs in a meaningful way. However, this may be problematic because BCTs can interact within an intervention, so attempts to isolate independent BCTs working alongside other BCTs may inadvertently lessen the effect of single BCTs. Notwithstanding this, there needs to be more clarity on which individual BCTs have been used and which outcomes they are targeting within interventions. Relatedly, there are overlaps with BCTs being used both in control conditions and in behaviour change interventions, making it difficult to identify BCTs unique to the interventions. Future interventions should make a conscious effort to remove BCTs in the control condition (if trying to isolate the effect of a BCT or set of BCTs) and/or clearly identify which BCTs are being used in control conditions. This will enable analysis of the potential moderating influence of BCTs in a control condition when assessing benefits seen in the intervention group. There is a need for clarity about follow-up conditions in intervention designs, including whether there is a period of nothing after the end of the intervention or an augmented follow-up period where some behaviour change intervention components (e.g. follow-up telephone calls, monitoring with devices, etc.) still occur. This has not always been clearly reported in studies but is important to assess the potential influence of any ongoing strategies on maintenance of gained benefit from intervention. There is also a dearth of research comparing behaviour change interventions with SET. Only three studies were included in our meta-analysis for the < 6-month outcomes and one study for the ≥ 6-month outcomes.

Learning from conducting the review: what constitutes daily habitual physical activity?

As discussed in *Chapter 2*, selecting studies with PA outcome data, we spent considerable time identifying if the outcome measures within studies were actually reporting habitual PA. We are presenting our systematic process, at ICAMPAM, of identifying whether outcome measures were fully acceptable, partially acceptable or inadequate in providing a robust measure of habitual PA. We used a four-item checklist and having at least one outcome measures of PA that partially met all four of these criteria was required for inclusion in the assessment of habitual PA in this review. We felt this was necessary to delineate daily habitual PA from PA as part of the intervention.

The difficulty involved in robustly identifying measures of habitual PA arose from various sources. PA is a multifaceted concept, incorporating dimensions of duration and timing, type and intensity (equivalent to the FITT – frequency, intensity, time and type – principles of describing exercise),[238] and we needed to ask questions in our screening about when PA was conducted, for how long and the type and intensity considered. The identification of adequate measurement was not only about identifying a tool (self-report or device-based) which is capable of such measurement, but also about identifying whether the tool had been used and reported in a manner which was consistent with measurement of habitual PA. For example, an accelerometer device is capable of measuring habitual PA, but in order to do so, the study must also specify a wear protocol that covers a sufficient part of the day (e.g. 24-hour wear), take processing and analysis decisions to only include data with sufficient data in analysis (e.g. at least 3 days of data), and report a suitable outcome measure (e.g. total volume of accelerometer counts). For many of the articles screened in the review, PA was not the primary focus of either the study or the article. This led to challenges in terms of the language used to describe PA and exercise, as this was not always consistent, meaning that care needed to be taken to read and interpret the meaning of what was reported. Additionally, many studies did not report sufficient information for a fully informed decision as to the suitability of measurement, which may be due to limited space to report on multiple outcome measures and low prioritisation of habitual PA as an outcome measure. A difficulty which is common to screening outcome measures (not only in this review) was the difficulty in obtaining the actual wording of self-report measures and/or use of named tools in a non-standard manner without explicit reporting of the changes.

Learning from conducting the review: rigour and reliability in behaviour change technique extraction

Although all the coinvestigators involved in the extraction of BCTs from the intervention and control groups of studies were trained in BCT extraction, there were many discrepancies in their independent extraction that required multiple discussions within the team. We originally chose three papers that we would all extract independently and then had a meeting to discuss which BCTs we coded and our TDF domain choices. We also produced a bespoke TiDIER extraction form to gather the information from each study in a replicable manner for retracing our steps. At that first meeting where we discussed the three papers, it was noted that the two psychologists within the team (Joanna McParland and

Lindsay Bearne) had a different approach and were stricter about whether a BCT should be coded or not compared with the other reviewers (Dawn Skelton, Trish Gorely, Sarah Audsley, Ukachukwu Abaraogu). Other reviewers (Dawn Skelton, Trish Gorely, Sarah Audsley, Ukachukwu Abaraogu) had, on occasion, decided that the BCT must be there as there was a 'mention' in the discussion or elsewhere in the paper. As a result of these discussions, it was decided early on that the reviewers had to be strict and only include a BCT if it was explicitly reported, and there was evidence of its involvement. For example, if 'education' was mentioned in the intervention description but no further detail was provided, then we could not be sure whether information about health consequences, or social comparison had been discussed, so these were not coded, as per the BCT coding instructions.

There was also considerable discussion to whether walking was considered the behaviour or outcome, as goal-setting to walk for 30 minutes a day, for example, could be both a 'goal for behaviour', but also a 'goal on the final outcome' of walking without pain for longer. 'Practice of the task' was automatically coded if there was a SET class, as participants would all be walking, but there was discussion about whether goal-setting to walk daily in unsupervised sessions constituted 'behavioural practice' or 'habit formation'.

We also discussed whether adding a device, such as a Fitbit, constituted 'adding objects to the environment', or whether social support should be coded under practical, emotional or unspecified. We had multiple meetings to discuss the principles of each BCT, particularly whether a one-off introduction session constituted 'behavioural practice/rehearsal' or whether a 'credible source' was codable when there was no mention of the training or qualifications of the person delivering the intervention. The inclusion of 'graded tasks' was often missed by different coders; however, there tended to be full agreement after discussion. At least 2–3 hours per individual study was required for extraction and discussion with the second coder to deal with discrepancies in the choice of BCT extraction. LB extracted all papers and provided consistency throughout this BCT extraction journey, with Ukachukwu Abaraogu, Dawn Skelton, Sarah Audsley, Trish Gorely and Joanna McParland as second extractors. These issues faced by the reviewers are common within the field of health psychology where it can be challenging to apply BCTs due to some ambiguity about their application to behaviours. More recently, a behaviour change ontology was developed, after the coding of the studies had been completed.[239] This new ontology contains 283 BCTs and provides a more granular definition of the BCTs to aid coding. Our coding had already been completed by the time this ontology was made available. We would consider using this in future investigations.

Learning from patient and public involvement

We had always anticipated that this review would concentrate on PA outcomes, but the strong opinion of our PPI team meant we asked for an extension so we could also extract secondary outcomes of physical function and other clinical outcomes. The involvement of the PPI team was crucial in ensuring that this review had most relevance to the population that these interventions are targeting. Without their input, this review would have had less relevance.

Implications for decision-makers

There is evidence, including UK-based evidence, highlighting the effectiveness of behaviour change interventions compared to non-SET controls to improve PA, and patient and clinical outcomes, among people with IC. However, evidence on maintaining PA for 6 months or more is limited, and no UK research has compared these interventions to SET. Our PPI involvement revealed significant demand and enthusiasm for the services about which there was no evidence. Our review indicates that most BCT interventions are feasible to implement and acceptable to patients with IC. These interventions could align with existing exercise services, including those provided by the NHS, private providers and voluntary organisations. They should be offered alongside SET to increase uptake to those who are unwilling or unable to attend SET. However, their acceptability by staff and across various geographical areas (e.g. urban and rural settings) requires investigation.

For future interventions, it is important to consider how to deliver them in ways that encourage access and uptake to people with IC, such as in community settings or through digital technology. Our PPI involvement suggested that attending SET might still be crucial for some patients to start to increase their PA. Therefore, no specific delivery strategy or setting is excluded, but each will present challenges in operationalising the intervention. Cost and resource

issues will be ongoing concerns. While no UK studies have evaluated the economic cost of delivering behaviour change interventions for people with IC, limited evidence from Sweden suggests that BCT interventions may be more cost-effective compared to SET or usual care.[201]

Our PPI involvement also raised concerns that, despite clear evidence of significant clinical benefits within accepted 'willingness to pay' thresholds and NICE guidelines, service commissioners seem reluctant to fund SET as a first-line therapy for most IC patients; and that this reluctance might also extend to behaviour change interventions. Thus, it is crucial to demonstrate how SET and BCT interventions can complement each other in future studies and to evaluate the health economics of both types of intervention.

