STUDY PROTOCOL

Evaluating the feasibility and acceptability of an exercise and behaviour change intervention in socioeconomically deprived patients with peripheral arterial disease: The textpad study protocol

Gabriel Cucato1*, Chris Snowden2, Emma McCone3, Craig Nesbitt3, Sandip Nandhra3, Mackenzie Fong3, Eileen Kane4, Maisie Rowland4, Nawaraj Bhattarat4, Paul Court5, Oliver Bell6, John Michael Saxton7, James Prentis2

1 Dept of Sport, Exercise and Rehabilitation, Northumbria University, Newcastle upon Tyne, United Kingdom, 2 Dept of Perioperative and Critical Care Medicine, Freeman Hospital, Newcastle upon Tyne, United Kingdom, 3 Northern Vascular Unit, Freeman Hospital, Newcastle upon Tyne, United Kingdom, 4 Newcastle University, Newcastle upon Tyne, United Kingdom, 5 Healthworks, Newcastle upon Tyne, United Kingdom, 6 Newcastle United Foundation, Newcastle upon Tyne, United Kingdom, 7 Dept of Sport, Health & Exercise Science, University of Hull, Hull, United Kingdom

* gacucato@gmail.com

Abstract

This pilot randomised controlled trial aims to assess the feasibility and acceptability of a 12-week home-based telehealth exercise and behavioural intervention delivered in socioeconomically deprived patients with peripheral artery disease (PAD). The study will also determine the preliminary effectiveness of the intervention for improving clinical and health outcomes. Sixty patients with PAD who meet the inclusion criteria will be recruited from outpatient clinic at the Freeman Hospital, United Kingdom. The intervention group will undergo telehealth behaviour intervention performed 3 times per week over 3 months. This program will comprise a home-based exercise (twice a week) and an individual lifestyle program (once per week). The control group will receive general health recommendations and advice to perform unsupervised walking training. The primary outcome will be feasibility and acceptability outcomes. The secondary outcomes will be objective and subjective function capacity, quality of life, dietary quality, physical activity levels, sleep pattern, alcohol and tobacco use, mental wellbeing, and patients’ activation. This pilot study will provide preliminary evidence of the feasibility, acceptability and effectiveness of home-based telehealth exercise and behavioural intervention delivered in socioeconomically deprived patients with PAD. In addition, the variance of the key health outcomes of this pilot study will be used to inform the sample size calculation for a future fully powered, multicentre randomized clinical trial.
Peripheral arterial disease (PAD) results from chronic atherosclerosis that progressively leads to partial or total obstruction of the arteries, thereby, reducing blood flow and oxygen delivery to the peripheral regions of the body [1]. The main symptom of PAD is intermittent claudication, characterized by pain, cramp, or burning that occurs in the lower limbs during walking exercise and is relieved by rest [2]. Due to these symptoms, patients with PAD experience lower physical function [3], impaired cardiovascular function [4, 5] and lower quality of life [6]. Based on evidence demonstrating the benefits of exercise on walking capacity [7], cardiovascular function [5, 8] and quality of life [7], supervised exercise training is recommended in the United Kingdom by the National Institute for Health and Clinical Excellence as first-line treatment of claudication caused by PAD [9]. The National Institute for Health and Clinical Excellence also recommends that patients with PAD are offered advice, support, and treatment for the secondary prevention of cardiovascular disease, including smoking cessation, diet, and weight management [9].

Despite these recommendations, supervised exercise is rarely delivered in the clinical setting [10] and, patients are not systematically offered evidence-based interventions that support behavioural modification. Ineffictual provision of and, referral to, behaviour change programmes may contribute to further deterioration of health, leading many patients to undergo surgical procedures for PAD management (e.g., stent or bypass). While these procedures may provide short term benefits, they incur greater risk and cost [11, 12]. Also, without comprehensive behavioural intervention, patients are likely to resume the same poor health behaviours that contributed to PAD development initially. Therefore, there is imperative to develop, evaluate and integrate into care pathways ‘prehabilitation’ interventions that optimise patient health, prevent further deterioration, and improve long-term outcomes. Moreover, since lower socioeconomic status is associated with poor health status, multiple risk factors, unhealthy lifestyle, and more barriers to behaviour change programs [13, 14], this intervention program would most likely benefit socioeconomically deprived patients.

Usually, supervised exercise programmes and behavioural interventions are delivered face-to-face. However, the COVID-19 pandemic has significantly changed the organizational structure of health institutions and diverted attention to the pandemic management [15]. There have also been reports of outbreaks during exercise sessions, limiting face-to-face delivery of care to high-risk populations [16, 17]. Thus, home-based intervention programs delivered remotely (telehealth) are welcome as they represent an alternative option to manage PAD when inpatient or person-to-person rehabilitation is not possible. In general, telehealth is a cost-effective strategy [18, 19] and one of the greatest advantages is the possibility to deliver for patients who do not have access to traditional rehabilitation services (people who live in remote or deprived areas). In this sense, a telehealth program including home exercise training and lifestyle advice could have a significant impact on treatment outcomes and it would represent a ‘COVID-proof’, cost-effective and scalable care delivery option for these patients.

