Exercise fidelity and progression in a supervised exercise programme for adults with venous leg ulcers

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Introduction

Venous leg ulceration is a chronic and devastating condition that affects approximately 1% of the adult population in the Western world (1). It costs up to 198 million sterling pounds in national healthcare expenditure in the U.K. alone (2), affecting significantly, in a negative manner patients' quality of life (3). Moreover, venous leg ulcers tend to recur quite frequently, with recurrence rates reaching 70% within a year of healing (4).

With such costs involved and the considerable devastation in patients' lives, it is no surprise that adjunct and alternative therapies to compression therapy (which is considered as the golden standard) (5) have been pursued (e.g. ultrasound (6), larval therapy (7), biomaterials (8)), with exercise and physical activity promotion being considered as well (e.g., walking (9), increased physical activity (10), resistance exercise (11)).

The concept of using exercise as an adjunct therapy to compression isn't new and indeed exercise is included as a recommendation in the NICE Clinical Knowledge Summary for venous leg ulcers' management (e.g., "regular walking", "exercising to improve calf muscle pump function") (12). Nevertheless, there is a fear shared by both clinicians and the patients that exercise may be either inappropriate or harmful and actually delay rather than promote healing (13,14). This notion together with the mixed results of previous studies (13,15-16), has limited the exploration of regimes that could potentially benefit patients and improve clinical outcomes. Overall, there is little published data on the ability of this patient group to undertake different types of exercise training and on rates of exercise progression. The data has the potential to inform practitioners and researchers involved in prescribing and supervising exercise with venous ulcer patients. .

FISCU (17) is a recently-completed, two-center study exploring the feasibility of using exercise as an adjunct therapy to compression in patients with venous leg ulcers. This trial represents an

attempt to implement a supervised exercise programme with this patient population, in a manner similar to what has been promoted successfully in other clinical populations in the UK (e.g. peripheral arterial disease (18), chronic obstructive pulmonary disease (19), cardiac diseases (20)). Central to the internal validity of all intervention trials is intervention fidelity, which refers to the extent an experimental manipulation has been implemented in a comparable manner to all participants, as intended (21). Furthermore, it is important to present all in-session exercise safety data to better inform clinicians, policy makers and patients with venous ulcers. As such, having published the main study findings, which supported the feasibility of conducting a future full-scale trial (17), our aim here was to present a detailed appraisal of exercise data collected during the FISCU trial, focussing on treatment fidelity and exercise progression.

Methods

FISCU was a two-arm, parallel-group, randomised feasibility trial that received ethical clearance from the NHS National Research Ethics Committee for Yorkshire and the Humber (14/YH/0091), and was prospectively registered (ISRCTN09433624). Thirty-eight adults who were receiving lower-limb compression for a new venous leg ulcer of greater than 1 cm diameter were recruited from tissue viability clinics and newspaper advertisement in Sheffield, United Kingdom. Following provision of consent and baseline assessment, participants were randomly assigned to receive usual care (n=20) or usual care plus a 12-week supervised exercise programme (n=18). A full description of the protocol is available elsewhere (22); however, for the purpose of this article the exercise training protocol is described below.

Exercise protocol

Following study enrolment and randomisation, exercise group participants were referred for a 12-week exercise intervention, undertaken 3 times per week (typically being delivered on Mondays, Wednesdays and Fridays to allow sufficient recovery between sessions). A maximum of an additional 2 weeks was allowed for the participants to complete the 36 sessions in case sessions were missed because of illness, family/work commitments or holiday. The sessions were supervised by an exercise physiologist and were typically undertaken in a group form (no more than 4 patients per session, to ensure proper supervision and adequate progression monitoring). Each exercise session lasted approximately 60 minutes and comprised a combination of aerobic, resistance and flexibility exercises. Each session began and ended with 5 minutes of low-intensity treadmill walking or cycling for a warm-up and cool-down, respectively. The aerobic component was aimed to last approximately 30 minutes, with the exercise mode being treadmill walking, cycling, or a combination of both, with the mode being determined by the physical function and preference of participants.

