

**Participant experiences in a feasibility trial of supervised exercise training in adults with venous leg ulcers: A qualitative study**

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Keywords:	Exercise, Feasibility, Qualitative, Participant experience, Venous leg ulcers
Abstract:	<p>Background: Exercise training may improve lower-limb cutaneous microvascular reactivity and clinical outcomes in adults with venous leg ulceration, however, there is a lack of research on patients views about the acceptability and feasibility of exercise interventions.</p> <p>Aim: The aim of this study was to explore participants experiences of a trial. Exploring the Feasibility of Implementing a Supervised Exercise Training and Compression Hosiery Intervention in Patients with Venous Ulceration (FISCU).</p> <p>Methods: Semi-structured face-to-face and telephone interviews were utilised to investigate participants experiences (n=16) of taking part in the FISCU trial. Data was analysed using thematic analysis.</p> <p>Results: Three overarching themes were identified and eleven sub-themes: (1) Sedentary cautious living (due to; pain and reduced mobility; treatment and perceived control; and advice to rest and be careful). (2) Key components of the exercise trial (including motivation; a individualised intervention supervised by a specialist exercise professional; and satisfaction with the intervention). (3) Benefits of exercise (physical benefits and healing; psychological wellbeing; positive impact on co-morbidities; and an improved self-management strategy).</p> <p>Discussion: This study found that an exercise intervention was viewed by participants as positive, acceptable and a feasible whilst living with a venous leg ulcer. An individualised and supervised exercise programme was key to build confidence to exercise.</p>

## 1 Introduction

### 2 Rationale

3 Exercise training can improve lower-limb cutaneous microvascular reactivity in adults with venous  
4 leg ulceration (VLU) (1). However, there is a lack of research on participants' views about the  
5 acceptability and feasibility of exercise as an adjunct therapy to compression therapy. The most  
6 common treatment for venous ulcers is compression therapy, providing graded external  
7 compression to the leg, opposing the hydrostatic forces of venous hypertension (2,3). It is accepted  
8 that in order to break the circle of ulceration and chronic venous insufficiency recurrence (which  
9 reaches up to 33% within a year) (4) lifestyle factors, such as nutrition, exercise and smoking, should  
10 also be considered as part of a strategy for managing venous leg ulcers (5). Published research from  
11 our group (6) and others (7,8) has explored the feasibility of using such interventions in this clinical  
12 group. Such modifiable lifestyle factors are mentioned in clinical guidelines on the management of  
13 VLU (9–11), but have received relatively little emphasis from a patient perspective to date.  
14  
15 Given the infancy of the research in the area there has been little exploration of patient-reported  
16 experiences of engaging in exercise therapy interventions designed to improve ulcer healing  
17 outcomes. However, NICE (9) and SIGN (10) guidelines currently advocate that people with VLU  
18 should be given advice about healthy lifestyle choices and patients are advised to keep physically  
19 active utilizing calf muscle pump exercises. The process of obtaining participant insight data is  
20 recommended by the Medical Research Council in the development and evaluation of complex  
21 health interventions (12). If people with VLU are expected to engage in and sustain these behaviors  
22 then we must understand the patient experience of doing so. Much contemporary research on  
23 active living behavior among older adults is guided by Social Cognitive Theory (SCT) (13). Physical  
24 activity interventions based on SCT have demonstrated success in promoting increased physical  
25 activity for people with VLUs (14) and have provided a framework to factors influencing adherence  
26 such as focusing on self-efficacy (15). Identifying the barriers, enablers and benefits of exercise

27 therapy in this population will help to plan effective interventions and inspire other members of this  
28 clinical population to initiate and maintain exercise therapy.

29

30 O'Brien and colleagues provided important qualitative insights into the perspectives of adults with  
31 VLU on the topic of exercise (16). Findings revealed that adults with VLU are interested in becoming  
32 active or maintaining active lifestyles. A host of noteworthy factors that underpin adults  
33 understanding of the relationship between chronic venous insufficiency and perceived or actual  
34 exercise patterns were uncovered through semi-structured interviews and discussions. These factors  
35 included that exercise knowledge can act as a motivator for exercise, adults with VLU can accrue  
36 general physiological benefits through exercise, and knowing if your condition was acute or chronic  
37 could influence one's appreciation of the importance of exercise for condition management.

38 Furthermore, this work offers important insights into perceived factors that limit exercising, how  
39 structured management facilitates exercise and critically how fear of harm impacts upon positive  
40 beliefs and attitudes to exercise (16). The current research project will add to existing knowledge by  
41 exploring the key components of an exercise intervention for people with VLU from the patient  
42 perspective.

43

#### 44 **Objective**

45 The aim of this study was to explore participants' experiences of taking part in a trial that  
46 investigated the feasibility of exercise training alongside compression therapy for management of  
47 VLU healing – "*Exploring the Feasibility of Implementing a Supervised Exercise Training and*  
48 *Compression Hosiery Intervention in People with Venous Ulceration*" (FISCU) - an NIHR-funded study  
49 (PB-PG-0213-30029). Given that exercise training for the management of VLU healing is an emerging  
50 potential new therapy, the research team was keen to understand participants' experiences and  
51 perspectives of the acceptability and feasibility of the exercise training programme.

52

## 53 **Methods**

### 54 **Study Design**

55 Ethical approval for this study was received from South Yorkshire Ethics Committee (14/YH/0091).  
56 The study utilised semi-structured face-to-face and telephone interviews to investigate participant's  
57 experiences of taking part in the FISCU trial. Face-to-face or telephone interviews were selected as  
58 they allowed for a more personalised experience to be explored rather than exploring themes in a  
59 group session, such as a focus group. To minimise the burden of travel on participants with limited  
60 mobility, face to face interviews were offered alongside their physiological follow-up health  
61 assessment. Prior to commencing the interviews, participants had completed 12 weeks of the FISCU  
62 trial participation (post-baseline). Participants who had been randomised to the exercise arm of the  
63 trial followed an exercise training programme whilst wearing their compression hosiery or  
64 bandaging as described in the trial protocol (17). This included three supervised exercise sessions  
65 each week comprising of aerobic, resistance and flexibility exercises.