This pilot randomized controlled trial will establish the feasibility and acceptability of a 12-week home-based telehealth exercise and behavioural intervention delivered in socioeconomically deprived patients with PAD. The programme will be developed and delivered collaboratively between Newcastle upon Tyne NHS Trust, Northumbria University, Newcastle University, Healthworks and Newcastle United Foundation Club. The use of premier football team branding has been shown to improve the effectiveness of exercise and weight loss interventions and improve recruitment of ‘hard to engage’ men [20, 21]. This study will also determine the preliminary effectiveness of the intervention for improving clinical and health outcomes.
Aims and objectives of the study

Primary aim
To investigate the feasibility and acceptability of a 12-week home-based telehealth exercise and behavioural intervention in socioeconomically deprived patients with PAD.

Primary objectives
To determine:
• Rates of patient screening, eligibility, recruitment, and retention to 12-week follow-up
• Patient compliance to the intervention (number of sessions attended and completed)
• Patient acceptability of the intervention through semi-structured qualitative interviews

Secondary aims
To determine the preliminary effectiveness of a 12-week home-based telehealth exercise and behavioural intervention compared to usual care.

Secondary objectives
To investigate whether a 12-week home-based telehealth exercise and behavioural intervention compared to usual care:
• Improves functional capacity
• Reduces alcohol and tobacco use
• Improve diet quality
• Improves quality of life and mental wellbeing
• Increases daily ambulatory physical activity levels

Tertiary aim
To explore the measurement of resource utilisation, costs and effects in an economic evaluation that would be conducted as part of a definitive randomized controlled trial.

Tertiary objectives
To develop and test tools to measure the costs and effects of the health economic evaluation of 12-week home-based telehealth exercise and behavioural intervention compared to usual care.

Materials and methods
Study design
This is a single centred feasibility study and pilot randomised control trial assessing a 12-week home-based telehealth exercise and behavioural intervention in socioeconomically deprived patients with PAD. The Recommendations for Interventional Trials [22] (SPIRIT) flow chart and enrolment schedule, interventions and assessments for the trial are given in Fig 1.
| TIMEPOINT | Enrolment | Allocation | Pre-evaluation | Intervention | Post-evaluation |
|-----------|-----------|------------|----------------|--------------|-----------------|
| ENROLMENT:| -t₁       | 0          | t₁             | t₂           | t₃              |
| Eligibility screen | X |           |                |              |                 |
| Informed consent | X |           |                |              |                 |
| Allocation     | X |           |                |              |                 |
| INTERVENTIONS:|           |            |                | X            |                 |
| Exercise and behavior change | | | |            |                 |
| Standard care   | | | | X           |                 |
| ASSESSMENTS:|           |            |                | X            |                 |
| Feasibility outcomes | | | |            |                 |
| Objective function capacity | X | | X | | |
| Subjective function capacity | X | | X | | |
| Quality of Life | X | | X | | |
| Dietary quality | X | | X | | |
| Physical activity levels | X | | X | | |
| Sleep | X | | X | | |
| Alcohol and tobacco use | X | | X | | |
| Mental wellbeing | X | | X | | |
| Patient activation | X | | X | | |
| Resource utilization | X | | X | | |

Fig 1. The recommendation of interventional trials (SPIRIT) schedule of enrolment, interventions, and assessments.

https://doi.org/10.1371/journal.pone.0269999.g001

**Ethical approval and consent to participate**

The protocol study was approved by the Research Ethics Committee of Human Research of Freeman Hospital (April 2021—IRAS Reference Number: 286735), registered and published in the ClinicalTrial.gov (registration number: NCT05260567) and will be conducted according to the principles of the Declaration of Helsinki. Patients will be provided with appropriate participant information sheets designed in compliance with national guidance. They will have adequate time to consider the information, ask questions and have them answered sufficiently. Patients will be advised that participation is voluntary and that they may withdraw from the
study at any time without having to provide a reason or affecting their care. Patients who are willing to participate will be asked to sign a consent form, and this process will be conducted by a trained delegated member of the research team. A copy of the signed consent form and participant information sheet will be filed in the patient’s medical notes and a further copy will be given to the patient. The original signed consent form will be retained in the Investigator site file and the patients’ general practiser will be informed of their participation in the study.

Eligible participants
Patients attending the Vascular Unit of Freeman Hospital–Newcastle Upon Tyne—UK with a diagnosis of PAD will be assessed for potential suitability by the clinical team and then contacted by the research team by telephone after their clinic appointment/further investigations. Patient eligibility will be based on the criteria below.

Inclusion criteria
• Diagnosis of PAD confirmed by ankle brachial index \(<0.90\) in one or both limbs
• Age \(\geq 40\) years
• Able to walk distance \(>50\)m
• Live in an area deemed in lowest 30% of super output area from Office of National Statistics

Exclusion criteria
• chronic limb threatening ischemia
• short claudication distance \(<50\)m
• severe heart disease (Grade III or IV, New York Heart Association)
• severe ischemic or haemorrhagic stroke or neurodegenerative diseases
• severe hypertension (systolic blood pressure of more than 180 mm Hg, and diastolic blood pressure of more than 100 mm Hg)
• uncontrolled cardiac disease (presence of complex arrhythmias, unstable angina during the previous month and myocardial infarction during the previous month)
• a resting heart rate of more than 120 beats per minute
• has already undergone angioplasty, bypass or other surgical intervention for PAD
• other severe comorbid conditions preventing the ability to engage in physical activity inability or unwillingness to undertake the commitments of the study

Randomisation
Patients will be randomised in a 1:1 ratio to either the home-based telehealth exercise and behavioural intervention or standard care. The randomization will be performed in blocks of 15 patients, using an online randomisation generator (www.randomizer.org).
Interventions

