A randomised controlled feasibility trial of a home-based walking behaviour-change intervention for people with intermittent claudication

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ABSTRACT

Walking treatment is recommended for improving intermittent claudication (IC), a debilitating symptom of leg pain caused by peripheral arterial disease. However, centre-based exercise programmes offered in a community or hospital setting are often not implemented or adhered to. We developed a home-delivered behaviour-change intervention, Motivating Structured walking Activity in Intermittent Claudication (MOSAIC), to increase walking in people with IC. A feasibility randomised controlled trial with nested qualitative interviews involving a subsample of trial participants was conducted. Feasibility criteria evaluated a) participant recruitment and retention; b) suitability of proposed outcome measures; and c) acceptability and adherence to the intervention and trial. Participants (adults ≥18 years diagnosed with IC identified from vascular outpatient clinics) were randomised 1:1 to receive MOSAIC treatment (two 60-minute home-based sessions and two 20-minute booster telephone calls incorporating behaviour-change techniques) or an attention-control comparison. Outcomes (baseline and 16-week follow-up) included: the 6-Minute Walk Distance (metres), pedometer-assessed daily walking activity (steps/day), health related quality of life, physical functioning, and beliefs about walking treatment, peripheral arterial disease, and self-regulatory processes. 24 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 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.

HIGHLIGHTS

- A home walking programme for intermittent claudication was feasible to deliver

- The 6-Minute Walk Distance is a feasible and clinically relevant outcome

- Strategies to reduce missing pedometer data should be employed

- Patients reported acceptability and therapeutic alliance following the programme

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INTRODUCTION

Peripheral arterial disease is a vascular condition characterised 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 ischaemic 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 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 centre-based programme, 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 programmes 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 home-based exercise is not effective [10]. One reason for this may be that few such programmes have incorporated theory-based strategies to change behaviour and enable uptake and long-term walking adherence required to sustain benefits [11, 12].

Essential conditions for individual behaviour change include positive and accurate beliefs about peripheral arterial disease (e.g., illness perceptions defined by the Common Sense Model of Illness Representations [13]) and walking treatment (e.g., beliefs defined by the Theory of Planned Behaviour [14]). Positive beliefs about walking defined by the Theory of Planned Behaviour 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 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 Behaviour provide useful models to underpin a walking behaviour-change intervention for people with intermittent claudication.

Behaviour-change techniques are strategies which help to translate theoretical determinants into practice [17]. Examples of behaviour-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 minimise resistance and ambivalence toward increasing walking). Home-delivered exercise programmes incorporating behaviour-change techniques are recommended for people with intermittent claudication [11] and could contribute to the development and evaluation of robust and feasible walking programmes.

Therefore, a brief, structured, home-delivered walking behaviour-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 developmental work [12, 20] and stakeholder feedback, including consultation with

PAD patients and healthcare professionals to improve the potential for implementation. The aim of this study was to evaluate the feasibility of a two-arm, single-blind, randomised 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 a) participant recruitment and retention; b) suitability of proposed measures to inform the selection of a primary outcome; and c) 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 randomised 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. Inclusion criteria were: adults aged ≥18 years with diagnosis of peripheral arterial disease and intermittent claudication established by a vascular clinician and confirmed by response to the San Diego Claudication Questionnaire [22]. Exclusion criteria were: asymptomatic peripheral arterial disease or rest pain established by the San Diego Claudication Questionnaire; revascularisation 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 Behaviour [14], and thus seeks to engender accurate and positive patient beliefs about their illness and about walking. These objectives were achieved through Motivational Interviewing, a collaborative and compassionate communication approach designed to increase personal motivation and commitment to behaviour change [23]. MOSAIC treatment comprised behaviour-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 programme of self-directed activity without supervision. A physiotherapist received 7.5 hours group training

in motivational interviewing (British Psychological Society accredited), 7.5 hours individual training in MOSAIC behaviour-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 behaviour based on British Heart Foundation recommendations [24] and mirrored the mode of delivery, frequency and duration of MOSAIC sessions. The attention-control was designed according to recommendations [25], in order to isolate the effect of walking behaviour-change techniques by balancing the duration and mode (i.e., face to face and telephone) of contact with the clinician between groups.

