

ORIGINAL ARTICLE

The co-design of an exercise-based, lifestyle intervention for people with venous leg ulcers; a self-care, expert-supported strategy for a chronic condition

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Abstract

Exercise is recommended as an adjunct treatment, alongside compression therapy to increase venous leg ulcer (VLU) wound healing times, however, there are no published programmes available that support patients to exercise at home on their own. To develop an exercise-based lifestyle intervention that is feasible and acceptable to people with VLUs, a participatory approach was utilised. Clinicians, researchers, and people living with VLUs collaborated in the design of “FISCU Home”. Two focus groups and nine interviews were conducted with people living with a VLU. Tissue viability nurses provided clinical expertise. Data was analysed through thematic analysis. Ten key themes were identified and incorporated into FISCU Home: (I) a condition-specific flexible programme, (II) personal assessment and tailored exercises, (III) tapered individualised support, (IV) short lower-intensity sessions, (V) chair-based options, (VI) falls prevention, (VII) accessible resources, (VIII) functional, compact, self-managed exercises, (IX) a behaviour change strategy, and (X) education. FISCU Home has integrated patients' needs and preferences with evidence-based principles and theory to create an exercise-based lifestyle intervention for people with VLUs. FISCU Home could provide a mainstream adjunct therapy in wound care and support the movement towards self-management.

KEYWORDS

Co-design, home-based exercise, lifestyle intervention, participatory research, venous leg ulcers

Key Message

- The aim of this study was to create an exercise-based, lifestyle intervention (FISCU Home) that is feasible and acceptable to people with VLUs.
- It is the first study with this clinical group to adopt a co-design approach.
- People living with VLUs, clinicians and researchers were involved in the collaboration.

- Exercise prescription for VLUs must be tailored to individual needs and be able to adapt to the non-linear healing cycle and unpredictable side effects of the ulcer.
- Simplicity should run through all elements of the programme.

1 | INTRODUCTION

There were an estimated 649 000 venous leg ulcers (VLUs) across England in 2019, costing the NHS around £2.5 billion in wound care. With a 4% annual increase forecast, the financial burden is projected to more than double over the next 20 years.¹ VLUs are also debilitating for the individual; the pain, lack of mobility, frustration, loss of independence and the social isolation that is often experienced leads to a significantly reduced quality of life.²

Compression therapy is the gold standard treatment for VLUs; however, delayed and lack of skilled application has led to sub-optimal practices in some localities,^{3,4} and patient adherence levels to this treatment are low.⁴ An accumulating number of unhealed ulcers (47% remain unhealed at 12 months),⁵ high rates of recurrence after wound closure (up to 55% recur within a year),⁶ and a rising number of new incidences associated with an aging population⁷ necessitates a look at adjunct therapies.

Previous research has established that exercise training can improve the functioning of the calf muscle pump and the other component elements of VLUs such as reduced ankle range of movement, diminished calf muscle strength, poor balance, and gait⁸ suggesting that prescribed exercise could be a viable adjunct to compression. To date, only a few studies^{9–14} including a previous trial (FISCU I) by our research group,¹³ have attempted to demonstrate this by directly investigating the effect of exercise on the healing rates of people with VLUs. Although based on small sample sizes, most of the studies reported faster wound healing times in the intervention groups (exercise + compression) when compared to the usual care (compression only) groups,^{10–14} some of the studies achieved good adherence^{9,13,14} and participants experienced high levels of satisfaction with the exercise regime.¹⁵ Whilst the evidence for a combined treatment of exercise and compression is promising, (with our FISCU I intervention yielding better results than the others, potentially due to the use of a structured aerobic exercise programme element, which is proven to improve the ulcer-affected microcirculation), two systematic reviews in this area have highlighted the need for further research.^{16,17}

Exercise, and in particular walking and simple stretches/ankle exercises are advocated in the national guidelines on VLU management,^{18,19} however, it appears this rather general recommendation is not consistent in everyday clinical practice; the majority of FISCU I participants could not recall

having received any exercise advice from health practitioners.¹⁵ A more standardised exercise prescription may ensure more consistent implementation.