The intervention has been co-designed with Newcastle upon Tyne NHS Trust, Northumbria University, Healthworks and the Newcastle United Foundation. Patients in the intervention group will receive educational materials and videos outlining the main intervention components and how health behaviours impact upon their condition. The videos will be Newcastle United Foundation Club/Healthworks branded and be developed by the individuals from these organizations. Patients will also receive a Newcastle United Foundation Club T-shirt. Shortly after allocation to the intervention group, patients will be contacted by a Health Trainer from Healthworks who will conduct an initial assessment and consultation. Health trainers have various qualifications in health care e.g., nutrition degree, Level 4 rehabilitation qualification, all receive Healthworks training in motivational interviewing and intervention delivery. Patients will meet with their dedicated health trainer weekly for one hour via phone call/videoconference for 12 weeks and discuss the behaviours outlined below. Health trainers use many behaviour change techniques to promote modification of risk factors such as goal setting, problem solving and self-regulation.

Smoking cessation

Self-reported smoking habits will be assessed at baseline. Patients who smoke will receive a cessation intervention from the health trainer i.e., discussion of previous quit attempts and benefits of quitting to aid in improving health and exercise capacity. If required, nicotine replacement therapy vouchers redeemable at their local pharmacy will be posted to the patient. An eight-week supply of e-cigarette cartridges may also supply.

Alcohol intervention

Health trainers will deliver a previously evaluated brief behavioural intervention to reduce alcohol intake to low-risk levels (<14 units per week) [23]. Intervention materials incorporate specific techniques that target intention formation and enactment of behaviour change (e.g. information on health consequences, social support, goal setting behaviour, problem solving, restructuring the physical environment). Patients suspected to have an alcohol use disorder or risky drinking at baseline will receive additional intervention from their general practitioner.

Nutrition

Patients will receive basic nutrition education and health eating advice in line with recommendations from the British Heart Foundation and Diabetes UK. Health Trainers will provide help to overcome barriers to healthy eating.

Mental well-being and finances

Patients will receive a light-touch intervention on sleep hygiene and stress management. If we discover that the patient is severely depressed, has self-harming concerns or suicidal thoughts the GP will be contacted, or patient signposted for further help. Health trainers will also help patients to determine their eligibility to receive benefits and, facilitate access and uptake if required.

Supervised exercise

The home-based exercise training will be performed twice a week for 12 weeks via Zoom (up to 5 patients per session). Each session will be comprised of warm-up (10 min), the main part (15 to 20 min), and cooldown (5 to 10 min). The training aims to develop resistance, aerobic
and functional capacity such as getting up, walking, pulling, pushing, throwing, and transferring body weight or external loads. An example of multimodal exercise training is shown in Box 1.

Box 1. Example of exercise training module in the intervention

| Duration  | Category      | Exercise                                                                                     | Intensity (Borg Scale) |
|-----------|---------------|----------------------------------------------------------------------------------------------|------------------------|
| 10 min    | Warm-up       | • Active and dynamic joint mobility; coordination, balance, displacement, spatial orientation and proprioception exercises. | Very light to fairly light |
| 15 to 20 min | Resistance    | • Resistance exercise for upper and lower limbs                                               | Somewhat hard to hard   |
|           |               | • 6 to 8 exercises                                                                           |                        |
|           |               | • 2–3 sets of 8 to 10 repetitions                                                            |                        |
|           |               | • Interval sets 1’30” a 2 min                                                                 |                        |
|           | Flexibility   | • Emphasis on joint mobility exercises,                                                     | Somewhat hard to hard   |
|           |               | • Maintenance of static positions combined with breathing techniques;                       |                        |
|           |               | • Proprioceptive neural facilitation techniques;                                             |                        |
|           |               | • 40 sec to 1 min each exercise                                                              |                        |
|           | Aerobic exercise (circuit training) | • Global exercises, involving large muscle groups focused on aerobic capacity. | Somewhat hard to hard   |
|           |               | • Circuit of 3 to 4 exercises                                                                |                        |
|           |               | • Stimulus– 30 sec to 1 min                                                                  |                        |
|           |               | • Passive interval (1 min)                                                                   |                        |
| 5 to 10 min | Cooldown      | • Active and static stretching exercises;                                                    | Very light to fairly light |
|           |               | • Breathing relaxation exercises;                                                             |                        |

The training intensity will be progressively adjusted by increasing the load (e.g., using common household objects), increasing the complexity, speed of movements and volume of exercises by varying circuits. The intensity of the exercise will be monitored using the Borg scale (from 0 to 20) with target intensity zone from 12 to 14 (Somewhat hard to hard) [24].

In addition to the home-based training sessions, patients will be encouraged to increase their physical activity. Patients will be provided with a Fitbit device to monitor their step count and will be recommended to increase their previous week’s average step count by 10%. Participants who have access to the internet will be asked to upload data to the Fitabase research platform. Data will be anonymised and will only be accessible to the research number.

**Usual care**

Patients randomized to the standard care group will receive general recommendations (Box 2) to modify risk factors and standard care as per trust guidelines given in their routine outpatient clinic appointment. Patients will also receive specific advice to perform unsupervised walking exercise for around 30 minutes three to five times a week, according to recently published NICE guidelines [9]. Patients will also receive a Fitbit device so they can measure their own exercise capacity and increase as recommended. They will be asked to upload their data to the research platform, if possible, as per the lifestyle intervention group.
Outcomes measurements

**Primary outcomes.** Feasibility will be determined by calculating the rate of patient screening, eligibility, recruitment, retention at 12 weeks and adherence to the intervention (number of sessions attended and completed). Patient acceptability of the intervention and study experience more broadly will be determined through semi-structured qualitative 1-2-1 interviews and/or focus groups. Given the challenges of conducting focus groups remotely, and anticipated characteristics of the participant group, we expect that 1-2-1 interviews will be more practical and facilitative. We will purposively sample participants from both study arms so that the experiences of patients from varied ethnic backgrounds, age and gender are represented. Acceptability of the intervention will be guided by Sekhon et al.’s Theoretical Framework of Acceptability [25] and the NIH Behavior Change Consortium’s Best Practices and Recommendations. We will also ask patients about their experience of participating in the study e.g., informed consent process, time commitment, acceptability of measures e.g. readability, burden etc. We will also ask for their experiences, thoughts, and attitudes towards current usual care for PAD. Interviews will be conducted until data saturation is reached in a maximum of 20 participants. All focus groups will be audio recorded and transcribed, and these data will be analysed thematically to generate themes and outcomes.

**Secondary outcomes.**

**Objective functional capacity.** Patients will complete the 6-minute walk test (6MWT) [26] at baseline and 12-week follow-up. Briefly, patients will be encouraged to “walk at their usual pace for six minutes and cover as much ground as possible” and rest if necessary. The outcomes will be the onset claudication distance (distance walked when the patients related the occurrence of symptoms of intermittent claudication [27]) and six-minute total walking distance (6MWD; the maximum distance achieved by the patient at the end of the test). The test will be administered by a trained member of staff and conducted in line with the American Thoracic Society guidance [26].

**Subjective functional capacity.** Patients will complete the Walking Impairment Questionnaire [28] at baseline and 12-week follow-up to assess three factors of walking impairment: walking distance, walking speed, and the ability to climb stairs. Patients will be asked how difficult it was to walk in these situations should answer as “none, slight, some, much or unable”. Each domain is anchored from 0, representing extreme limitation, to 100 representing no difficulties. Patients will also complete the Walking Estimated Limitation Calculated by History questionnaire [29] at both time points. Patients report how long they can walk at certain speeds, and then how they would rate their speed of walking relative to their relatives, friends, or people at same age.

---

**Box 2. Walking intervention for patients randomised to standard care**

| Step | Description |
|------|-------------|
| 1.   | Warm up. Stretch your calf and thigh muscles in each leg for 10 to 15 seconds. |
| 2.   | Start walking. Walk at a fast-enough pace for about 5 minutes, even though it may cause some mild pain. |
| 3.   | Stop and rest. After 5 minutes of mild or moderate pain, stop and rest until the pain goes away. |
| 4.   | Repeat the walk-and-stop routine several times. During the first two months of your walking program, build up slowly to walking a total of 35 minutes each session, not counting the rest breaks. Keep adding a few minutes until you’re at the goal of walking 50 minutes. |
| 5.   | Cool down. Finish by walking slowly for 5 minutes. Then, stretch your calf and thigh muscles again. |
| 6.   | Stick with it. |

---
Quality of life

Patients will complete the vascular quality of life questionnaire [30] at baseline and 12-week follow-up. The measure is composed of six items evaluating the impact of vascular disease on social aspects and capacity to perform daily activities. Each item is scored 1–4. The total score is achieved by summarizing the score on each item, resulting in a score between 6 and 24. Higher value indicates better health status. Patients will also complete the EuroQoL questionnaire (EQ-5D-5L) [34] at both study time points which measures five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression [31]. The digits for the five dimensions can be combined into a 5-digit number that describes the patient’s health state [32].

Dietary quality

Participants will complete the Short Form Dietary Questionnaire which comprises 24 items that collect data on dietary intake frequency. Participants’ responses will be used to derive a dietary quality score. The tool is shown to be a valid method of assessing dietary quality in UK adults [33].

Physical activity levels

Daily ambulatory activity will be assessed using a wrist-worn accelerometer (Fitbit Charge HR) which measures step count, resting heart rate and time in sedentary behaviour as well as light, moderate and vigorous activities. Fitbit devices have been shown to have good concurrent validity for measuring sedentary behaviour and physical activity compared to research-grade accelerometers [34–36]. Patients will be instructed to wear the device every day during the study and asked to charge the device every 48–36 hours overnight. Patients’ anonymised activity data will be uploaded to the Fitbit online dashboard (Fitabase) and extracted by researchers for analyses.

Sleep

Sleep quality and quantity will also be recorded by the Fitbit device. Patients’ anonymised sleep data will be uploaded to Fitabase and extracted by researchers for analyses. Wrist-worn Fitbit devices are shown to have good validity for obtaining gross estimates of sleep parameters [37].

Alcohol and tobacco use

The 3-item Alcohol Use Disorders Identification Test—Consumption (AUDIT-C) screening tool [38] will be administered to patients at baseline and 12-week follow-up to identify alcohol use disorders or risky drinking. The tool has good validity in diverse populations [39, 40]. If the patient is suspected to have an alcohol use disorder or risky drinking based on their AUDIT C score, their general practitioner will be contacted to offer further input and advice. Patients will complete a standard 30 second carbon monoxide breath test at baseline and follow-up to formally assess smoking status. This is not an aerosol generating procedure and therefore will be appropriate to use. Self-reported smoking habits will be assessed at baseline and follow-up. Patients will be asked to report their current tobacco smoking status and frequency of smoking cigarettes/other tobacco products and, previous tobacco smoking status.
Mental wellbeing

Patients will complete the 14-item hospital anxiety-depression score [41] at baseline and 12-week follow-up. The 14-item instrument is comprised of a depression subscale and anxiety subscale which are each assessed through 7-items. Respondents will be asked to rate their mental and emotional state over the past week. The hospital anxiety-depression score has good validity in community and clinical populations [41, 42].