Research recommendations

A well-designed, UK-based, high-powered multisite RCT on behaviour change interventions should be conducted to assess their benefits on daily PA in individuals with IC. This trial should have a longer-term follow-up, an inbuilt process evaluation/feasibility component to test its acceptability by healthcare professionals, and a comprehensive economic evaluation. It would be prudent to also evaluate behaviour change interventions against SET alone and/or in addition to SET in the future trial. For the trial, detailed and standardised reporting of intervention components and contents. Including the BCTs used in each arm, for both intervention and control groups should be clearly outlined in intervention manuals. One of the ways to conceptualise this trial is to enrol patients into SET, where possible, with a long-term BCT intervention to promote PA, plus remote monitoring using devices, such as smartwatch app or step counter.

Aside from the proposed RCT, there is an urgent need for methodological work to produce a tool to clarify measurement and reporting of habitual PA (excluding exercise or activities that are part of the intervention component) in behaviour change interventions and systematic reviews.

Conclusions

Despite the limited evidence and potential concerns, current reviews suggest that behaviour change interventions for PAD and IC are effective at increasing PA, at least in the short term and offer a potential alternative to SET. Exploratory NMAs indicated that they might be more effective than SET for long-term PA outcomes. BCT interventions are effective at improving patient and clinical outcomes in the short and medium terms, and there was no evidence that they were less effective than SET. BCT interventions are feasible, acceptable and safe to people living with IC. Regarding the content of these interventions, the most commonly used BCTs were identified. However, we could not determine the influence of individual BCTs or the number of BCT groups on the intervention's effectiveness. We concluded that interventions aimed at increasing PA by enhancing patients' intentions tend to have more favourable outcomes than those that do not focus on improving these intentions. The findings of our review are relevant for designing interventions, but the diversity and details of our meta-analysis and qualitative review findings, along with the heterogeneity of the studies analysed, limit the direct application of these findings to clinical practice at this time. To realise the benefits of this research in clinical practice, we recommend using these findings to develop further clinical trials, as suggested in our research recommendations.

Additional information

CRediT contribution statement

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Acknowledgments

We thank Chidinma Ofodum for her assistance with studies screening and data extraction for this review.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

This research involved review of existing literature and did not require ethical approval.

Information governance statement

Glasgow Caledonian University is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. This study did not handle any personal information. Under the Data Protection legislation, Glasgow Caledonian University is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here – https://gcu.ac.uk/aboutgcu/universitygovernance/data-protection/rights. This report did not access any personal data, only published data from research studies.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/ZBNG5240 .

Primary conflicts of interest: Ukachukwu O Abaraogu received the following grants to his institution in the time frame of this work: NIHR HTA funding NIHR130664, NIHR 203430. He has no conflicts of interest.

Philippa Dall received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664, EU ITN Health CASCADE, Forces in Mind Trust (T4VET), CSO (SUSSED). She was Editor-in-Chief of the Journal for the Measurement of Physical Behaviour and received an honorarium. She was a member of the Expert Working group on Communication and Surveillance for the UK Chief Medical Officers 2019 and a Core Committee member (2020) UK Physical Activity Expert Committee for Surveillance, for which travel expenses were reimbursed.

Chris Seenan received the following grants to his institution in the time frame of this work: NIHR HTA funding NIHR130664, Scottish Heart and Arterial Risk Prevention Charity (MaVERIC). He is a member of the Trial Steering Committee – An investigation of the efficacy of the SensTrain device for the management of phantom limb pain: A randomised, single-blind placebo-controlled Trial. [PHANTOM RELIEF Trial]. He is a member of Executive Committee

of the Physiotherapy Pain Association and Consortium Lead for Scotland for the Council for Allied Health Professions Research. These positions are voluntary.

Sarah Rhodes received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664, NIHR RfPB PB-PG-1217-20039, NIHR Research Design service (RDS) (advisor), UK Health and Safety Executive grant for the PROTECT National Core Study, UK Office of National Statistics CIS funding. She receives an Honorarium for Statistical Editing for Wiley Journal of Maternal and Child Nutrition. She received support to travel to Tanzania to work on grant proposal from MRC Global Health. She is a member of Trial Steering Committee for NIHR Public Health funded E-Plays-2 trial (no payment). She will be a member of NIHR RfPB North West panel from September 2024.

Trish Gorely received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664, CSO (acceptability/feasibility study of a greenspace programme for mental health and problem substance use); UKRI Knowledge Transfer Partnership (walking challenge incentive to support young people's physical health, mental health and social well-being), IDEAS fund (OUT and About in the Highlands) and North Cancer Alliance (prehabilitation during cancer treatment). She receives royalties from Taylor Francis for a Textbook: Psychology of Physical Activity. She is a member DMEC for NIHR funded: Walk with Me project and a member of the trial steering committee for NIHR-funded project: A cluster randomised controlled trial of a Peer-Led physical Activity iNtervention for Adolescent girls (Plan-A) (no payment).

Joanna McParland received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664, NIHR 203430 (PI). She receives an Honorarium for being Editor of Health Psychology Open. She is Co-Chair of the International Association for the Study of Pain Social Aspects of Pain Special Interest Group, Lead of academic group for British Psychological Society Division of Health Psychology Scotland and member of Scottish Network of Pain Psychologists (no payment).

Julie Brittenden received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664. She was a member of the NIHR HTA General Committee (1 August 2016–30 November 2021) and is a member of the NIHR HTA – Fast Track Funding Committee (1 June 2024–).

Ebuka M Anieto received the following grants to his institution in the time frame of this work: NIHR HTA funding NIHR130664. He is a member of Ethics Committee, School of Allied Health Sciences, University of Suffolk, and Research Lead, Physiotherapy Team, School of Allied Health Sciences, University of Suffolk. No conflict of interest.

Lorna Booth received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664. No conflicts of interest.

Cathy Gormal and Jeremy Dearling (PPI representatives) received payments for attending meetings and feeding back on documents, time for reviewing papers for inclusion in the reviews, at INVOLVE rates, as members of the PPI Team.

Jeremy Dearling has received travel expenses to attend a number of meetings on behalf of many organisations; CRUK, UKCCRG, UEA, the Stroke Association and a meeting organised from the National Cardiac Surgery trials Initiative. He reviews for the BMJ, the HRA REC Newcastle 1 and also the NIHR.

Candida Fenton received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664. She has no other conflicts of interest.

Sarah Audsley received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664; Orthopaedic Research UK (Keep Exercising and Stay Steady). She has no other conflicts of interest.

Kimberley Fairer received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664. She is the Education Officer on the BACPAR (British Association of Chartered Physiotherapists in limb Absence Rehabilitation) executive committee, no payment received. She received funding from the NIHR Oxford

BRC Research Internship, within her NHS employment, to learn research processes, and completed an initial review of current exercise interventions for claudication, 2023. She was a member of the Vascular Society ASM organising committee (BACPAR programme) 2023–4.

