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A randomized controlled feasibility trial of a home-based walking behavior–change intervention for people with intermittent claudication

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Walking treatment is recommended for improving intermittent claudication (IC), a debilitating symptom of leg pain caused by peripheral arterial disease. However, center-based exercise programs offered in a community or hospital setting are often not implemented or adhered to. We developed a home-delivered behavior-change intervention, MOtivating Structured walking Activity in Intermittent Claudication (MOSAIC), to increase walking in people with IC. A feasibility randomized controlled trial with nested qualitative interviews involving a subsample of trial participants was conducted. Feasibility criteria evaluated participant recruitment and retention; suitability of proposed outcome measures; and acceptability and adherence to the intervention and trial. Participants (adults aged ≥18 years diagnosed with IC identified from vascular outpatient clinics) were randomized 1:1 to receive MOSAIC treatment (two 60-minute home-based sessions and two 20-minute booster telephone calls incorporating behavior-change techniques) or an attention-control comparison. Outcomes (baseline and 16-week follow-up) included the 6-minute walking distance (meters), pedometer-assessed daily walking activity (steps/d), health-related quality of life, physical functioning, and beliefs about walking treatment, peripheral arterial disease, and self-regulatory processes. Twenty-four participants (mean age: 66.8 ± 9.4 years, 79% male) were included. Feasibility criteria achieved were recruitment rate (25%), participant retention (92%), and adherence to assigned treatment or attention-control sessions (71%). Missing data rates were <10% for all outcomes except for baseline daily walking activity (36%). The trial protocol and interventions were acceptable to participants and the clinician. In conclusion, the MOSAIC trial was feasible to conduct, with the exception of high missing pedometer data. The intervention is an acceptable approach to facilitate walking among people with IC. (J Vasc Nurs 2018;37:135-143)

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INTRODUCTION

Peripheral arterial disease is a vascular condition characterized by atherosclerotic narrowing or occlusion in the arteries of the lower limb, which affects up to 20% of older adults.[1] A common symptom of peripheral arterial disease is intermittent claudication, a debilitating ischemic leg pain that occurs during walking. Intermittent claudication contributes to reduced mobility, low quality of life, and increased cardiovascular risk,[2,3] and it is therefore an important but complex condition to manage.

Guidelines recommend walking as the first-line treatment for all patients presenting with intermittent claudication,[4] comprising 30 minutes of supervised exercise on at least 3 days per week, at an intensity eliciting moderate symptoms within 3–5 minutes. However, recommendations are often not implemented due to the costs and expertise required to initiate and deliver a center-based program, such as those offered in a community or hospital setting.[5] Instead, patients often receive simple "go home and walk" advice from a clinician, which is varied and ineffective.[6,7] Home-based exercise programs offer structure and supervision beyond simple walking advice and may overcome barriers related to travel and accessibility,[8] particularly among patients with limited mobility. In addition, most people with intermittent claudication report a preference for home-delivered exercise.[9] However, evidence from systematic reviews is limited and inconsistent and suggests that home-

based exercise is not effective.[10] One reason for this may be that few such programs have incorporated theory-based strategies to change behavior and enable uptake and long-term walking adherence required to sustain benefits.[11,12]

Essential conditions for individual behavior change include positive and accurate beliefs about peripheral arterial disease (eg, illness perceptions defined by the Common Sense Model of Illness Representations[13]) and walking treatment (eg, beliefs defined by the Theory of Planned Behavior[14]). Positive beliefs about walking defined by the Theory of Planned Behavior have been associated with greater motivation to walk, self-reported walking activity, and walking capacity in people with intermittent claudication.[15,16] In addition, illness perceptions including beliefs about the controllability and cause of peripheral arterial disease (PAD) and patients' understanding of their PAD have been associated with greater walking capacity.[16] Therefore, the Common Sense Model of Illness Representations and Theory of Planned Behavior provide useful models to underpin a walking behavior–change intervention for people with intermittent claudication.

Behavior-change techniques are strategies that help to translate theoretical determinants into practice.[17] Examples of behavior-change techniques include simple tasks such as setting walking goals, learned skills including action planning (planning when, where, and how to walk), or complex approaches delivered by qualified clinicians including motivational interviewing (exploring ways to minimize resistance and ambivalence toward increasing walking). Home-delivered exercise programs incorporating behavior-change techniques are recommended for people with intermittent claudication[11] and could contribute to the development and evaluation of robust and feasible walking programs.

