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Leg strengthening exercise to improve standing blood pressure response during muscle tensing in the treatment of orthostatic hypotension

Submission date
11/02/2020

Recruitment status
No longer recruiting

Registration date
19/02/2020

Overall study status
Completed

Last Edited
02/09/2022

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
When we stand up gravity pulls blood into our legs, lowering our blood pressure (BP). Our body must react to keep blood flowing to the brain, when this process fails we develop orthostatic hypotension (OH). This is very common and debilitating in older people. This population are keen to avoid further medication and have prioritised non-drug therapies for research. When we tense our leg muscles, blood is forced back up towards the head (this is the skeletal muscle pump). This improves BP in 44% of older people with OH. The aim of this 'proof of concept' study is to see if the skeletal muscle pump can become more effective by strengthening the leg muscles.

Who can participate?
Older people, aged over 60, with orthostatic hypotension and who are able to stand

What does the study involve?
Participants are randomly allocated to either 2, 3, or 4 weeks of baseline observation. Then all participants receive an individualised 8-week leg strengthening exercise programme, which they perform at home. A research assistant (RA) visits participants each week to monitor BP, strength and exercise progress. One month later the outcomes are measured again and they are offered an interview to explore whether the intervention was acceptable and how it could be improved. Participants also visit the Freeman Hospital four times over the course of the study to assess changes in the skeletal muscle pump. This is done by applying a large blood pressure cuff around the leg while contracting the muscles.

What are the possible benefits and risks of participating?
If the exercise does improve the standing BP, the results will be used to develop a clinical trial. The study hopes to benefit people in the future but will be of no personal benefit to participants. The main risk is the inconvenience of research visits. There may some muscle soreness from the exercise programme.

Where is the study run from?
The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2017 to September 2020

Who is funding the study?
NIHR Newcastle Biomedical Research Centre (UK)

Who is the main contact?
Dr James Frith
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
R&D08657

Study information

Scientific Title
Targeting the skeletal muscle pump to aid standing in elders with postural hypotension

Acronym
TASKMASTER

Study objectives
Improving the strength of the skeletal muscles in the lower limbs in older people with OH will result in a more effective skeletal muscle pump, reducing pooling of blood, and increasing their standing blood pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/05/2008, North East - York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; Tel: +44 (0)207 1048091; Email: nrescommittee.northeast-york@nhs.net), REC ref: 18/NE/0173

Study design
Interventional case series

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Orthostatic hypotension

Interventions
Lower limb strengthening exercises:
1. Duration: 8 weeks
2. Frequency: four times per week
3. Intensity: 5-minute warm-up, 30-minute strength exercises, 5-minute cool-down. Challenging, individualised with progressive difficulty, using graded resistance bands
4. Type: moderate lower limb strength exercises, including, sit-to-stand, heel raises, knee extension, hip adduction and abduction and ‘pelvic tilting’ in a seated position
5. Equipment: graded resistance bands
6. Special considerations: given the orthostatic symptoms, exercise will begin in the seated position, progressing to standing position, catered to individual’s needs

The researchers will recruit 15 older people with OH and monitor their BP, muscle strength and skeletal muscle pump efficiency before, during and after an exercise programme. They will randomise participants to either two, three, or four weeks of baseline observation. Then all participants will receive an individualised 8-week leg strengthening exercise programme, which they will perform at home. A research assistant (RA) will visit participants each week to monitor BP, strength and exercise progress. One month later the outcomes will be measured again and they will be offered a qualitative interview to explore whether the intervention was acceptable and how it could be improved. Participants will also visit the Freeman Hospital four times over the course of the study to assess changes in the skeletal muscle pump. This is done by applying a

large blood pressure cuff around the leg while contracting the muscles. The analysis will focus on clinical rather than statistical significance. If the exercise does improve the standing BP, the results will be used to develop a clinical trial.

Intervention Type
Behavioural

Primary outcome(s)
Systolic BP drop upon standing, measured using a non-invasive, continuous BP monitor (Taskforce, CNSystems) at baseline and completion (12 weeks)

Key secondary outcome(s))
Measured at baseline and 12 weeks:
1. Calf muscle strength measured using a dynamometer
2. Ejection fraction and refill time of blood from the right and left calf, measured using air plethysmography
3. Transcutaneous tissue oxygen saturation (TOS): anterior muscle area, measured using optical TOS probe (LEA O2C)
4. Venous return (the volume of venous blood returning to the heart), measured using impedance cardiography (Taskforce CNSystems)
5. Peripheral resistance (vasodilation due to muscle activity) measured using impedance cardiography (Taskforce CNSystems)
6. Symptoms during standing measured using Orthostatic Hypotension Questionnaire 3

Exploratory outcome measures:
1. Adherence to the intervention assessed using self-directed exercise diary at 12 weeks
2. Safety assessed using self-directed exercise diary at 12 weeks
3. Acceptability of and barriers to the intervention assessed using qualitative interviews at 12 weeks

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Older people, aged over 60 years
2. With a clinical diagnosis of orthostatic hypotension
3. Who are able to stand

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex

All

Key exclusion criteria
1. Unable to participate in physical therapy
2. Acute illness requiring hospitalisation within previous 6 weeks
3. Any physical or cognitive impairment which would prevent engagement with self-directed physical therapy, or ability to follow instructions and complete assessments
4. Receiving physical therapy in other settings, or having received therapy in the previous 12 weeks which involved the lower limbs, or performs regular strengthening exercises of the lower limb (e.g. regular attendance at the gym)
5. Ulceration to the lower limbs
6. Participants who wear compression garments will be required to remove these for assessments

Date of first enrolment
01/09/2018

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type

Government

Funder Name
NIHR Newcastle Biomedical Research Centre

Alternative Name(s)
Newcastle Biomedical Research Centre, Newcastle NIHR Biomedical Research Centre

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data will not be available as participants have not provided consent specifically for their data to be used outside of this study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes