ELSEVIER

Home-based Circuit Training and Community Walking for Intermittent Claudication

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Background: Supervised exercise training is recommended for people with peripheral artery disease (PAD), yet it remains underutilized. Home-based exercise programs (HBEPs) are a potential alternative. The aim of this study was to assess the feasibility of conducting a full scale trial of a 12-week HBEP for people living with symptomatic PAD.

Methods: In a randomized feasibility trial, patients with intermittent claudication were allocated to either an HBEP or a nonexercise control. The HBEP group was given a Fitbit to use during a 12-week exercise program comprising of personalized step goals and a resistance-based circuit to be undertaken at home twice weekly. The primary outcome was feasibility, assessed via eligibility, recruitment, attrition, tolerability, and adherence. Acceptability was assessed via semi-structured interviews. Secondary analysis was undertaken to determine the feasibility of collecting clinical outcome data.

Results: 188 people were screened, 133 were eligible (70.7%), 30 were recruited (22.6%) and one withdrew (3.33%). Mean adherence to the daily step goal was 53.5% (range = 29.8–90.5%), and 58.6% of prescribed circuits were completed of which 56.4% were at the desired intensity. Six adverse events were recorded, 3 of which were related to study involvement. No significant differences were observed in exploratory outcomes. Small clinically important differences were seen in walking speed and pain-free treadmill walking distance which should be confirmed or refuted in a larger trial.

Conclusions: The HBEP was feasible and well tolerated, with successful recruitment and minimal attrition. The intervention was acceptable, with walking seen as more enjoyable than circuit exercise. The WALKSTRONG program may be suitable for those who will not, or cannot, take part in supervised exercise outside of the home.

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INTRODUCTION

Intermittent claudication (IC) is the classic symptom of peripheral artery disease (PAD), characterized as exertional leg pain relieved with rest.[1] PAD is estimated to affect 237 million people worldwide.[2] Walking ability is impaired[3] and quality of life (QoL) reduced.[4] Guidelines recommend supervised exercise programs (SEPs) as first-line therapy,[5] with a substantial research base demonstrating their effectiveness. Despite strong evidence,[6] SEPs are not routinely provided, and uptake, and adherence is poor.[7] These issues stem from lack of funding, ambiguous exercise prescription guidelines,[8] and barriers to participant engagement such as time, travel, and financial constraints.[9,10]

Home-based exercise programs (HBEPs) may be safe[11] and preferable for people with PAD,[12,13] with the potential to improve uptake of exercise therapy. However, they are not as effective as SEPs,[14] unless accompanied by wearable activity monitors (WAMs).[15] HBEPs consist of either a home-based alternative of SEPs (walking to severe claudication pain 2−3 times per week),[16] or generic targets to increase physical activity.[17] Although step goals may promote awareness of routine daily physical activity, the recent LITE trial demonstrated that sustained bouts of walking to the point of claudication may be required.[18,19]

A third exercise modality rarely utilized in HBEPs is resistance training. Despite concurrent frailty/sarcopenia in PAD,[20] and evidence suggesting resistance training improves walking performance in this population,[21] it is rarely incorporated into HBEPs. To date, only one study has attempted to implement such training alongside community walking.[22] Circuit training combined with physical activity goals presents an opportunity to incorporate all of these modalities into one intervention. Therefore, the aim of the study was to assess the feasibility of conducting a full scale randomized controlled trial (RCT) of home-based circuit training and community walking in people with IC in the UK.

METHODS

Trial Design

We conducted a feasibility, parallel-group, assessor blind RCT comparing an HBEP with nonexercise control for people with IC. The trial was prospectively registered with ClinicalTrials.gov: NCT05059899 and the protocol published.[23] Ethical approval was granted by the Coventry University (P123339) and local NHS (Coventry & Warwickshire REC: 21/WM/0208) research ethics committees. The trial is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT).[24]

Participants

People referred to vascular clinics with confirmed symptomatic PAD (Ankle/Brachial Index <0.90) were eligible. Participants must have been aged ≥18 years, able to walk independently, and have capacity to provide informed consent. Exclusion criteria included walking impairments other than PAD, asymptomatic PAD or chronic limb threatening ischemia, active cancer treatment, unstable angina, or recent myocardial infarction.