Therefore, a brief, structured, home-delivered walking behavior–change intervention, MOtivating Structured walking Activity in Intermittent Claudication (MOSAIC), was systematically developed.[18] MOSAIC builds on previous research[19] and has been refined based on the developmental work[12,20] and stakeholder feedback, including consultation with PAD patients and health-care professionals to improve the potential for implementation. The aim of this study was to evaluate the feasibility of a two-arm, single-blind, randomized controlled trial comparing MOSAIC to an attention-control consistent with Consolidated Standards of Reporting Trials (CONSORT) guidelines,[21] which is an evidence-based, minimum set of recommendations for reporting randomized trials and facilitates complete and transparent reporting, critical appraisal, and interpretation.

Specific feasibility objectives explored are participant recruitment and retention; suitability of proposed measures to inform the selection of a primary outcome; and the acceptability of and adherence to the MOSAIC intervention and trial. Feasibility criteria are defined in Table 1.

METHODS

Study design and research governance

A two-arm single-blinded feasibility randomized controlled trial was conducted, with a nested qualitative study (study registration: ISRCTN55465549). The nested qualitative study involved a subsample of participants of the trial and allowed the exploration of participants' and a clinician's experiences of receiving or delivering the intervention and participating in the trial between April and October 2014. This work was supported by The Dunhill Medical Trust (grant number: RTF09/0110). Ethical and research governance approval was obtained from the UK Health Research Authority National Research Ethics Service (reference 14/NW/0089) and King's College Hospital and Guy's & St Thomas' Hospital NHS Foundation Trusts, London, UK. The investigation conforms with the principles outlined in the Declaration of Helsinki.

Participants

Potential participants who completed a previous observational study[16] were identified from vascular outpatient clinics at two NHS Hospital Foundation Trusts in London, UK, and screened for eligibility. The inclusion criterion was adults aged ≥18 years with a diagnosis of peripheral arterial disease and intermittent claudication established by a vascular clinician and confirmed by the response to the San Diego Claudication Questionnaire.[24] Exclusion criteria were asymptomatic peripheral arterial disease or rest pain established by the San Diego Claudication Questionnaire; revascularization scheduled in the upcoming 4 months; comorbidity other than intermittent claudication self-reported as the primary limitation of walking; contraindication to walking; and/or inability or refusal to provide informed consent.

Interventions

MOSAIC is a theory-based intervention underpinned by the Common Sense Model of Illness Representations[13] and Theory of Planned Behavior[14] and thus seeks to engender accurate and positive patient beliefs about their illness and walking. These objectives were achieved through motivational interviewing, a collaborative and compassionate communication approach designed to increase personal motivation and commitment to behavior change.[25] The MOSAIC treatment comprised behavior-change techniques targeting walking[17] (Supplementary Table 1), which were incorporated based on their correspondence with constructs from the theories underpinning MOSAIC and evidence for techniques that may be useful when targeting walking in this population.[12] MOSAIC treatment was delivered over 12 weeks and included two 60-minute individual face-to-face sessions (weeks 1 and 2) at participants' homes and two 20-minute booster telephone calls (weeks 6 and 12). After week 12, the aim was for participants to continue a program of self-directed activity without supervision. A physiotherapist received 7.5 hours of group training in motivational interviewing (British Psychological Society accredited), 7.5 hours of individual training in MOSAIC behavior-change components and delivery, including role-play with feedback provided by the study investigators, and regular supervision and feedback via email and telephone to support treatment fidelity.

The attention-control targeted dietary behavior based on British Heart Foundation recommendations[26] and mirrored the mode of delivery, frequency, and duration of MOSAIC sessions. The attention control was designed according to recommendations[27] to isolate the effect of walking behavior–change techniques by balancing the duration and mode (ie, face-to-face and telephone interactions) of contact with the clinician between groups.