Resistance and flexibility exercises were performed for approximately 20 minutes in order to improve calf muscle pump function, leg (predominantly calf) muscle strength, and joint (predominantly ankle) mobility. Resistance exercises mainly involved dynamic body-weight exercises with or without the use of dumbbells and stability balls (e.g., calf raises and partial squats). Exercise was aimed to be performed for two or three sets of 10 to 15 repetitions to the point of moderate muscle fatigue (23). For flexibility, static stretches were performed for all of the major muscle groups of the legs, for a total of 60 seconds per muscle group (comprising 3 × 20-second stretches), held at the point of mild discomfort (23).

Exercise intensity: prescription and measurement

The intensity of aerobic and resistance exercises was guided using Borg's 6-20 ratings of perceived exertion (RPE) scale (24), aiming for an exertion level of 12 to 14 ("moderate" to "somewhat hard") on the 6-20 scale, which equates to the ventilatory threshold (24). Each patient was familiarized with the scale and the recommended researcher instructions for scale administration were used (25). Perceived exertion, heart rate (via telemetry; Polar RS400, Kempele, Finland), and aerobic and resistance exercise indices (e.g., treadmill speed and gradient) were recorded at regular intervals during the whole session to allow accurate quantification of the exercise stimulus and to facilitate progression of the programme over time.

Exercise safety

Compression garments (stockings/bandages) were monitored throughout each exercise session. The exercise supervisor was instructed to terminate the session if these were affected by exercise, with participants being referred to the tissue-viability nursing team for re-application, and additional visits were to be noted for the health-economics analyses. Our safety monitoring procedure indicated that all serious adverse events, as well as all non-serious adverse events that are deemed to be related to participation in the research (e.g., exercise strains or injuries, excessive wound discharge, in-session exercise bandage slipping) were to be recorded during the period between provision of informed consent through to 12 months after randomisation. Participants were asked to contact the study team to inform them about adverse events if and when they occur. Study investigators also questioned participants about the occurrence of adverse events during each participant study visit.

Statistical analysis

Descriptive statistics were used to calculate the session attendance data, completion rates as per protocol for aerobic (duration, intensity, combination of duration and intensity), resistance (intensity, number of exercises, sets, repetitions) and flexibility exercises (number of exercises, duration, intensity), and present baseline demographics. The Shapiro-Wilk test was used to assess data normality and Mauchly's Test of Sphericity was used to indicate data sphericity (the assumption of sphericity was not violated in any case). Exercise progression was assessed by comparing Session 1 (baseline), with Sessions 18 (midpoint) and 36 (intervention completion) using Analysis of Variance (ANOVA) for Repeated Measures (SPSS v.23, Armonk, NY: IBM Corp). Post-hoc analysis was undertaken using Bonferroni corrected t-tests. To calculate the effect sizes we used eta-square for ANOVA assessments and Cohen's d for post-hoc analysis, using the magnitudes determined by Cohen (26): For η^2 0.01 is considered a small effect, 0.06 is considered a medium effect and 0.14 is considered a large effect. Similarly for Cohen's d: 0.2 is considered a small effect, 0.5 is considered a medium effect and 0.8 is considered a large effect. Data are described as means (SD), unless otherwise stated. Significance set at $p<0.05$ and for post hoc analysis at $p<0.0167$.

Results

Participants

Characteristics of the 18 exercise-group participants are shown in Table 1. Ten of these participants were female and the mean ± SD age, stature and body mass were 66.9 ± 13.9 years, 171.1 ± 11.9 cm and 102.1 ± 29.4 kg, respectively. Median ulcer size was 4.9 cm^2.

Attendance

The overall exercise attendance rate was 79% (512/648), with 13 of the 18 participants (72%) attending all exercise sessions. Amongst those who completed the study, 411/468 sessions were completed within the 12-week period, with the rest (57/468) being completed within the additional 2-week period. Of the five participants who did not complete all sessions, one withdrew fully from the trial before the 3-month follow-up assessment due to non-ulcer-related health problems, and four withdrew from treatment (i.e. stopped attending before the end of the 12-week intervention period) but remained in the study (one due to ulcer-related problems, three due to non-ulcer-related health problems). These five participants had completed 2, 4, 6, 15 and 17 exercise sessions, respectively, before withdrawing. Reasons for not attendance included lack of transportation (n=34), non-ulcer related health reasons (n=74) and ulcer-related health reasons (n=32), with more than one reasons given on some occasions.

Exercise Safety

No serious, in-session adverse events were experienced and the bandaging was also not disrupted during any exercise session. Two incidents of excessive fluid discharge were detected the day after exercise sessions, possibly or probably related to exercise. Following consultations with healthcare personnel, these were dealt by postponing the exercise session following the incident reporting

(incident 1) and temporarily removing the resistance element from the training programme (incident 2).

Exercise choices

The majority of the participants (72%) chose treadmill as their main aerobic mode of training at baseline, with the rest preferring cycling due to frailty and lack of confidence with exercising on the treadmill. One participant changed briefly from treadmill to exercise cycle, before reverting to treadmill again. Only one of the participants was training via exercise cycle at the end of the 12-week intervention, with the rest of the participants that completed the intervention using the treadmill instead.

In regards to the resistance element of the intervention, four participants started the programme stating that they were unable to do squats, step-ups or calf raises. This number was reduced to two at the end of their participation (they were however, able to complete the rest of the regime). Finally, one of the participants could not do squats on Session 18, due to a pre-existing pain unrelated to exercise, completing however, the rest of the session without issues. The participant completed his programme as well.

Exercise Intensity

All of the aerobic and 91% of the resistance training components, across all participants, were performed at the desired moderate intensity, as determined using RPE responses in the 12-14 range (Tables 2 and 4).

154 *Exercise Progression*

155 Table 3 presents data on changes in the duration of the aerobic component and the number of
156 repetitions completed for four lower-limb resistance exercises. The number of minutes spent on
157 aerobic exercise increased through the 12-week period (Baseline: 19 min (8), Mid-point: 26 min
158 (5), End-point: 29 min (3)).

159 Performance of the participants in the resistance exercise indices was also improved (Table 3): For
160 example, calf raises increased from 19 (13) at baseline, to 36 (13) at mid-point, reaching 42 (14) at
161 the end of the intervention.

162

163 *Exercise Fidelity*

164 For the aerobic exercise element all completed sessions were completed according to the
165 prescribed intensity. For resistance this was the case in 466/512 (91%) completed sessions.
166 Duration of the exercise elements was close to the prescribed duration as well (413/512 = 81% for
167 aerobic, 474/512 = 93% for resistance). The majority of those not completing the prescribed
168 duration were at the beginning of their programme, and was due to lack of physical fitness (n=4),
169 discomfort (n=2) and unfamiliarity with the training equipment/exercises (n=4) – with more than
170 one reason being given by some participants.

171 Similarly, the main reason for resistance components not being completed according to protocol
172 was lack of physical fitness. This, however, became less of an issue as the programme progressed,
173 reaching almost 100% completion in the last sessions.

Finally, flexibility exercises were completed as per protocol in regards to duration and number of exercises.

Discussion

Using a supervised exercise regime as an adjunct therapy to reduce venous leg ulcer healing time, represents a plausible, yet largely unassessed therapeutic strategy (16). The lack of appropriately designed studies, which would substantiate its use and the fear of healthcare professionals and the patients themselves about the safety and applicability of exercise are two main reasons, why the advice of a more "active lifestyle" is not being taken up more widely within this patient population (13,14).

We have recently presented data supporting the feasibility of a full-scale trial of adjunctive exercise therapy for venous leg ulceration (17). The aim of the current paper was to undertake a detailed evaluation of the exercise session data. When adhering to pre-determined safety criteria, our results show primarily a very high fidelity of our proposed programme. It is evident from our data that not only is it possible to exercise this primarily-older and largely-frail, patient population at moderate intensities, but it is also possible to see a positive exercise progression over the duration of a medium-term training programme. This is the first study to report in-session data on this patient group and this acts as a comparator for researchers and practitioners embarking on similar trials with exercise as a therapy with this patient group.

Attendance, compliance, and safety

Our overall session attendance (79%) for the 18 participants across the 12-week exercise intervention compares well with an attendance range of 58–77% for other exercising, clinical populations (27,28). Our attendance results can be interpreted even more favourably to those

196 achieved in other exercise studies, considering the fact that ours was a time-demanding (e.g. 3
197 times per week), 3-month intervention, focusing on a group which is older, sedentary and without
198 an exercising culture; the large majority of our participants have not previously followed an
199 exercise programme. Consequently, it can be postulated that our participants were keen to
200 embrace such an intervention and participated whole-heartedly. Our results also show that most
201 missed sessions can be accounted to reasons unrelated to the exercise programme (e.g. illnesses
202 and family commitments) rather than the exercise programme itself. This knowledge, combined
203 with the very good safety record (e.g., no participants had their compression garments affected
204 during the exercise sessions), is a sign of trust of moving the intervention into the next stage, that
205 of the definitive trial. Nevertheless, much more data is required to evaluate the safety of the
206 intervention properly in this patient group.