Patient activation

The Patient Activation Measure (PAM®) [43] measures patients’ knowledge, skills and confidence in managing their condition. PAM licences are available from NHS England and Improvement as part of the Supported Self-management component of the Personalised Care Programme. At baseline and 12-week follow-up patients will respond (strongly disagree/disagree/agree/strongly agree/N/A) to 13 statements related to their confidence in managing their health. Patients’ PAM score (0–100) will place them within one of four activation categories, providing insight into a range of health-related characteristics and behaviours. The PAM has been validated for use in adults with long term conditions [44–46].

Resource utilisation

The case report forms will measure the resource utilisations by each patient. The case report forms will be administered to each patient at baseline and 12-week follow-up in both arms of the trial asking them to report any health care resources they have utilised in the preceding 12 weeks.

Health economics

The trial will not be adequately powered to conduct a formal health economic evaluation, therefore the data accrued from the pilot trial will be reported using descriptive statistics to explore the differences in resource utilisations, costs and effects between the trial arms. We will also assess the completion rates for the health economics data collection tools, responses for each question and health state utility values. At baseline and 12-week follow-up, all patients will complete the following: EuroQol’s EQ-5D-5L, EQ-5D VAS questionnaire and case report forms measuring health resource utilisation.

Study power

As per good practice recommendations for pilot studies [47], we will aim to recruit 30 patients to each arm and obtain a total sample of 60 participants. The findings of the current study will be used to inform the power calculations of a future definitive randomised controlled trial.

Statistical plan

Primary outcome data will be reported as descriptive statistics, including rates of: patient screening, eligibility, recruitment and retention to 12-week follow-up and survey completion. Qualitative interview data will be analysed thematically to generate themes. Exploratory between-group analyses will be conducted to determine preliminary intervention effectiveness. Normality and homogeneity of variance will be performed using the Shapiro-Wilks and Levene tests, respectively. For comparison of the variables at the pre-intervention, we will perform a one-way ANOVA. To analyze the responses before and after the intervention period, two-way analysis of variance for repeated measures will be used, with the main factors being
the group (and the time (pre and post-intervention) with Newman-Keuls post-hoc test. The level of significance will be set at $P < 0.05$.

**Trial status**

Enrolment of patients started in February 2022.

**Discussion**

To the best of our knowledge, this is the first study to assess the feasibility and acceptability of a 12-weeks home-based telehealth exercise and behavioural intervention delivered in patients with PAD living in socioeconomically deprived areas. In addition, this study will also determine the preliminary effectiveness of the intervention for improving clinical and health outcomes in these patients.

Supervised exercise training and secondary cardiovascular prevention are considered a cornerstone for clinical treatment in patients with PAD due to the benefits in different health parameters, such as functional capacity, cardiovascular function, and quality of life [5, 7, 48, 49]. Despite these benefits, in the UK patients has limited access to supervised exercise training in the clinical setting and, patients are not systematically offered evidence-based interventions that support behavioural modification for their risk factors [10]. In addition, a recent study found that financial limitations and travel distances were cited as barriers to participation in supervised exercise training in PAD patients in the UK. [10]. To tackle these barriers, we will test the feasibility, acceptability and effectiveness of a home-based exercise and behavioural intervention in patients with PAD. This program will be delivered remotely to patients living in socioeconomically deprived areas in the North East of England, known as one of the highest prevalence of unhealthy habits in the UK [50].

If effective, we can support preliminary evidence that our home-based telehealth behavioural intervention may be a feasible strategy for PAD treatment and can be incorporated into public services deliveries. In addition, the variance of the key health outcomes of this pilot study will be used to inform the sample size calculation for a future definitive multicentre randomized clinical trial.

**Supporting information**

S1 Checklist. SPIRIT 2013 checklist: Recommended items to address in a clinical trial protocol and related documents.

(DOC)

S1 File.

(PDF)

**Author Contributions**

**Conceptualization:** Gabriel Cucato, Chris Snowden, Emma McConne, Craig Nesbitt, Sandip Nandhra, Mackenzie Fong, Eileen Kane, Maisie Rowland, Nawaraj Bhattarai, Paul Court, Oliver Bell, John Michael Saxton, James Prentis.

**Funding acquisition:** James Prentis.

**Methodology:** Gabriel Cucato, Craig Nesbitt, Sandip Nandhra, Maisie Rowland, Paul Court, Oliver Bell, John Michael Saxton, James Prentis.

**Project administration:** Emma McConne, Mackenzie Fong.
Writing – original draft: Gabriel Cucato, Chris Snowden, Emma McCone, Mackenzie Fong, Eileen Kane, John Michael Saxton, James Prentis.

Writing – review & editing: Gabriel Cucato, Chris Snowden, Emma McCone, John Michael Saxton, James Prentis.