Outcomes

Outcomes were assessed at baseline and 16-week follow-up by a blinded assessor (M.N.G.H.) during a 90-minute appointment at the School of Population Health & Environmental Sciences, King's College London (London, UK). There was no treatment delivered to

TABLE 1

OBJECTIVES AND CRITERIA USED TO EVALUATE THE FEASIBILITY OF THE MOSAIC TRIAL AND INTERVENTION

Feasibility objectives	*Feasibility criteria*	*Feasibility outcome*
To evaluate study recruitment and retention of participants	A target sample of 24 participants (25% recruitment from initial cohort) will be achieved.	Achieved (n = 24, 25% recruitment rate)
	Study retention at 16-wk follow-up will be at least 60% (n = 14/24)[12,22]	Achieved (92% study retention at 16-wk follow-up)
To explore the suitability of proposed measures and identification of the primary outcome	Missing data at each time point will be less than 10% for each outcome[23].	Achieved in part: missing data <10% was achieved for 6-minute walking distance, and all patients reported outcome measures at baseline and 16-wk follow-up and for pedometer-based daily walking activity at 16-wk follow-up. However, missing data rate was 36% for baseline daily walking activity
	Sufficient data will be collected to explore change and responsiveness of objective walking outcomes.	Achieved: daily walking activity increased after treatment and decreased after attention control and was more responsive than the 6-minute walking distance, whereas the opposite pattern was found for the 6-minute walking distance, which was a less responsive outcome.)
To explore adherence to and acceptability of the MOSAIC interventions and trial protocol	At least 60% (n = 14/24) of participants will complete all treatment and attention-control sessions.	Achieved (71% adherence to protocolized sessions)
	Participants and the clinician will report positive experiences of MOSAIC treatment and the study protocol.	Achieved (narrative reports were positive and constructive)

MOSAIC = MOtivating Structured walking Activity in Intermittent Claudication.

participants between the 12-week MOSAIC booster call and 16-week follow-up assessment; this brief gap enabled evaluation of the short-term sustained effects of MOSAIC treatment on outcomes.

Sociodemographic and clinical characteristics (baseline only) were assessed by self-report and included age, gender, ethnicity, smoking status, cardiovascular risk factors, medication for intermittent claudication, symptom duration, walking advice, past participation in supervised exercise therapy, and lower-limb symptom classification established using the San Diego Claudication Questionnaire.[24]

Two potential primary outcomes were considered: 1) Walking capacity was defined as the 6-minute walking distance (meters) assessed during a standardized 6-minute walk test,[22] and 2) Daily walking activity was measured by the mean daily step count assessed over 6 days using a triaxial pedometer worn on the hip (Omron Walking Style Pro 2.0; HJ-322U-E, Omron Healthcare UK, Ltd, Milton Keynes, UK). Participants were given written and verbal instructions on how and when to wear the pedometer at their baseline and follow-up assessments. They were also instructed to return the pedometer after the 6-day data-collection period in an anonymous envelope by prepaid post or at baseline only via handover to the visiting clinician during their first treatment session. A 6-day data-collection period was implemented to capture a combination of weekdays and weekends and because this allowed practical

collection of pedometers by the clinician at the 1-week MOSAIC treatment session. Pedometers were not provided and used as part of the MOSAIC treatment.

Patient-reported outcome measures included daily physical activity (Baltimore activity scale for intermittent claudication),[28] quality of life (Medical Outcomes Survey Short Form-12 version 2),[29] walking treatment beliefs (validated 23-item Theory of Planned Behavior Questionnaire),[30] illness perceptions (Revised Illness Perception Questionnaire),[31] and self-regulatory processes (validated 10-item questionnaire)[32] assessed at baseline and 16 weeks.

On completion of the feasibility trial, a subsample of participants and the clinician were invited to an audio-recorded semistructured interview, which followed a topic guide exploring the acceptability of the trial procedures and the intervention received. Participants were purposively sampled by group allocation, ethnicity (white vs other), gender, past supervised exercise therapy, and median age of sample (<66 vs ≥66 years) to a target sample of 12 or until data saturation was achieved. Interviews were conducted by a single researcher (M.N.G.H.) who maintained a reflexive diary.

Sample size and randomization

As this was a feasibility study, a power calculation was not conducted, and a convenience sample of 24 participants was targeted. After obtaining informed consent and completion of baseline assessments, participants were randomly allocated to either MOSAIC or an attention-control group by simple balanced two-way randomization. The randomization sequence was determined using an online random-number generator (www.randomizer.org) to produce an output of 12 allocations per group and was retained by the principal investigator (L.M.B.). The outcome assessor notified the principal investigator by email when a participant completed their baseline assessment, and the principal investigator then allocated the participant to the next consecutive group on the list.