### 66 **Sample**

67 Qualitative sub-study inclusion criteria required that participants were:

68 i) part of the main trial

69 ii) minimum of 12-weeks post baseline.

### 70 **Recruitment**

71 Sixteen participants with VLU were recruited using purposive sampling that ensured a mixture of  
72 genders and younger and older participants. Participants included those treated with a mixture of  
73 compression hosiery and bandaging. Participants were approached either in person or by telephone  
74 by the main research assistant on the study to take part in the qualitative study as they were due to  
75 complete their 12-week follow-up assessment. All participants that were asked to take part in the  
76 interview agreed to take part.

77

**78 Data collection**

79 A semi-structured interview guide was formulated based upon previous literature and the authors  
80 past experience in qualitative research (see Table 1). Rapport was established with all participants  
81 with the interviewer prior to conducting the interviews by taking their health and fitness  
82 assessments. Interviews took place at Sheffield Hallam University (the same location as the exercise  
83 sessions and health assessments).

84

85 All interviews were audio recorded and transcribed verbatim. Interviews lasted between 15 minutes  
86 and 60 minutes according to the length of participant responses. All transcripts were checked for  
87 accuracy, with a sample being reviewed by co-investigators. After 16 interviews there was an  
88 agreement between authors that data saturation was reached and that no new information relevant  
89 to the research aims was evident.

90

**91 Data analysis**

92 The interview data was analysed by a process guided by the principles of thematic analysis (18) and  
93 in particular framework analysis (19). Framework analysis offers a systematic approach that is  
94 somewhat inductive, that is, it is based in the original interview transcripts but framed within an *a-*  
95 *priori* framework such as a topic guide whereby questions are known at the outset of the interview.

96 Framework analysis is well-suited to the needs of health services research and participants with long  
97 term health conditions (16). The five stages of framework analysis consist of (i) familiarisation (ii)  
98 reading and re-reading the transcripts (iii) identifying a thematic framework (iv) coding or indexing  
99 (v) charting and mapping (19).

100

101 An initial thematic framework was produced drawing upon the trial *a-priori* interviews and reading  
102 the transcripts highlighting salient issues. Transcripts were coded to offer insight into the topic areas  
103 being investigated, making constant reference to the study aim. Multiple codes were assigned to

104 elements of the data. Any feature of the data which revealed insight into the phenomenon being  
105 studied was eligible for coding. Coded data extracts (quotes) were charted for each participant case.  
106 Comparison of coded quotes was conducted within and between the transcripts. Codes were  
107 subsequently collated to illustrate broad themes and define further sub-themes. Discussions and  
108 consensus between lead researchers finalised the mapping and interpretation of key themes and  
109 sub-themes.

110

111 Prior to analysis, participants were offered the opportunity to review their transcripts providing  
112 triangulation to the methods and verification of content. HC performed the initial coding, who has  
113 over a decade of experience in qualitative research methods and has published numerous  
114 qualitative research studies on exercise for people with long term chronic health conditions. SK led  
115 the interviews and reviewed the codes and also has several years' experience in qualitative research  
116 methods in exercise for people with different medical conditions. A third mixed methods researcher  
117 EM transcribed the interviews verbatim and independently read the transcripts and read the  
118 thematic framework and confirmed the validity of the themes and sub-themes.

119

### 120 3. Results

121 Sixteen participants took part in this qualitative study (12 face to face and four telephone interviews)  
122 out of the 39 participants who took part in the main research trial. All except one participant were  
123 White British (similar ethnicity to participants on the FISCU trial). Fifty six percent of the participants  
124 were male (n =9). The mean age of participants was 65 ± 11 years. Eighty one percent were retired  
125 and the remainder (19%) were employed in a sedentary occupation. The mean time since  
126 participants' first VLU diagnosis was 7 ± 11 years. At the time of interview the mean duration of  
127 participants current VLU was 7 ± 14 months.

128

129 Three overarching themes and eleven sub-themes were identified through thematic data analysis  
130 (presented in Figure 1):

- 131 1) Sedentary cautious living can be due to; fear of movement because of pain and reduced  
132 mobility; treatment and perceived control; and advice to rest and be careful.
- 133 2) Key components of the exercise trial included; motivation for taking part; an individualised  
134 intervention supervised by a specialist exercise professional; and satisfaction with the  
135 exercise intervention.
- 136 3) Benefits of exercise included; perceived physical benefits and healing; psychological  
137 wellbeing; positive impact on co-morbidities; and an improved self-management strategy.

138

### 139 **1. Sedentary cautious living**

#### 140 **1.1. Fear, pain and reduced mobility**

141 Participants' insights revealed a chronic, complex and unpredictable condition which at times could  
142 be painful, physically limiting and emotionally challenging with the potential to negatively impact  
143 their well-being and quality of life and ability to exercise. Therefore, many participants were  
144 uncertain and (in some cases) fearful about participating in an exercise programme. Half of the  
145 participants had experienced pain that was considered to be a significant debilitating feature of the  
146 condition. For example, one participant stated:

147

148 *"There has been times when the pain has controlled me and that can be challenging because I try not*  
149 *let them dominate my life but sometimes you do have to sit back and say well today I'm just going to*  
150 *sit here" (participant 014, exercise group).*

151

#### 152 **1.2. Treatment and perceived control**

153 It was not uncommon for participants to be treated in a specialist tissue viability clinic two to three  
154 times a week to have their wounds redressed and re-banded. Some participants were concerned