Randomization, Allocation Concealment, and Sample Size

Participants were randomized on a 1:1 basis, using a computerized randomization program (https://www.sealedenvelope.com). To ensure allocation sequence concealment, the principal investigator (AW) requested randomization after completion of the baseline assessment. All subsequent outcome assessments were undertaken by a researcher blinded to group allocation (FD). With feasibility of study procedures being the primary outcome, no formal sample size calculation was completed. We aimed to recruit a total of 30 participants.[25]

Home-based Exercise Program

The full intervention is described elsewhere.[23] Briefly, participants were given a Fitbit Charge 4© and a personalized daily step goal, initially based on a 10% increase from baseline levels (determined with an accelerometer). Circuit sessions were completed individually by participants twice per week at home. Sessions consisted of a 10-min warm up of light pulse raising movements, followed by 6 intervals of 2 min of walking/marching on the spot to elicit severe claudication pain (3−4 on pain scale), and interspersed with 6 resistance exercises to be done for 2 min at a rating of perceived exertion (RPE) of 11−14 while claudication pain subsided (see supplementary material). Participants used household items to increase resistance to elicit the desired RPE. Each session ended with a 10-min light cool down. Telephone check-ins occurred every 2 weeks with an exercise physiologist, and included discussions around compliance, progression or regression. If participants' average daily steps exceeded their goal, and they were meeting their goals over 50% of the time in the preceding 2 weeks,

a further increase of 10% over the most recent average step count was applied. Walking bouts during the circuits were extended or increased in intensity if participants were no longer experiencing severe claudication pain after 2 min. The exercise program lasted 12-weeks in total.

Nonexercise Control

Current UK guidelines for people living with IC are that standard care should include management of cardiovascular risk factors and referral to a SEP. Due to the focus of the current study being the feasibility of undertaking a full scale RCT of the WALKSTRONG program, control participants did not receive any intervention. The nonexercise control group was, therefore, provided with advice on physical activity using British Heart Foundation leaflets.[26] Those in the control group were offered an opportunity to participate in the intervention following completion of the study.

Outcome Measures

Outcomes are detailed in full elsewhere.[23] The primary outcome was feasibility, based on recruitment, attrition, tolerability, and adherence/compliance to the intervention. Adherence to the circuits was established by recording the number of circuit sessions completed, via a self-report exercise diary. For daily steps, participants were given a study-specific Fitbit account, and were required to synchronize their activity monitor with the Fitbit app to allow the researchers to monitor daily step counts. Compliance with step goals was determined by recording the number of daily steps, as well as the number of days individual step targets were met. Circuit fidelity was assessed by recording the claudication pain rating and RPE for every circuit exercise completed.

Acceptability was assessed by conducting semi-structured interviews with a subset of intervention completers, decliners and dropouts. All participants eligible for the WALKSTRONG trial were eligible for an interview. Those who participated had an optional clause when providing informed consent to agree to a future interview. They were subsequently approached following completion of the trial. Those who declined were approached via telephone, with consent being audio recorded. One-off interviews were conducted with a topic guide that was flexible to allow for follow-up discussion, and sought to gain information surrounding participants' thoughts on the structure of the program and experiences while talking part, or reasons for declining. Interviews were audio recorded using a Dictaphone (Olympus DM-770) and transcribed verbatim.

As part of the refinement process for a full scale RCT, the feasibility of collecting a range of secondary clinical outcomes was evaluated. Walking ability was assessed via both a six-minute walk[27] and graded treadmill test.[28] Grip strength was determined using a handheld hydraulic dynamometer (Baseline, USA) and lifestyle physical activity was quantified by wearing an ActiGraph wGT3X-BT around the waist for 7 days prior to and following completion of the intervention. The SF-36,[29] EQ-5D-5L[30] and VascuQol[31] questionnaires assessed QoL. To determine concentrations of systemic inflammation and vascular remodeling biomarkers, whole blood was drawn at each visit using standard venepuncture techniques, allowed to clot, and centrifuged at 3,000 rpm for 10 min, with serum aliquoted and stored at −80°C. High sensitivity C-reactive protein was measured using an automated analyzer (Randox laboratories Ltd. Crumlin, UK). Interleukin-6, tumor necrosis factor alpha and vascular endothelial growth factor were measured with multiplex assays according to manufacturer instructions (R&D kit: LXSAHM-03 L152945) on a Luminex® MAGPIX (Luminex®, Austin, USA).