Analyses

Statistical analyses were conducted using the SPSS Statistics Software version 21.0 (IBM Statistics Inc, Armonk, NY). Sociodemographic and clinical characteristics are presented as means ± standard deviation (SD) for continuous variables and frequencies (%) for categorical variables. The rate of missing data was defined as the proportion (%) of participants with incomplete data for a variable at a given assessment time point. Change scores from baseline to 16-week follow-up for 6-minute walk distance and daily walking activity are reported as absolute (mean ± SD) and relative (%) scores. To explore responsiveness of the 6-minute walk distance and daily walking activity outcomes, the standardized response mean was calculated as the mean change scores divided by the SD of the change scores of the MOSAIC treatment arm.

Qualitative thematic content analysis of transcribed audio-recorded interviews was conducted using NVivo 9 (QSR International Ltd, Southport, UK) following a recommended protocol.[23] Themes were member-checked with participants to support resonance and validity.

RESULTS

Participant recruitment and retention

Among a cohort of 94 patients, 33 could not be contacted, 15 declined to be screened, and 46 were screened for eligibility. A target sample of 24 met the eligibility criteria and were enrolled onto the study (Figure 1). There were no differences between those enrolled and those who declined or were ineligible in terms of age (mean 66.8 vs 67.4 years) or gender (24% of men vs 33% of women invited). The mean age of the participants was 66.8 years (SD = 9.4, range: 52–90), and the majority were male (n = 19/24) and of white ethnicity (n = 19/24). There were no substantial differences in sociodemographic or clinical characteristics at baseline between participants in either study group (Table 2).

Figure 1 illustrates how the target recruitment rate of 25% was achieved from the source population and overall study retention at 16-week follow-up of 92% (n = 22/24). All MOSAIC treatment group participants were retained to follow up. One participant in the attention-control group was undergoing cancer screening and reported this new health issue as a priority, so withdrew from the study. A second participant in the attention-control group rescheduled his follow-up appointment twice, but did not attend; no reason was given. Participants lost to follow-up were younger than those who completed the study (mean ± SD: 57.0 ± 2.8 years vs 67.6 ± 9.8 years, respectively) and were both male.

Suitability of proposed measures

Missing data rates for all patient-reported outcomes was <10% at each time point, and there were no missing data for the 6-minute walk distance; therefore, feasibility criteria were achieved for these outcomes.

By contrast, missing data rates were 36% (4 treatment and 4 attention-control groups) and 9% (1 treatment and 1 attention-control group) for daily walking activity at baseline and 16 weeks, respectively. At baseline, one participant (MOSAIC) dropped and damaged the pedometer, and two participants (one MOSAIC and one attention-control group) returned their pedometers 1 day early. There were no reasons given for missing baseline pedometer data by the remaining participants. At 16 weeks, one participant (MOSAIC) returned the pedometer one day early due to travel plans and one (attention-control group) returned the pedometer after the device's 21-day data storage window.

Change scores for patient-reported outcomes and their associations with the 6-minute walking distance and daily walking activity are illustrated in Supplementary Table 2. The SF-12v2 mental component summary score increased from baseline in the MOSAIC treatment group (mean ± SD change: 2.76 ± 3.56) and decreased in the attention control (mean ± SD change: −2.07 ± 7.90). By contrast, the physical component summary score decreased from baseline in the treatment group (1.16 ± 5.09) and increased in the attention-control group (mean ± SD change: 6.7 ± 7.0). Walking treatment beliefs (Theory of Planned Behavior constructs), illness perceptions (Common Sense Model of Illness Representations constructs), and self-regulatory processes were positive after the MOSAIC treatment compared with baseline, with the exception of the following Common Sense Model of Illness Representations constructs: identity and cyclical timeline which were unchanged and personal control which was declined. By contrast, patterns of change in psychosocial outcomes in the attention-control group were variable. The magnitudes of the associations between daily walking activity and 6-minute walking distance was r = 0.82 and

