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Effectiveness and acceptableness of an exercise regime using a portable device to improve leg lymphoedema

Submission date
13/01/2020

Recruitment status
No longer recruiting

Registration date
29/01/2020

Overall study status
Completed

Last Edited
03/05/2023

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic lymphoedema is a long-term medical condition that results in swelling of the limbs or other body parts. The cause of fluid build-up in particularly the arms and/or legs is problems with the lymphatic system, which is a network of glands and vessels that helps fight infection and remove excess liquid in the body. Lymphoedema of the legs is common in people who: may have another chronic condition such as heart failure, COPD, or vascular disease; are inactive for long periods; are overweight or obese; or have had cancer treatment to e.g. the pelvis. There is some evidence to suggest that specific resistance exercise of the calf muscle – moving the front of the foot up and down by plantar flexion, similar to what a drummer does when using the foot pedal of a drum - may improve the calf muscle pump function and help reduce fluid build-up. It has been shown that at least in the short-term there is better blood flow and endurance if the calf muscle is exercised in this manner.
As yet there remains considerable uncertainty as to the effects of an exercise programme on leg lymphoedema symptom control. There is very limited research data available on the medium- to long-term effects of calf muscle exercising by lymphoedema patients on the volume of the legs. This trial is to determine if the use of a CE-approved plantar flexion pedal, developed by StepIt Ltd, will be of benefit to people with lymphoedema of the leg.

Who can participate?
People aged 18 years or above, diagnosed with chronic leg lymphoedema

What does the study involve?
Participants will be randomly allocated to receive treatment as usual or to use a StepIt Pedal to use daily for calf muscle exercises. Participants in the Step It intervention group will be asked to do the Step It exercises for 10 minutes, two times daily, for 12 weeks, and record a diary.

What are the possible benefits and risks of participating?
For the participants in the control group there is no direct benefit in taking part in this study. The participant will be cared for in exactly the same manner as the participant normally would. For participants in the Step It intervention group, there may be benefits in terms of improved

lymphoedema symptom control compared to normal standard care. However, this has not yet been proven and established, and this study aims to assess this. There is no intended clinical benefit from taking part in this study. Those participants who are given a Step It pedal can keep the device after completion of the study if they wish to do so.
There is no anticipated personal safety risk associated with taking part in this study. If participants' lymphoedema specialist or the research team learn of important new information that might affect participants' desire to remain in the study, he or she will tell the participant. This will take more time and effort compared to the standard treatment.
Appropriate precautions are in place to ensure participants' medical and personal information is kept safe: all data will be kept in secure environments, following the requirement of the General Data Protection Regulations, the Data Protection Act, and the NHS Code of Confidentiality. Any data that is released (i.e. for publication) will contain no information that could lead to the identification of an individual participant. In the consent form, we will ask participants' permission to store participants' data related to this study.

Where is the study run from?
Carleton Clinic (UK)

When is the study starting and how long is it expected to run for?
January 2020 to March 2023

Who is funding the study?
1. StepIt System AB (Sweden)
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Mr Leon Jonker

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
265968

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 43999, IRAS 265968

Study information

Scientific Title
PEDAL: Plantar Exercise, Daily, for Lymphoedema, a single-centre, controlled, prospective, randomized feasibility trial

Acronym
PEDAL

Study objectives
PEDAL wishes to determine the feasibility of conducting a full RCT in the future, while also assessing the acceptability and effectiveness of the StepIt device and accompanying exercise regime in the management of leg lymphoedema. As such, the study does not lend itself to a hypothesis. However, a future hypothesis would be that characteristics of lymphoedema such as increased leg volume, increased ankle circumference, and decreased ankle range of motion would improve, and lymphoedema-related quality of life would improve also.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/06/2021, Yorkshire & The Humber – Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 1048 018; nrescommittee.yorkandhumber-leedseast@nhs.net), ref: 19/YH/0413