Statistical Analysis

All continuous data were summarized as mean and standard deviation or median and interquartile range. Categorical data were summarized as frequency count and percentage. Secondary analyses were conducted according to the intention to treat model. All secondary outcome data was examined at baseline, following the 12-week intervention and after 24-weeks (no participant contact occurred in the last 12 weeks). Presuming data fulfilled the necessary assumptions, changes in outcomes were assessed with a mixed model repeated measures analysis of variance, with group allocation and time point as the between- and within-group factors respectively. Post hoc analysis was conducted on any significant differences, which was inferred with an alpha of $P < 0.05$. Partial eta squared (η_p^2) was reported as effect size. Results of all exploratory analysis were interpreted and reported with full knowledge that a power calculation had not been completed. All quantitative data were analyzed using R (v4.0.3).[32]

Qualitative data obtained during semistructured interviews were subject to inductive thematic analysis, whereby themes were gleaned from the data.[33] The main themes were agreed upon by AW and AH via a 'critical friend' approach.[34] Interview data

Table I. Baseline characteristics of study participants

Variable	Nonexercise ($n = 14$)	Home-based exercise ($n = 16$)
Female sex	1 (7.1)	3 (18.8)
Age (years), mean (SD)	68.1 (8.5)	68.3 (9.6)
Caucasian ethnicity	12 (85.7)	14 (87.5)
Body mass index (kg/m^2), mean (SD)	30.9 (5.3)	30.1 (5.1)
ABPI, mean (SD)		
Right	0.74 (0.26)	0.79 (0.19)
Left	0.71 (0.21)	0.69 (0.17)
Smoking status		
Current	4 (28.6)	3 (18.8)
Previous	7 (50.0)	10 (62.5)
Never	3 (21.4)	3 (18.8)
Comorbidities		
Cardiovascular disease	7 (50.0)	11 (68.8)
Hypertension	9 (64.3)	10 (62.5)
Hypercholesterolemia	11 (78.6)	13 (81.3)
COPD/asthma	2 (14.3)	4 (25.0)
Stroke/TIA	3 (21.4)	2 (12.5)
Kidney disease	2 (14.3)	2 (12.5)
Diabetes	10 (71.4)	5 (31.3)
Cancer	1 (7.1)	4 (25.0)
Musculoskeletal disease	6 (42.9)	5 (31.3)
Medications		
Statins	13 (92.9)	14 (87.5)
Antiplatelet	14 (100.0)	16 (100.0)
Antihypertensive	11 (78.6)	9 (56.3)
Beta-blockers	4 (28.6)	8 (50.0)

Data are presented as count (%) unless otherwise stated.
ABPI, ankle brachial pressure index; COPD, chronic obstructive pulmonary disorder; TIA, transient ischemic attack; SD, standard deviation.

were managed and analyzed using the software package NVIVO (v1.5).

RESULTS

Most participants were Caucasian males, had bilateral PAD, and were former smokers (Table I). Over half had cardiovascular disease, hypertension, and hypercholesterolemia. All were taking antiplatelet medication, and most were prescribed antihypertensive therapy and/or a statin. There were more participants with diabetes in the nonexercise group; however, all other baseline characteristics were similar between groups.

Feasibility

Between May–November 2022, 188 people were screened, of whom 133 (70.7%) were eligible, and 30 consented (22.6%) (Fig. 1). Reasons for exclusion included not owning a smartphone, requiring a walking aid, or asymptomatic PAD. The main reasons for declining participation included lack of interest, walking being too difficult, or lack of time. One participant in the intervention group withdrew after 1 week, stating a change in medication reduced energy levels. Furthermore, 1 participant in the intervention group failed to attend the final reassessment.

All participants in the intervention group wore their Fitbit devices and synchronized with the Fitbit app to upload step data, recording steps for 1,241 out of a possible 1,344 days (92.3%). On average, 53.5% of daily step counts met or exceeded step goals across all participants (range: 29.8–90.5%). Figure 2 shows daily step goals across the 12-week program. Of a possible 384 exercise circuits, 211 (54.9%) were recorded in logbooks. Of these, 119 (56.4%) were completed at the correct intensity. On average, claudication pain ratings and RPEs were 3/4 and 13/20 respectively (see Fig. 3).

