


ORIGINAL ARTICLE

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

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Despite exercise being included in the recommended advice for patients with venous leg ulcers, there is a fear shared by clinicians and patients that exercise may be either inappropriate or harmful and actually delay rather than promote healing. Therefore, before implementing a larger-scale study exploring the effects of a supervised exercise programme in patients with venous ulcers being treated with compression therapy, it is important to assess exercise safety as well as fidelity and progression in a feasibility study. Eighteen participants randomised in the exercise group were asked to undertake 36 (3 times/week for 12 weeks) 60-min exercise sessions, each comprising moderate-intensity aerobic, resistance, and flexibility exercise components. For the purposes of this paper, we analysed the data collected during the exercise sessions. The overall session attendance rate was 79%, with 13 of 18 participants completing all sessions. No in-session adverse events were reported; 100% aerobic components and 91% of resistance components were completed within the desired moderate-intensity target. Similarly, 81% of aerobic components and 93% of flexibility components were completed within the prescribed duration targets. Our data showed that patients with venous ulcers could safely follow a supervised exercise programme incorporating moderate-intensity aerobic, resistance, and flexibility components.

KEYWORDS

aerobic exercise, exercise progression, intervention fidelity, safety, venous ulcers

1 | 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 health care expenditure in the UK alone,² significantly affecting, 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 to patients' lives, it is no surprise that adjunct and alternative therapies to compression therapy (which is considered the golden standard)⁵ have been pursued (eg, ultrasound,⁶

larval therapy,⁷ biomaterials⁸), with exercise and physical activity promotion also being considered (eg, walking,⁹ increased physical activity,¹⁰ resistance exercise¹¹).

The concept of using exercise as an adjunct therapy to compression is not new, and indeed, exercise is included as a recommendation in the NICE Clinical Knowledge Summary for the management of venous leg ulcers (eg, "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 have the potential to inform practitioners and researchers involved in prescribing to and supervising the exercise of venous ulcer patients.

Exploring the Feasibility of Implementing a Supervised Exercise Training and Compression Hosiery Intervention in Patients with Venous Ulceration (FISCU)¹⁷ is a recently completed, two-centre 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 (eg, peripheral arterial disease,¹⁸ chronic obstructive pulmonary disease,¹⁹ cardiac diseases²⁰). 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.

2 | 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 a diameter greater than 1 cm were recruited from tissue viability clinics and newspaper advertisement in Sheffield, UK. 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 elsewhere²²; however, for the purpose of this article, the exercise training protocol is described below.

2.1 | 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

Key Messages

- supervised exercise has been used successfully in many clinical populations; nevertheless—and despite exercise being included in the clinical recommendations for people with venous ulcers (VLUs)—it has never been tested in this clinical population
- we aimed to evaluate the fidelity and exercise progression of a supervised exercise programme in patients with venous ulcers being treated with compression therapy; 18 people with VLUs were asked to attend 36 sessions of supervised exercise consisting of aerobic, resistance, and flexibility exercises within a space of 12 weeks
- the overall session attendance rate was 79%, with 13 of 18 participants completing all 36 sessions, while no in-session adverse events were reported; the vast majority of aerobic and resistance exercise components were completed within the desired moderate-intensity targets and within the prescribed duration targets.

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 min and comprised a combination of aerobic, resistance, and flexibility exercises. Each session began and ended with 5 min of low-intensity treadmill walking or cycling for a warm up and cool down, respectively. The aerobic component was aimed to last approximately 30 min, 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 min 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 (eg, calf raises and partial squats). Exercise was aimed to be performed for 2 or 3 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 s per muscle group (comprising 3 × 20-s stretches), held at the point of mild discomfort.²³

2.2 | 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 the

ventilatory threshold.²⁴ Each patient was familiarised 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 (eg, 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.

2.3 | 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 (eg, 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.

2.4 | 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, IBM Corp., Armonk, New York). 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 Cohen²⁶: 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 was set at $P < .05$ and for post hoc analysis at $P < .0167$.

3 | RESULTS

3.1 | Participants

Characteristics of the 18 exercise group participants are shown in Table 1. Ten of these participants were female, and the mean \pm 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 .

3.2 | 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 of 468 sessions were completed within the 12-week period, with the rest (57/468) being completed within the additional 2-week period. Of the 5 participants who did not complete all sessions, 1 withdrew fully from the trial before the 3-month follow-up assessment because of non-ulcer-related health problems, and 4 withdrew from treatment (ie, stopped attending before the end of the 12-week intervention period) but remained in the study (1 because of ulcer-related problems, 3 because of non-ulcer-related health problems). These 5 participants had completed 2, 4, 6, 15, and 17 exercise sessions 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 1 reason given on some occasions.