207 When evaluating the fidelity of exercise training interventions researchers should ideally consider
208 both session attendance and meeting the prescribed exercise intensity, as this interaction
209 constitutes the dose of the intervention and influences the physiological response to exercise
210 training (21). Although in our case this might have been considered as a relatively easy task (as our
211 aim was to have participants exercising at "moderate" intensity, e.g. 12-14 in the 6-20 RPE Borg
212 scale), which is considerably lower to that sought by high intensity training (e.g., 85–95% of peak
213 heart rate) (29) exercise regimes, results should not be overlooked: our participants' unfamiliarity
214 with exercise interventions and in some cases frailty, meant that even the intended moderate
215 intensity could potentially be difficult to achieve in practice. For the aerobic exercise element of
216 our intervention this was achieved and maintained throughout the duration of the intervention,
217 matching the performance of other regimes, conducted in clinical settings, in older clinical
218 populations (e.g. Alzheimer's Disease) (30). Results differ in regards to resistance and flexibility, as

219 certain participants found difficulty to complete all resistance exercises to the required level
220 (Table 3) or intensity (Table 4). This was mainly due to frailty and lack of physical fitness (number
221 of sets/repetitions for resistance) or patients finding the exercises easier than expected (intensity
222 for flexibility). This can only be considered as part of our learning process to introduce more
223 challenging exercises (for flexibility) and a varying introductory pace (for resistance), in the future
224 study stages.

225

226 *Exercise progression*

227 The main aim of this article was to present our findings on attendance, compliance and safety.
228 Nevertheless, our detailed collection and analysis of exercise training data permits the objective
229 appraisal of our regime in regards to exercise progression as well: To facilitate a positive
230 adaptation to training, the prescription of exercise needs to advance over time (27). Many
231 programmes have failed to achieve this, presenting a need to re-define targets, following an in-
232 programme assessment (31) (which can be costly and resource-intensive). In the study presented
233 in this article, we used relative measures of exercise intensity to assess adherence to the
234 prescribed intensity. The fact that our aim was achieved was reflected in all of our exercise
235 indices, which show a statistically-significant increase in most measures, as well as a moderate-to-
236 large effect sizes: this demonstrates a clear exercise progression. Although it is difficult to
237 compare our findings with that of other trials in clinical or older populations (as in-session data is
238 not usually reported), our data is equally- or more favourably- comparable to similar interventions
239 in other clinical populations where physical functioning indices appear to be reduced (e.g. chronic
240 kidney disease) (32) or improved (e.g. older people living in retirement communities (33), multiple

241 sclerosis (34)) when compared with normative values. It remains to see whether this exercise
242 progression will be achievable in the definitive trial as well, nevertheless, the indicators are
243 encouraging, suggesting that participants with venous ulcers can benefit in multiple ways (e.g.
244 improved cardiorespiratory endurance (35) and better physical function (27), which are related to
245 high exercise session attendance) by taking part in such an intervention combining medium-
246 intensity aerobic, flexibility and resistance exercise, as previous studies in clinical populations have
247 shown (36,37).

248 *Limitations*

249 With this study exploring the feasibility of the intervention, the number of participants was
250 relatively small to what the definitive trial is expected to include. With that in mind findings should
251 be treated as indicative. Additionally, an in-depth assessment of fidelity in a definitive, multi-
252 centre exercise intervention will examine the consistency of the exercise dose across the different
253 sites, something that was not possible on this occasion. Finally, we cannot rule out the possibility
254 of underreported RPE scores due to the influence of observer sex as it has been suggested that
255 male participants report lower RPE values when a female observer, as opposed to male, is in the
256 room (38). Nevertheless, our sessions were delivered by both male and female physiologists and
257 our findings appear to be consisting throughout the intervention, hence the likelihood of that is
258 small.