155 about the added commitment of travelling to starting an exercise programme on top of treatment  
156 time commitments. A combination of treatment modalities included compression bandaging and  
157 compression hosiery, dressings antibiotics, pain-killer medication, skin care regimes with creams  
158 Some of individuals also felt that compression stockings and bandages limited motion and leg  
159 muscle activity. Showering and bathing were highlighted as day to day activities that were negatively  
160 impacted by the condition. Some participants needed assistance to get their compression stockings  
161 on and off which caused a challenge to personal hygiene for exercising, stating:

162

163 *"It is difficult to wash and I can't get my stockings on and off on my own without help" (participant*  
164 *015, exercise group).*

165

166 Most participants had experienced the condition for several months and even years and several  
167 participants disclosed that the near constant intrusion into their lives had created behaviour  
168 patterns based around settling for doing less, just pottering, talking themselves out of doing physical  
169 activity, becoming more sedentary than they were previously. For example one participant said:

170

171 *"I tend to settle for stuff ... this sitting doing nothing kind of thing you think oh well maybe if I'd been*  
172 *a bit the other way I'd been thinking no you need to get up and do something don't just settle for*  
173 *this" (participant 019, exercise group).*

174

175 Participants also felt limited as to how much personal influence they had on the ulcer healing  
176 process:

177

178 *"I seem to win little battles with them, they seem to start to heal and then they deteriorate again it's*  
179 *like two steps backwards one step forwards. I've really struggled for the past on and off for 10 years"*  
180 *(participant 013, Exercise group).*



181

182 In some participants it was clear their ulcer experience had a negative impact on their lives and they  
183 were 'fed-up' with the condition:

184

185 *"The last thing I want to do is going back to sitting doing nothing because it really is soul destroying*  
186 *and it's that makes you feel worthless because you can't do anything "* (participant 019, Exercise  
187 *group).*

188

### 189 **1.3. Advice to rest and be careful**

190 The key messages of advice regarding condition management that participants readily recalled were;  
191 to be careful, protect the leg from knocks and elevate the leg such as playing with grandchildren,  
192 dogs jumping up at them, exposure to insect bites in summer and generally being in a state of  
193 heightened awareness. This had resulted in the majority of the participants living what can be  
194 described as anxious and "cautious lives" including avoidance of physical activity. Participants felt  
195 health professionals to rest emphasised the importance to be cautious:

196

197 *"I dared not exercise or move in case it made the leg ulcer worse. I was frightened that if I*  
198 *accidentally knocked it I would be back to square one again. So I just started doing less and less*  
199 *activity" (participant 014, Exercise group).*

200

201 *"They've (nurses) always told me you know rest keep your leg up that is what I was told before for*  
202 *years" (participant 009, exercise group).*

203

204 The constant perceived risk of aggravating a current ulcer or somehow triggering a new ulcer  
205 created feelings of fear towards activity. Participants were constantly mindful and fearful of the risk  
206 of making things worse, possible recurrences and set-backs. One participant recalled:

207

208 *"I was simply worn out but it was difficult my greatest fear was getting it so badly infected that I*  
209 *would end up with gangrene" (participant 001, exercise group)*

210

211 Reflections on exercise advice from health care professionals concluded that the majority of  
212 participants (n=12) had not received any specific exercise advice and that the benefits of exercise  
213 had never been explicitly linked to their condition:

214

215 *"They didn't suggest exercise they just say elevate your leg keep it elevated you know, go and lay*  
216 *down for an hour every afternoon and do it that way but that's all they could say" (participant 017,*  
217 *exercise group).*

218

219 The lack of specific advice on exercise goals was perceived to be confusing:

220

221 *"It is contradictory in a way I had this out with the nurse yesterday when she wrapped my legs will*  
222 *break it down a bit more on my right leg with ulcer she says 'you are resting aren't you?' and I said*  
223 *yes course I am and I put my legs up while you know while I am sat watching telly and that and*  
224 *'you're exercising them aren't you?' so it's like contradicting itself are you resting a lot or are you*  
225 *exercising it is contradictory to what they want me to do" (participant 008, exercise group).*

226

## 227 **2. Key components of the exercise trial**

### 228 **2.1. Reasons for taking part in the project**

229 Participants commented that they chose to take part in the study for the following reasons: to help  
230 with research, to learn more about exercise, to meet other people, have an incentive to leave the  
231 house, a perception that the study was trust-worthy being run by a university and was unlikely to do  
232 harm. Participants stated:

233

234 *"It was positive it was a different treatment it wasn't just drugs it wasn't just bandages it was an*  
235 *alternative to try something new because I've had this ulcer for years" (participant 001, exercise*  
236 *group).*

237

238 The support of family and a health care professional advocating and endorsing study participation,  
239 helped participants decide to take part in the study:

240

241 *"I actually saw this booklet and I took the trouble to read it because I could see the word exercise and*  
242 *then I saw there was a personal trainer and I thought that sounds interesting. I thought well I will just*  
243 *send an email on for a bit more information and that and I spoke to my family my daughter and my*  
244 *son and that and said what I was thinking of doing and they just said just go for it. So I thought well it*  
245 *can't do any harm" (participant 009, exercise group).*

246

247 A couple of participants did offer these comments which demonstrate their partial understanding of  
248 the aetiology of the condition and how exercise might be beneficial for their condition:

249

250 *"She (nurse) often mentioned, she would say things like you should you get up and do stuff. But*  
251 *nobody has actually said till I came here, or pointed out the benefits towards healing a leg ulcer, but*  
252 *after it was said to me, well that kind of makes complete sense. It's (exercise has) got to benefit*  
253 *everything you do but I think when you think about exercise, you don't apply the benefits to the*  
254 *healing process. You don't think about that, but once it's mentioned it become obvious and you think*  
255 *we'll of course" (participant 019, exercise group)*

256

257 **2.2. Individualised intervention**

258 The supervised exercise intervention was specifically tailored to the condition and also took account  
259 of existing co-morbidities, was described as being adapted to the individual's ability with gradual,  
260 paced progression of exercise intensity. For those who took part in the exercise intervention arm of  
261 the trial and completed the interview they described the set routine of exercises as being  
262 manageable as they were able to perform the exercises within their own limitations whilst wearing  
263 compression hosiery or bandages:

264

265 *"Well we have been doing the treadmill then various stretching exercises, ankle exercises, standing*  
266 *up & sitting down, going up and down on tip toes "* (participant 015, exercise group).