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Lymphoedema

Interventions
Participants will be randomised to either the control group (standard care) or the intervention group (standard care plus use of a StepIt pedal) for 12 weeks. Those in the intervention group will be issued with a StepIt Pedal to use daily for calf muscle exercises. These exercises consist of resisted plantar flexion while seated, performed 2 times daily in the pattern of: 1 minute exercise / 1 minute rest, 10 times (participants may alternate legs as an alternative to merely resting both legs for 1 minute). The participants will be asked to keep an exercise diary to record their activity. At their discharge visits participants are asked to provide their opinion on trial participation. All participants will have demographic data obtained and the following base line measures. In brackets it will state when these measures are recorded:
- Leg volume and ankle size using circumference (baseline, week 6, week 12)
- Ankle range of motion using a goniometer, (baseline, week 12)
- Visual analogue pain score, (baseline, week 6, week 12)
- Generic and lymphoedema-specific Quality of life assessment (baseline, week 6, week 12)

Intervention Type
Other

Primary outcome measure
1. Participants' experience of and compliance to StepIt exercise regime measured using a bespoke questionnaire at 12 weeks
Assessed at the end of the study:
2. Recruitment and attrition rates, willingness of patients to be randomised, response rates to questionnaires, and degrees of missing data
3. Testing of eligibility criteria and ability/willingness of clinical staff to partake in recruitment of participants
4. Ability of site and clinicians to recruit and randomise patients, irrespective of care setting
5. To assess any training requirements
6. Adequacy of duration of follow-up (e.g. in relation to lymphoedema management and outcomes)
7. Fitness for purpose of data collection methods including across and between care settings
8. Number of and character of adverse events

Secondary outcome measures
Clinical outcome measures
1. Leg volume (measured using Kunhke's technique), at week 0, 6, 12
1.1. Measured only between 9.30am to 3.30pm
1.2. Where possible the same rater is used for each participant; name of rater will be recorded.
2. Ankle circumference measurement, using lateral malleolus as reference point at week 0, 6, 12
3. Clinician's oedema severity score at week 0, 6, 12
4. Ankle range of motion in degrees measured using goniometer at week 0, 6, 12
5. Pain score is measured using the visual analogue score (VAS) at week 0, 6, 12
6. Quality of life is measured using two tools -- EQ-5D-5L and LYMQOL-L Questionnaire -- at week 0, 6, 12

7. Participant opinion on trial participation, at week 12 (StepIt users only) measured using a bespoke questionnaire
Assessed at the end of the study:
8. Patient withdrawal rates due to change in management (e.g. need for surgery, hospital admission, infection, or other) calculated at the end of the study recruitment window
9. Leg infection rates, primarily cellulitis, calculated using a survey of patient notes at the end of the study

Overall study start date
01/01/2019

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Over the age of 18
2. Diagnosis of chronic leg lymphoedema (chronicity > 3 months). This includes primary or secondary lymphoedema
3. Lymhpoedema can be present in one leg or both legs
4. Newly presenting to lymphoedema service or existing patients
5. Same type of compression therapy for at least two months
6. Presence of leg ulcer is not an exclusion criterion
7. Command of English, verbal and in writing
8. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

Total final enrolment
28

Key exclusion criteria
1. Unable to fully understand the consent process and provide informed consent due to either language barriers or mental capacity
2. Currently receiving, or within six months of receiving, chemotherapy or radiotherapy for cancer

3. Surgery on lower limb within last three months
4. Surgery within last month
5. BMI > 40
6. Active infection in one or both of the legs treated with systematic antibiotics (or within one week of finishing antibiotics)
7. Inability to comply with the StepIt pedal exercise, e.g. due to fixed ankle or other pathology that impedes using the StepIt pedal. This will be established during the screening/consent process by trialling the StepIt pedal and the movement involved in clinic
8. Commenced, or change in dosage of, diuretic medication in last three months

Date of first enrolment
01/02/2020

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Carleton Clinic
Cumwhinton Road
Carlisle
United Kingdom
CA1 3SX

Sponsor information

Organisation
Cumbria Partnership NHS Foundation Trust

Sponsor details
known as North Cumbria Integrated Care NHS Foundation Trust since Oct 2019
Voreda House
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Sponsor type
Hospital/treatment centre

Website
https://www.cumbriapartnership.nhs.uk/

Funder(s)

Funder type
Industry

Funder Name
Step It System AB

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/05/2023

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.1	24/11/2021	06/05/2022	No	No
Other unpublished results		30/03/2023	03/05/2023	No	No
HRA research summary			28/06/2023	No	No