259 *Conclusions*

260 This is the first study to provide a detailed quantification of the exercise sessions performed across
261 an exercise intervention combining aerobic, resistance and flexibility exercises for patients with
262 venous ulcers. The data will act as a comparator for researchers embarking on similar trials and

advocating exercise to this patient group in their practice. Our findings showed that our participants trained at the intended exercise intensity, improving their performance amongst all exercise domains in which they trained (e.g., number of minutes in aerobic exercise, number of squats and calf raises etc), without having their safety compromised. We conclude that it is possible to exercise this patient population at moderate exercise intensities. This is purposeful for further studies which consider deploying similar supervised exercise regimes as an adjunct therapy to compression, in an attempt to reduce healing times in patients with venous ulcers.

Conflicts of Interest

None to declare.

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Tables

Variable	Exercise group (n=18)
Age, years	66.9 (13.9)
Gender, number male/female	8/10
Stature, cm	171.1 (11.9)
Body mass, kg	102.1 (29.4)
Ulcer size, cm^2, median (range)	4.9 (1.9 to 136.4)
Duration of ulcer, months, median (range)	5 (1 to 72)
Ankle-brachial index	1.05 (0.14)
Ankle circumference, cm	27.1 (5.5)
Calf circumference, cm	37.3 (7.6)
Comorbidities, n (%)	
Hypertension	7 (39)
History of other CVD	1 (6)
Non-insulin-dependent diabetes	4 (22)
History of cancer	2 (11)
Hypercholesterolemia	1 (6)

Table 1: Exercise group participant characteristics (Values are mean (SD) unless otherwise stated; CVD, cardiovascular disease).

Variable	Estimated Range *(Moderate Intensity 60% - 80%)*	Base-Line (n= 18)	Mid-point (n= 13)	Intervention End (n=13)	P value; η^2	Post Hoc (Baseline-Midpoint); Cohen's d	Post Hoc (Baseline-Intervention End); Cohen's d	Post Hoc (Midpoint-Intervention End); Cohen's d
Aerobic Training HR	91-121 (10-13)	103 (14)	107 (12)	112 (18)	0.7; 0.01	0.38; 0.32	0.14; 0.35	0.45; 0.30
Aerobic Training RPE	12-14	12(0)	12(0)	12(0)	0.3; 0.05	0.71; 0.65	0.14; 0.26	0.13; 0.37
Resistance Training RPE	12-14	12(1)	12(0)	12(0)	0.3; 0.05	0.5; 0.25	0.14; 0.62	0.92; 0.38

Table 2: Changes in Exercise Intensity Indices between Exercise Sessions ($p<0.05$ for Repeated Measures ANOVA and $p<0.0167$ for post-hoc analysis).

	Base-Line (n=18)	Mid-point (n=13)	Intervention End (n=13)	P value; η^2	Post Hoc (Baseline-Midpoint); Cohen's d)	Post Hoc (Baseline-Intervention End); Cohen's d	Post Hoc (Midpoint-Intervention End); Cohen's d
Aerobic (Min)	19 (8)	26 (5)	29 (3)	<0.01; 0.35	<0.01; 1.10	<0.01; 1.82	0.11; 0.68
Squats	5 (12)	14 (18)	36 (18)	<0.01; 0.42	0.08; 0.64	<0.01; 2.10	<0.01; 1.21
Sit to Stand	12 (10)	29 (17)	36 (19)	<0.01; 0.32	<0.01; 1.21	<0.005; 1.68	0.28; 0.43
Step Ups	14 (15)	24 (18)	31 (22)	0.04; 0.14	0.13; 0.56	<0.01; 0.98	0.29; 0.42
Calf Raises	19 (13)	36 (13)	42 (14)	<0.01; 0.35	<0.01; 1.21	<0.01; 1.62	0.28; 0.43

Table 3: Changes in Aerobic and Resistance Exercise Indices between Exercise Sessions ($p<0.05$ for Repeated Measures ANOVA and $p<0.0167$ for post-hoc analysis).

Element	Fidelity Element	Percentage of Completion According to Protocol
Aerobic	Duration	81%*
	Intensity	100%
	Duration and Intensity	81%
Resistance	Number of Exercises	62%
	Repetitions	78%
	Sets	73%
	Intensity	91%
Flexibility	Duration	93%
	Number of Exercises	93%

Table 4: Assessment of Exercise Fidelity (* ≥25 minutes of total duration of aerobic exercises).