267

268 Another participant also stated:

269

270 *"Yes you can do proper exercises that are aimed at that sort of thing rather than just walking;*  
271 *walking is fine but to be able to do exercises that you know are working on the leg area and that*  
272 *problem"* (participant 017, exercise group).

273

### 274 **2.3. Supervised by a specialist exercise professional**

275 The exercise programme offered a further social benefit of engaging in a supportive therapeutic  
276 relationship with the exercise instructor. Given that participants were undergoing treatment at the  
277 time of the study and had not experienced a similar type of approach having a supervised  
278 intervention was an important consideration for ensuring safety, monitoring intensity and  
279 progression and an opportunity to openly discuss the condition:

280

281 *"Yeah and it gives you a lot of confidence knowing that there is somebody there knowing you don't*  
282 *want to get you heart rate above a certain amount there's someone there to reign you in if you're*

283 *trying to push too hard or gee you up if you're not going as hard as you should think that's very good*  
284 *thing" (participant 019, exercise group).*

285

286 Another participant commented:

287

288 *"But here whether or not it's because you got personal training with you and talking to you, you don't*  
289 *really realise actually what you doing when you're on it (the treadmill) but I mean I got up to the 15*  
290 *which is the highest incline you can get on it and I've never done that before. I've noticed when I'm*  
291 *out walking I'm walking quicker I am walking better people have told me I am walking better"*  
292 *(participant 009, exercise group).*

293

#### 294 **2.4. Satisfaction with the exercise intervention**

295 All participants remarked that they had enjoyed the exercise intervention and they reported that it  
296 had been a worthwhile experience:

297

298 *"I am very happy about the research programme, everyone has been really nice and it has benefited*  
299 *me in a big way" (participant 007, exercise group)*

300

301 Another participant agreed:

302

303 *"the advice has been perfect perfectly pitched for the purpose so no I can't think of anything that*  
304 *could be bettered I just think it's all a benefit" (participant 019, exercise group).*

305

306 An additional participant commented:

307

308 *"The benefits I got from the course itself I feel a lot better from attending it and the instructor was*  
309 *excellent very, very helpful and I had a good experience" (participant 008, exercise group).*

310

311 The only features of the study that were not well received related to accessing the venue in the cold  
312 weather, for some it was awkward having to make the journey on buses as this was time consuming.

313 Additionally one participant suggested it would be good to have additional peers exercising at the  
314 same time to foster a social atmosphere (group sessions were available where possible for other

315 participants):

316

317 *"Although I did enjoy it, at that time of year it was very cold and a lot of travelling on buses which is*  
318 *very hard work for me" (participant 001, exercise group).*

319

### 320 **3. Benefits of exercise**

#### 321 **3.1. Physical benefits and healing**

322 Participants communicated that the exercise training resulted in improvements in their physical  
323 health that translated into meaningful, functional improvements in well-being, such as being able to  
324 walk further and quicker, helping with weight loss, reducing fatigue, and feeling stronger in the legs.

325 For example one participant reported:

326

327 *"I have a vast improvement to the way I'm feeling to the way I'm holding myself the way I move*  
328 *people are saying you look totally different you're walking a lot better I'm walking a lot further and*  
329 *it's not until I felt the benefits from this that I realised fully how bad things had got "(participant 019,*  
330 *exercise).*

331

332 Another participant mentioned:

333

334 *"Over last few weeks I've noticed a big change in my legs I feel a lot more sturdy on my legs and I*  
335 *don't seem to tire as quick either but that might be due to the weight loss as well but I think it's all*  
336 *combined factors" (participant 014, exercise group).*

337

338 Performing exercise had for one participant prevented the usual pattern of fluid build-up which was  
339 associated with ulcer onset:

340

341 *"The benefits I've had from this are absolutely amazing I don't feel like the same fella anymore and*  
342 *I'm sure I heal quickly anyway but I'm sure the fact that I'd started exercising also had a lot to do with*  
343 *that and its healed and it's been healed for a few weeks" (participant 019, exercise group).*

344

345 *Another participant said:*

346

347 *"I should say from the beginning it just sort of healed so quickly that you know I have never seen my*  
348 *leg heal that quickly before I can honestly say that and I think they were a bit surprised at the clinic"*  
349 *(participant 009, exercise group).*

350

351 *An additional participant talked about their improvements:*

352

353 *"I can do 30mins now and we started at 10/15 minutes so it's all built up and improved everything*  
354 *and I say the ulcer is almost healed almost, I'm sure the exercise has helped it, definitely" (participant*  
355 *017, exercise group).*

356

### 357 **3.2. Psychological well-being**

358 Several participants reported a new confidence in one's ability to exercise which was mediated by  
359 progression in fitness and increased exercise competence:

360

361 *"The exercise has been useful in as I say helping your well-being and I've really enjoyed it and look*  
362 *forward to coming, I look forward to it" (participant 015, exercise group)*

363

### 364 **3.3. Positive impact on co-morbidities**

365 Participants explained how they were not only living with venous leg ulceration but also with other  
366 conditions. The types of conditions included; Type II diabetes, musculoskeletal conditions (back),  
367 depression, anxiety, Rheumatoid Arthritis, COPD, and knee pain. The presence of other long-term  
368 co-morbidities was responsible for further limiting daily activities and general health and well-being.  
369 Participants expressed the view that the current FISCU exercise intervention although designed  
370 specifically for adults with leg ulcers also had transferable benefits which helped them manage the  
371 symptoms of their other conditions:

372

373 *"I've got COPD and the programme that I've had has been modified to allow for my breathing, I feel*  
374 *like a different fella from the one that came in here a few weeks ago (participant 019, exercise*  
375 *group)."*

376

377 The same participant noted:

378

379 *"I'm moving better and faster because of this programme compared to when I first came. For*  
380 *example if I parked in the car park and made my way up here I would have to stop half a dozen times*  
381 *to catch my breath now I'm parking up and coming straight up. If you'd have told me before I started*  
382 *that I would be able to do that I would have laughed at you... the benefits I feel from this programme*  
383 *are just immeasurable "(participant 019, exercise group).*

384

### 385 **3.4. Improved self-management strategy for a long term health condition**



386 A common finding for the majority who engaged in the exercise arm of the study was that they were  
387 capable of participating in structured exercise and could obtain meaningful well-being benefits from  
388 that participation. For many this was counter-intuitive as previously held beliefs to rest and "be  
389 careful" had led to talking oneself out of activities and adopting a more sedentary lifestyle. The  
390 realisation that participants could perform exercise training that might result in improved ulcer  
391 healing was a powerful incentive to adhere to the programme and continue exercising beyond the  
392 study. For example, one participant thought:

393

394 *"I've always had the opinion that when you've got leg ulcers you don't need to be going to the gym,*  
395 *that's it, you don't do it. Now I'm thinking the total opposite I'm thinking really I do need to get back*  
396 *in that gym and even my nurse said you want to carry on doing this now because she said I've noticed*  
397 *the improvement in your ulcers "* (participant 014, exercise group).

398

399 With other participants stating:

400

401 *"I'd convinced myself I couldn't do stuff and you and this programme have convinced me that I can*  
402 *and I can do a lot more than I thought I could"* (participant 019, exercise group)

403

404 *"Instead of just sat looking at the television I've started to take the dog for a walk or go to the shops*  
405 *to get some fruit... things I'm doing different now and staying more active which I plan to continue"*  
406 *(participant 021, exercise group).*

407

## 408 **Discussion**

409 The purpose of this research was to understand participants' experience taking part in a trial that  
410 investigated the feasibility of supervised aerobic and resistance exercise training alongside  
411 compression therapy for management of venous leg ulcer (VLU). Interviews indicated that the

412 exercise intervention was viewed as positive, acceptable and a feasible approach to physical activity  
413 whilst living with a VLU. Themes that emerged included participants adopting sedentary and  
414 cautious living prior to the programme due to fear of movement linked to pain, reduced mobility,  
415 the time burden of treatment and advice to rest and be careful. Confidence to take part increased by  
416 having exercise sessions supervised by a health professional tailored to meet their individual's needs  
417 and medical conditions. Participants reported that the training programme had benefits including  
418 both physical and mental wellbeing, quality of life and a positive impact on additional comorbidities.  
419 Our findings suggest that participants value support on how to exercise safely to give them the  
420 confidence to become more physically active.

421  
422 Participants expressed fear prior to commencing the exercise intervention over knocking the leg  
423 with the ulcer causing either pain or regression of healing. Fear of injury is related to fear of  
424 movement or *kinesiophobia* (20) which is associated with avoidance of physical activity so as to  
425 minimize the risk of injury or re-injury. Avoidance of accident or trauma to the leg through safety  
426 thinking, precautions, compression treatment and clothing is an important issue in preventing leg  
427 ulcers. However, fear becomes dysfunctional as soon as it goes beyond safety thinking and  
428 precautions (21). This was seen in those individuals who felt that physical activity was a risk-taking  
429 action, as in 'fear of injury'. Qualitative research exploring perspectives of adults with VLU on  
430 exercise agree with these findings that patient's fear of harm can impact upon their positive beliefs  
431 and attitudes to exercise (7,22). This suggests that experiential learning whilst participants take part  
432 in a supervised exercise training programme can reduce fear of harm, particularly if participants  
433 experience benefits of exercise opposed to an adverse effect.

434  
435 Participants described previously receiving conflicting advice from health professionals on whether  
436 they needed to rest and 'elevate the leg' or take part in exercise. This is similar to findings to  
437 previous research which found that participants reported contradictory advice given from health

438 professionals in relation to exercise or physical activity (23). Our findings agree with Roaldsen *et al*  
439 (2011) who reported that lifestyle advice such as 'live as usual' and contradictory exercise advice, is  
440 not a useful approach (21). This confusing advice could be due to the lack of current guidelines for  
441 participants in relation to what type of exercise or physical activity is recommended for their chronic  
442 disease of VLU. However, the research providing the evidence base to underpin guidelines on  
443 physical activity for VLU is growing (8,24–26). This suggests that providing specific information rather  
444 than general advice on exercise is important for people with leg ulcers. This guidance needs to  
445 include information on the specific types of activity that are suitable.

446

447 Participants felt that supervised exercise sessions tailored towards their individual needs increased  
448 their confidence to be physically active. According to Social Cognitive Theory (SCT) the construct of  
449 self-efficacy, or confidence, is a key determinant of self-management of behaviours (27). Previous  
450 research has found that self-efficacy is significantly related to adherence to an exercise programme  
451 for people with leg ulcers (15). The mechanism behind increased self confidence in our study is likely  
452 to be due to increased participant belief that they were able to achieve their exercise goals.

453

454 Our study found that travel to and from the exercise facilities was reported to be a barrier for some  
455 participants, particularly those with limited mobility. Travel to and from exercise facilities has  
456 previously been reported to be a barrier to exercise and physical activity (28). The concept of lack of  
457 time is particularly pertinent for people with leg ulcers who are visiting tissue viability clinics several  
458 times a week, perhaps alongside work or other family commitments, over several months or years  
459 (16). Other research has looked at the patient experience of both supervised and home based  
460 exercise for participants with leg ulcers (23,29). Home based exercise programmes with telephone  
461 support have been found to increase a patient's self-efficacy (15). A home-based exercise, with  
462 specialised exercise instruction at the start of the programme to increase patient confidence, would  
463 be a useful area for further research, particularly for participants with reduced mobility for travel.

