A physiotherapist-led behaviour-change intervention to facilitate walking in people with Intermittent Claudication: feasibility of a randomised controlled trial

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Introduction

Intermittent claudication (IC) cause by peripheral arterial disease affects an individual’s physical function, mental health and quality of life. Management guidelines recommend 30-60 minutes walking exercise, 3 times/week for 3 months but adherence to walking tends to be poor. The MOTivating Structured walking Activity for Intermittent Claudication (MOSAIC) intervention is a systematically developed, physiotherapist-led, behaviour-change intervention which aims to increase walking in people with IC. This feasibility study evaluated the suitability of outcomes (e.g. candidate primary measures: 6-Minute Walk Distance (6MWD), pedometer-assessed walking), rates of participant retention and adherence to and acceptability of MOSAIC to inform the development of a trial.

Methods

Design: A mixed-methods feasibility and acceptability study of a single-blinded two-arm randomised controlled trial.

Participants: Adults with IC confirmed by a vascular specialist clinician were recruited from two public hospital trusts in the United Kingdom.

Procedure: Following baseline assessment, participants were randomised 1:1 to MOSAIC or an Attention Control focused on diet and risk factor management. Both groups received two 60-minute home visits (weeks 1 and 2) and two 20-minute follow-up telephone consultation (weeks 6 and 12) by a trained, Band 6 physiotherapist. All participants were reassessed at 16 weeks and a subsample of participants were interviewed. Clinical measures included 6-Minute Walk Distance and mean Daily Walking Activity assessed by pedometer over 6 days.

Feasibility Success Criteria

- Study retention
- Protocol compliance
- Treatment effect estimate on walking outcomes
- Acceptability

Results

24 Adults (79% male, mean (SD) age 66.8 (9.4) years) were recruited to the study (25% recruitment).

- 92% of participants were retained to the 16-week follow-up (Figure 1)
- 71% of participants completed all MOSAIC and attention control sessions

Figure 1. Proportions of participants lost to follow-up (LTFU) and who did not complete the intervention protocols.

- Sufficient data enabled exploratory analyses of treatment effects and precision (Figure 2)

Figure 2. Change in 6-Minute Walk Distance and pedometer-based Daily Walking Activity following MOSAIC or an attention control (n=22)

Conclusions

Overall, rates of participant retention and intervention adherence were high, and the intervention and trial processes were acceptable. The 6MWD was the superior outcome. Informed by this successful feasibility study, the MOSAIC intervention was refined and a multi-centre, 2-arm, superiority trial (primary outcome: 6MWD at 3 months) with a nested qualitative study and process evaluation was developed to investigate the efficacy of MOSAIC compared to usual care in people with IC.

MOSAIC intervention

- Format: One-to-one physiotherapist-led individualised sessions
- Duration: Four sessions delivered over 12 weeks
- Location: Hospital or home depending on patient preference
- Content: Motivational interviewing and behaviour change techniques targeting walking
- Supporting material: Provision of a pedometer, manual and exercise diary as motivational tools

Implications

If efficacious, MOSAIC will enable people with IC to improve their symptoms and mobility by increasing knowledge and self-management skills. It will provide physiotherapists with additional skills and treatments to help support patients with IC.