Lindsay Bearne received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664; NIHR HS&DR Developing a role for patients and the public in the implementation of health and social care research evidence into practice (PIPER); NIHR HS&DR Implementation of Comprehensive Geriatric Assessment based perioperative medicine services to improve clinical outcomes for older patients undergoing elective and urgent surgery with cost-effectiveness (POPs UP); NIHR INSIGHT: Inspiring Students into Research (South London Collaboration); NIHR RfPB Preventing kidney injury using carbon dioxide in patients with PAD and Chronic Kidney Disease (CKD) having arterial intervention: the KID trial; NIHR Community Rehabilitation Research incubator hub (Institution); NIHR evidence (CCF CED) research contract-Exploring engagement, understanding and perceived value of NIHR Evidence outputs with practitioners and decision-makers; Health Education England Integrated Clinical Academic (ICA) Awarded to King's College London; NIHR HTA Gait interventions for patients newly diagnosed with rheumatoid arthritis of the foot or ankle; NIHR evidence (CCF CED) research contract Research Disseminating scientific evidence to healthcare professionals using social media: A review and qualitative study; NIHR evidence (CCF CED) research contract-Understanding how members of the public from underserved communities' access and use scientific evidence: A scoping review and qualitative study; Dunhill Medical Trust-A brief physiotherapist-led behaviour change intervention to facilitate walking in older people with PAD: A randomised controlled trial; King's College Hospital Charity A study to scope the feasibility and applicability of remote rehabilitation provision for COVID-19 survivors; and a part time secondment to the NIHR Evidence and dissemination team. She is the Chair of Programme Steering Committee NIHR PGfAR Development and evaluation of the Digital-My Arm Pain Programme for improving painful distal upper limb musculoskeletal disorders (D-MAPP), member of the Programme Steering Committee: BOOST Programme of research, member of the steering committee: OTTER, Arthritis Research UK funded Project (ARUK Ref: 21019), a member of Steering Committee NIHR RfPB A feasibility study to assess the design of a multi-centre randomised controlled trial of the clinical and cost-effectiveness of a caregiving intervention for people with chronic musculoskeletal pain and Associate Editor Rheumatology Advances in Practice journal. She is also a member of the NIHR Pre doctoral academic and practitioner fellowship committee, a member of the NIHR Research for Patient benefit London Region panel and the Wellcome Trust Global Health Doctoral Fellowship selection panel. She receives no payment for these.

Dawn A Skelton received the following grants to her institution in the time frame of this work: NIHR HTA funding NIHR130664; NIHR ARC National Priority for Ageing, Dementia and Frailty (Evaluating the implementation of the FaME programme – FLEXI); Medical Research Council PHIND (Physical Activity, Social connectedness and Healthy Ageing); Chief Scientists Office (AQUAtic exerciSe ThEraPy for fall prevention in older adultS – AQUASTEPS); Orthopaedic Research UK (Development and feasibility of a digital health intervention to encourage exercise maintenance after falls prevention exercise programmes end – KESS); European Commission: Horizon H2020-MSCA-ITN – Health CASCADE; Baily Thomas Charitable Fund – Toileting Assessment and Toilet Training for Adults with Learning Disabilities with Incontinence; NIHR Health Technology Assessment – Clinical and Cost-Effectiveness of an In-Home Personalised Health Promotion Intervention Enabling Independence in Older People with Mild Frailty (HomeHealth); European Commission: Horizon H2020-MSCA-IF-2017 Standard EF Fellowship – Get Ready; Wellcome Public Engagement Fund – A strong and balanced offer; Bailey Thomas Foundation – Reasonable adjustments to provide equitable assessment, screening and treatment of osteoporosis for people with learning disabilities: A feasibility study; NIHR Health Technology Assessment – ELECtric Tibial nerve stimulation to Reduce Incontinence in Care homes; Innovate UK – Mira Rehab Ltd A multi-centre, cluster randomised controlled trial comparing falls prevention Exergames with remote monitoring against standard falls prevention programmes for community dwelling older adults at risk of falls; NIHR CLAHRC (Collaboration for Leadership in Applied Health Research and Care) – PHysical activity Implementation Study In Community-dwelling AduLts (PhISICAL) Implementation of FaME; Norwegian Research Council – FALLPREVENT – Consultancy on implementation of national falls prevention programme. She has received support for travel to attend Singapore Congress of Physiotherapy in July 2024 (Keynote). She is the Chair of Academic Advisory Group, PACES Project, MRC/CSO funded project, University of Glasgow; Chair of Programme Steering Committee for the NIHR PGfAR Programme RECREATE Study (Development and evaluation of strategies to reduce sedentary behaviour in patients after stroke and improve outcomes). She was Chair of Trial Steering Committee – Implementation of a Frailty Care bundle (FCB) for older people in acute care settings: an implementation science study (University College Cork);

member of Trial Steering Committee for the NIHR-funded Gentle Years Yoga Trial; Chair of the Data Monitoring and Ethics Committee for NIHR PHR project 13/164/51: The REACT (REtirement in ACTion) study and member of the Data Monitoring and Ethics Committee for PreventIT, EC funded study. She is currently a member of the Scientific Advisory Board for the Older People and Frailty Policy Research Unit (OPFPRU) funded by the NIHR; Chair of *N*-FIT – National FaME Implementation Team; member of the four Nations National Falls Prevention Co-ordination Group; member of BEPOP 'Benchmarking Exercise Programmes for Older People' Steering Committee; member of the Royal Osteoporosis Society Clinical and Scientific Advisory Community (CSAC), member, UK Stroke Forum; member, Community Rehabilitation Alliance; member of the NHS Lanarkshire Falls Strategy Group; Steering Committee member, British Geriatric Society (BGS) Falls and Bone Health Section. She has been Chair of four Nations National Falls Prevention Co-ordination Groups Task and Finish Groups on 'Deconditioning' and 'Training and Evaluation' member of Public Health England Modelling Advisory Group on the Wider Impacts of COVID-19 on Physical Activity, Deconditioning and Falls in Older Adults; member of Public Health England's Health Economics commissioning Framework: Falls Prevention Steering Group; Scientific Co-chair First World Congress on Falls and Postural Stability, Kuala Lumpur; Chair of the Royal Osteoporosis Society Working Group on Exercise and Bone Health to produce Expert Statement on Exercise and Osteoporosis; Chair of Older People Panel for update of the CMO Physical Activity Guidelines for Health, Departments of Health of the four nations. She is currently a member of the NIHR Advanced Fellowship Selection Committee and a Carnegie Research Assessor for the Carnegie Research Incentive Grants for Early Career Researchers. All these positions are voluntary. She is a Director of Later Life Training Ltd, a not-for-profit training company and owns eight shares (no dividends) and gets an Honorarium for updating training manuals or delivering training.

Publications

Abaraogu UO, Dall P, Seenan C, Rhodes S, Gorely T, McParland J, *et al.* Effect of behavior-change interventions on daily physical activity in patients with intermittent claudication: the OPTIMA systematic review with meta-analysis. *Eur J Prev Cardiol* 2025;**32**:156–68. https://doi.org/10.1093/eurjpc/zwae296

Presentations at conferences

Abaraogu U, Dall P, Rhode S, Anieto E, Booth L, Seenan C, *et al. Behaviour Change Interventions and Habitual Physical Activity in People with Intermittent Claudication: A Systematic Review and Meta-analysis*. Scottish Physical Activity Research Connections (SPARC), Edinburgh, UK, 8 November 2023.

Dall P, Skelton DA, Seenan C, Rhodes S, Gorely T, McParland J, *et al. Development of a Screening Tool to Identify Self-report and Device-based Measures of Habitual Physical Activity for Use in a Systematic Review: The Optima Study*. Oral presentation at ICAMPAM, Rennes, France, 18–21 June 2024.