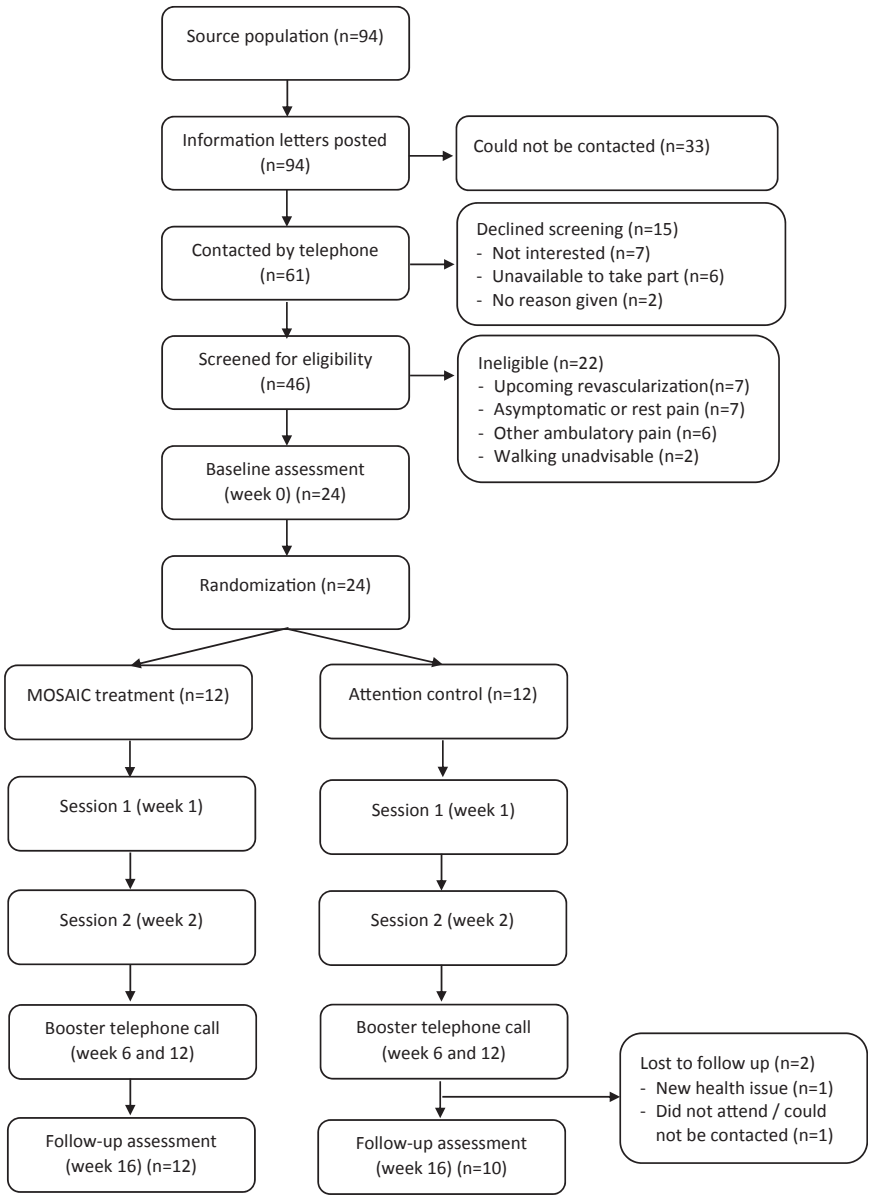

Figure 1. *Flow of participants through the MOSAIC feasibility randomized controlled trial. MOSAIC = MOtivating Structured walking Activity in Intermittent Claudication.*

r = 0.59 for the treatment and attention-control groups, respectively. Associations between psychosocial constructs and walking outcomes were variable (Supplementary Table 2).

The 6-minute walking distance decreased from baseline to 16-week follow-up in participants in the MOSAIC group (mean: −8.52 m [SD = 42.29], −4.24%; n = 12) and increased in the attention-control group (mean: 9.88 m [SD = 42.15], 1.01%; n = 10). The standardized response mean for 6-minute walking distance change scores in the MOSAIC group was 0.20 (Table 3).

Daily walking activity increased from baseline to 16-week follow-up in the MOSIAC group (mean: 836.91 steps/d [SD = 625.83], 29.98%; n = 6) and decreased in the attention-control group (mean: −29.47 steps/d [SD = 1471.43], −2.41%; n = 7). The standardized response mean for daily walking activity change scores among the MOSAIC group was 1.34 (Table 3).

Acceptability of and adherence to the MOSAIC intervention and trial

Adherence to the allocated treatment was 67% (8/12) for MOSAIC group and 90% (n = 9/10) for the attention-control group. All participants completed sessions 1 and 2 delivered via home visits. However, 4 participants in the MOSAIC group and 2 participants in the attention-control group did not receive one booster telephone call because their phone was not answered at the scheduled appointment time and they could not be reached to reschedule the call before their follow-up assessment.