464

465 Some patients faced practical barriers including limitation of movement and challenges maintaining  
466 personal hygiene after exercising due to bandages and dressings, or needing assistance to get their  
467 compression hosiery on and off. Previous research also reports participants discussing difficulties  
468 getting into the bath or being unable to have their foot or leg washed for a long time (30). Other  
469 literature also found patients feared compressions stockings and bandages limiting motion and leg  
470 muscle activity (21). Participants found that timing exercise sessions before an appointment with a  
471 specialist tissue nurse or using assisting devices to help get compression hosiery on and off enabled  
472 them support with personal hygiene. This highlights the importance of education about how to  
473 manage side effects of physical activity including advice on practical considerations for VLU.

474

475 An important aspect to self-management of a long term health condition is an understanding of the  
476 benefits of physical activity specifically in relation to that condition (21). However, research suggests  
477 that there is lack of patient knowledge about leg ulcer healing and prevention of reoccurring (31).  
478 Our study supports previous work suggesting that participants who understand the underlying  
479 pathophysiology of chronic venous insufficient are more likely to be able to relate the benefits of  
480 exercise such as improving blood flow to improving their condition and poor venous return (16,21).

481 The current therapy for leg ulcer healing is compression bandaging, however, this can affect range of  
482 ankle motion which can affect walking. Previous researchers have suggested that an opportunity  
483 exists for health professionals to teach simple exercises to activate the calf muscle pump (32) and  
484 maintain or improve their range of ankle motion by demonstrating simple ankle movement and  
485 heel-raising exercises, perhaps whilst bandaging their ulcers (16).

486

487 Participants perceived that exercise had improved their physical health including a positive impact  
488 on other co-morbidities and overall wellbeing. Research has shown participants who adhere to the  
489 exercise programme as an adjunctive treatment to standard care are more likely to heal and have

490 better functional outcomes than those who do not adhere to the exercises in conjunction with usual  
491 care (8). Previous research found one of the main reasons participants with VLU did not adhere to  
492 leg exercises included health deterioration of their other chronic conditions (15). Participants  
493 appraised their overall well-being within the context of living with leg ulceration and existing co-  
494 morbidities; at times co-morbidities were as debilitating if not more so than leg ulceration. The  
495 importance of well-being and proactive preventative approaches (such as exercise) rather than a  
496 sole focus on treatment (in a hospital or clinic setting) is emphasised as important for people with  
497 VLU (33).

498

#### 499 **Strengths and limitations**

500 The research provides in-depth insight into the specific experiences of participants taking part in a  
501 supervised exercise intervention for adults with VLU. Hence the aim was achieved and important  
502 influences to participation in exercise were identified. The findings can be used to extrapolate  
503 practical implications for promotion of physical activity and exercise for people with leg ulcers. The  
504 consistency of themes with previous literature supports the credibility of the findings and  
505 methodological rigour. However, the findings should be considered in light of methodological issues.  
506 Firstly, the sample was not necessarily representative of the wider VLU population. The majority of  
507 patients interviewed were of White British Ethnicity (similar to those who took part on the RCT),  
508 therefore caution should be applied when generalising these results to patients from other cultural  
509 backgrounds. Secondly, consideration needs to be given that this study used a mixture of face to  
510 face and telephone interviews. From the researchers' perspective, face to face interviews provided  
511 richer data compared to telephone, as the researcher was able to convey more empathy using body  
512 language. Telephone interviews were offered to participants who were unable to travel due to their  
513 leg ulcers or other commitments (such as multiple visits to the leg ulcer clinic or needing to wait in  
514 for the day for a nurse to dress their ulcers). Interviews have been used by previous researchers to  
515 gather perspectives of adults with VLU (16) and can therefore be considered a valid approach.

516 Thirdly, participants included those with a range of treatment including both compression hosiery  
517 and bandaging, however different treatment may affect mobility and therefore experience of  
518 exercise. Previous research has found patients report a difference in mobility depending on  
519 compression versus bandaging, as bandaging can restrict mobility more than compression hosiery  
520 (34). Therefore, future studies may wish to focus on larger and more representative samples, and  
521 participant experiences of exercise comparing those with compression hosiery with multiple layer  
522 bandaging.

523

#### 524 **Implications for practice**

525 The current advice from many health professionals to rest and be careful can lead to participants  
526 living more sedentary lifestyles which in turn can lead to poorer physical and psychological well-  
527 being for participants with VLU. Participants report that supervised exercise can lead to a perception  
528 of increased confidence to be physically active and physical benefits such as accelerated venous  
529 ulcer healing and a positive impact on other health conditions. Exercise therapy has the potential to  
530 holistically improve well-being in participants with VLU by addressing both their leg ulceration and  
531 existing co-morbidities.

532

#### 533 **Conclusion**

534 The current study found that the opportunity to engage in a supervised, individualised exercise  
535 intervention specifically for the purpose of managing leg ulceration was welcomed by people with  
536 leg ulcers who had taken part in the exercise intervention. The opportunity to safely exercise and  
537 experience tangible benefits in physical and psychological health offered participants a new  
538 approach to future self-management. This was seen as an extension to specialist care fulfilling a gap  
539 in current provision. Overall, an individualised and supervised exercise programme was viewed by  
540 participants as an acceptable and feasible approach for people with VLU as part of a self-  
541 management strategy.