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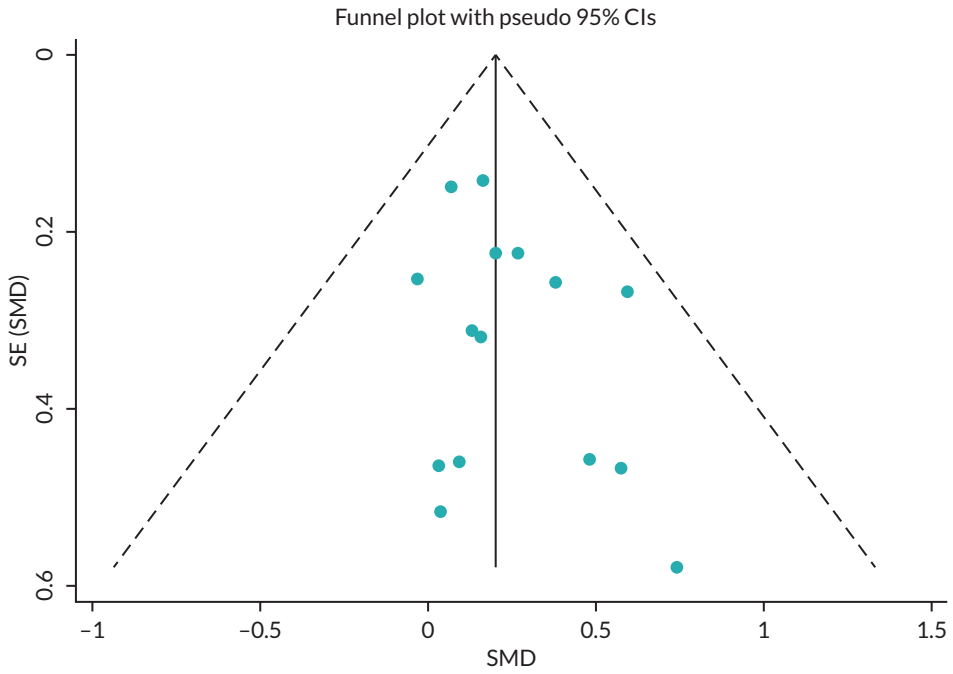
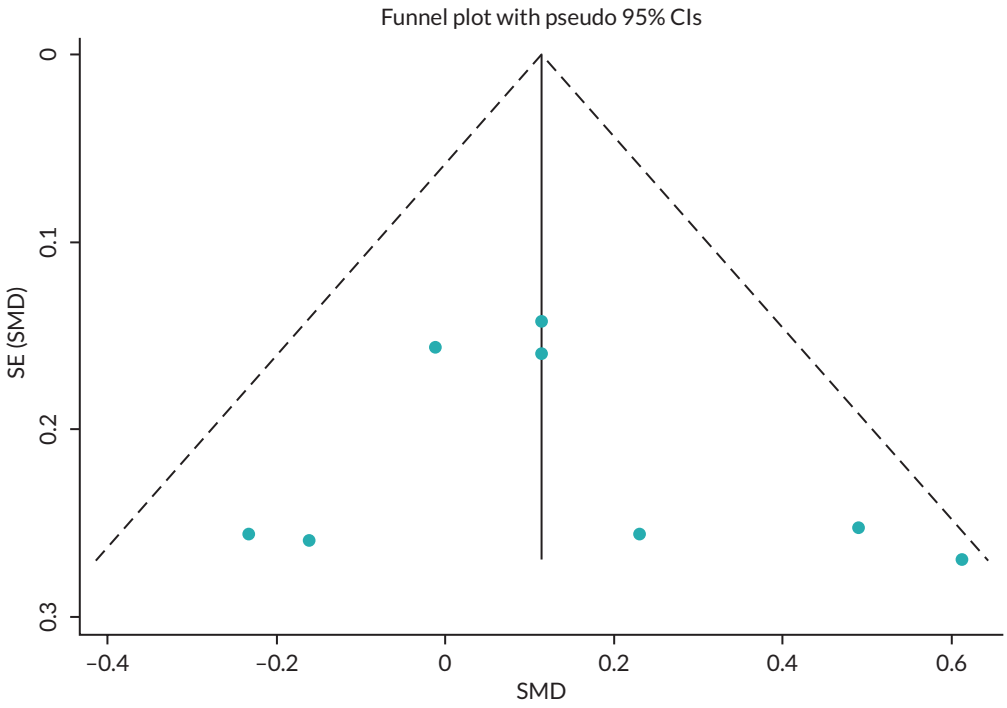
Appendix 1 Funnel plot for the meta-analysis of the effect of behaviour change interventions on short-term (< 6 months) volume of physical activity



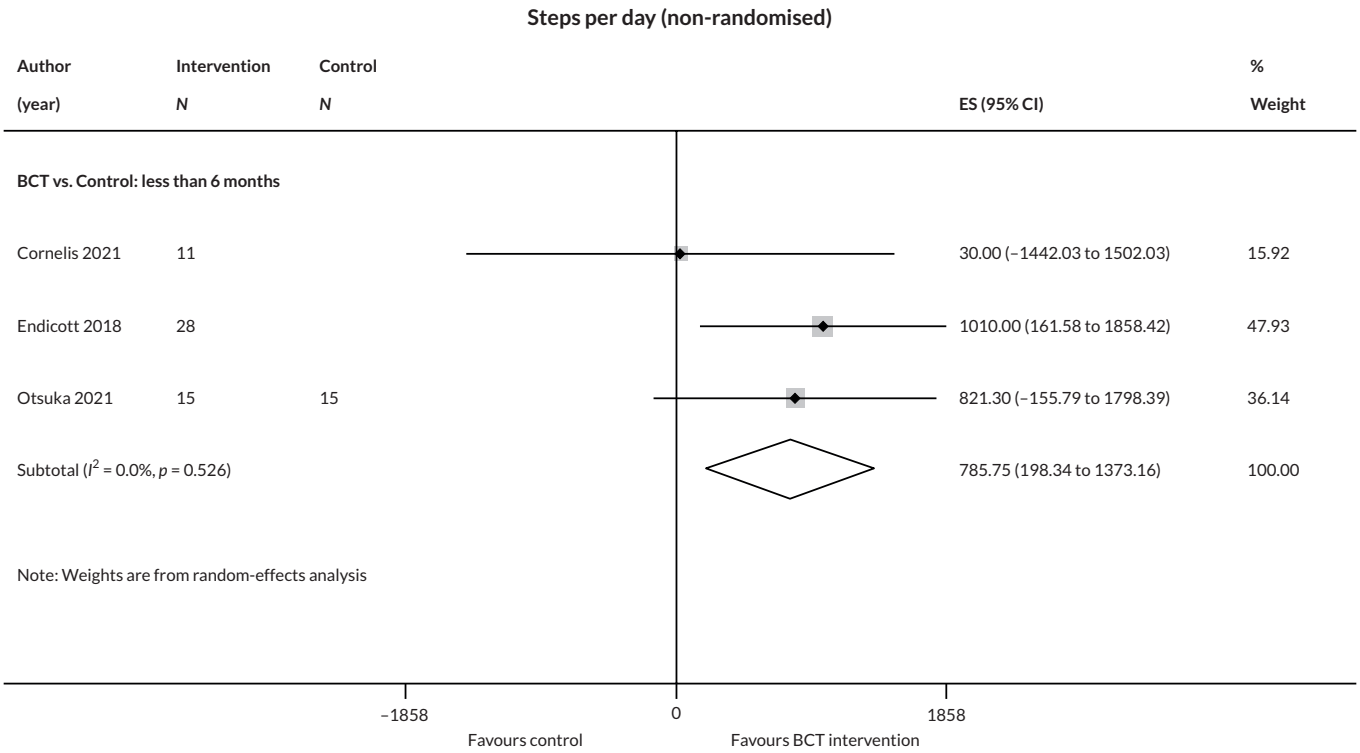
Appendix 2 Funnel plot for meta-analysis of the effect of behaviour change interventions on medium-term (≥ 6 months) volume of physical activity



Appendix 3 Table showing data from non-randomised data of the effect of behaviour change intervention on habitual physical activity compared to non-supervised exercise controls

Study	Measure	Control	*N* intervention	*N* control	Difference (95% CI)
Short term					
Cornelis 2021	Steps per day	Non-supervised	11	–	30 (−1442 to 1502)
Endicott 2018	Steps per day	Non-supervised	28	–	1010 (162 to 1858)
Otsuka 2021	Steps per day	Non-supervised	15	15	821 (−200 to 1841)
Jonason 1981	Km per week (questionnaire)	Non-supervised	15	15	0.20 (SD not reported)

Appendix 4 Forest plot showing meta-analysis of non-randomised data of the effect of behaviour change intervention on habitual physical activity compared to non-supervised exercise controls



Appendix 5 Results of network meta-analysis of volume of physical activity comparing interventions by modality of delivery for short-term outcomes

Column vs. row	Attention control/usual care	Supervised exercise	BCT with tech	Other BCT
Attention control/usual care		0.27 (−0.02 to 0.56)	0.18 (−0.03 to 0.38)	0.18 (−0.03 to 0.39)
Supervised exercise			−0.10 (−0.45 to 0.26)	−0.10 (−0.45 to 0.26)
BCT with tech				0.00 (−0.29 to 0.29)
Other BCT				

Note
Shading key: Yellow, unclear whether or not two types of intervention differ.