References
1. Bradberry JC. Peripheral arterial disease: pathophysiology, risk factors, and role of antithrombotic therapy. J Am Pharm Assoc (2003). 2004; 44(2 Suppl 1):S37–44; quiz S-5. Epub 2004/04/21. https://doi.org/10.1331/154434504322904596 PMID: 15095934.

2. Meijer WT, Hoes AW, Rutgers D, Bots ML, Hofman A, Grobbee DE. Peripheral arterial disease in the elderly: The Rotterdam Study. Arterioscler Thromb Vasc Biol. 1998; 18(2):185–92. Epub 1998/03/04. https://doi.org/10.1161/01.ATV.18.2.185 PMID: 9484982.

3. Gardner AW, Clancy RJ. The relationship between ankle-brachial index and leisure-time physical activity in patients with intermittent claudication. Angiology. 2006; 57(5):539–45. Epub 2006/10/28. https://doi.org/10.1177/0003319706293114 PMID: 17067975.

4. Lima AH, Soares AH, Cucato GG, Leicht AS, Franco FG, Wolosker N, et al. Walking Capacity Is Positively Related with Heart Rate Variability in Symptomatic Peripheral Artery Disease. Eur J Vasc Endovasc Surg. 2016; 52(1):82–9. Epub 2016/05/06. https://doi.org/10.1016/j.ejvs.2016.03.029 PMID: 27161329.

5. Ritti-Dias RM, Correia MA, Andrade-Lima A, Cucato GG. Exercise as a therapeutic approach to improve blood pressure in patients with peripheral arterial disease: current literature and future directions. Expert Rev Cardiovasc Ther. 2019; 17(1):65–73. Epub 2018/11/28. https://doi.org/10.1080/14779072.2019.1553676 PMID: 30481076.

6. Raja A, Spertus J, Yeh RW, Secemsky EA. Assessing health-related quality of life among patients with peripheral artery disease: A review of the literature and focus on patient-reported outcome measures. Vasc Med. 2021; 26(3):317–25. Epub 2020/12/10. https://doi.org/10.1177/1358863X20977016 PMID: 33295253.

7. Lane R, Harwood A, Watson L, Leng GC. Exercise for intermittent claudication. Cochrane Database Syst Rev. 2017; 12:CD000990. Epub 2017/12/27. https://doi.org/10.1002/14651858.CD000990.pub4 PMID: 29278423.

8. Cornelis N, Nassen J, Buys R, Fourneau I, Cornelissen V. The Impact of Supervised Exercise Training on Traditional Cardiovascular Risk Factors in Patients With Intermittent Claudication: A Systematic Review and Meta-Analysis. Eur J Vasc Endovasc Surg. 2019; 58(1):75–87. Epub 2019/06/04. https://doi.org/10.1016/j.ejvs.2018.12.014 PMID: 31153735.

9. Layden J, Michaels J, Berrum S, Higgins D, Guideline Development Group. Diagnosis and management of lower limb peripheral arterial disease: summary of NICE guidance. BMJ. 2012; 345:e4947. Epub 2012/08/10. https://doi.org/10.1136/bmj.e4947 PMID: 22875949.

10. Harwood AE, Pymer S, Ibbegazene S, Ingle L, Caldwell E, Birkett ST. Provision of exercise services in patients with peripheral artery disease in the United Kingdom. Vascular. 2021; 17085381211035259. Epub 2021/08/06. https://doi.org/10.17708/17085381211035259 PMID: 34348503.

11. Reynolds MR, Apruzzese P, Galper BZ, Murphy TP, Hirsch AT, Cutlip DE, et al. Cost-effectiveness of supervised exercise, stenting, and optimal medical care for claudication: results from the Claudication: Exercise Versus Endoluminal Revascularization (CLEVER) trial. J Am Heart Assoc. 2014; 3(6):e001233. Epub 2014/11/13. https://doi.org/10.1161/JAHA.114.001233 PMID: 25392894.

12. Mazari FA, Khan JA, Carradice D, Samuel N, Gohil R, McCollum PT, et al. Economic analysis of a randomized trial of percutaneous angioplasty, supervised exercise or combined treatment for intermittent claudication due to femoropopliteal arterial disease. Br J Surg. 2013; 100(9):1172–9. Epub 2013/07/12. https://doi.org/10.1002/bjs.9200 PMID: 23842831.

13. Michie S, Jochelson K, Markham WA, Bridle C. Low-income groups and behaviour change interventions: a review of intervention content, effectiveness and theoretical frameworks. J Epidemiol Commun Health. 2009; 63(8):610–22. https://doi.org/10.1136/jech.2008.078725 PMID: 19386612.

14. Foster HME, Celis-Morales CA, Nicholl BI, Petermann-Rocha F, Pell JP, Gill JMR, et al. The effect of socioeconomic deprivation on the association between an extended measurement of unhealthy lifestyle factors and health outcomes: a prospective analysis of the UK Biobank cohort. Lancet Public Health. 2018; 3(12):E576–E85. https://doi.org/10.1016/S2468-2667(18)30200-7 PMID: 30467019.

15. Luo H, Lie Y, Prinzen FW. Surveillance of COVID-19 in the General Population Using an Online Questionnaire: Report From 18,161 Respondents in China. JMIR Public Health Surveill. 2020; 6(2):e18576. Epub 2020/04/23. https://doi.org/10.2196/18576 PMID: 32319956.
16. Lendacki FR, Teran RA, Gretsch S, Fricchione MJ, Kerins JL. COVID-19 Outbreak Among Attendees of an Exercise Facility—Chicago, Illinois, August-September 2020. Mmwr-Morbid Mortal W. 2021; 70(9):321–5.