Narrative accounts by 12 participants (6 from MOSAIC and 6 from attention-control group) and the clinician demonstrated the acceptability of the trial and treatment protocol and included suggestions to improve the program in future. Four themes were identified from the qualitative interviews: 1) acceptability of

TABLE 2

BASELINE SOCIODEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF PARTICIPANTS IN THE MOSAIC FEASIBILITY TRIAL

Variable	*Treatment, n (%)*	*Attention Control, n (%)*
Age	66.3 ± 8.8*	67.1 ± 11.2*
Body mass index, kg/m^2	28.6 ± 5.0*	26.5 ± 5.0*
Male gender	9 (75.0)	10 (83.0)
Married	6 (50.0)	7 (58.3)
White ethnicity	11 (91.6)	9 (75.0)
Current smoker	4 (33.3)	6 (50.0)
Cardiovascular risk factors		
Diabetes	3 (25.0)	4 (33.3)
Hypertension	10 (83.3)	8 (66.7)
Dyslipidemia	8 (66.7)	5 (38.5)
Cardiovascular disease	8 (66.7)	4 (33.3)
Pharmacological pain management	2 (16.6)	1 (8.3)
Walking advice	6 (50.0)	7 (58.3)
Past supervised exercise therapy	5 (38.5)	3 (25.0)
Past revascularization	1 (8.3)	2 (16.6)
Lower-limb symptom classification		
Atypical intermittent claudication	7 (58.3)	6 (50.0)
Classic intermittent claudication	5 (38.5)	6 (50.0)
Duration of intermittent claudication < 1 y	1 (8.3)	0

MOSAIC = MOtivating Structured walking Activity in Intermittent Claudication; SD = standard deviation.

n = 24 (12 per group).

*Data are mean ± SD.

TABLE 3

BASELINE, 16-WK FOLLOW-UP AND CHANGE SCORES FOR 6-MINUTE WALKING DISTANCE AND DAILY WALKING ACTIVITY

Outcome	*Treatment, mean ± standard deviation*	*Attention control, mean ± standard deviation*
6-Minute walking distance		
Participants	12*	10*
Baseline, meters	390.44 ± 101.81	378.05 ± 157.06
Follow-up, meters	381.92 ± 113.51	387.93 ± 161.84
Change, meters	−8.52 ± 42.29	9.88 ± 42.15
Change, %	−4.23 ± 12.56	1.01 ± 13.346
Standardized response mean	0.20	Not applicable
Daily walking activity		
Participants	6*	7*
Baseline, steps/d	2247.02 ± 1652.05	4343.28 ± 3098.87
Follow-up, steps/d	3083.94 ± 1882.59	4313.80 ± 1113.45
Change, steps/d	836.91 ± 625.83	−29.47 ± 1471.43
Change, %	29.98 ± 17.57	−2.41 ± 40.81
Standardized response mean	1.34	Not applicable

*Data are the valid numbers of participants.

the research process and protocol, 2) acceptability of the treatment and attention-control interventions, 3) perceived expectations and outcomes of the treatment and attention-control interventions, and 4) clinician's role as a person and professional (Supplementary Table 3). There were no reported harms or potential adverse events.

DISCUSSION

This study demonstrated the feasibility and acceptability of a two-arm randomized controlled trial comparing a behavior-change intervention targeting walking to an attention control among people with intermittent claudication. Criteria reflecting recruitment, retention, and adherence to the protocol and interventions were achieved. Results additionally inform the selection of suitable primary and secondary outcomes and aspects of the protocol which could be improved.

Study retention was high (92% overall) compared with other home-based walking interventions for intermittent claudication, which report rates at 12 or 24 weeks ranging from 61% to 100%.[12,33] A target recruitment rate of 25% was achieved, enabling successful piloting of screening procedures. Participants were drawn from a limited cohort previously recruited to an observational study, and so the recruitment rate

and timeframe should be adjusted when planning a full-scale trial, taking into account known challenges to recruiting people with intermittent claudication to exercise trials.[34,35] However, successful enrollment to the initial observational study[16] demonstrated that people with intermittent claudication could be identified from the vascular outpatient setting and were interested, willing, and available to participate in research exploring walking as treatment for their condition.

There were no missing 6-minute walking distance data at any time points, suggesting that this is a robust and feasible outcome measure. The 6-minute walking distance is a valid, reliable, and sensitive measure of functional capacity in individuals with cardiovascular diseases[36] and correspondent with accelerometer-derived daily physical activity in people with intermittent claudication,[37] providing a meaningful indicator of activity. In addition, our participants reported completing the walk test as acceptable.