As the trials in this area^{9–14} have used different exercise modalities, measurement methods and parameters drawing comparisons are difficult and there is uncertainty regarding the optimal exercise dose (frequency, intensity, duration, type) and the relative merits of a supervised versus home-based exercise regime for this clinical population. Whilst the exercise dose prescribed in the gym-based FISCU I study¹³ was proven feasible, the sample consisted of relatively high-functioning VLU participants, (mobile; able to travel to the community exercise facility), it is unknown if this exercise prescription will be effective for lower-functioning individuals with VLUs (house-bound, minimally ambulatory, older, frailer, multimorbidity). To target a wider VLU population and reach those confined to their home, a group with significantly lower healing rates (six-month healing rate is 45%, compared to 70% for those attending specialist clinics),¹⁸ a home-based intervention is warranted. As this approach does not require a gym, expensive equipment or as much supervision, it may offer a more scalable, cost-effective solution to the NHS. Implementing a supported but self-managed strategy will give people with VLUs the opportunity to actively participate in their own treatment, aligning with the NHS plan to make patient empowerment and involvement a priority,²⁰ and supporting the current movement in ulcer management towards self-care.¹

Retention is a core challenge for self-managed home-based exercise programmes. When an identical exercise protocol was applied, adherence from people with VLUs was significantly higher in the face-to-face clinical setting than the home-based setting.^{11,12} This finding is consistent with the wider research involving older adults, which reports considerably lower levels of adherence to unsupervised exercise programmes when compared to supervised programmes.²¹

Applying behaviour change theory and established behaviour change techniques may optimise concordance to a home-based intervention. Nurse-led educational self-management programmes have demonstrated that implementing a behaviour change strategy can have a positive impact on levels of physical activity in people with VLUs.^{22,23} Incorporating a participatory research approach (engaging with those who are not necessarily trained in

research but belong to or represent the interests of the people who are the focus of the research)²⁴ has also been shown to have a positive impact on enrolment and adherence rates,^{25,26} as well as increasing the utility, efficiency, and impact of a complex intervention.²⁷ Thus, the primary aim of Phase 1 of the FISCO II study (Phases 2 and 3 are described elsewhere)²⁸ was to collaborate with those who have lived experience of VLUs and those who work in tissue viability to co-design a home-and exercise-based lifestyle intervention that is underpinned by behaviour change theory and the evidence base (informed by qualitative & quantitative findings and modelled on the exercises that were successful in the previous community-based FISCO I trial).¹³ To our knowledge, this study is the first to use a participatory research approach in the design of a home-based exercise regime for people with VLUs and one of the first to identify which components are required to optimise outcomes.

2 | METHODS

2.1 | Study design

Underpinned by the principles of pragmatism and informed by the MRC complex interventions framework,²⁷ the FISCO II study is a three-phase, mixed methods, health behaviour change intervention. Phase 1 (the focus of this paper) involved the co-design, development, and piloting of an exercise programme specifically for people with VLUs who are housebound. A participatory approach was adopted, recognising that individuals living and working within a specific context have a deep understanding of the challenges they face, and their knowledge can provide greater insight and add value to research by ensuring it is relevant and acceptable to end-users.

The co-design process involved consultation and collaboration with tissue viability nurses through a study steering group and Lower Leg Champion meetings, which were part of an initiative that the Sheffield Tissue Viability Service already had in place, so inconvenience was minimised. Two focus groups were conducted with people living with VLUs. This method enabled individuals to share their related experiences from which insight and ideas emerged, multiple opinions were captured and consensus on each aspect of the exercise programme could be explored. The study also included one-to-one home-based interviews so those unable to travel could still participate.

The study adhered to UK General Data Protection Regulation and the NHS Code of Confidentiality. Ethical approval was granted by the London-Surrey Research Ethics Committee. The SRQR²⁹ checklist was followed as it has been designed to improve reporting and transparency in qualitative research.

2.2 | Sample

Study inclusion criteria required that participants:

1. Had at least one VLU with a minimum diameter ≥ 1 cm.
2. Had an ankle brachial pressure index (ABPI) ≥ 0.8 .
3. Were able and willing to tolerate high compression and were receiving treatment in a home setting.
4. Were aged ≥ 18 years.
5. Were primarily housebound.

