Supervised exercise training as an adjunct therapy for venous leg ulcers: a randomised controlled feasibility trial

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Online Supplement 1 - Further particulars of the supervised exercise programme

Goals of the intervention	The primary goal of the supervised exercise programme was to reduce ulcer healing time via training-induced improvements in calf muscle pump function, ankle range of motion, and lower-limb cutaneous microvascular function. Secondary goals were reduce cardiovascular disease risk, to improve health-related quality of life, and to improve several aspects of physical fitness including cardiorespiratory fitness, muscle strength and endurance, and flexibility.
Materials used in intervention delivery	Each exercise site was equipped with: two motorized treadmills (Life Fitness 95T Achieve); two upright exercise bikes (Life Fitness 95C Achieve); pairs of dumbbells ranging 2-20 kg; one height-adjustable step; one medium-sized stability (Swiss) ball; one seated leg press machine (Life Fitness Signature Series); Theraband; Polar heart rate monitor; Borg 6-20 rating of perceived exertion scale; radio for music; water-dispensing machine; two large fans on stands
Procedures used in the intervention	Participants were invited to attend 3 sessions of supervised exercise each week for 12 weeks (total of 36 sessions). Each exercise session was scheduled to last approximately 60 minutes and to comprise a combination of aerobic, resistance and flexibility exercises. Sessions were typically delivered on Mondays, Wednesdays and Fridays to allow sufficient recovery between sessions, and were performed either in the late morning, afternoon or early evening. A maximum of 14 weeks was allowed for the participants to complete the 36 sessions, for if sessions were missed due to, for example, illness or holiday. Warm-up: Each session began with a 5-minute warm-up of low-intensity treadmill walking or cycling, determined by participants' physical function and preferences. The target for the warm-up period was for the participant to exercise at an exertion level of no higher than 11 (light) on Borg's 6-20 rating of perceived exertion (RPE) scale. Aerobic component: The aerobic component was scheduled to last approximately 30 minutes, with the exercise mode being treadmill walking, cycling, or a combination of both, determined by the physical function and preference of participants. Treadmill hill-walking was the preferred mode, since it promotes greater recruitment of the calf musculature than cycling. The intensity of exercise was guided by the use of Borg's 6-20 scale, with participants encouraged to exercise at an exertion level of 12-14 (somewhat hard). Resistance component: Resistance exercises were performed for approximately 15 minutes. Four exercises were scheduled to be completed in each session: two targeting the calf muscles and two targeting the muscles of the thigh and hips. The exercises involved dynamic body-weight exercises with or without the use of dumbbells and stability balls. An example calf exercise used was the standing calf raise. Example thigh/hip exercises included partial squats and the chair sit-to-stand exercise. Exercises were performed for 2-3 sets of 10-15 repetitions to the point of moderate muscle fatigue. Cool-down and flexibility component: Participant completed a 5-minute cool-down of low-intensity treadmill walking or cycling, as in the warm-up. Static stretches were be performed for calves, quadriceps and hamstrings, for a total of 60 seconds per muscle group (comprising 3 × 20-second stretches), held at the point of mild discomfort.
Intervention provider	The exercise programme was supervised by exercise physiologists who have several years' experience of exercise supervision and prescription. The exercise physiologists all received at least one day of training specific to the trial from one of the study investigators (GT) who has completed trials of supervised exercise training in several different patient populations.

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Mode of delivery	All sessions were supervised. A maximum of 4 participants to 1 supervisor was allowed, to ensure patient safety, successful delivery of the exercise session and all relevant data collection.
Where the intervention is delivered	The exercise programme was delivered at the Centre for Sport and Exercise Science at Sheffield Hallam University, with Human Performance Centre at the University of Lincoln acting as the second delivery site.
How the intervention is personalised and adapted	At the start of the programme, the exercise physiologist responsible for delivery determined which exercises the participants preferred and which were the most appropriate based on the participants' levels of physical fitness and mobility. The initial goal was for participants to build up to completing three, one-hour sessions of exercise each week as described above. Once the session frequency and duration targets were met, the intensity of the specific exercises were progressed on an individual basis. For the aerobic component, the speed and incline of the treadmill and the resistance level of the bike was increased to keep the participant within the RPE range of 12-14. For the resistance component, the weight or type of exercise used was adapted so that the participant continued to reach the point of moderate muscle fatigue within 10-15 repetitions.
Strategies to maintain intervention fidelity	The timing of the sessions was flexible to help participants achieve three sessions per week. Free parking was offered and participants receive up to £5 per visit towards travel expenses. Each session was supervised by an investigator who has received specific training for this trial. One study investigator (GT) provided oversight to the delivery of the exercise intervention, and this included regularly observing sessions and checking CRFs for errors.
Processes for evaluating intervention attendance and compliance	A specially-designed Exercise Session Case Report Form (CRF) was completed every session. The following information was written at the top of each of these forms: participant initials and trial ID number; date and time of session; session and week numbers; supervisor name(s). The supervisor also recorded the type of compression garment being worn by the participant, or “none” if that is the case (note: the participant was allowed to complete an exercise session without compression garments being worn; however, they were encouraged to wear them in future sessions). The participant was fitted with a Polar heart rate monitor at the start of each session. During the warm-up, aerobic and cool-down sections, RPE (Borg 6-20 scale), heart rate (via telemetry) and exercise type and settings (e.g. treadmill speed and gradient) were recorded for the last 15 seconds of each 5-minute period. This allowed accurate quantification of the exercise stimulus and progression of the programme over time. Similarly, the types of resistance and flexibility exercises performed were recorded, along with details of number of sets, repetitions and end-exercise RPE. Compression garments (stockings/bandages) were monitored during each exercise session: our protocol suggested that if affected by exercise, participants were to be referred to the tissue-viability nursing team for re-application, with additional visits being noted for the health-economics analyses (this wasn't necessary during the study). If sessions were missed, the reason(s) for this were documented on the CRF.