Outcomes

Outcomes were assessed at baseline and 16-week follow-up by a blinded assessor (MGH) 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 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 [22].

Two potential primary outcomes were considered: a) Walking capacity was defined as the 6 Minute Walk Distance (metres) assessed during a standardised 6-minute walk test [26]; and b) Daily walking activity was measured by the mean daily step count assessed over 6 days using a tri-axial 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 pre-paid 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 MOSAIC treatment.

Patient reported outcome measures included (i) daily physical activity (Baltimore Activity Scale for Intermittent Claudication);[27] (ii) quality of life (Medical Outcomes Survey Short Form-12 version 2) [28], (iii) walking treatment beliefs (validated 23-item Theory of Planned Behaviour Questionnaire) [29], (iv) illness perceptions (Revised Illness Perception Questionnaire) [30], and (v) self-regulatory processes (validated 10-item questionnaire) [31] 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 semi-structured interview, which followed a topic guide exploring the acceptability of the trial procedures and intervention received. Participants were purposively sampled by group allocation, ethnicity (white versus other), gender, past supervised exercise therapy, and median age of sample (<66 versus ≥66 years) to a target

sample of 12 or until data saturation was achieved. Interviews were conducted by a single researcher (MGH) who maintained a reflexive diary.

Sample size and randomisation

As this was a feasibility study, a power calculation was not conducted, and a convenience sample of 24 participants was targeted. Following informed consent and completion of baseline assessments participants were randomly allocated to either MOSAIC or an attention-control group by simple balanced two-way randomisation. The randomisation 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 (LMB). 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 in SPSS Statistics Software version 21.0 (IBM Statistics Inc., Armonk, NY, USA). Sociodemographic and clinical characteristics are presented as means ±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 standardised 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 [32]. 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 versus 67.4 years) or gender (24% of men versus 33% of women invited). Participants were mean 66.8 (SD=9.4, range 52-90) years of age, and the majority were male (n=19/24) and 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 versus 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 group) 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, 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 6-Minute Walk 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 (mean ±SD change 6.7 ±7.0). Walking treatment beliefs (Theory of Planned Behaviour constructs), illness perceptions (Common Sense Model of Illness Representations constructs) and self-regulatory processes were positive following 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 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 Walk Distance were r=0.82 and r=0.59 for the treatment and attention-control, respectively. Associations between psychosocial constructs and walking outcomes were variable (Supplementary Table 2).

6-Minute Walk 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 standardised response mean for 6-Minute Walk 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/day [SD=625.83], 29.98%; n=6) and decreased in the attention-control group (mean -29.47 steps/day [SD=1471.43], -2.41%; n=7). The standardised response mean for daily walking activity change scores among the MOSAIC group was 1.34 (Table 3).

<u>Acceptability of and adherence to the MOSAIC intervention and trial</u>

Adherence to the allocated treatment was 67% (8/12) for MOSAIC 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 MOSAIC and 6 attention control group) and the clinician demonstrated the acceptability of the trial and treatment protocol and included

suggestions to improve the programme in future. Four themes were identified from the qualitative interviews: 1) Acceptability of 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; 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 randomised controlled trial comparing a behaviour-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 61–100% [12, 33]. The 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 enrolment 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 Walk Distance data at any time points, suggesting this is a robust and feasible outcome measure. The 6-Minute Walk 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 compared with the 6-Minute Walk Distance; this is likely because daily walking activity is a direct target of the intervention, reflecting behaviour change, and a more proximal outcome. However, it was less feasible measure due to a high proportion of missing baseline data. Interestingly, missing pedometer data was 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 scope for employing pedometers or other devices as motivational self-monitoring tools comprising part of 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 mean 836 steps/day, 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/minute [39]. Accordingly, participants in the MOSAIC group increased daily walking activity by mean 8.6 minutes/day, or approximately 60 minutes/week.