Six adverse events occurred during the study; 3 in the intervention group which were related to study participation, including exercise induced angina, light-headedness while exercising, and a diagnosis of plantar fasciitis. The remaining 3 unrelated events

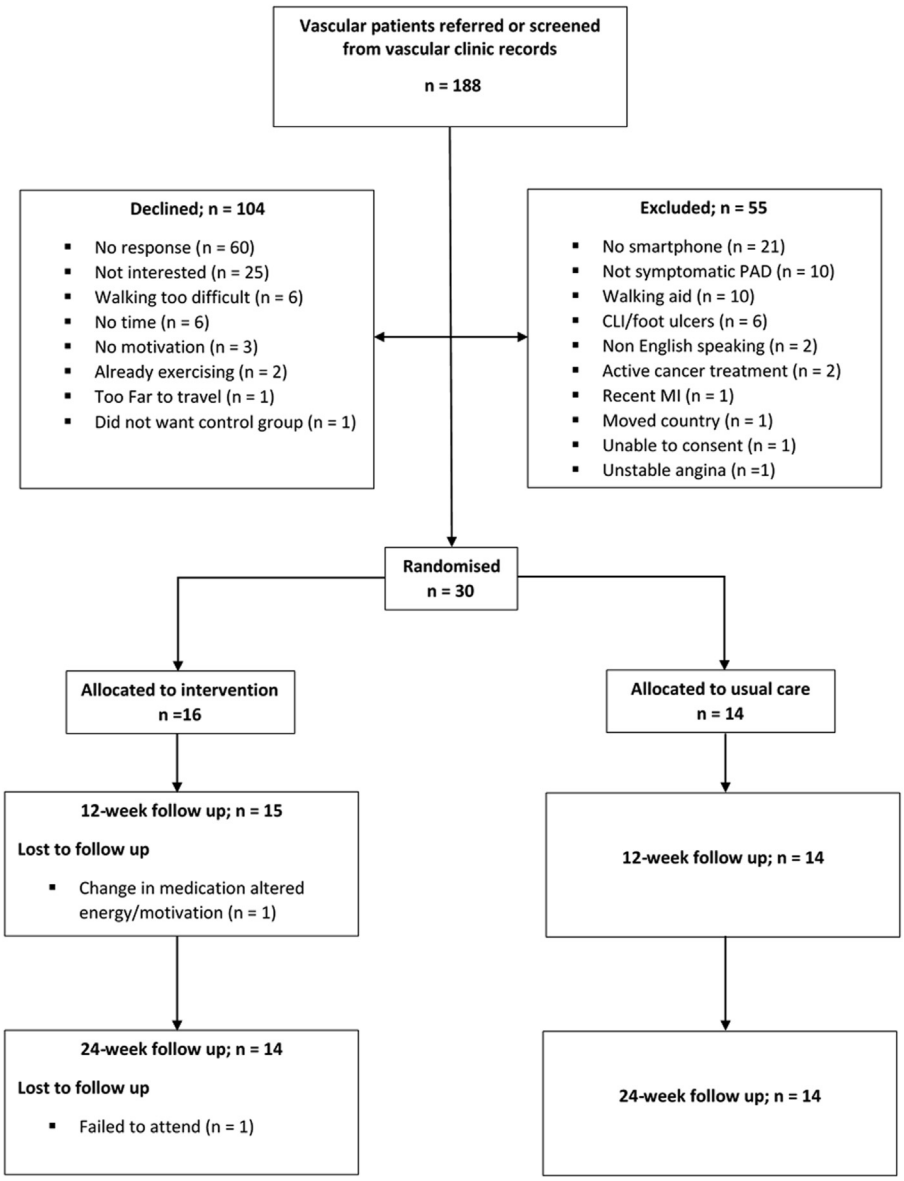

Fig. 1. Participant flow chart.

were in the control group, including a herniated disc and 2 cases of COVID-19 infection. No serious adverse events were reported. Identification of these events will have led to further treatment for participants, and so can be seen as a beneficial outcome.