2.3 | Recruitment

To reach the target demographic, a purposive sampling strategy was adopted. Individuals who had been unable to participate in the community FISCO I¹³ study due to limited mobility, were invited to take part and community nursing teams across Sheffield handed out information packs and promoted the study to suitable patients. Advertisements were also placed in the local newspaper.

2.4 | Data collection

A semi-structured interview guide was formulated based on our previous FISCO I study and the literature in this area. It was reviewed by the research team. The guide focused discussion on participants' thoughts about engaging in an exercise programme, the challenges that could be encountered with a primarily self-managed format, the preferred type/amount of support and instruction, the elements that could encourage and promote continued adherence, the content and format of the exercise manual (a resource that will provide instructions on how to perform the exercises) and how prospective participants could be approached. Exercises that had been beneficial with other older population groups were demonstrated and participants discussed, which they felt were most suitable.

The focus groups took place at Sheffield Hallam University in a room located near the entrance to Collegiate Hall, so it was easily accessible for those with limited mobility and where required, taxis were arranged to assist with travel to and from the university. K.P. and E.M. conducted the focus groups and interviews. Both researchers have worked with clinical population groups for over a decade and are experienced in qualitative data collection methods. The focus groups were approximately 1 h, and the interviews lasted up to 30 min. Each one was audio recorded, transcribed verbatim and identifiers removed. Prior to taking part each participant provided written consent. After two focus groups and nine interviews, the research team agreed that no new themes were emerging, and data saturation

had been reached. Transcripts were returned to participants, and they were given the opportunity to add or edit any information and confirm accuracy.

2.5 | Data analysis

To gain an in-depth meaning and interpretation of the data, the principles of thematic analysis were followed by applying Braun and Clarke's³⁰ six-phase framework. The first step involved becoming familiar with the data. K.P. and E.M. read and re-read the transcripts from the focus groups, interviews and meetings and made notes. In the second step, a coding frame was devised that included deductive codes based on the interview guide and inductive codes that had emerged from participant accounts. After each researcher coded a transcript independently, they met to compare and refine codes before moving on to the remaining transcripts. During the third phase patterns and trends were examined and codes were charted and collated into themes. After a review (step four) K.P. and E.M. finalised the mapping of key themes and sub-themes (step five). Before proceeding to the write-up (step six), a third qualitative researcher, M.B. cross-checked the final themes against the transcripts, the study objectives and interview guide to confirm validity.

3 | RESULTS

The sample consisted of eighteen participants; focus group one (N = 6), focus group two (N = 3) and face-to-face home-based interviews (N = 9). All participants were White British, reflecting the ethnography of the vast majority of people with VLUs in Sheffield, had a mean age of 76.5 years and 61% (n = 11) were women. The participants were at various stages of the ulcer healing process (at the time of data collection, the mean duration for a current VLU was 11 months), had a wide range of ulcer histories (the mean time since first VLU diagnosis was 7.5 years) and the majority had other comorbidities.

Through thematic analysis, ten themes were identified, and they make up the key components of a home- and exercise-based lifestyle intervention for people with VLUs (see Figure 1).

3.1 | A flexible programme that supports the healing cycle and side effects of the VLU

Many of the participants had experienced severe pain when their ulcer first developed and felt that exercise



FIGURE 1 The ten key components of a home- and exercise-based lifestyle intervention for people with VLU based on a co-design approach.

would not have been possible during that time. For example, one participant recalled:

When the ulcer began, I could barely put my foot down, I could barely walk on it. The district nurse was coming every other day to dress it. I think the exercise at the beginning I could not have done it, but a little later on it would be alright (Interview 09).

Several of the participants also described occasions when their ulcer became infected and during these times the pain was debilitating and weight-bearing movement intolerable:

When my legs got infected, they flared up in a rash and blister. I could not stand the pressure to put the weight on my foot. ...Gradually now as it is starting to respond to treatment I can now walk slowly with the stick, put my foot down (Focus Group 1, F3).

at the worst was when I could not do anything... when I've had it, the infection like that was bad pain, and I probably could not have done it then (exercise) (Focus group 2, F1).