By contrast, the 6-Minute Walk Distance decreased following 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 (i.e., 30 minutes on at least 3 days/week, or 90 minutes/week) [4], so was unlikely to be sufficient to improve 6-Minute Walk 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 behaviour change techniques, such as graded tasks (e.g., gradually increasing walking goals until 30 minutes is achieved) and providing feedback on the outcome of walking (e.g., explicit feedback on symptom improvements) [17].

Qualitative data provide insight to 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 generalisable; however, in-depth qualitative data provided by the clinician regarding MOSAIC delivery was 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 meant data were insufficient to inform a power calculation for a definitive trial; however, findings highlight feasibility of the 6-Minute Walk Distance as a primary outcome and our observational data including a larger sample (n=142)[16] using this measure can inform future sample size. Randomisation took place prior to completion of baseline pedometer data collection, which was carried out over the subsequent 6-day period. Therefore, this outcome was not a requisite for enrolment, 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 Walk 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 behaviour-change techniques.

 In conclusion, a randomised trial of a brief walking behaviour-change intervention for people with intermittent claudication was feasible. MOSAIC was acceptable to participants, and, by incorporating explicit behaviour change techniques may address the need for effective home-based exercise programmes for people with IC [10]. This trial does not allow conclusions

about the efficacy of MOSAIC treatment on walking outcomes, but has informed the design of a definitive evaluation.

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Figure 1. Flow of participants through the MOSAIC feasibility randomised controlled trial
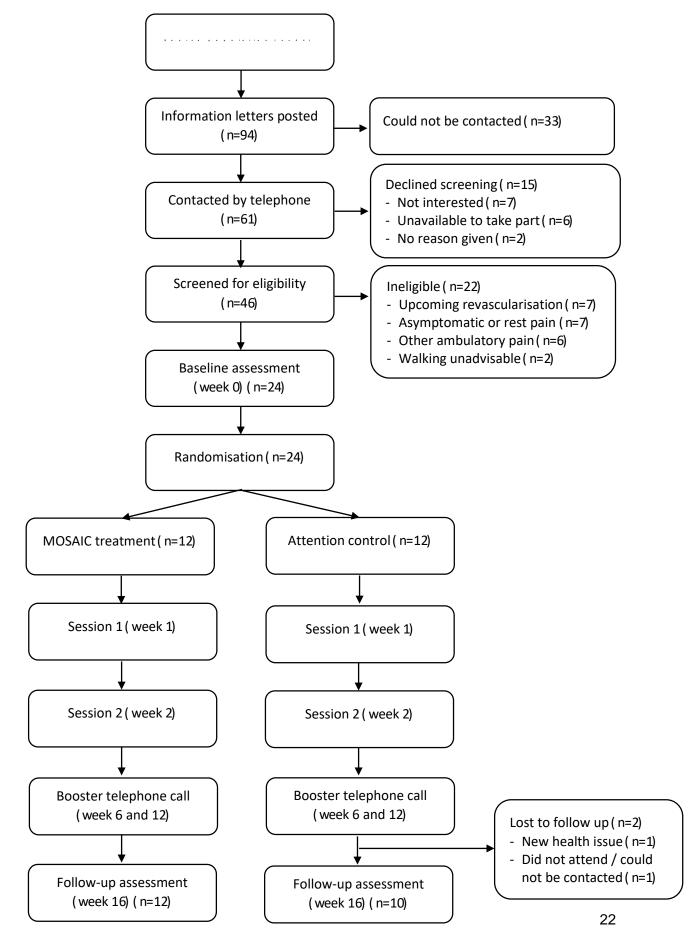
Table 1. Objectives and criteria used to evaluate the feasibility of the MOSAIC trial and intervention