Acceptability

Only the minimal qualitative dataset required to determine feasibility for a full RCT is reported. The authors plan to publish the full findings at a later date. Semistructured interviews were conducted with 5 participants who completed the intervention, and 4 people who declined participation. The 3 main themes that emerged were: 1) Participant experiences, 2) participant feedback, and 3) facilitators and barriers. Interviews highlighted that the structure of the HBEP was acceptable and was accommodated well into daily life; however, the daily step goals were more enjoyable than the circuits. However, it was reported that the program lacked the community interaction of SEPs. Reasons for declining were largely mental (motivation and wanting to relax in retirement) and physical (comorbidities and pain avoidance). The autonomy/motivation required for unsupervised exercise

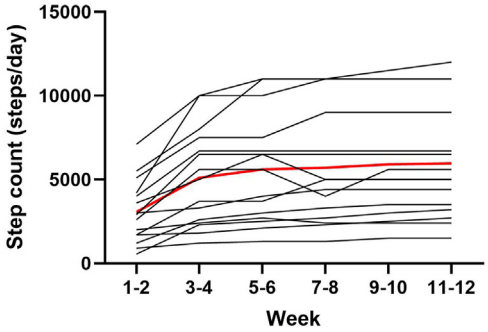

Fig. 2. Daily step goals at each check in for all home-based exercise group participants (black lines) and average step goal at each check in (red line). Step goals were increased at each check in if participants were exceeding their goals over 50% of the days of the preceding 2 weeks.

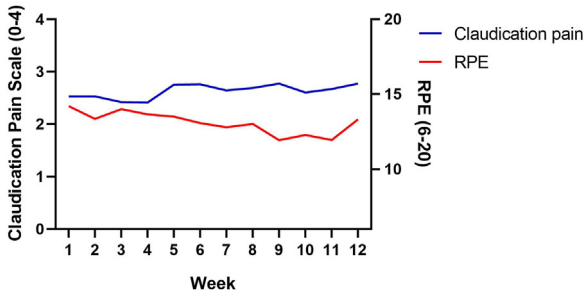

Fig. 3. Average claudication pain rating (blue line) and rating of perceived exertion (red line) during home-based circuits throughout the 12-week exercise program.

was discussed by both groups. Those who completed the program noted improvements in symptoms and stated they had sustained an increase in physical activity beyond the end of the study.

Secondary Outcomes

Two participants did not return questionnaires and accelerometers. Treadmill and 6-min walk tests were not performed for 14% and 8% of visits respectively due to participants being ineligible to exercise at the time of reassessment. Blood samples were unobtainable for 30% of visits due to an inability to locate suitable veins.

There were no significant differences in any exploratory outcomes either between or within groups at 12- and 24-weeks (Table II/ Supplementary Table 1); however, minimally clinically important differences (MCID) were seen in walking speed in the intervention group[35] and pain-free treadmill walking distance in both groups.[36]

DISCUSSION

We aimed to assess the feasibility of conducting a full scale RCT of the WALKSTRONG program. The study was successful with satisfactory participant recruitment and retention. The program was generally viewed as acceptable by participants; however, adherence and compliance with the intervention varied.

Recruitment was successful, with a similar rate to that of another feasibility trial for IC.[37] The low participant attrition is also consistent with studies of similar design/size.[17,22,37] This shows people with IC are willing to participate in HBEPs. Adherence to wearing a Fitbit was high; however, adherence to the circuit was lower, supported by the interview data revealing the circuits to be less enjoyable than the daily walking. This was similar to Cornelis et al.,[22] who reported that home-based resistance band exercises were less enjoyable than walking. A potential explanation is that 60% of participants in Cornelis et al. experienced movement related fear of pain (kinesiophobia). As the walking bouts in the circuits were designed to elicit severe claudication pain, this could present significant challenges for participants and, if so, may explain our poor adherence. Although pain avoidance was a reason for declining participation, it was not mentioned by any of the completers in our study. This may indicate a bias in our cohort, where those who agreed to participate were less pain averse, and therefore not as likely to report issues with the claudication pain intensity of the program.