17. Groves LM, Usagawa L, Elm J, Low E, Manuzak A, Quint J, et al. Community Transmission of SARS-CoV-2 at Three Fitness Facilities—Hawaii, June-July 2020. Mmwr-Morbid Mortal W. 2021; 70(9):316–20. https://doi.org/10.15585/mmwr.mm7009e1 PMID: 33661861

18. Dixon P, Hollinghurst S, Ara R, Edwards L, Foster A, Salisbury C. Cost-effectiveness modelling of telehealth for patients with raised cardiovascular disease risk: evidence from a cohort simulation conducted alongside the Healthlines randomised controlled trial. BMJ Open. 2016; 6(9):e012355. Epub 2016/09/28. https://doi.org/10.1136/bmjopen-2016-012355 PMID: 27670521.

19. Nizeyimana E, Joseph C, Louw QA. A scoping review of feasibility, cost-effectiveness, access to quality rehabilitation services and impact of telerehabilitation: A review protocol. Digit Health. 2022; 8:2052076211066708. Epub 2022/03/01. https://doi.org/10.1177/20520762211066708 PMID: 35233074.

20. Pringle A, Zwolinsky S, McKenna J, Daly-Smith A, Robertson S, White A. Delivering men’s health interventions in English Premier League football clubs: key design characteristics. Public Health. 2013; 127(8):716–26. Epub 2013/07/23. https://doi.org/10.1016/j.puhe.2013.04.011 PMID: 23870844.

21. Pringle A, Zwolinsky S, McKenna J, Robertson S, Daly-Smith A, White A. Health improvement for men and hard-to-engage-men delivered in English Premier League football clubs. Health Educ Res. 2014; 29(3):503–20. Epub 2014/03/25. https://doi.org/10.1093/her/cyu009 PMID: 24659420.

22. Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gotzsche PC, Krleza-Jeric K, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. Ann Intern Med. 2013; 153(3):200–7. Epub 2013/01/09. https://doi.org/10.7326/0003-4819-153-3-201302200-00003 PMID: 23295597.

23. Snowden C, Lynch E, Avery L, Gerrand C, Gilvarry E, Goudie N, et al. Preoperative Behavioural Intervention versus standard care to Reduce Drinking before elective orthopaedic Surgery (PRE-OP BIRDS): protocol for a multicentre pilot randomised controlled trial. Pilot Feasibility Stud. 2018; 4:140. Epub 2018/08/22. https://doi.org/10.1186/s40814-018-0390-4 PMID: 30128165.

24. Borg GA. Psychophysical bases of perceived exertion. Med Sci Sports Exerc. 1982; 14(5):377–81. Epub 1982/01/01. PMID: 7154693.

25. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Serv Res. 2017; 17(1):88. Epub 2017/01/28. https://doi.org/10.1186/s12913-017-2031-8 PMID: 2816032.

26. Laboratories ATSCoPSICPF. ATS statement: guidelines for the six-minute walk test. Am J Respir Crit Care Med. 2002; 166(1):111–7. Epub 2002/07/02. https://doi.org/10.1164/ajrccm.166.1.at1102 PMID: 12091180.

27. Montgomery PS, Gardner AW. The clinical utility of a six-minute walk test in peripheral arterial occlusive disease patients. J Am Geriatr Soc. 1998; 46(6):706–11. Epub 1998/06/13. https://doi.org/10.1111/j.1532-5415.1998.tb03804.x PMID: 9625185.

28. Nicolai SP, Kruidenie LM, Rouwet EV, Graffius K, Prins MH, Teijink JA. The walking impairment questionnaire: an effective tool to assess the effect of treatment in patients with intermittent claudication. J Vasc Surg. 2009; 50(1):89–94. Epub 2009/07/01. https://doi.org/10.1016/j.jvs.2008.12.073 PMID: 19563956.

29. Tew GA, Nawaz S, Humphreys L, Ouedraogo N, Abraham P. Validation of the English version of the Walking Estimated-Limitation Calculated by History (WELCH) questionnaire in patients with intermittent claudication. Vasc Med. 2014; 19(1):27–32. Epub 2014/01/24. https://doi.org/10.1177/1358863X14520870 PMID: 24452834.

30. Nordanstig J, Wann-Hansson C, Karlsson J, Lundstrom M, Pettersson M, Morgan MB. Vascular Quality of Life Questionnaire-6 facilitates health-related quality of life assessment in peripheral arterial disease. J Vasc Surg. 2014; 59(3):700–7. Epub 2013/12/18. https://doi.org/10.1016/j.jvs.2013.08.099 PMID: 24342060.

31. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011; 20(10):1727–36. Epub 2011/04/12. https://doi.org/10.1007/s11136-011-9903-x PMID: 21479777.

32. van Hout B, Janssen MF, Feng YS, Kohlmann T, Busschbach J, Golicki D, et al. Interim scoring for the EQ-5D-5L: mapping the EQ-5D-5L to EQ-5D-3L value sets. Value Health. 2012; 15(5):708–15. Epub 2012/08/08. https://doi.org/10.1016/j.jval.2012.02.008 PMID: 22867780.

