Development and piloting of SEDRIC: Structured EDucation for Rehabilitation in Intermittent Claudication

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BACKGROUND: Supervised walking exercise can markedly improve walking capacity and quality of life in patients with intermittent claudication due to peripheral arterial disease. Unfortunately, supervised exercise programs are resource intensive, provision is limited, and patients cite accessing services as a barrier to participation. Basic walking advice from clinicians rarely leads to successful behaviour change, and the evidence for structured, home-based exercise programs is weak and mixed (Al-Jundi *et al.*, 2013, EJVES, 46, 690-706).

PURPOSE: To develop and pilot a pragmatic structured education program that promotes self-managed walking exercise in individuals with intermittent claudication.

PROGRAM DEVELOPMENT: Five focus groups were conducted (n=24) to inform the development of the education program. A theory-based curriculum was written by a clinical exercise scientist and a behaviour change specialist, with input from patients and clinicians. Educational resources were developed and the workshop facilitators received training in structured education. Three practice workshop sessions were conducted (n=18), the last of which was independently assessed for quality assurance. An overview of the SEDRIC programme is given in Figure 1. Further details are available on request (garry.tew@york.ac.uk).

Figure 1. The SEDRIC programme

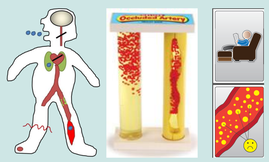
SEDRIC
WALK AWAY THE PAIN

- 3-hour group-based education workshop
- 2 educators, 6–10 patients
- Written, theory-driven curriculum
- Person-centred philosophy

Patient story (30 min)
- Name?
- Diagnosis story?
- Symptoms?
- Causes?
- Consequences?
- Treatments?
- Key question?

→ Professional story (50 min)
- What is claudication?
- Cause of pain?
- Complications?
- Risk factors?

→ Walking (80 min)
- Types/benefits of physical activity?
- Guidelines?
- Mechanisms?
- Time → Steps (pedometer)
- Opportunities/Barriers?
- Goals/Action planning



→ Telephone follow-up at 2 weeks

PILOT STUDY DESIGN: Patients with stable intermittent claudication were randomised (ratio 3:2) to receive the SEDRIC programme or a brief information leaflet via post (control). Participants in the intervention group attended one of three SEDRIC workshops held at Sheffield Hallam University between November 2013 and April 2014. Outcome measures assessed at baseline and 6 weeks included daily steps (tri-axial accelerometer), walking capacity (6-minute walk test [6MWT], Walking Estimated Limitation Calculated by History [WELCH] questionnaire), quality of life (Intermittent Claudication Questionnaire [ICQ]), and personal control over illness (Brief Illness Perceptions Questionnaire [BIPQ]). Exit interviews were conducted to assess the acceptability and usefulness of the intervention.

RESULTS - PARTICIPANTS: Twenty three patients were recruited between August 2013 and April 2014 from the Northern General Hospital, Sheffield, UK. 96% (22/23) completed to follow-up. Figure 2 shows the CONSORT flowchart and Table 1 the baseline characteristics.

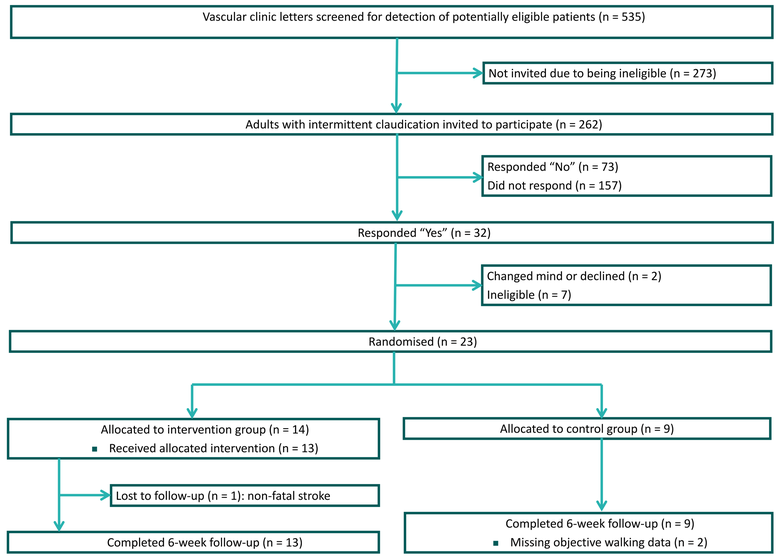


Figure 2. CONSORT diagram.