Yet compliance with the prescribed circuit intensity and daily step goals were poor in the present study. Although participants' step count targets were higher after 12-weeks compared to baseline, this tended to plateau halfway through the program (see Fig. 2). This could indicate gains in physical activity occur early on in a program, and that the remaining weeks should prioritize maintaining these changes. However, a more likely explanation may be that after 4–6 weeks, motivation, and thus compliance began to suffer. Poor compliance may be due to the lack of supervision, or check-ins being every other week, rather than weekly, thus only those with motivation to exercise independently were likely to adhere/comply. The HONOR program had telephone check-ins progressively phased out over the course of the intervention,[38] and did not demonstrate improvements to walking performance, reinforcing the importance of regular contact with the research team. This also highlights

Table II. Mean difference for exploratory outcomes from baseline to follow-up time points by treatment arms

	Baseline to 12-weeks (95% CI)		Baseline to 24-weeks (95% CI)	
Variable	Nonexercise	HBEP	Nonexercise	HBEP
Six minute walk test				
PFWD (m)	9.83 (−36.4 to 56.1)	13.5 (−53.7 to 80.8)	−0.77 (−52.1 to 50.6)	−35.9 (−99.6 to 27.9)
MWD (m)	5.97 (−12.3 to 24.2)	4.11 (−16.5 to 24.7)	1.36 (−24.4 to 27.1)	3.61 (−28.7 to 35.9)
Speed (m/s)	−0.02 (−0.10 to 0.06)	0.04 (−0.01 to 0.08)	−0.02 (−0.11 to 0.07)	0.04 (−0.03 to 0.11)
Graded treadmill test				
PFWD (m)	63.0 (12.3−114.0)	49.5 (−77.0 to 176.0)	34.6 (−33.0 to 102.0)	71.2 (−85.3 to 228.0)
MWD (m)	39.5 (−14.3 to 93.2)	12.8 (−40.8 to 66.4)	51.2 (−11.1 to 114.0)	−0.16 (−55.1 to 54.8)
Functional test				
Grip strength (kg)	1.50 (−0.77 to 3.77)	1.67 (−0.15 to 3.49)	1.43 (−0.39 to 3.25)	0.5 (−2.12 to 3.12)
Physical activity				
Daily step count (steps/day)	−483.0 (−1,287.0 to 322.0)	−226.0 (−647.0 to 195.0)	−642.0 (−1,618.0 to 334.0)	−66.6 (−723.0 to 590.0)
MVPA (min)	−19.2 (−62.6 to 24.1)	−22.0 (−44.1 to 0.01)	−20.7 (−68.8 to 27.4)	−31.1 (−64.7 to 2.50)
Quality of life				
VascuQol	−0.08 (−0.53 to 0.36)	−0.02 (−0.61 to 0.57)	0.17 (−0.33 to 0.66)	0.14 (−0.28 to 0.55)
SF-36 PCS	0.36 (−3.12 to 3.85)	0.18 (−2.95 to 2.59)	−0.72 (−4.97 to 3.54)	0.30 (−4.11 to 3.52)
SF-36 MCS	−1.98 (−6.72 to 2.76)	−0.36 (−5.88 to 5.17)	2.89 (−3.11 to 8.88)	0.92 (−3.53 to 5.37)
EQ-5D-5L	−0.04 (−0.17 to 0.09)	−0.06 (−0.23 to 0.12)	0.01 (−0.05 to 0.08)	−0.03 (−0.22 to 0.17)
EQ-5D-5L VAS	−3.93 (−12.0 to 5.14)	0.08 (−8.24 to 8.39)	−5.93 (−16.7 to 4.80)	0.46 (−12.9 to 13.9)
Biomarkers				
hsCRP (mg/mL)	−5.55 (−19.0 to 7.94)	2.80 (−1.00 to 6.61)	−5.56 (−19.4 to 8.28)	0.81 (−0.03 to 1.64)
IL-6 (pg/mL)	−0.29 (−1.80 to 1.22)	0.64 (−1.03 to 2.31)	−0.36 (−1.02 to 0.30)	0.06 (−0.41 to 0.53)
TNF-a (pg/mL)	1.19 (−0.23 to 2.62)	−0.89 (−3.18 to 1.39)	0.57 (−0.30 to 1.44)	−0.11 (−0.84 to 0.62)
VEGF (pg/mL)	19.0 (−7.01 to 45.1)	−9.28 (−35.8 to 17.3)	7.29 (−10.4 to 25.0)	−0.08 (−6.71 to 6.55)