TABLE 1 Exercise group participant characteristics (values are means (SD) unless otherwise stated)

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)

CVD, cardiovascular disease.

3.3 | 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 health care personnel, these were dealt with by postponing the exercise session following the incident reporting (incident 1) and temporarily removing the resistance element from the training programme (incident 2).

3.4 | Exercise choices

The majority of the participants (72%) chose treadmill as their main aerobic mode of training at baseline, with the rest preferring cycling because of 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 1 of the participants was training via exercise cycle at the end of the 12-week intervention, with the rest of the participants who completed the intervention using the treadmill instead.

With regard to the resistance element of the intervention, 4 participants started the programme stating that they were unable to do squats, step-ups, or calf raises. This number was reduced to 2 at the end of their participation (they were, however, able to complete the rest of the regime). Finally, 1 of the participants could not do squats on Session 18 because of a pre-existing pain unrelated to exercise, although completing the rest of the session without issues. The participant completed his programme as well.

3.5 | 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 to 14 range (Tables 2 and 3).

3.6 | Exercise progression

Table 4 presents data on changes in the duration of the aerobic component and the number of repetitions completed for 4 lower limb resistance exercises. The number of minutes spent on aerobic exercise increased through the 12-week period (Baseline: 19 min (8), Mid-point: 26 min (5), End-point: 29 min (3)).

TABLE 3 Assessment of exercise fidelity

Element	Fidelity element	Percentage of completion according to protocol (%)
Aerobic	Duration	81 ^a
	Intensity	100
	Duration and intensity	81
Resistance	Number of exercises	62
	Repetitions	78
	Sets	73
	Intensity	91
Flexibility	Duration	93
	Number of exercises	93

^a ≥25 min of total duration of aerobic exercises.

Performance of the participants in the resistance exercise indices was also improved (Table 4); for example, calf raises increased from 19 (13) at baseline to 36 (13) at mid-point, reaching 42 (14) at the end of the intervention.

3.7 | Exercise fidelity

For the aerobic exercise element, all sessions were completed according to the prescribed intensity. For resistance, this was the case in 466 of 512 (91%) completed sessions. Duration of the exercise elements was close to the prescribed duration as well (413/512 = 81% for aerobic, 474/512 = 93% for resistance). The majority of those not completing the prescribed duration was at the start of their programme and was a result of the lack of physical fitness ($n = 4$), discomfort ($n = 2$), and unfamiliarity with the training equipment/exercises ($n = 4$)—with more than 1 reason being given by some participants.

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

Finally, flexibility exercises were completed as per protocol with regard to duration and number of exercises.

4 | 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

TABLE 2 Changes in exercise intensity indices between exercise sessions ($P < .05$ for repeated measures ANOVA and $P < .0167$ for post-hoc analysis)

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)	.7; .01	0.38; 0.32	0.14; 0.35	0.45; 0.30
Aerobic training RPE	12–14	12 (0)	12 (0)	12 (0)	.3; .05	0.71; 0.65	0.14; 0.26	0.13; 0.37
Resistance training RPE	12–14	12 (1)	12 (0)	12 (0)	.3; .05	0.5; 0.25	0.14; 0.62	0.92; 0.38

TABLE 4 Changes in aerobic and resistance exercise indices between exercise sessions ($P < .05$ for repeated measures ANOVA and $P < .0167$ 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)	<.01; 0.35	<0.01; 1.10	<0.01; 1.82	0.11; 0.68
Squats	5 (12)	14 (18)	36 (18)	<.01; 0.42	0.08; 0.64	<0.01; 2.10	<0.01; 1.21
Sit to stand	12 (10)	29 (17)	36 (19)	<.01; 0.32	<0.01; 1.21	<0.005; 1.68	0.28; 0.43
Step ups	14 (15)	24 (18)	31 (22)	.04; 0.14	0.13; 0.56	<0.01; 0.98	0.29; 0.42
Calf raises	19 (13)	36 (13)	42 (14)	<.01; 0.35	<0.01; 1.21	<0.01; 1.62	0.28; 0.43

appropriately designed studies that would substantiate its use and the fear of health care 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 this study was to undertake a detailed evaluation of the exercise session data. When adhering to pre-determined safety criteria, our results primarily show the 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.