542

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547

548 **References**

- 549 1. Tew GA, Gumber A, McIntosh E, Kesterton S, King B, Michaels JA, et al. Effects of supervised  
550 exercise training on lower-limb cutaneous microvascular reactivity in adults with venous  
551 ulcers. *Eur J Appl Physiol.* 2018;118(2):321–9.
- 552 2. Eberhardt RT, Raffetto JD. Chronic venous insufficiency. *Circulation.* 2014;130(4):333–46.
- 553 3. O’Meara, S., Cullum, N., Nelson, E. A., & Dumville JC. Compression for venous leg ulcers.  
554 *Cochrane database Syst Rev.* 2012;11.
- 555 4. Kulkarni SR, Gohel MS, Whyman MR, Poskitt KR. Significance of limb trauma as an initiating  
556 factor in chronic leg ulceration. *Phlebology.* 2008;23(3):130–6.
- 557 5. A national clinical guideline. In *Guideline No. 120.* Edinburgh; 2010.
- 558 6. Klouzakakis M, Tew GA, Gumber A, Crank H, King B, Middleton G, et al. Supervised exercise  
559 training as an adjunct therapy for venous leg ulcers: a randomized controlled feasibility trial.  
560 *Br J Dermatol.* 2018;178(5):1072–82.
- 561 7. O’Brien JA, Finlayson KJ, Kerr G, Edwards HE. Testing the effectiveness of a self-efficacy based  
562 exercise intervention for adults with venous leg ulcers: Protocol of a randomised controlled  
563 trial. *BMC Dermatol.* 2014;14(1):1–9.
- 564 8. O’Brien J, Finlayson K, Kerr G, Edwards H. Evaluating the effectiveness of a self-management  
565 exercise intervention on wound healing, functional ability and health-related quality of life  
566 outcomes in adults with venous leg ulcers: a randomised controlled trial. *Int Wound J.*  
567 2016;14(1):130–7.

- 568 9. National Institute of Health and Care Excellence. Leg Ulcers - Venous [Internet]. 2016.  
569 Available from: <http://cks.nice.org.uk/leg-ulcer-venous>
- 570 10. Scottish Intercollegiate Guidelines Network. Management of chronic venous leg ulcers: A  
571 national clinical guideline. Edinburgh; 2010.
- 572 11. Australian Wound Management Association. Australian and New Zealand Clinical Practice  
573 Guideline for Prevention and Management of Venous Leg Ulcers. 2011.
- 574 12. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating  
575 complex interventions: The new Medical Research Council guidance. *Br Med J*.  
576 2008;337(1655):979–83.
- 577 13. Bandura A. Self-efficacy: The exercise of control. Macmillan; 1997.
- 578 14. Heinen M, Borm G, Vleuten C Van Der, Evers A, Oostendorp R, Achterberg T Van.  
579 International Journal of Nursing Studies The Lively Legs self-management programme  
580 increased physical activity and reduced wound days in leg ulcer patients : Results from a  
581 randomized. *Int J Nurs Stud* [Internet]. 2012;49(2):151–61. Available from:  
582 <http://dx.doi.org/10.1016/j.ijnurstu.2011.09.005>
- 583 15. O'Brien J, Finlayson K, Kerr G, Shortridge-Baggett L EH. Using a theoretical approach to  
584 identify factors influencing adherence to an exercise programme for adults with venous leg  
585 ulcers. *J Health Psychol*. 2018;5(23):691–700.
- 586 16. O'Brien J, Finlayson K, Kerr G, Edwards H. The perspectives of adults with venous leg ulcers on  
587 exercise: an exploratory study. *J Wound Care*. 2014;23(10):496–509.
- 588 17. Klonizakis M, Tew G, Michaels J, Saxton J. Exercise training improves cutaneous microvascular  
589 endothelial function in post-surgical varicose vein patients. *Microvasc Res*. 2009;78(1):67–70.
- 590 18. Braun, V. Clarke V. Using thematic analysis in psychology Virginia. *Qual Res Psychol*.  
591 2006;3(2):77–101.
- 592 19. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the  
593 analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol*.



- 594 2013;13(1):1–8.
- 595 20. Kori SH. Kinisophobia: a new view of chronic pain behavior. *Pain Manag.* 1990;1(1):35–43.
- 596 21. Roaldsen KS, Biguet G, Elfving B. Physical activity in patients with venous leg ulcer - between  
597 engagement and avoidance. A patient perspective. *Clin Rehabil.* 2011;25(3):275–86.
- 598 22. Roaldsen K, Elfving B, Stanghelle JK, Talme T, Mattsson E. Fear-avoidance beliefs and pain as  
599 predictors for low physical activity in patients with leg ulcer. *Physiother Res Int.*  
600 2009;14(3):167–80.
- 601 23. O'Brien J, Edwards H, Stewart I, Gibbs H. A home-based progressive resistance exercise  
602 programme for patients with venous leg ulcers: A feasibility study. *Int Wound J.*  
603 2013;10(4):389–96.
- 604 24. Yim E, Kirsner RS, Gailey RS, Mandel DW, Chen SC, Tomic-Canic M. Effect of physical therapy  
605 on wound healing and quality of life in patients with venous leg ulcers a systematic review.  
606 *JAMA Dermatology.* 2015;151(3):320–7.
- 607 25. Tew GA, Gumber A, McIntosh E, Kesterton S, King B, Michaels JA, et al. Effects of supervised  
608 exercise training on lower-limb cutaneous microvascular reactivity in adults with venous  
609 ulcers. *Eur J Appl Physiol.* 2018;118(2):321–9.
- 610 26. Smith D, Lane R, McGinnes R, O'Brien J, Johnston R, Bugeja L, et al. What is the effect of  
611 exercise on wound healing in patients with venous leg ulcers? A systematic review. *Int*  
612 *Wound J.* 2018;15(3):441–53.
- 613 27. Goldberg JF. Albert Bandura and the Exercise of Self-Efficacy. *J Cogn Ther.* 1999;9(49):601–2.
- 614 28. Chao D, Foy CG, Farmer D. Exercise adherence among older adults: challenges and strategies.  
615 *Control Clin Trials.* 2000;5(21):S212-7.
- 616 29. Jull A, Parag V, Walker N, Maddison R, Kerse N, Johns T. The PREPARE pilot RCT of home-  
617 based progressive resistance exercises for venous leg ulcers. *J Wound Care.* 2009;18(12):497–  
618 503.
- 619 30. Walshe C. Living with a venous leg ulcer: a descriptive study of patients' experiences. *J Adv*