33. Cleghorn CL, Harrison RA, Ransley JK, Wilkinson S, Thomas J, Cade JE. Can a dietary quality score derived from a short-form FFQ assess dietary quality in UK adult population surveys? Public Health Nutr. 2016; 19(16):2915–23. Epub 2016/05/18. https://doi.org/10.1017/S1368980016001099 PMID: 27181696.
34. Redenius N, Kim Y, Byun W. Concurrent validity of the Fitbit for assessing sedentary behavior and moderate-to-vigorous physical activity. BMC Med Res Methodol. 2019; 19(1):29. Epub 2019/02/09. https://doi.org/10.1186/s12874-019-0668-1 PMID: 30732582.

35. Brewer W, Swanson BT, Ortiz A. Validity of Fitbit’s active minutes as compared with a research-grade accelerometer and self-reported measures. BMJ Open Sport Exerc Med. 2017; 3(1):e000254. Epub 2017/10/12. https://doi.org/10.1136/bmjsem-2017-000254 PMID: 29018543.

36. Tedesco S, Sica M, Anciello A, Timmons S, Barton J, O’Flynn B. Validity Evaluation of the Fitbit Charge2 and the Garmin vivosmart HR+ in Free-Living Environments in an Older Adult Cohort. JMIR Mhealth Uhealth. 2019; 7(6):e13084. Epub 2019/06/21. https://doi.org/10.2196/13084 PMID: 31219048.

37. Haghayegh S, Khoshnevis S, Smolensky MH, Diller KR, Castriotta RJ. Accuracy of Wristband Fitbit Models in Assessing Sleep: Systematic Review and Meta-Analysis. J Med Internet Res. 2019; 21(1):e16273. Epub 2019/11/30. https://doi.org/10.2196/16273 PMID: 31778122.

38. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. Arch Intern Med. 1998; 158(16):1789–95. https://doi.org/10.1001/archinte.158.16.1789 PMID: 9738608.

39. Haghayegh S, Khoshnevis S, Smolensky MH, Diller KR, Castriotta RJ. Accuracy of Wristband Fitbit Models in Assessing Sleep: Systematic Review and Meta-Analy sis. J Med Interne t Res. 2019; 21(1):e16273. Epub 2019/11/30. https://doi.org/10.2196/16273 PMID: 31778122.

40. Frank D, DeBenedetti AF, Volk RJ, Williams EC, Kivlahan DR, Bradley KA. Effectiveness of the AUDIT-C as a screening test for alcohol misuse in three race/ethnic groups. J Gen Intern Med. 2008; 23(6):781–7. Epub 20080418. https://doi.org/10.1007/s11606-008-0594-0 PMID: 18421511.

41. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand. 1983; 67(6):361–70. https://doi.org/10.1111/j.1600-0447.1983.tb09716.x PMID: 6880820.

42. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. J Psychosom Res. 2002; 52(2):69–77. https://doi.org/10.1016/s0022-3999(01)00296-3 PMID: 11832252.

43. Hibbard JH, Mahoney ER, Stockard J, Tusler M. Development and testing of a short form of the patient activation measure. Health Serv Res. 2005; 40(6 Pt 1):1918–30. https://doi.org/10.1111/j.1475-6773.2005.00438.x PMID: 16336556.

44. Moljord IE, Lara-Cabrera ML, Perestelo-Pérez L, Rivero-Santana A, Eriksen L, Linaker OM. Psychometric properties of the Patient Activation Measure-13 among out-patients waiting for mental health treatment: A validation study in Norway. Patient Educ Couns. 2015; 98(11):1410–7. Epub 20150623. https://doi.org/10.1016/j.pec.2015.06.005 PMID: 26146239.

45. Hellström A, Kassaye Tessma M, Flink M, Dahlgren A, Schildmeijer K, Ekstedt M. Validation of the patient activation measure in patients at discharge from hospitals and at distance from hospital care in Sweden. BMC Public Health. 2019; 19(1):1701. Epub 20191219. https://doi.org/10.1186/s12889-019-8025-1 PMID: 31856796.

46. Ngooi BX, Packer TL, Kephart G, Warner G, Koh KW, Wong RC, et al. Validation of the Patient Activation Measure (PAM-13) among adults with cardiac conditions in Singapore. Qual Life Res. 2017; 26(4):1071–80. Epub 20160919. https://doi.org/10.1007/s11136-016-1412-5 PMID: 27645458.

47. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. J Eval Clin Pract. 2004; 10(2):307–12. PMID: 15189396.

48. Chehuen M, Cucato GG, Carvalho CRF, Ritti-Dias RM, Wolosker N, Leicht AS, et al. Walking training at the heart rate of pain threshold improves cardiovascular function and autonomic regulation in intermittent claudication: A randomized controlled trial. J Sci Med Sport. 2017; 20(10):886–92. Epub 2017/03/21. https://doi.org/10.1016/j.jsams.2017.02.011 PMID: 28389218.

49. Grizzo Cucato G, de Moraes Forjaz CL, Kanegusuku H, da Rocha Chehuen M, Riani Costa LA, Wolosker N, et al. Effects of walking and strength training on resting and exercise cardiovascular responses in patients with intermittent claudication. Vas cular-European Journal of Vascular Medicine. 2011; 40(5):390–7. https://doi.org/10.1024/0301-1526/a000136 PMID: 21948782.

50. Bhatnagar P, Wickramasinghe K, Williams J, Rayner M, Townsend N. The epidemiology of cardiovascular disease in the UK 2014. Heart. 2015; 101(15):1182–9. Epub 20150603. https://doi.org/10.1136/heartjnl-2015-307516 PMID: 26041770.