Table 1. Participant characteristics at baseline.

	Intervention (n=14)	Control (n=9)
Age (years)	69.1 ± 7.6	67.8 ± 14.1
Sex ratio (male/female)	10/4	6/3
Ankle brachial index	0.67 ± 0.17	0.64 ± 0.18
Duration of claudication (months)	31 ± 24	40 ± 40
Risk factor history		
Diabetes mellitus	1	2
Hypertension	9	7
Current smoking	0	0
Former smoking	10	5
Comorbid cardiovascular diseases		
History of stroke/TIA	0	1
History of coronary artery disease	2	3
Medication		
Anti-platelet/Anti-coagulant	14	7
Statin/Lipid-lowering drug	14	7
Disease distribution		
Aorto-iliac	5	3
Femoro-popliteal	5	4
Infra-geniculate	1	1
Bilateral claudication	3	1

Data are mean ± SD, or frequencies

RESULTS – EFFICACY: Outcome measure data are presented in Table 2. At 6-week follow-up, the intervention group showed improvements in walking capacity, disease-specific quality of life, and personal control over illness. The mean difference in 6-minute walking distance was 44.9 m (95% CI, 6.9 to 82.9). The accelerometer-measured daily step count did not change significantly between groups.

Table 2. Outcome measures.

	Intervention	Control	Adjusted difference (95% CIs)	*P* value
Daily steps	n=9	n=6		
Baseline	6213.0 (3881.9)	4764.5 (2539.1)		
6 weeks	5695.9 (2990.9)	4270.7 (2261.1)	369.5 (-987.8 to 1726.9)	.56
Objective walking capacity (6MWT, m)	n=12	n=7		
Baseline	367.3 (94.3)	355.3 (82.7)		
6 weeks	390.2 (93.9)	334.6 (77.6)	44.9 (6.9 to 82.9)	.02
Subjective walking capacity (WELCH)	n=13	n=9		
Baseline	34.3 (19.8)	27.9 (13.2)		
6 weeks	46.7 (21.1)	20.0 (16.1)	21.8 (8.6 to 35.0)	.003
Disease-specific quality of life (ICQ)	n=13	n=9		
Baseline	32.7 (16.5)	44.8 (18.1)		
6 weeks	24.7 (9.7)	43.3 (18.9)	-10.6 (-18.9 to -2.3)	.015
Personal control over illness (BIPQ)	n=13	n=9		
Baseline	4.5 (2.5)	3.3 (3.0)		
6 weeks	4.8 (2.5)	2.3 (2.4)	2.37 (0.02 to 4.72)	.048

Data are mean ± SD, unless otherwise stated.

RESULTS – ACCEPTABILITY: The exit interviews indicated that participants valued attending the SEDRIC workshop, that it provided them with a greater understanding of their condition, and that they had been walking for exercise more since attending. Selected quotes:

- *"It's sort of, err, enlightened me to the fact that, err, walking is a good, err, you know, err, therapy for what I've got."*
- *"I liked everything. I thought the timing was perfect … they were very, very caring to myself, the people were very nice… I could ask him stuff, I could say anything … I felt as though I was being looked after."*
- *"The workshop was really good; it was well run… It was well paced… It worked for all of us."*

A key element of the programme was that the SEDRIC educators taught workshop participants how to use a pedometer to monitor their everyday step counts. A suggested set of targets for increasing steps was offered. Feedback indicated that the pedometer part of the SEDRIC programme was valued, and useful for motivation, self-monitoring and goal setting.

CONCLUSIONS: We have developed a pragmatic, group-based, structured education program called SEDRIC that aims to promote self-managed walking exercise in individuals with intermittent claudication. The results of the pilot study suggest that the intervention is feasible, acceptable, and useful for eliciting meaningful improvements in walking capacity and quality of life. Further work is needed to optimise the delivery of the intervention and to determine long-term clinical and cost effectiveness.

Details of future work and publications will be posted here: www.sedrictrial.co.uk

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