- 620 Nurs. 1995;22(6):1092–100.
- 621 31. Finlayson K, Edwards H, Courtney M. Factors associated with recurrence of venous leg ulcers:  
622 A survey and retrospective chart review. *Int J Nurs Stud.* 2009;8(46):1071–8.
- 623 32. Padberg FT, Johnston M V., Sisto SA, Burnand KG, Wakefield TW, Perkowski P. Structured  
624 exercise improves calf muscle pump function in chronic venous insufficiency: A randomized  
625 trial. *J Vasc Surg.* 2004;1(39):79–87.
- 626 33. Upton D, Andrews A, Upton P. Venous leg ulcers: what about well-being? *J Wound Care.*  
627 2014;23(1):14–7.
- 628 34. Persoon A, Heinen MM, Van Der Vleuten CJM, De Rooij MJ, Van De Kerkhof PCM, Van  
629 Achterberg T. Leg ulcers: A review of their impact on daily life. *J Clin Nurs.* 2004;13(3):341–54.  
630

### Key Messages

- The aim of this study was to explore participants' experiences of taking part in a trial that investigated the feasibility of exercise training alongside compression therapy for management of venous leg ulcer (VLU) healing.
- Sixteen participants took part in semi-structured face to face or telephone interviews analyzed through thematic analysis.
- Participants reported that sedentary cautious living can be due to fear of movement due to pain, the time burden of compression treatment, and conflicting advice from health professionals to rest compared to be active.
- Supervised exercise by a specialist professional tailored towards patient's individual needs was viewed as a key component to an exercise intervention to increase patient's confidence to exercise.
- Participants perceived that the exercise intervention offered benefits in physical and mental wellbeing, quality of life and also a positive impact on other comorbidities.

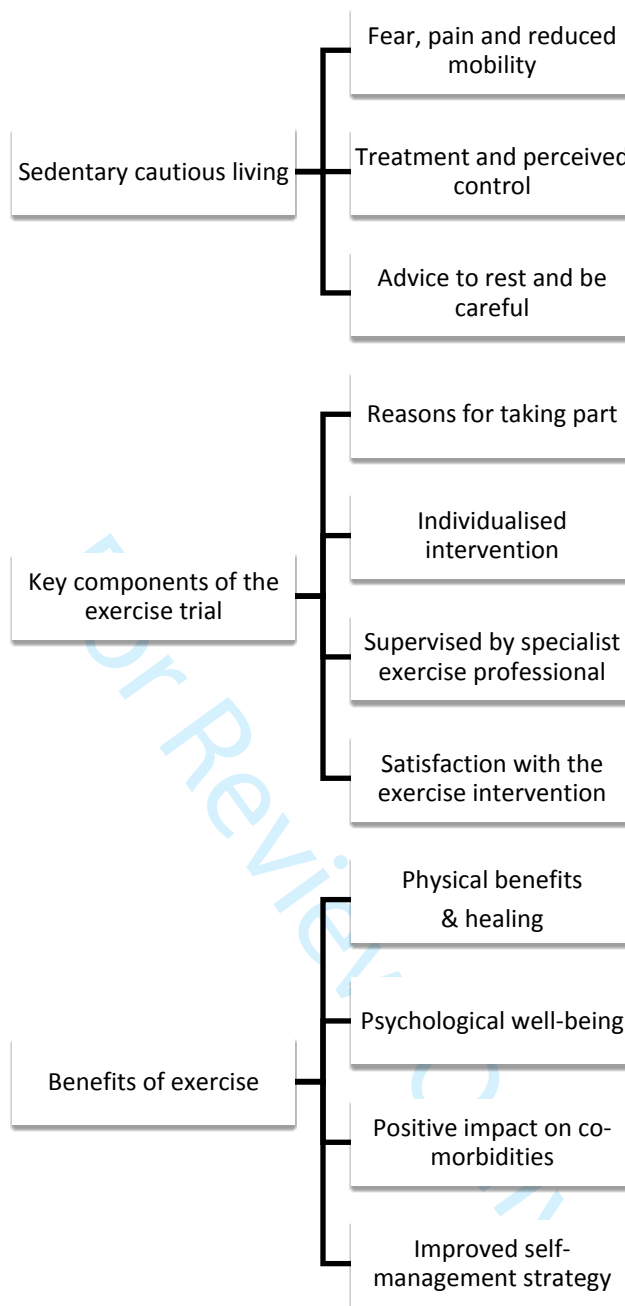


Figure 1: Themes from participant views taking part in an exercise randomised control trial

Table 1: Semi structured interview topic guide

**Background:**

- **What is it like living with a leg ulcer?** (Prompts: How long have you had your ulcer? What symptoms do you have? How does a leg ulcer affect your day to day activities?)
- **What advice have you received about how to manage your condition?** (Prompts: Tell me about your treatment. What advice have you received from health professionals? Have health professionals discussed exercise, and if so what information has been provided?)

**The research study:**

- **What were your main reasons for taking part in the study?** (Prompts: How did you hear about the research? What did family/ friends or health professionals think about taking part in the project? Prior to taking part in the research study did you have any views or experience exercising with a leg ulcer?)
- **How did you find taking part in the research study and exercise sessions?** (Prompts: What did you enjoy? What didn't you enjoy? Was there anything that could be improved?)
- **Have you experienced any benefits from taking part in the exercise study, and if so what?** (Prompts: Physical benefits? Mental benefits? Quality of life? Other?)
- **Have you experienced any downsides from taking part in the study, and if so what?**
- **Are there any other comments that you'd like to make about taking part in the research?** (Prompts for brief answers: Could you expand on that....? Could you be more specific...? Do you mean...?)