Appendix 6 Probability of ranking, mean rank and surface under the cumulative ranking curve from network meta-analysis of short-term volume of physical activity

	Interventions			
Rank	**Attention control/usual care**	**Supervised exercise**	**BCT with tech**	**Other BCT**
Best	0	58.9	18.7	22.4
2nd	0.2	21.2	40.4	38.2
3rd	11	16.9	36.7	35.4
Worst	88.8	3	4.2	4
MEAN RANK	3.9	1.6	2.3	2.2
SUCRA	0	0.8	0.6	0.6

Appendix 7 Results of network meta-analysis of volume of physical activity comparing interventions by modality of delivery for medium-term outcomes

Column vs. row	Attention control/usual care	Supervised exercise	BCT with tech	Other BCT
Attention control/usual care		−0.16 (−0.75 to 0.43)	0.11 (−0.29 to 0.52)	0.16 (−0.06 to 0.38)
Supervised exercise			0.27 (−0.44 to 0.99)	0.32 (−0.30 to 0.95)
BCT with tech				0.05 (−0.41 to 0.51)
Other BCT				

Note
Shading key. Yellow, unclear whether or not two types of intervention differ.

Appendix 8 Probability of ranking, mean rank and surface under the cumulative ranking curve from network meta-analysis of medium-term volume of physical activity

	Interventions			
Rank	**Attention control/usual care**	**Supervised exercise**	**BCT with tech**	**Other BCT**
Best	1.2	10.5	41.6	46.7
2nd	22.9	9.2	26.9	41
3rd	56.7	13.6	19.2	10.5
Worst	19.2	66.7	12.3	1.8
Mean rank	2.9	3.4	2	1.7
SUCRA	0.4	0.2	0.7	0.8

Appendix 9 Grading of self-report tools for assessment of habitual physical activity

The self-report measures from studies which otherwise met the criteria for inclusion in the quantitative review were checked to decide whether they adequately assessed habitual PA (See *Assessment of measurement of habitual physical activity and selecting studies with physical activity outcome data* for details on the criteria used). Data to make this assessment were initially derived from the text of the articles. Additional information was also sought to aid the decision, including literature referenced in the articles, copies of the questionnaire questions and other literature reporting on the tool [identified through non-systematic searches, including Google (Google Inc., Mountain View, CA, USA)]. The purpose of additional searches was to clarify suitability of the tool to measure habitual PA and was not intended to be comprehensive.

This appendix has an entry for each self-report measure assessed (listed alphabetically). The entry consists of: (1) text relevant to measurement of habitual PA (reported in quotes) from articles being assessed for inclusion, sources cited within those articles, and wider searches; (2) reproduction of questions and items from the self-report tool; (3) researcher notes; (4) a completed screening tool table; and (5) an overall decision on whether the self-report measure met the criteria as a measure of habitual PA. The appendix reports on the suitability of both the tool as a whole and the way in which it was implemented in the relevant study. The screening was conducted by one researcher (PD) and reviewed by a second (DS), with differences resolved through discussion.

Baltimore Activity Scale for Intermittent Claudication

Relevant Studies: Galea *et al.* (MOSAIC feasibility trial);[149] Gardner *et al.*[162]

Galea *et al.* 2019 state 'Patient-reported outcome measures included daily physical activity (Baltimore activity scale for intermittent claudication)'

Gardner *et al.*[162] state '**Baltimore Activity Scale for Intermittent Claudication**. Self-reported physical activity level was assessed with the Baltimore Activity Scale for Intermittent Claudication questionnaire for patients with PAD'.

Both citing: Gardner AW, Montgomery PS. The Baltimore activity scale for intermittent claudication: a validation study. *Vasc Endovascular Surg* 2006;**40**:383–91.

Gardner and Montgomery 2006[240] include the Baltimore Activity Scale for Intermittent Claudication in an appendix:

Baltimore Activity Scale for Intermittent Claudication (BASIC) Name:_____ Date:_____ BASIC Total Score (0–10):_____ Please circle the appropriate number (a, b, or c) that best describes your answer to each question.

1. How many blocks can you walk before you feel pain in your leg?
   a. < 1 block. b. Between 1 and 2 blocks. c. More than 2 blocks.
2. What happens when you feel the pain while you walk?
   a. Stop walking. b. Slow down. c. Continue walking at the same pace.
3. How often do you walk at a fast pace?
   a. Rarely/never. b. Sometimes. c. Frequently.
4. How often do you walk up and down stairs?
   a. Rarely/never. b. Sometimes. c. Frequently.
5. How often do you walk up and down hills?
   a. Rarely/never. b. Sometimes. c. Frequently.

Note: The scoring for each question is as follows: a = 0 points, b = 1 point, c = 2 points. The BASIC total score is the sum of points from the five questions.

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	No. The questionnaire asks about general function/capacity
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	No. The questionnaire is structured to report on physical function/capacity
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	No. Considers specific types of walking, but not general PA
4	Does the measurement report outcomes which represent habitual PA?	No. This is a measure of physical function/capacity and report a score according to ability

Decision: This is a measure of physical function/capability, and not a measure of habitual PA.

City Blocks Walked in Last Week

Relevant Studies: (GOALS Trial);[153–156,199] specifically, McDermott *et al.*[154]

McDermott *et al.*[154] state 'Participants were also asked about the number of city blocks walked in the past week (exploratory outcome)'.

Citing: Garg PK, Liu K, Tian L, Guralnik JM, Ferruci L, Criqui MH, *et al.* Physical activity during daily life and functional decline in peripheral arterial disease. *Circulation* 2009;**119**:251–0.

Garg PK, Tian L, Criqui MH, Liu K, Ferrucci L, Guralnik JM, *et al.* Physical activity during daily life and mortality in patients with peripheral arterial disease. *Circulation* 2006;**114**:242–8.

From Garg *et al.*[206] Patient-Reported Physical Activity Measures. Patient-reported physical activity was measured with a questionnaire derived from the Harvard Alumni Activity Survey that has previously been validated in the Cardiovascular Health Study and the Women's Health and Aging Study. The physical activity questionnaire asked, 'During the last week, how many city blocks or their equivalent did you walk? Let 12 city blocks equal 1 mile'. It also asked, 'In the last week, about how many flights of stairs did you climb up? A flight is 10 steps'.

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Yes. Asks about previous week
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	Yes. Asks about all time walking
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	Yes. Only asks about walking and stair climbing, but not limited to exercise
4	Does the measurement report outcomes which represent habitual PA?	Partial. Reports volume of total distance walked

Decision: This is a partially acceptable measure of habitual PA.

Edinburgh Claudication Questionnaire

Relevant Studies: Fowler *et al.*[184]

> *Fowler et al.*[184] *stated 'men were asked to complete the Edinburgh Claudication Questionnaire and to estimate their maximum walking distance before the onset of pain in the legs (< 100 yards, 100–440 yards, more than 440 yards, or no pain on walking). Other sections of the questionnaire concerned current smoking habits, patterns of physical activity [weekly frequency and duration of vigorous and non-vigorous activity and of walking for fitness or recreation. "Vigorous" exercise was defined as non-work activity that made the man breathe harder or puff and pant, while "non-vigorous" activity covered all other forms of exercise including walking (National Heart Foundation 1991)]. A man was classified as "physically active" if he engaged in either vigorous or non-vigorous exercise at least weekly'.*

Citation for Edinburgh Claudication Questionnaire was:

Leng GC, Fowkes FG. The Edinburgh Claudication Questionnaire: an improved version of the WHO/Rose Questionnaire for use in epidemiological surveys. *J Clin Epidemiol* 1992;**45**:1101–09.

