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Trial of isometric exercise to lower blood pressure

Submission date 17/03/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/04/2025	**Overall study status** Ongoing	
Last Edited 11/04/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
High blood pressure (BP) affects more than one in four adults in England and only one in three patients are being treated effectively. The cost of not being treated effectively is approximately £2.1 billion per year, mainly due to care related to strokes and heart attacks. Treatment of high BP includes changes to lifestyle, such as more physical activity and/or taking medication. Unfortunately, over 50% of hypertensives fail to reduce their BP to healthier levels as they do not fully adopt treatment. Evidence suggests that isometric exercise (IE) can lower BP a greater amount with less time and effort than other recommended types of exercise. Studies have shown that eight minutes of personalised IE, performed three times a week for 4 weeks can reduce resting BP significantly in unmedicated people. This study follows preliminary research by the same team, which considered whether wall-squat IE (squatting with your back against the wall) could be delivered in the NHS. Results found that participants easily achieved and enjoyed the exercise at home. Healthcare professionals also thought it was an achievable intervention. The IE has since been developed for patients to exercise at home without any involvement from a healthcare professional (self-delivered). A larger study is now needed to confirm if IE results in a consistent reduction in people's BP. This study aims to confirm whether wall-squat IE training will reduce BP in people with high BP.

Who can participate?
Adult patients aged 18 years and over with a high BP diagnosis and without any complex health conditions.

What does the study involve?
A broad approach is being used to ask people to take part, including those from underserved groups. This will include advertising on social media, through community settings, GP surgeries, hospitals and pharmacies. All participants will be given a BP monitor and healthy lifestyle advice, and be asked to record their BP at 4 weeks, 3 months and 6 months. Half the participants will be randomly enrolled on an IE training programme for 6 months. This involves completing three IE wall-squat sessions per week, taking less than 15 minutes each time. Participants will complete online questionnaires on diet and exercise at baseline, 3 months, 6 months (and 12 months in the IE subgroup) and quality of life questionnaire at baseline and 3 months (also at 12 months in the IE subgroup).

Patient and Public Involvement
The study was designed with patient/public contributors and has continued support from three public co-applicants who are part of the study team.

What are the possible benefits and risks of participating?
Participants will benefit from receiving a BP monitor to measure their BP at home. Participants may benefit from improvements in leg strength and fitness over the training period. They may also experience an improvement in their BP measurements (even in the control group with the lifestyle advice).
Participants may experience typical reactions to performing exercise, including a burning sensation in the legs and an increased heart rate. There is potential to experience slight muscle aching in the two days after the exercise when participants first start to do the exercise programme. The risk of sudden heart problems (like a heart attack) during or after doing isometric exercise is very low.

Where is the study run from?
Kent and Canterbury Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2024 to March 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) (UK)

Who is the main contact?
Prof. Chris Farmer, c.farmer-357@kent.ac.uk

Study website
https://www.isofitter.org.uk/

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
331559

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR207256, CPMS 57418

Study information

Scientific Title
Randomised controlled effectiveness trial (RCT) of isometric exercise (IE) in adults with stage 1 and 2 hypertension

Acronym
ISOFITTER

Study objectives
Self-prescribed intermittent exercise (IE) at home, when combined with standard care, is more effective in reducing systolic blood pressure (SBP) in individuals with Stage 1 and 2 hypertension compared to standard care alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/02/2025, London - Bromley Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8124; bromley.rec@hra.nhs.uk), ref: 24/LO/0911

Study design
Randomized controlled type-1 hybrid effectiveness-implementation trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Internet/virtual

Study type(s)
Treatment, Efficacy

Participant information sheet
Participant information material can be found at https://www.isofitter.org.uk/signup

Health condition(s) or problem(s) studied
Stage 1 and 2 hypertension

Interventions
This study is a multi-centre randomised controlled trial (RCT) of an isometric exercise intervention for participants with Stage 1 and Stage 2 hypertension. The design follows an effectiveness-implementation hybrid type-1 design, involving a parallel RCT of standard care plus isometric exercise (IE) versus standard care alone. Standard care is lifestyle advice as per National Institute for Health and Care Excellence (NICE) guidance with or without a single antihypertensive agent (excluding beta-blockers due to impact on heart rate and possible attenuation of the benefit of IE). Stratified randomisation will ensure balanced groups based on age, sex, hypertension stage and treatment status.

The study involves a screening period to confirm hypertension and eligibility, after which eligible participants will be randomised to receive access to a self-prescribed IE programme in addition to standard care advice for six months or continue with standard care advice alone. Participants will be allocated using data capture software REDCap. A randomisation list will be independently created and checked before being uploaded to REDCap. At the end of the follow-up period, all participants will have access to the IE programme content, including control participants, should they wish to try the IE programme and as an incentive to continue as a control in the study until then.