The participants reported that levels of pain tended to be highest at the outset of an ulcer and during periods of

infection. During these challenging times, it would be incredibly difficult, and for some unfeasible to commence or continue an exercise programme, thus adherence may be affected. Participants also felt that if their ulcer became infected or was leaking heavily, having the option of a break or the flexibility to scale the exercise programme back would be essential. There was a desire among participants to keep their bandages “clean and dry” so exercises that place less pressure on the ulcer, monitoring leakage and aligning exercise days with the times bandages are changed would be important. Participants mentioned being on strong pain killers and felt it would be useful to have advice on how to manage pain relief during the intervention. Aligning further with the healing process was the suggestion from one participant to revisit exercises, for example, something that may have been too painful in week 1, might not be by week 8.

Whilst doing three exercise sessions per week was generally considered feasible, achieving the right balance was emphasised:

But yeah I think three times a week is ok because really you need the same amount of rest as you do exercise, dont you? That's it (Focus group 2, F1).

Participants felt outlining specific days/times for sessions and having the schedule visible, for example, on their calendar/diary, would help remind them to do it, however, flexibility and understanding around the schedule may be required at times as individuals also mentioned having good and bad days with their ulcers and other ailments:

I mean sometimes I can curl my leg back and other times it's that swollen, this right knee that it will not go” (Focus group 2, F1).

The pain I've had recently has been awful and I just cannot get any sleep (Focus group 2, F3).

3.2 | A personal assessment and a tailored programme

Nearly all the participants described living with other co-morbidities, musculo-skeletal issues such as knee and back problems and arthritis were the most common and participants felt these health conditions would impact their ability to undertake exercise:

My problem with exercising is a little bit like this lady, it is arthritis, I've got arthritis in my

hips and knees and when I went to the doctors, they said they would not refer me to a consultant until I'd lost 10 stones. So since then, I have put half a stone on, because it just seemed totally unsurmountable. (Focus Group 1, F1).

Well, it would not be the ulcer leg that would be the problem it would probably be the other leg, which has got the dodgy knee! (Focus Group 2, F1).

Participants mentioned suffering with leg oedema and explained that it is hard to lift their legs because of swelling and heaviness. A focus on exercises that also reduce fluid would be important. Participants with this condition felt they would not be able to wear ankle weights so alternative exercise progressions would be required for example, range of movement could be increased, or reps/sets adjusted instead.

There may also be individual cases where the location of the ulcer might preclude an exercise, as one participant points out:

I could not do ankle circles at the moment because my ulcer is right down at the ankle area” (Focus group 1, F3).

This patient group requires a personal assessment at the start so that an exercise programme can be designed that is suitable and tailored to individual needs. This necessity is clearly highlighted by one participant:

...everybody's got different things wrong with them, like I'm restricted to a lot of stuff because of my back. Not just my legs and my diabetes and ulcers and stuff, it is what you can physically do with such as your back and arthritis and stuff ...you cannot tar us all with the same brush if you know what I mean. We all cannot do the same exercises. It is impossible that we'll all be able to” (Focus group 1, M2).

3.3 | Tapered individualised support

As the exercises need to be tailored to the individual and the correct technique learned at the beginning, participants thought it would be important to have more intensive contact with an instructor at the start and then tapering could be considered:

I think the initial instruction from somebody who knows is very useful because they'd tell

you the right way to do these exercises or the appropriate adaptation for the exercises you cannot do (Focus group 1, F3).

...And then see how they go on and then perhaps after the first few weeks make it less once you can see they have got used to it (Interview 02).

Participants felt that they would need some form of on-going support and reassurance to give them the impetus to continue the programme, but there were differing views on how much contact would be required ranging from weekly to monthly and moderation was also emphasised:

What I'd like is for someone to call once a week, I'll do this because they'll be coming next Monday sort of thing (Interview 02).

Well, I would not want you ringing up every 5 min, are you doing your exercises (laughing) (Interview 04).

You do not want to be on the phone all the time to them ...you have just got to keep people interested in it and just, without pestering and lecturing to them (Interview 03).

Having a discussion around the amount of contact required at the start of the programme would ensure individual needs in this area are met however setting a minimum threshold in advance would avoid extreme variation. In terms of how support is provided, face-to-face contact would be preferred but phone calls would also be welcomed, with some individuals highlighting they would just need extra time to reach the phone.

I think a visit is better, you can see what they are doing and their reactions (Interview 02).