Leng and Fowkes[241] has an appendix with the Edinburgh Claudication Questionnaire:

The Edinburgh Claudication Questionnaire

1. Do you get a pain or discomfort in your leg(s) when you walk? Yes/No/I am unable to walk 0.
   If you answered 'Yes' to question (I), please answer the following questions. Otherwise you need not continue.
2. Does this pain ever begin when you are standing still or sitting? Y/N.
3. Do you get it if you walk uphill or hurry? Y/N.
4. Do you get it when you walk at an ordinary pace on the level? Y/N.
5. What happens to it if you stand still? Usually continues more than 10 minutes/Usually disappears in 10 minutes or less.

Where do you get this pain or discomfort? Mark the place(s) with 'x' on the diagram below. Front/Back (diagram of the legs front and back).

A positive classification of IC requires all of the following responses: 'Yes' to (I), 'No' to (2), 'Yes' to (3), and 'usually disappears in 10 minutes or less' to (5); grade 1 = 'No' to (4) and grade 2 = 'Yes' to (4). If these criteria are fulfilled, a definite claudicant is one who indicates pain in the calf, regardless of whether pain is also marked in other sites; a diagnosis of atypical claudication is made if pain is indicated in the thigh or buttock, in the absence of any calf pain. Subjects should not be considered to have claudication if pain is indicated in the hamstrings, feet, shins, joints or appears to radiate, in the absence of any pain in the calves.

It was initially assumed from the article, that the 'other sections of the questionnaire' referred to other sections of the Edinburgh Claudication Questionnaire. However, after reviewing the questions it is clear that the Edinburgh Claudication Questionnaire does not assess PA. We have therefore not completed the screening tool. The suitability of the unnamed questionnaire to measure habitual PA is reviewed later in the appendix.

International Physical Activity Questionnaire short

Relevant Studies: Bearne *et al.*[198]; Bearne *et al.*[195] and Quirk *et al.*[182]

Quirk *et al.*[182] report they use the Short IPAQ, without elaborating on the content, or referencing an IPAQ version.

Bearne *et al.*[198] 2019 refer to the self-report tool for measurement of PA as 'The 7-item Brief IPAQ will estimate daily physical activity' and cite the original Craig *et al.* IPAQ article: Craig CL, Marshall AL, Sjöström M, Bauman AE, Booth ML, Ainsworth BE, *et al.* International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc* 2003;**35**:1381–95.

Bearne *et al.*,[195] refer to 'physical activity estimated by the Brief International Physical Activity Questionnaire (defined as energy expenditure completed over the past 7 days [metabolic equivalent of task minutes per week]; higher scores indicate greater energy expenditure; no minimal clinically important difference defined)' and also reference the Craig *et al.* 2003 article.

From supplemental material 1: 'Brief International Physical Activity Questionnaire (IPAQ)[242] is a valid and reliable 7-item measure of daily physical activity. The self-administered short form asks participants to recall the frequency (days) and duration (minutes) of moderate and vigorous activities, walking for ≥ 10-minute bouts, and sitting over the last 7 days'.

The Craig *et al.*[242] article initially refers to the short IPAQ as having nine items. But the appendix shows the short IPAQ as having seven items. It is odd to call something the brief IPAQ when short IPAQ is the standard way of referring to it. But the seven items cover what the appendix is reporting as being asked, so it seems fair to conclude they are the same.

Short IPAQ Questions:

1. During the last 7 days, on how many days did you do VPAs like heavy lifting, digging, aerobics, or fast bicycling?
2. How much time did you usually spend doing VPAs on one of those days?
3. During the last 7 days, on how many days did you do MPAs like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.
4. How much time did you usually spend doing MPAs on one of those days?
5. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?
6. How much time did you usually spend walking on one of those days?
7. During the last 7 days, how much time did you spend sitting on a week day?

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Yes. The tool asks about the last 7 days
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	Partial. The tool does ask only about activities of at least 10 minutes' duration (excluding those of shorter duration). This is acceptable
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	Yes, the tool asks about time spent in VPA, MPA and walking
4	Does the measurement report outcomes which represent habitual PA?	Depends. Different outcomes can be reported: Yes. The volume outcome of MET hours per week; Yes. The duration of time spent in any activity (walking, moderate and vigorous). No. Duration of time spent only in moderate and/or vigorous activities

Decision: Depending on outcome reported in the article, this could be a partially acceptable measure of habitual PA.

Kaiser Physical Activity Survey

Relevant studies: Pochstein *et al.*[175]

From: Ainsworth BE, Sternfeld B, Richardson MT, Jackson K. Evaluation of the Kaiser physical activity survey in women. *Med Sci Sports Exerc* 2000;**32**:1327–38.

> *Kaiser Physical Activity Survey. The KPAS is a self-administered eight-page instrument designed to obtain information about women's physical activity habits. The survey contains 75 items and takes about 20 min to complete. The survey has seven sections: housework/caregiving, occupation, active living habits, sports/exercise activities, personal feelings about exercise, contemplation about exercise, and personal characteristics. The first four sections are used to classify physical activity status. With the exception of the caregiving section, summary indexes are computed from five-level categorical responses to questions about participation in various activities. Responses range from 1 for 'never' to 5 for 'always'. For the sports/exercise section, respondents also are asked to identify the frequency and duration for the three most frequent sports/exercise activities performed in the past yr. For the caregiving section, four-level categorical responses, ranging from 1 for 'none' to 4 for '20 hours or more per week' reflect the time per week spent in caregiving activities. A detailed description of the KPAS survey and scoring procedures is given by Sternfeld et al. (19).*

The survey has four sections and asks a range of different questions.

Section I: household and family care activities. 11 questions of the format 'We want to know about your activities at home during the past year. how much time did you spend. . .' For example, caring for a child or children under the age of 2.

Section II: occupational activities. Seven questions asking what the occupation is, and employment status, comparing strenuousness of work to others, asking is tires after work, and how often do you . . . sit, stand, walk, lift heavy loads, sweat from exertion.

Section III: active living habits. Four questions, asking: how many minutes you walk/bike to travel, how long you watch TV, whether you walk for more than 15 minutes at a time or bike for more than 15 minutes at a time.

Section IV: participation in sports and exercise. Fourteen questions. First asks to compare with other women about how active they all, whether they played sports/exercise at all, and if they ever got sweaty. Then for each of the top three sports (if done), list what it was (researcher assigned a MET value), ask how many months and how many hours a week did in last year.

Scoring varies depending on section, but gives a score, rather than a measure of volume or intensity.

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Yes. The tool asks about the last year
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	Yes. The tool explores PA at home, at work, during leisure and for transport
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	Yes. The tool asks about time spent in exercise, but also considers walking and household tasks
4	Does the measurement report outcomes which represent habitual PA?	No. The tool reports a score, and does not report on, for example, volume of PA or intensity of PA
Decision: Not a measure of habitual PA.		

Kaiser Physical Activity Survey – adapted for Pochstein *et al.* (2010)

Relevant studies: Pochstein *et al.*[175]

Pochstein *et al.* state:

> *Physical activity was assessed in line with the guidelines of the International Physical Activity Questionnaire (IPAQ, Booth, 2000)*[243] *and an adapted form of the Kaiser Physical Activity Survey (Ainsworth, Sternfeld, Richardson & Jackson, 2000)*[244] *by differentiating five categories of physical activity. These five categories comprise (1) endurance sports, (2) muscle training, (3) gymnastics, (4) play sports and (5) exercises specifically geared to the disease (e.g. gait training, back training, etc.). For each of the four weeks before the interview or before the onset of the disease-related pain, patients were asked to report both the average frequency per week and the average duration per category of movement.*

The Booth, 2000 article, is a description of different ways of describing (and assessing) self-reported PA, and how they may differ internationally. It is not specifically related (as far as we can tell) to the IPAQ – and it is not clear to what is meant by that section. It is not specifically a reference to using the IPAQ. So, our understanding is that they used an adapted version of the KPAS.

