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Getting a grip on hypertension in Uganda: giving repetitive isometric exercise for blood pressure control

Submission date 29/10/2024	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 31/10/2024	**Overall study status** Ongoing	
Last Edited 30/10/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Even though medication treatments for high blood pressure (hypertension) have known effective results, other complementary interventions could help control blood pressure in hypertensive patients. Isometric handgrip training (IHT), a form of resistance training, is a promising simple and low-cost intervention. IHT consists of doing multiple static forearm contractions on a stress ball, separated by short periods of rest. Most research on IHT to date has had few, mostly White participants in high-income settings. However, understanding the efficacy of IHT in a Ugandan context will inform treatment strategies for hypertensive patients in Uganda. This study aims to see if IHT has an impact on the blood pressure levels of hypertensive patients after 12 weeks of training. The study will determine the effects of IHT compared to usual care in a population of hypertensive patients at the Allan Stone Community Health Clinic (Kyabirwa, Uganda)

Who can participate?
Patients aged over 18 years old with a diagnosis of stage 1 hypertension, as defined per the clinic standards

What does the study involve?
Consenting participants will be randomly separated into two groups: a “control” group that will receive the standard care for hypertension given at the Allan Stone Community Health Clinic, and an “intervention” group that will perform IHT sessions 3 times a week for 12 weeks, in addition to receiving standard care.

IHT sessions will consist of 4 two-minute forearm contractions performed on a stress ball, using alternate hands with 1 minute rest periods between contractions. Weekly training sessions will be held at the Allan Stone Community Health Clinic for a small group of participants and will be supervised by a member of the research team. If unable to attend the group sessions, participants will have the option to participate in an individual training session with research staff at another time during the week.

Data will be collected at 4 different time points: 1) at the baseline visit; 2) at the 1st monthly clinic visit (1 month); 3) at the 2nd monthly clinic visit (2 months); and 4) at the endline visit (3 months).

Blood pressure will be measured for all participants during the clinic visits at baseline, 1, 2, and 3 months.

Both groups will answer a questionnaire about sociodemographics, lifestyle, health information and hypertension knowledge during the baseline clinic visit. A shorter version of the questionnaire will be completed during the clinic visits at 1, 2, and 3 months.

Participants in the "intervention" group will be asked to answer additional questions about their experience with IHT during the endline clinic visit at 3 months. They could also be invited to participate in an interview to further discuss their experience with IHT and home-based IHT.

What are the possible benefits and risks of participating?
If participants are prescribed hypertensive medication by the clinic during their participation, the cost of the medication and associated care will be covered by the study. The results obtained from this study will contribute to the advancement of scientific knowledge in this field of research. Time spent participating in this research project and transit are the main inconveniences associated with this study. Participants may experience numbness and/or tingling in the arm while their blood pressure is being measured. IHT is a safe intervention for adults with hypertension, and the risk of experiencing tendonitis in the arm from the handgrip exercise is low if the exercise is performed correctly. To ensure proper exercise technique, a member of the research team will supervise the IHT training sessions. The research team will also closely monitor participants' blood pressure and any safety events.

Where is the study run from?
The study, managed by the University of Montreal, will take place at the Allan Stone Community Health Clinic (Kyabirwa, Uganda).

When is the study starting and how long is it expected to run for?
March 2023 to July 2026

Who is funding the study?
The Canadian Institutes of Health Research (CIHR)

Who is the main contact?
Dr Kate Zinszer, kate.zinszer@umontreal.ca

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Estimating the efficacy of isometric handgrip training on lowering blood pressure in patients with hypertension in Eastern Uganda compared to usual treatment

Acronym
GRIP in Uganda

Study objectives
The hypothesis that 12 weeks of isometric handgrip training (IHT) will produce statistically significant reductions in resting systolic blood pressure (BP) when compared to standard care for hypertension will be tested.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 19/06/2024, Clinical Research Ethics Committee at the University of Montreal (C.P. 6128, succ. Centre-ville, Montreal, H3C 3J7, Canada; +1 514-343-6111 #1896; timothee.gallen@umontreal.ca), ref: 2024-5649