Feasibility objectives	Feasibility criteria	Feasibility outcome
1) to evaluate study recruitment and retention of participants	1.1. A target sample of 24 participants (25% recruitment from initial cohort) will be achieved.	1.1 Achieved (n=24, 25% recruitment rate)
	1.2. Study retention at 16 week follow-up will be at least 60% (n=14/24)[12,26]	1.2 Achieved (92% study retention at 16 week follow-up)
2) to explore the suitability of proposed measures and identification of the primary outcome	2.1. Missing data at each time point will be less than 10% for each outcome[32].	2.1 Achieved in part: (Missing data <10% was achieved for 6-Minute Walk Distance and all patient reported outcome measures at baseline and 16-week follow-up, and for pedometer-based daily walking activity at 16 week-follow up. However, missing data rate was 36% for baseline daily walking activity)
	2.2 Sufficient data will be collected to explore change and responsiveness of objective walking outcomes.	2.2 Achieved: (daily walking activity increased following treatment and decreased following attention-control and was more responsive compared with the 6-Minute Walk Distance, whereas the opposite pattern was found for 6-Minute Walk Distance, which was a less responsive outcome.)
3) to explore adherence to and acceptability of the MOSAIC interventions and trial protocol	3.1 At least 60% (n=14/24) of participants will complete all treatment and attention-control sessions.	3.1 Achieved (71% adherence to protocolled sessions)
	3.2 Participants and the clinician will report positive experiences of MOSAIC treatment and the study protocol.	3.2 Achieved (narrative reports were positive and constructive)

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[a]	67.1 ±11.2[a]
Body mass index, kg/m^2	28.6 ±5.0[a]	26.5 ±5.0[a]
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)
Dyslipidaemia	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 revascularisation	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 year	1 (8.3)	0

n=24 (12 per group). [a]Data are mean ±SD.

Table 3. Baseline, 16 week follow-up, and change scores for 6-Minute Walk Distance and daily walking activity

Outcome	Treatment, mean ±SD	Attention-control, mean ±SD
6-Minute Walk Distance		
Participants	12[a]	10[a]
Baseline, metres	390.44 ±101.81	378.05 ±157.06
Follow-up, metres	381.92 ±113.51	387.93 ±161.84
Change, metres	-8.52 ±42.29	9.88 ±42.15
Change, %	-4.23 ±12.56	1.01 ±13.346
Standardised response mean	0.20	Not applicable
Daily walking activity		
Participants	6[a]	7[a]
Baseline, steps/day	2247.02 ±1652.05	4343.28 ±3098.87
Follow-up, steps/day	3083.94 ±1882.59	4313.80 ±1113.45
Change, steps/day	836.91 ±625.83	-29.47 ±1471.43
Change, %	29.98 ±17.57	-2.41 ±40.81
Standardised response mean	1.34	Not applicable

[a]Data are the valid numbers of participants.

Supplementary Table 1. Behaviour Change Techniques included in a walking behaviour-change intervention for people with intermittent claudication (MOSAIC)

Behaviour Change Technique	Definition	Delivery of Behaviour Change Technique	Example of Mapped Construct from the TPB or CSM
Social support (general)	Advise on, arrange, or provide social support, or non-contingent praise or reward for performance of the behaviour, and encouragement and counselling when directed at the behaviour (e.g., motivational interviewing)	Physiotherapist trained in motivational interviewing, values-based goals elicited to support autonomy, change talk facilitated through patient-centred dialogue	Subjective Norm (TPB) and the personal schematic illness representation (CSM)
Information about health consequences	Provide information about health consequences of performing the behaviour	Potential benefits of walking discussed, including ability to walk further before pain onset or need to stop and rest.	Attitude (TPB)
Goal setting (behaviour)	Set or agree on a goal defined in terms of the behaviour to be achieved	Walking goal defined in terms of frequency, duration, intensity, and context. Based on current walking with the aim of progressing toward recommended walking level	Intention (TPB)
Goal setting (outcome)	Set or agree on a goal defined in terms of a positive outcome of wanted behaviour	Value-based goal identified which would be facilitated by improved walking (e.g., work, hobby, social activity)	Intention (TPB)
Problem solving	Analyse or prompt analysis of factors influencing the behaviour and generate or select strategies that include	Participants encouraged to identify barriers which may prevent them achieving their goal, and realistic solutions discussed and agreed	Perceived behavioural control (TPB)