Pochstein *et al.*[175] talk about using an adapted version of the KPAS. It is not clear what has been used or how, but the output is not consistent with how the KPAS is reported.

In Pochstein *et al.*,[175] they asked about five categories of PA: (1) endurance sports, (2) muscle training, (3) gymnastics, (4) play sports and (5) exercises specifically geared to the disease. All of which relate to exercise and not habitual PA. What has been reported as an outcome measure is 'sports volume in minutes', presumably the time spent doing sports. This could be obtained from section IV of the KPAS. It is not certain that this is what was done, but it feels likely.

Also note that Pochstein *et al.*,[175] asked about the previous 4 weeks, and not the previous year.

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Yes. The adapted tool asks about the four weeks
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	No. The adapted tool only asks about exercise
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	No. The adapted tool only asks about five types of exercise
4	Does the measurement report outcomes which represent habitual PA?	No. Reports a measure of duration of but time spent in specific type/intensity of PA that is not acceptable
Decision: Not a measure of habitual PA.		

National Health Interview Survey Questionnaire part B

Relevant Studies: Collins *et al.* (2009)[158]

> *From Collins et al., 2009 Part B of the NHIS was used to collect information about quantity and types of physical activity used in the prior 2 weeks. Participants were asked to report the number of times they engaged in vigorous activities (defined as activities that caused heavy sweating or large increases in the heart rate), moderate activity (defined as activity that caused only light sweating or moderate increases in heart rate), strengthening activity (defined as lifting weights or performing calisthenics), and stretching activity (defined as yoga, bending side-to-side, toe touches, or leg stretches). For all 4 levels of activity, participants were asked to report the number of times and the time intervals. With the exception*

of strengthening exercises, participants were asked to report the length of time (e.g., in minutes or hours in which they engaged in each level of activity). We converted the reported time into minutes.

Citing: Centers for Disease Control and Prevention. *National Health Interview Survey*. Washington, DC: US Dept of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Health Statistics; 1990.

Questions for 1990, section W is about physical activity. P195 on the pdf 'sr10_181.pdf'

Set out as a table. Asks four sections of question about a number of activities: the questions are:

2a In the past 2 weeks (outlines in the calendar) beginning Monday (date), and ending this past Sunday (date), have you done any of the following exercises, sports or physically active hobbies? (Tick box of listed activities)
2b How many times in the past 2 weeks did you (play/go/do) activity in 2a? (Response is a number of times)
2c On the average, about how many minutes did you actually spend (activity in 2a) on each occasion? (Response is a number of minutes)
2d What usually happens to your heart rate or breathing when you (activity in 2a)? Did you have a small, moderate, or large increase, or no increase at all in your heart rate or breathing? (Responses tick boxes: small/moderate/large/none)

Items listed as potential responses to 2a:

Walking for exercise/jogging or running/hiking/gardening or yard work/aerobics or aerobic dancing/other dancing/calisthenics or general exercise/golf/tennis/bowling/biking/swimming or water exercise/yoga/weight lifting or training/basketball/baseball or softball/football/soccer/volleyball/handball, racquetball, or squash/skating/skiing/plus, two options to report an 'other' activity.

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Yes. The tool reports over two weeks
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	Yes. The tool asks about all activities in that period
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	No. Limited to vigorous or moderate activites, stretching or strengthening exercises; walking only included if for exercise, and then only processed in article if described as having moderate increase in breathing
4	Does the measurement report outcomes which represent habitual PA?	No. The tool reports a measure of duration, but of time spent in specific type/intensity of PA that is not acceptable
Decision: This is a measure of time spent in exercise and MVPA but not a measure of habitual PA.		

Self-Reported Time Walking

Relevant Studies: Siercke *et al.* (CIPIC Rehab Study)[167]

Siercke *et al.* state 'Daily physical activity was measured by self-reported number of times per week of walking or physical exercise activity of at least 30 minutes'.

Citing: Klarlund Pedersen B, Andersen LB. *Fysisk aktivitet: håndbog om forebyggelse og behandling*. Version: 4.0, revideret. In: Kbh, editor. Danish Health Authority: SST, Rosendahls-Schultz Distribution; 30 November 2018.

The document cited is a handbook of PA (written in Danish, information comes via Google Translate). It covers PA recommendations, factors that influence PA and the relationship of PA to various conditions. Measurement is only mentioned (so far as we can tell) to place epidemiological information in context – for example, describing self-reported and device-based measures of PA in longitudinal cohort to describe change in PA through childhood.

Therefore, the information we have is only from the Siercke *et al.* 'self-reported number of times per week of walking or physical exercise activity of at least 30 minutes'.

At baseline – in *Table 1*, PA is presented as *n* (%) for:

'exercise of 30 minutes/week (with categories of 0 times, 1–2 times, 3–6 times, 7 times); walking of 30 minutes/week (with categories of 0 times, 1–2 times, 3–6 times, 7 times); physical activity ≥ 30 minutes/day.'

In *Tables 2* and *3*, data are presented as *n* (%) for PA.

Although it is not explicit, the values for baseline for 'physical activity ≥ 30 minutes/day' in *Table 1* match up with 'physical activity' in *Tables 2* and *3*, so assume these are the same (although labelled differently).

We are unsure how to interpret the other two outcomes, as given overall as duration per week, but then a number of times – which would often equate to number of days. However, these values are only reported for baseline, so do not matter for decisions for inclusion in the systematic review.

The outcome measure of PA ≥ 30 minutes/day doesn't specify whether this is exercise or walking. However, examining the values for baseline, there are *n* = 3 individuals who report exercise of at least 30 minutes/day on *n* = 7 days, and *n* = 19 individuals who report walking of at least 30 minutes/day on *n* = 7 days, and *n* = 21 individuals reported as having 'physical activity' of 30 minutes/day on *n* = 7 days. So, neither exercise nor walking is sufficient on its own to account for the 'physical activity'. If summed, there would be one person over the value reported for 'physical activity', but it is plausible that one person reported 7 days for both exercise and walking.

Therefore, we conclude the outcome reported is the number of people reporting time spent in exercise and/or walking of at least 30 minutes/day.

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Yes. Reported for a week
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	No. Only considers reporting walking and/or PA that is at least 30 minutes per day, and thus could miss a larger portion of habitual PA
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	Yes. Covers walking and physical exercise activity
4	Does the measurement report outcomes which represent habitual PA?	Partial. Reports the number of people meeting a duration threshold for PA (which includes exercise and walking)

Decision: No. Only asked for frequency of days doing at least 30 minutes, which leaves room for lack of reporting of low levels of habitual PA.

Stanford Patient Education Exercise Behaviour Questionnaire

Relevant Studies: Collins *et al.* (2010) and Collins *et al.* (2009)[150,158]

> *From Collins et al. 2011. Exercise Behaviors Questionnaire. We administered the Stanford Patient Education Research Center Exercise Behavior Survey during each follow-up phone call. The exercise behaviors survey is a six-item instrument with questions regarding the type of activity and the length of time during which the patient engaged in that activity during the past week.*

Citing: 'Lorig K, Stewart A, Ritter P, Gonzalez V, Laurent D, Lynch J. Outcome Measures for Health Education and other Health Care Interventions. In *Stanford Chronic Disease Self-Management Study*. Thousand Oaks, Calif., Sage Publications, 1996, p. 24–25'

Questionnaire downloaded from: https://selfmanagementresource.com/resources/evaluation-tools/english-evaluation-tools/

Asks six questions for the previous week (even if not typical), with duration responses of none/< 30 minutes/week, 30–60 minutes/week, 1–3 hours/week and > 3 hours/week.