Participants felt time constraints would prevent involvement from family or friends and most viewed the exercise programme as an activity they would do independently. There was also a desire to go at their own pace without being watched. A peer support option was put forward, but there was a mixed response with some feeling they would only require professional support.

3.4 | Short, lower-intensity sessions

Several of the individuals in this patient group are contending with severe physical limitations:

Just walking up the corridor to the lift I have to keep stopping (Interview 6).

Simple things like last night my son drove us...and it took me ages to lift my leg up, I could not get up over the sill of the car (Focus group 1, F1).

Now I've developed heart problems I tire out really quickly (Focus group 2, F2).

Focusing on 4 or 5 key exercises, including rest intervals or the flexibility to return to it later in the day would help make the sessions more manageable. Participants felt the exercise should be lower intensity and the session shorter to avoid inducing leg ulcer side effects:

the harder you make it the more pain it will bring out, I think with leg ulcers you do not want to do too much exercise, it is gotta be like low and slow (Interview 03).

You do not want it weeping, so not heavy exercise (Interview 06).

I could not sustain 60 min of exercise (Focus group 1, F1).

The Rating of Perceived Exertion (RPE) scale³¹ was explained to participants as intensity was monitored using this method in the previous community-based FISCO I study. Some individuals understood how it would work while others found it a little confusing. Participants felt it would also be useful to monitor pain during sessions.

3.5 | Chair-based exercises

A proportion of the participants had extremely limited mobility and used a walking aid to move around the home. They described being restricted or unable to stand for any length of time; for these individuals, a chair-based programme would be the only option:

I mean I'm not really able to move about very much for the last few years anyway but as I say I'm not against any exercise it's just I could not stand and do any exercises...I could perhaps sit down and do some if it were possible (Interview 06).

A seated element was also welcomed by those who were worried about placing too much pressure on their

ulcer or had concerns about their balance or placing too much strain on their back. There was general agreement that chair-based exercises would be appropriate and achievable.

A movement towards an integrated programme which combines seated and standing exercise could offer a progressive element where suitable. Individuals who mentioned breathing issues may also find an integrated approach beneficial as the lower-intensity seated exercises would provide active recovery intervals.

3.6 | Falls prevention

Whilst there were participants who felt they could manage the standing exercises; there was concern about the risk of falling and for them having the appropriate support and balance aids would be paramount. To enhance safety participants put inventive suggestions forward, for example, instead of walking a figure of 8 around two chairs placed a few meters apart, walking around a dining table and using the bottom stair and holding on to a rail rather than using a step box. Finding out about an individual's falls history and assessing risk will be an essential part of the initial screening with this patient group and the suitability of an exercise will also be considered in relation to the demands it places on balance.

3.7 | User-friendly paper-based resources

Participants would like the exercise manual to include plenty of diagrams or photos, content that is easy to understand and print that is large and clear. They felt a logbook was a good idea, as it can track progress and remind them if a session has been completed. The participants would prefer the resources to be paper-based not electronic:

I do not want to look at an Ipad or a computer, I'd rather have a little booklet in front of me to look at (Interview 02).

I'm not good on computers so it would have to be written down (Interview 06).

3.8 | Functional, compact, self-managed exercises

Participants felt functional exercises like sit-to-stand were good because they mirror everyday moves and would be simple to grasp however, some would need to "build up"

to them and felt the proposed adaptations to the original FISCO I intervention¹³ would be more suitable, for example, using hands initially as levers to help with standing.

Some of the participants mentioned having limited space in their homes, so compact exercises that require minimal equipment would be necessary. Trip hazards would also be avoided if equipment was minimised.

As the exercises would be mainly undertaken independently it would be important to ensure they could be completed unassisted. For example, some individuals highlighted that they would not be able to move a pedal exerciser into position and get their feet into the foot pedals without assistance, while exercises with the band might not be possible as some mentioned being unable to reach down far enough to place it around their ankles. Floor-based exercises would also be unsuitable for this patient group; participants mentioned being unable or having difficulties getting up from the floor.