4.1 | 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% to 77% for other exercising, clinical populations.^{27,28} Our attendance results can be interpreted even more favourably to those achieved in other exercise studies, considering the fact that ours was a time-demanding (eg, 3 times per week), 3-month intervention, focusing on a group that is older, sedentary, and without an exercising culture; the large majority of our participants have not previously followed an exercise programme. Consequently, it can be postulated that our participants were keen to embrace such an intervention and participated wholeheartedly. Our results also show that most missed sessions can be accounted by reasons unrelated to the exercise programme (eg, illnesses and family commitments) rather than the exercise programme itself. This knowledge, combined with the very good safety record (eg, no participants had their compression garments affected during the exercise sessions), is a sign of trust of moving the intervention into the next stage, that of the definitive trial. Nevertheless, much more data are required to evaluate the safety of the intervention properly in this patient group.

When evaluating the fidelity of exercise training interventions, researchers should ideally consider both session attendance and meeting the prescribed exercise intensity as this interaction constitutes the dose of the intervention and influences the physiological response to exercise training.²¹ Although, in our case, this might have been considered a relatively easy task (as our aim was to have participants exercising at “moderate” intensity, eg, 12 to 14 in the 6–20 RPE Borg scale), with values considerably lower to that sought by high-intensity training (e.g., 85%–95% of peak heart rate)²⁹ exercise regimes, results should not be overlooked: our participants' unfamiliarity with exercise interventions and, in some cases, frailty meant that even the intended moderate intensity could potentially be difficult to achieve in practice. For the aerobic exercise element of our intervention, this was achieved and maintained throughout the duration of the intervention, matching the performance of other regimes, conducted in clinical settings, in older clinical populations (eg, Alzheimer's Disease).³⁰ Results differ with regard to resistance and flexibility as certain participants found it difficult to complete all resistance exercises at the required level (Table 4) or intensity (Table 3). This was mainly because of frailty and lack of physical fitness (number of sets/repetitions for resistance) or patients finding the exercises easier than expected (intensity for flexibility). This can only be considered a part of our learning process to introduce more challenging exercises (for flexibility) and a varying introductory pace (for resistance) in the future study stages.

4.2 | Exercise progression

The main aim of this article was to present our findings on attendance, compliance, and safety. Nevertheless, our detailed collection and analysis of exercise training data permits the objective appraisal of our regime with regard to exercise progression as well; to facilitate a positive adaptation to training, the prescription of exercise needs to advance over time.²⁷ Many programmes have failed to achieve this, presenting a need to re-define targets following an in-programme assessment³¹ (which can be costly and resource-intensive). In the study presented in this article, we used relative measures of exercise intensity to assess adherence to the prescribed intensity. The fact that our aim was achieved

was reflected in all of our exercise indices, which show a statistically significant increase in most measures, as well as moderate to large effect sizes; this demonstrates a clear exercise progression. Although it is difficult to compare our findings with that of other trials in clinical or older populations (as in-session data are not usually reported), our data are equally or more favourably comparable to similar interventions in other clinical populations where physical functioning indices appear to be reduced (eg, chronic kidney disease)³² or improved (eg, older people living in retirement communities,³³ multiple sclerosis³⁴) when compared with normative values. It remains to be seen whether this exercise progression will be achievable in the definitive trial as well; nevertheless, the indicators are encouraging, suggesting that participants with venous ulcers can benefit in multiple ways (eg, improved cardiorespiratory endurance³⁵ and better physical function,²⁷ which are related to high exercise session attendance) by taking part in such an intervention combining medium-intensity aerobic, flexibility, and resistance exercise, as previous studies in clinical populations have shown.^{36,37}

4.3 | Limitations

With this study exploring the feasibility of the intervention, the number of participants was relatively small to what the definitive trial is expected to include. With that in mind, findings should be treated as indicative. In addition, an in-depth assessment of fidelity in a definitive, multicentre exercise intervention will examine the consistency of the exercise dose across the different sites, something that was not possible on this occasion. Finally, we cannot rule out the possibility of underreported RPE scores because of the influence of observer gender as it has been suggested that male participants report lower RPE values when a female observer, as opposed to male, is in the room.³⁸ Nevertheless, our sessions were delivered by both male and female physiologists, and our findings appear to be consistent throughout the intervention; hence, the likelihood of that is small.

4.4 | Conclusions

This is the first study to provide a detailed quantification of the exercise sessions performed across an exercise intervention combining aerobic, resistance, and flexibility exercises for patients with 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 (eg, 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 that will consider deploying similar supervised exercise regimes as an adjunct therapy to compression in an attempt to reduce healing times in patients with venous ulcers.

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Conflict of interest

The authors declare no potential conflict of interests.

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