Pedometer-measured daily walking activity provided a more responsive outcome than the 6-minute walking distance; this is likely because daily walking activity is a direct target of the intervention, reflecting behavior change, and a more proximal outcome. However, it was a less feasible measure due to a high proportion of missing baseline data. Interestingly, missing pedometer data were lower and within the feasibility criteria at follow-up assessment. This may be due to a learning effect, which could be addressed by further instruction and practice using the pedometer with the patient at baseline. Alternatively, study participation may have increased motivation or the likelihood of remembering to wear the pedometer. Another solution to improve data collection may be the use of advanced technologies, such as wrist-worn devices with in-built sensors which are acceptable and validated in older people with cardiovascular conditions[38] and capture physical activity data beyond simple step count. Alternately, there may be a scope for using pedometers or other devices as motivational self-monitoring tools comprising a part of the MOSAIC treatment rather than an outcome measure.

Despite missing data, it was possible to explore the magnitude of change for both walking outcomes. The MOSAIC group increased daily walking activity by a mean 836 steps/d, which corresponds with other pedometer-based interventions.[39,40] In older adults and individuals with long-term conditions, including peripheral arterial disease, 30 minutes of walking is approximately equivalent to 3000 steps, assuming an average cadence of 100 steps/min.[39] Accordingly, participants in the MOSAIC group increased daily walking activity by a mean 8.6 min/d or approximately 60 min/wk.

By contrast, the 6-minute walking distance decreased after MOSAIC and increased in the attention-control group. This might be explained because the change in daily walking activity was below the walking guideline threshold for people with intermittent claudication (ie, 30 minutes on at least 3 d/wk or 90 min/wk),[4] so it was unlikely to be sufficient to improve the 6-minute walking distance. This explanation is consistent with a meta-analysis of trials investigating the effect of interventions using motivational interviewing, which demonstrated a small effect on physical activity, but not physical function in people with long-term conditions.[41] The challenge of achieving walking guidelines might be addressed by adding behavior-change techniques, such as graded tasks (eg, gradually increasing walking goals until 30 minutes is achieved), and providing feedback on the outcome of walking (eg, explicit feedback on symptom improvements).[17]

Qualitative data provide insight into the potential for MOSAIC to facilitate a collaborative therapeutic relationship between the patient and clinician, which may enable patient adherence to MOSAIC, satisfaction, and self-management.[42]

This study has several strengths. The feasibility success criteria included quantitative and qualitative data. MOSAIC was developed systematically and informed by previous findings and stakeholder feedback from patients with intermittent claudication and a clinician. Validated self-reported and objective measures of recommended outcomes for trials of vascular patients were explored,[43] including psychosocial factors and walking which provided clinically meaningful outcomes for efficacy and process evaluations. This intervention is consistent with recommendations for a case-management approach,[44] providing tailored and flexible care, targeting healthy lifestyle changes according to evidence-based recommendations for management of intermittent claudication.

Limitations include recruitment of one clinician only, which meant the feasibility of training and treatment delivery is not generalizable; however, in-depth qualitative data provided by the clinician regarding MOSAIC delivery were corroborated by experiences of patients. Our sample drawn from participants of a previous study might have been motivated to participate, increasing the risk of selection bias. Our small sample data were insufficient to inform a power calculation for a definitive trial; however, findings highlight feasibility of the 6-minute walking distance as a primary outcome, and our observational data including a larger sample (n = 142)[16] using this measure can inform future sample size. Randomization took place before completion of baseline pedometer data collection, which was carried out over the subsequent 6-day period. Therefore, this outcome was not a requisite for enrollment, contributing to the volume of missing data. We did not evaluate treadmill-walking performance as a potential outcome measure based on evidence that corridor-based walking outcomes (such as the 6-minute walking distance) are more acceptable to people with intermittent claudication and better reflect daily walking activity.[37] We were unable to evaluate mediating effects of change in theoretical constructs or behavior-change techniques.

In conclusion, a randomized trial of a brief walking behavior–change intervention for people with intermittent claudication was feasible. MOSAIC was acceptable to participants, and by incorporating explicit behavior-change techniques, it may address the need for effective home-based exercise programs for people with IC.[10] This trial does not provide conclusions about the efficacy of MOSAIC treatment on walking outcomes but has informed the design of a definitive evaluation.

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SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jvn.2018.11.001.

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