3.9 | Behaviour change strategy

Participants felt that the most challenging aspect of a home-based exercise programme would be adherence. Comparisons were made with the group class format and the general feeling was that it would require more self-discipline at home, and it would be easier to lapse. The overriding element that would motivate individuals to continue was seeing visible results, for some, it would be important to see direct improvements relating to the ulcer or healing timeline, while for others more general improvements in mobility and being able to undertake daily activities would promote sustained effort. To tap into this motivational facet, it would be important to understand which result was most meaningful to the individual and provide regular reviews and follow-up assessments to demonstrate change. This could be supported and aligned with a goal-setting strategy.

Participants would also be encouraged to continue the programme if it was enjoyable, self-paced, achievable, and progressive:

If it's doable and not something that you think oh this is a chore, you will be more likely to stick at it (Focus group 2, F2).

I went to a once-a-week exercise class for people who'd had COPD or heart problems and I was the worst one in the class. And I've not had a heart problem and I've not got COPD, but I just could not keep up with the other people who had and I felt so embarrassed about that it I just stopped going (Focus group 1, F1).

Ultimately it is progression that's what I'm wanting to see and then I would not get bored (Interview 04).

Having someone "check-up" or having to "report back" would also drive motivation, as one participant explains:

I do need that kick up the backside, I really do, if you know that phone call's coming, you know that, well, I better do something because then they are going to ask me (Focus group 2, F1).

Participants also felt that setting a schedule, establishing a routine, and completing a logbook would help remind and keep them engaged in the programme.

3.10 | An endorsed and educational promotion pathway

Participants felt the community nurses were best placed to promote the exercise intervention because they have regular contact and patients would trust their recommendations. Advice to date from health professionals has centred around elevating legs and not doing too much, as one participant explains:

A lot of people have been told like to leave them and let them rest and put your feet up and rest (Interview 03).

Ambiguity and caution around exercise can stem from these messages. A crucial first step in the process must involve raising awareness among health professionals about the beneficial impact of exercise on VLU healing. To promote this knowledge and new approach to people with VLUs who are housebound, it will be necessary for researchers to collaborate with community nursing teams.

Other suggestions on how to publicise the programme included using the local radio, newspaper, G.P. surgeries or clinics and via eye-catching leaflets. Altruistic reasons such as "being able to give back", reading/hearing about other patients' positive experiences and a clear message that conveys the impact the exercise programme could have on quality of life would influence the participants decision to take part.

4 | DISCUSSION

A home-and exercise-based, lifestyle intervention (FISCU Home), based on our previous community-based lifestyle

intervention,¹³ that enables people with VLUs to follow a self-managed, adjunct therapy in a safe way, has been co-designed with people with VLUs, clinicians and researchers. This collaborative work, which is the first co-design attempt for this clinical group, was undertaken with VLU participants who were primarily housebound, to ensure that similar people in different locations will be able to complete the intervention. Previous research in this area^{9-12,14} including FISCU I¹³ recruited patients who were receiving VLU treatment in community health centres indicating they were not housebound and therefore more high functioning. The present study was aimed at people who are typically older and frailer and as evident from the findings endure severe physical limitations, have multi-comorbidities and their functional ability significantly impaired.

The national guidelines on VLU management¹⁸ advise regular walking but this type of guideline, where one-size fits and assumes a prototypic state, this blanket recommendation is not feasible for many people with VLU who are housebound. The FISCU I model¹³ provides a more malleable framework with its repository of evidence-based aerobic, resistance and flexibility exercises from which a programme can be tailored to meet individual needs. To make the intervention feasible and suitable for this VLU subgroup ten key components have been identified (See Figure 1) and will be incorporated into the home-based trial.

FISCU Home will adopt a more dynamic person-centred approach to exercise prescription. This is supported by 3 key factors:

1. There is a wide variation in physical function, for some ambulatory exercise is feasible while for others a chair-based programme would be required.
2. Other co-morbidities might pose greater challenges to undertaking exercise than the ulcer.
3. Individuals experience a non-linear dynamic healing process where there is disparity in symptoms and side effects such as pain and leakage.