Questions are how much time in total did you spend on each of the following:

1. Stretching or strengthening exercises (range of motion, using weights, etc.).
2. Walk for exercise.
3. Swimming or aquatic exercise.
4. Bicycling (including stationary exercise bikes).
5. Other aerobic exercise equipment (Stairmaster, rowing, skiing machine, etc.).
6. Other aerobic exercise (specify).

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Yes. Measures over previous week
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	Yes. Asks about all time in that week
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	No. Only assesses time spent in exercise. Although walking for exercise is included, incidental walking or other walking is not
4	Does the measurement report outcomes which represent habitual PA?	No. Although categories of time spent in exercise are converted to a duration, thus assessing volume. This only applies to duration of exercise
Decision: Not a measure of habitual PA.		

Unnamed Questionnaire

Relevant studies: TrackPAD study[190,200]

Paldan *et al.*[190] state 'The secondary outcome measures were changes in physical activity' and 'The patients were asked to fill out a questionnaire package at both time points, including self-reported physical activity, demographic characteristics, and the PAD-QoL questionnaire'.

There is no further information in the article relating to the questions asked about PA.

The results table has a row called:

'Reported physical activity (days per week), mean (SD)'

So extremely limited information about the self-report measure used.

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Unclear. No information
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	Unclear. No information
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	Unclear, but likely No, the reported outcome is 'reported PA' – no specification about type/intensity, so it may cover the whole range. However, the article reports the outcome in number of days. For most individuals you might expect some level of habitual PA on all days, so the implication here is that the question is limited to a specific type (e.g. exercise) or duration (e.g. 30 minutes) each day
4	Does the measurement report outcomes which represent habitual PA?	Unclear, but likely No. The tool reports a measure of frequency, the number of days of PA. Although there is no suggested limit in the type/intensity of PA, to report the number of days implies that a restriction was placed on the question that has not been reported

Decision: With current information, we cannot be certain. But the likelihood is that this does not report habitual PA, but reports on the frequency of a subset of activity which does not count as habitual PA by our criteria.

Unnamed Questionnaire

Relevant studies: Jonason *et al.* (1981)[173]

> *Jonason et al.*[173] *state Before and after home-training, after group-training, and six months after the end of group-training, the patients answered a questionnaire concerning the frequency and duration of PA, in the form of calisthenics and walking, and to what level of leg pain (according to the Borg scale) the activity was performed*

There is no further information in the article relating to the questions asked about PA. The results tables have rows called:

'Walking activity (km per week)'

'Gymnastic training (min per week)'

So extremely limited information about the self-report measure used.

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Unclear, but likely Yes. No information about recall period of the tool, but outcomes were reported as 'per week', implying a recall period of at least a week
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	Unclear, No information
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	Yes. The tool asks about walking and one type of other activity (called 'calisthenics' in the text and 'gymnastic training' in the results table). Note the other type of activity would not meet the criteria on its own (i.e. without the walking)
4	Does the measurement report outcomes which represent habitual PA?	Partial. Reports a measure of volume for walking of distance walked. Additionally reports a measure of duration for a specific type/intensity of PA which would not be acceptable on its own (only in combination with walking). This is not acceptable on its own, and because walking activity is reported as a distance (and not a duration) these cannot be combined
Decision: With current information, we cannot be certain. But the likelihood is that this partially reports habitual PA, as it reports distance of walking 'per week'.		

Unnamed Questionnaire

Relevant studies: Fowler *et al*. (2002)[184]

> *Fowler et al.[184] stated men were asked to complete the Edinburgh Claudication Questionnaire and to estimate their maximum walking distance before the onset of pain in the legs (less than 100 yards, 100-440 yards, more than 440 yards, or no pain on walking). Other sections of the questionnaire concerned current smoking habits, patterns of physical activity [weekly frequency and duration of vigorous and non-vigorous activity and of walking for fitness or recreation. 'Vigorous' exercise was defined as non-work activity that made the man breathe harder or puff and pant, while 'non-vigorous' activity covered all other forms of exercise including walking (National Heart Foundation 1991)]. A man was classified as 'physically active' if he engaged in either vigorous or non-vigorous exercise at least weekly.*

It is clear that the Edinburgh Claudication Questionnaire (see above) itself does not have any PA measurement. Therefore, in the statement in Fowler *et al.*,[184] we conclude that 'Other sections of the questionnaire' refers to the entire self-report tool used in that study, and not to the specific component of it (i.e. the Edinburgh Claudication Questionnaire).

There are no further citations or supplementary information, and so we rely on the information in the article.

Results are reported in *Table 3* (2 months) and *Table 4* (12 months): for example, '*Table 3*. Comparison of study groups at follow-up at 2 months. Data are percentages except where indicated otherwise'.

For PA, data are reported as percentage of the respondents meeting four different criteria:

> *walking for recreation (≥ 3/week)*
> *vigorous activity (≥ 1/week)*
>
> *more activity than usual*
>
> *membership of an exercise group.*

The values meeting the first criterion, that is walking for recreation ≥ 3/week, would meet a partially acceptable outcome measure.

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Unclear, but likely yes. The article reports 'weekly frequency', which implies being reported over the course of at least a week
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	Partial. Excludes work-time VPA
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	Yes. Covers vigorous activity, non-vigorous activity, walking for fitness and walking for recreation
4	Does the measurement report outcomes which represent habitual PA?	Partial. Reports the percentage of the group meeting a threshold for walking for recreation
Decision: Partial. Reports on recreational walking as the number of participants meeting a criteria of doing this three times per week.		

Walking Diary

Relevant Studies: Wullink *et al*. (2001)[181]

> *Wullink et al.*[181] *stated Walking-diary. As part of the HCM, patients kept track of their walking exercises in a walking-diary. Apart from their experiences (see above), they had to report where they had been walking to, at which place the onset of pain was, and at which place they decided to stop, which was not always at the maximum level of pain. The quantitative effect measures of the diary were walking frequency and reported maximum distance.*
> *The walking-diaries were completed at home by the patients. The reported distances were measured by the researcher using a calibrated bicycle odometer (Sigma Sport Baseline 500, Sigma Sport, Neustadt, Germany), which has an accuracy of 10 m. A belt pedometer was not used, because patients with intermittent claudication change their walking speed when pain occurred, and possibly also their step length. In healthy subjects, step length decreased by lowering speed (21). The average maximum distance at baseline and after 24 weeks was calculated with the maximum distance reported in the diary in the first and the last 7 days, respectively.*

No supporting citation, no additional supplemental material.

Therefore, we have only the text to go on.

Reports only on walking, and frequency and maximum distance, and it is difficult (for me now) to see how that could be put together into a measure of amount of 'habitual physical'. It is unclear how the reported distance is calculated from the diary – although it is called 'reported maximum walking distance' rather than 'total distance'

Does the tool measure habitual PA?

#	Criteria	Y/Part/N
1	Does the measurement consider PA over a suitable total time frame to represent habitual PA?	Yes. Assessment reported from first and last 7 days of diary, so assessed over a week
2	Does the measurement consider PA over an adequate part of each day of measurement to represent habitual PA?	No. States asked to report on walking exercise (which were prescribed as part of the intervention), and not all habitual PA
3	Does the measurement consider a suitable range of types and intensities of PA to be considered habitual PA?	No. Only asks about walking for exercise for the intervention, which has a required intensity
4	Does the measurement report outcomes which represent habitual physical activity?	No. Reports on frequency of walking, but in bouts per day without any volume metric attached. Also reports on MWD, which is a measure of performance/capacity and not volume of habitual PA

Decision: Concentrates on reporting walking exercise as part of the intervention. Although reported as outcome measures, no clear attempt to record habitual PA more generally. Outcomes reported do not report habitual PA.

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