The study will be delivered remotely through an online platform to most participants. Where participants require additional support, this will be provided via telephone, videoconference, in person or a mixture of these routes. Data collection will be online unless additional support is required and completed after consent at screening, 4 weeks, 3 months and 6 months. A subset of participants in the intervention arm will also be followed up at 12 months for longer-term longitudinal data. Data collected will include hypertension diagnosis information, blood pressure, heart rate, medication details and previous medical history. Participants will complete online questionnaires on diet and exercise at baseline, 3 months, 6 months (and 12 months in the IE subgroup) and quality of life questionnaire at baseline and 3 months (also at 12 months in the IE subgroup). An IE experience questionnaire will be completed at 4 weeks, at which point participants in the IE arm will also be invited to attend an optional online focus group or telephone interview.

Intervention Type
Behavioural

Primary outcome measure
Average home systolic blood pressure (SBP) measured using a home BP monitor, change from baseline to 3 months

Secondary outcome measures
1. Proportion of participants with home average BP of ≤135/85 mmHg measured using a home BP monitor at 4 weeks, 3 months, 6 months and 12 months.
2. Average Home Systolic blood pressure measured using a home BP monitor, change from baseline to 4 weeks.
3. Average Home Systolic blood pressure measured using a home BP monitor, change from baseline to 6 months.
4. Average Home Systolic blood pressure measured using a home BP monitor, change from baseline to 12 months in the IE group.
5. Average Home Diastolic blood pressure measured using a home BP monitor, change from baseline to 4 weeks.
6. Average Home Diastolic blood pressure measured using a home BP monitor, change from baseline to 3 months.
7. Average Home Diastolic blood pressure measured using a home BP monitor, change from baseline to 6 months.
8. Average Home Diastolic blood pressure measured using a home BP monitor, change from baseline to 12 months in the IE group.
9. Fidelity of intervention using the number of perceived exertion scores within the range 7-9 during the last exercise bouts collected using participant-reported data in the first week of intervention in the first 50 IE participants.
10. Participant experience (acceptability, adoption and feasibility) of intervention measured

using an IE experience questionnaire, considering barriers and facilitators using focus groups at 4 weeks.
11. Change from baseline in the use and cost of NHS services by participants in both groups, measured using the Health Resources Utilisation Questionnaire at 3 months and 6 months.
12. Change from baseline in Quality of Life in both groups measured using the EQ-5D-5L questionnaire at 3 months and 6 months.
13. Total of equipment, supplies and staff costs measured using internal cost records and staff time and hourly rate records as total cost of the intervention, using costing analysis throughout the study.
14. Total of equipment, supplies and staff costs divided by the number of participants measured using internal cost records and staff time and hourly rate records as total cost per participant, using cost analysis throughout the study.
15. Quality of life (QOL), quality adjusted life years (QALYs) and NHS costs measured using the EQ-5D-5L questionnaire and the Health Resources Utilisation Questionnaire for cost consequence analysis of the intervention, including QALYs in both groups at 3 months and 6 months
16. Evaluation of lifestyle changes using changes from baseline in physical activity and diet recorded in both groups at 3 months.
17. Evaluation of lifestyle changes using changes from baseline in physical activity and diet recorded in both groups at 6 months.
18. Evaluation of lifestyle changes from baseline following IE uptake, using changes to physical activity and diet changes recorded in the IE group at 12 months.

Overall study start date
01/06/2024

Completion date
31/03/2027

Eligibility

Key inclusion criteria
Participants with Stage 1 or 2 Hypertension who have uncomplicated hypertension and may be on a single anti-hypertensive agent who are:
1. Aged 18+ years old
2. Stage 1 or 2 hypertension (≥140/90 -179/119 mmHg) that has been diagnosed by a health care professional and confirmed by a GP
3. Able to undertake an IE intervention
4. Able to self-monitor BP
5. Prescribed no more than 1 anti-hypertensive agent

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit

99 Years

Sex
Both

Target number of participants
542

Key exclusion criteria
1. Alteration to antihypertensive medications (either dose or number of medications) within 6 weeks prior to screening
2. Receiving a β-blocker
3. Averaged home SBP <120 mmHg following 3 days screening
4. Ischaemic heart disease, stroke or transient ischaemic attack in the past 3 months
5. Moderate or severe valvular heart disease, atrial or ventricular arrhythmia, congenital or inherited heart condition
6. Pregnancy or actively trying to conceive
7. Enrolled in CTIMP/device/another interventional study of BP.
8. Any condition that would be made worse by doing the wall squat exercise

Date of first enrolment
14/04/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent & Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
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Sponsor information

Organisation

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/02dqqj223

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Alan Squirrell Artificial Kidney Unit Trust

Results and Publications

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

Intention to publish date
31/03/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Professor Chris Farmer, c.farmer-357@kent.ac.uk

IPD sharing plan summary
Available on request