The efficacy of tailored exercise prescription has been demonstrated in patients with knee osteoarthritis and comorbidity.³² Methods such as adapting exercises to the comorbidity-related symptoms and monitoring these symptoms during sessions were linked to good adherence. This is significant as previous VLU studies have highlighted that comorbidity is highly prevalent and contributes to exercise non-adherence.³³ A movement towards individualised prescription is also apparent in oncology research.³⁴ Their approach has embraced auto-regulation, a concept that recognises that an individual's ability to tolerate exercise may vary from day to day,

depending on the symptoms and side effects they experience and by adjusting the prescription outcomes can be optimised. These adaptive dynamics can create more sustainable programmes because they promote enjoyment and adherence through increased autonomy.³⁵

FISCU Home will provide an individualised support component. The amount of clinical contact provided by other self-managed exercise programmes in this area^{9–12,14} has varied, and the evidence does not support a particular threshold. Recognising that the participants in this study would like more time with an instructor at the beginning and some participants would benefit from extra contact throughout the programme supports a personalised tapering approach with a minimum threshold. Tapering where more intensive support is provided initially and then reduced has been used effectively in physical activity interventions with other sedentary groups.³⁶ Participants would prefer face-to-face instruction rather than telephone support. The need to accommodate this preference is reinforced by a previous VLU study which found low adherence to their home-based programme was in part due to the lack of face-to-face support.¹² The facilitator will be required to advise on the practicalities of exercising with VLUs, like FISCU I¹⁵ the need to align exercise sessions with nurse visits was evident, but it was also apparent in the current study that pain management should be addressed.

Participants in this co-design study viewed the exercise programme as a pursuit they would do independently. Although most of the research with older adults has found that social support is positively associated with levels of physical activity,³⁷ the participants in this study felt either it was not a viable option because their family or friends would not have time, or they felt it would have a negative impact. Current research also highlights the value of peer support³⁸ however some participants felt they only required facilitator expertise and thought this element would be unnecessary and so it will not be used in this trial.

In the community-based FISCU I intervention, the aim was to build up to three one-hour sessions per week. The participants in this study felt that reaching one hour of exercise would be an unrealistic goal, research also indicates that 25 to 30 min is likely to be the maximum time people commit to a home-based session.³⁹ Participants did however feel they could manage exercise three times per week, so whilst the duration of sessions has been modified for the home-based trial, it will still gradually increase as natural exercise progression occurs and the number of weekly sessions will remain the same, with 36 sessions in total. With this subgroup, more flexibility around the 12-week programme and the option to pause may be required due to ulcer-related reasons such

as infections or for non-ulcer-related issues such as arthritic flare ups. Sessions will follow a similar structure (warm up, aerobic, resistance, flexibility and cool down) but there will be modified and adapted versions of the exercises (and some new additions) under however, the same exercise categories.

FISCU Home will incorporate a falls prevention component. This topic has not surfaced in previous qualitative VLU research,^{15,40} however it appeared to be an element of concern in our discussions with our housebound participants. This VLU subgroup have many of the risk factors associated with falls: advanced age, use of assistive devices, and impaired mobility and gait.⁴¹ Improvements in balance are linked to a reduction in falls and falls-related injuries.⁴² Exercises that have a dual function will be included in this programme, for example, a heel-to-toe (tandem) walk can help improve balance whilst also activating the calf muscles. The ambulatory exercises in this intervention will incorporate balance aids, be modified to minimise falls risk and a falls history and assessment will form part of the initial screening.

FISCU Home will also provide a range of chair-based exercise options and have an emphasis on shorter, less intensive sessions. Participants were worried about the possibility of doing too much exercise and it having an adverse effect on pain and healing. A previous qualitative study has highlighted that the fear of harm is common among people with VLUs and is associated with low levels of physical activity and avoidance behaviour.⁴⁰ A graded exposure treatment programme has had a significant impact on fear-avoidance beliefs in patients with chronic musculoskeletal pain.⁴³ Shorter sessions that involve chair-based exercises will form the base of FISCU Home from which participants can progress. This base level will be appropriate for individuals where fear of harm is high and or for those with severe physical limitations. Whilst the RPE scale was used effectively in the previous FISCU I trial¹³ it was apparent that some participants found it a little confusing and so there might be cases where the facilitator may need to provide additional guidance on how to use it. Where suitable, a pain scale will be used to monitor pain levels.