	overcoming barriers and / or increasing facilitators		
Action planning	Prompt detailed planning of behaviour performance, including at least one of: context, frequency, duration, or intensity	Action plan worksheet completed, recording details of the context, frequency, duration and intensity of walking goal	Intention-Behaviour Translation (TPB)
Self-monitoring of behaviour	Establish a method for the person to monitor or record their behaviour as part of a behaviour-change strategy	Physiotherapist discussed methods to monitor daily walking (e.g., wearing a watch, or using landmarks to note distance achieved)	Self-Regulation (CSM) and Intention-Behaviour Translation (TPB)
Review behavioural goals	Review behavioural goals jointly and consider modifying goal or behaviour-change strategy in light of achievement	Walking discussed relative to goals and revised as appropriate to be more achievable or challenging	Self-Regulation (CSM) and Intention-Behaviour Translation (TPB)
Review outcome goals	Review outcome goals jointly and consider modifying goals in light of achievement	Value-based goal considered relative to walking and revised if no longer salient	Self-Regulation (CSM) and Intention-Behaviour Translation (TPB)
Feedback on behaviour	Monitor and provide informative or evaluative feedback on performance of the behaviour	Walking completed by participant is discussed considering individual goals are recommended walking treatment for IC	Self-Regulation (CSM) and Intention-Behaviour Translation (TPB)

CSM, Common Sense Model of Illness Representations; TPB, Theory of Planned Behaviour.

Supplementary Table 2. Mean change from baseline and correlations between change scores of patient reported outcomes and walking outcomes

Variable	Treatment group			Attention-control group		
	Change, mean (SD)	6MWD, r (n=7–12)	Daily walking activity, r (n=5–6)	Change, mean (SD)	6MWD, r (n=8–10)	Daily walking activity, r (n=5–7)
Theory of Planned Behaviour Questionnaire						
Attitude	1.50 (5.92)	0.52	0.60	-1.11 (5.23)	0.32	0.02
Subjective norm	0.33 (5.57)	0.15	0.60	3.11 (5.41)	0.33	-0.69
Perceived behavioural control	1.58 (6.05)	0.06	0.57	3.75 (7.17)	0.63	-0.33
Intention	0.83 (3.56)	0.11	0.71	2.33 (3.97)	-0.10	-0.75
Revised Illness Perceptions Questionnaire						
Identity[a]	0.00 (1.91)	0.32	0.02	1.20 (2.44)	-0.31	-0.27
Acute timeline[a]	-0.83 (2.64)	0.02	0.01	-0.40 (3.34)	-0.19	0.45
Cyclical timeline[a]	0.00 (2.48)	-0.02	0.99	1.30 (2.16)	0.18	-0.74
Treatment control	1.16 (3.24)	0.05	0.80	-0.60 (2.99)	-0.33	-0.46
Personal control	-0.08 (2.35)	0.50	0.82	0.40 (5.17)	0.20	-0.10
Coherence	1.17 (3.10)	-0.07	0.56	-0.40 (3.20)	-0.24	0.24
Consequences[a]	-2.25 (3.22)	-0.12	0.27	-1.20 (1.69)	-0.72	0.06
Psychological attributions	-1.75 (3.33)	0.20	0.69	1.40 (4.25)	-0.08	0.14
Risk factor attributions	-0.67 (2.06)	0.48	0.40	0.33 (3.08)	-0.01	0.64
Immunity attributions[a]	-0.42 (1.51)	0.36	0.81	1.20 (1.35)	-0.12	-0.06
Accident/chance attributions[a]	0.33 (0.78)	0.21	0.01	0.10 (1.20)	-0.21	0.32
Emotion[a]	-1.17 (2.25)	0.02	-0.08	1.50 (4.99)	0.49	-0.35
Self-Regulatory Processes						
Action planning[b]	13.56 (2.55)	-0.22	0.16	11.7 (4.29)	0.28	0.44
Action control[b]	19.00 (2.44)	0.31	NA[c]	16.7 (4.64)	0.14	0.87
Barrier self-efficacy	2.00 (8.27)	0.71	0.94	7.70 (18.02)	0.47	-0.10
MOS Short Form-12v2						
Mental component summary score	2.76 (3.56)	0.07	-0.06	-2.07 (7.90)	0.32	0.05
Physical component summary score	1.16 (5.09)	0.32	0.69	6.70 (7.00)	0.05	-0.26
Baltimore Activity Scale for Intermittent Claudication	1.08 (1.24)	0.67*	0.47	0.60 (1.89)	-0.60	0.04

Outcomes were assessed at baseline and 16-week follow-up. Valid data (casewise) reflecting associations with 6-Minute Walk Distance (6MWD) were available for n=7–12 (treatment) and n=8–10 (attention-control). Valid data (casewise) reflecting associations with daily walking activity were available for n=5–6 (treatment) and n=5–7 (attention-control). [a]A decreased score denotes improvement. [b]Action planning and action control reflect absolute scores at post-intervention assessment. [c]Degrees of freedom insufficient to run the analysis (n=2). *p<0.05.

Supplementary Table 3. Themes identified from semi-structured interviews with 12 patients with IC and a physiotherapist who participated in the MOSAIC feasibility trial

Theme	Description	Examples from participants with intermittent claudication	Examples from a physiotherapist
Acceptability of the research process and protocol	Participant experiences of assessments and appointments, and suggestions for improving the study conduct	• Participants had limited expectations of the study, and expressed uncertainty. This was alleviated upon taking part • Despite uncertainty, positive experiences were reported overall • Walking and questionnaire assessments were relevant and appropriate, and enabled reflection on their condition • Pedometers were comfortable, non-intrusive, and sometimes used for self-monitoring	
Acceptability of MOSAIC and attention-control intervention	Format and content of the interventions, including mode of delivery, information provision, and materials	• Participants appreciated home visits and supportive telephone calls, although some would opt for hospital visits • Ample time with the physiotherapist was central to the experience and therapeutic relationship • Positive and useful information and support gained from interventions, although benefits may be gained from delivery earlier in diagnosis	• Home delivery facilitated a patient-centred and collaborative approach • Booster telephone calls may be enhanced with additional structure • Intervention was sufficiently flexible to tailor for participants at various stages of motivation, and challenges in the goal setting process could be overcome
Perceived expectations and outcomes of the treatment	Participant expectations prior to the study commencing, and	• Reports of improved psychological and emotional wellbeing and uptake of healthy behaviours	

and attention-control interventions	outcomes including cognitions, behaviour-change, and walking	• Positive behaviour change reported. This was detailed and specific to walking in MOSAIC participants and described broad lifestyle change among attention-control group • Challenges to behaviour change were reported in both groups, including those who increased healthy behaviours.	
Physiotherapist role as a person and professional	Participant expectations of physiotherapy, individual qualities, professional expertise, consistency and relationship building	• Positive qualities, knowledge, and skills of the physiotherapist helped benefit from the experience • Physiotherapist was suitable for delivering this intervention • Participants would recommend the treatment to others with peripheral arterial disease	• Intervention was suitable for delivery by a physiotherapist • A collaborative therapeutic stance was supported by training and intervention components