HBEP, home-based exercise program; PFWD, pain-free walking distance; MWD, maximum walking distance; MVPA, moderate-vigorous physical activity; PCS, physical composite score; MCS, mental composite score; VAS, visual analog scale; hsCRP, high sensitivity c-reactive protein; IL-6, interleukin 6; TNF-a, tumor necrosis factor alpha; VEGF, vascular endothelial growth factor.

the importance of integrating robust behavior change strategies and techniques into HBEPs. e.g., the GOALS program was an HBEP that had participants meet as a group weekly, where they would discuss goal setting/self-monitoring, utilizing social cognitive theory.[39] However, requiring onsite visits to promote behavior change may create additional travel barriers. Both the HONOR and LITE trials implemented remotely monitored coaching; however, on-site sessions were still utilized for the first month.[19,38] This might suggest that only those most motivated to exercise should be offered a fully remote HBEP. Further research may be required to determine the effectiveness of entirely online behavioral coaching in this population. Addressing the issues with compliance in this way may also prevent the decline in pain-free walking distances observed after 24 weeks.

No significant changes were seen in any secondary clinical outcomes; however, this study was not designed/powered to provide definitive evidence of clinical benefit. Lack of benefit could have been due to poor intervention compliance. However, a similar study, also with poor compliance, demonstrated significant improvements in claudication pain onset time and cardiorespiratory fitness.[17] A reported explanation was that participants were walking quicker in daily living. However, in the present study, a small MCID was seen in walking speed[35] following the intervention, yet significant improvements to walking performance were not observed. This discrepancy is likely due to the different contexts in which walking speed was seen to increase. In the present study, walking speed was measured during a 6-min walk test, where a participant would walk faster to try and increase their distance. In the study by Duscha et al., walking was seen to increase in daily living, being more moderately to vigorously active, representing a greater tolerance to exercise, which may explain why it translated to improvements in walking performance and cardiorespiratory fitness. A lack of blinding of researchers by Duscha et al. may also explain the greater improvements observed. Gardner et al.[16] also demonstrated significant improvements in a wide range of clinically relevant outcomes. In addition to having onsite visits, exercise prescription was monitored using step cadence and duration, rather than just a logbook. Therefore, researchers had more detailed information on exercise volume, which, combined with onsite visits, may have motivated participants to adhere. Given the present study utilized a Fitbit, circuits could have been prescribed using the heart rate of claudication onset.[40] However, this would have required more onsite visits, further reinforcing the issue of travel barriers.

This study is not without limitations. Although some self-monitoring and self-regulation is required when utilizing WAMs, no specific behavior change strategies or techniques were implemented. As previously mentioned, an entirely remote form of behavioral coaching may not provide any additional benefit, and onsite coaching would require further travel. With participants volunteering, some selection bias existed, as several participants had previously completed a SEP, although all were still symptomatic. We recruited low numbers of females and non-Caucasians; however, the included participants are generally representative of the UK IC population.[41] Additionally, information regarding disease location (i.e. iliac and/or tibial arteries) was not available, limiting analysis on whether this affected engagement with or response to exercise.

The WALKSTRONG program was well tolerated and feasible, with an acceptable recruitment rate and minimal attrition. The intervention was viewed as acceptable to participants, although walking was seen as more enjoyable than circuit exercise. Our data have provided early indications that a program of resistance training and walking, monitored with a WAM may be beneficial. Future iterations should explore remotely delivered behavioral coaching and virtual familiarization sessions to improve compliance. With more research as part of a fully powered trial, this HBEP may be a valid alternative for those with IC who are motivated to exercise, but are unable to attend a SEP.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Alexander Waddell: Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Conceptualization. **Francesca Denton:** Writing – review & editing, Investigation. **Richard Powell:** Writing – review & editing, Investigation. **David R. Broom:** Writing – review & editing, Conceptualization. **Stefan T. Birkett:** Writing – review & editing, Conceptualization. **Gordon McGregor:** Writing – review & editing, Conceptualization. **Amy E. Harwood:** Writing – review & editing, Conceptualization.

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SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.avsg.2024.01.016.

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