FISCU Home will use paper-based resources. Although the use of digital technology has increased in those aged seventy-five and over there is still a large majority that do not engage,⁴⁴ and this was evident in this study. Even among those participants who had digital tools there was still a strong preference for a paper-based format because they felt it would be more straightforward. Previous home-based exercise programmes for VLUs have also tended to be paper-based,¹² however a recent falls prevention study with older adults has compared digital and paper-based exercise programmes and

reported similar adherence levels.⁴⁵ To ensure the exercise manual and logbook are user-friendly, the VLU participants were involved in their design.

FISCU Home will include a behaviour change strategy. Low retention rates are often reported by self-managed exercise programmes¹¹ and the participants in this study also felt adherence would be a key challenge for them. The motivational interviewing approach that worked well in the original FISCU I model¹³ will be utilised and a more comprehensive strategy based on social cognitive theory will be embedded as research has indicated self-efficacy (a belief about one's ability to successfully perform a behaviour),⁴⁶ and outcome expectations (a belief about the likelihood of the behaviour leading to a specific outcome),⁴⁶ have a significant impact on exercise adherence in people with VLU.³³ A desire from the participants in this study to have a programme that was safe, achievable and one where they could see results, assimilates to these psychological constructs. These constructs will be targeted through a graded, individualised programme with tapered support, which includes a lower number of exercises (a higher rate of compliance is associated with those prescribed fewer exercises)⁴⁷ that are functional, easy to grasp and can be undertaken independently. Self-regulatory behaviour change techniques have also been shown to promote exercise adherence in clinical populations.^{48,49} Goal setting, reviews, feedback, and a monitoring system will be part of the intervention. Participants felt remembering to do the exercises would be a challenge. Reminder strategies will be incorporated, and a logbook will be a useful reminder tool as well as also retrospectively showing improvement. These features will not be overly complex, as participants had a desire for simplicity, the aim will be to minimise cognitive demands and make sure processes are not overwhelming for this elderly group. The strategy in this study embeds elements of our "six pillars of adherence" framework (on this occasion being, "reminders", "simplicity", "education", "reachability"), which have been successfully implemented in previous interventions, developed, and delivered by our research group.⁵⁰

FISCU Home will be promoted and endorsed through an educational pathway. Previous research^{15,40} has reported that the advice from health professionals regarding ulcer self-care and exercise was ambiguous and contradictory, the findings from this study indicate there has been no change. This is a concern because it leads to sedentary cautious living.¹⁵ Working collaboratively with community nursing teams to increase awareness about the positive effect exercise can have on the ulcer healing process will be an important part of Phase 2 of this study. Exploring how health professionals feel about exercise as an adjunct treatment for VLUs will be a useful area for further research.

4.1 | Strengths and limitations

Measuring the impact of the participatory approach was beyond the scope of this study due to time and funding constraints, however the intervention will be evaluated in Phases 2 and 3 of this study and will provide some insight. The VLU participants in this sample were volunteers and of White British ethnicity so caution must be applied when generalising these results to the wider clinical population. This study used a multi-method approach (focus groups and interviews), this within-methods triangulation can validate data and increase the credibility of findings.

5 | CONCLUSION

The burden and devastating effect of VLUs are ever-increasing, there is a clear need for supplementary treatments, particularly for those who are housebound, a hidden group with complex needs and poorer healing rates. FISCU Home represents a pragmatic intervention that could be accessible to every individual with a VLU and have health benefits that extend beyond wound healing. Through a participatory approach, the present study has yielded insight into the needs and preferences of this clinical group. It has taken on the key challenge of balancing standardisation and customisation with the aim of creating a home-and exercise-based lifestyle intervention for people with VLUs that is effective and sustainable. FISCU Home could provide a mainstream adjunct therapy in wound care and support the movement towards self-management therefore implementation and evaluation are timely and will follow in phases 2 and 3 of this study.

AUTHOR CONTRIBUTIONS

Emma McIntosh was involved in recruitment, data collection, data analysis and draft of the manuscript. Markos Klonizakis conceived the study, acquired funding, and was involved in reviewing and editing. Maria Levesley advised on the clinical aspects of the study supported recruitment, and reviewed the manuscript. Pip Logan and Michelle Horspool participated in the development of the study and reviewed and edited the manuscript. All authors have read and approved the final manuscript.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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