2. Approved 27/07/2024, Mbarara University of Science and Technology Research Ethics Committee (P.O. Box 1410, Mbarara, -, Uganda; +256 485433795; sec.rec@must.ac.ug), ref: MUST-2024-1547

3. Approved 22/08/2024, Uganda National Council for Science and Technology (Plot 6, Kimera Road, Ntinda, P.O. Box 6884, Kampala, -, Uganda; +256 414705500; info@unsct.go.ug), ref: HS4712ES

Study design
Single-centre two-arm parallel randomized controlled superiority trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice, Medical and other records

Study type(s)
Efficacy

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

Health condition(s) or problem(s) studied
Hypertension stage 1 (BP >140-159/90-99 mmHg)

Interventions
Participants will be randomized with equal allocation to intervention and control groups. A computer-generated randomization will be used for random permuted blocks of 4, 6, or 8 to allocate participants to either of the arms.

The control group will receive standard care for hypertension for a duration of 12 weeks, as per clinic standard practice. Standard care at the clinic is based on Ugandan Ministry of Health clinical guidelines. Health behaviour and lifestyle guidance provided by clinic staff are the first line of treatment for patients with BP >140 mmHg/90 mmHg (stage 1 HTN) but below 160 mmHg /100 mmHg (stage 2 HTN). If there is no improvement after three months of follow-up with stage 1, drug therapy is initiated in combination with continued lifestyle and health behaviour guidance. If there is no improvement after one month of drug therapy initiation, it is then classified as stage 2 HTN. The recommended drug therapies are calcium channel blockers as first line treatment.

The intervention group will receive standard care for hypertension and will perform IHT sessions three time a week for a duration of 12 weeks. In-person IHT sessions will be held at the Allan Stone Community Health Clinic. Each training session will consist of 4 two-minute isometric handgrip contractions performed at a rating of perceived exertion of a 6 on a 10-point scale (equivalent to ~30% maximal voluntary contraction), using alternate hands with 1 minute rest periods between contractions. Participants will attend 3 supervised group sessions per week. If participants are not able to attend the group sessions, participants will have the option to participate to an individual training session with research staff at another time during the week.

Intervention Type
Behavioural

Primary outcome measure
Mean resting systolic BP will be measured using the validated automated Omron HEM-907XL device at baseline, 1, 2 and 3 months

Secondary outcome measures
1. Mean resting diastolic BP measured using the validated automated Omron HEM-907XL device at baseline, 1, 2 and 3 months
2. The need for HTN medication measured using clinical guidelines and BP levels at 3 months
3. Safety outcomes (hospital admission for hypertensive crisis, severe (>180/110 mmHg), new myocardial infarction, transient ischemic attack, new embolic event) measured by a questionnaire and medical records throughout the 12 weeks of intervention
4. Intervention and control group adherence measured by IHT sessions attendance and monthly clinic visits throughout the 12 weeks of intervention
5. HTN medication adherence measured through self-report and pill counting at baseline, 1, 2 and 3 months
6. Sociodemographic and general health information measured by a questionnaire at baseline, 1, 2 and 3 months
7. Economic benefits of the intervention measured by tracking the cost of the intervention, guided in-person IHT sessions, healthcare utilization for HTN-related services, hypertensive medications, and transport to the clinic throughout the 12 weeks of intervention
8. Knowledge, attitudes, and practices (KAP) about HTN measured by a questionnaire at baseline and 3 months
9. Experience with IHT measured by a questionnaire at 3 months
10. Acceptability of IHT and home-based IHT measured by a semi-structured interview at 3 months

Overall study start date
01/03/2023

Completion date
31/07/2026

Eligibility

Key inclusion criteria
1. Diagnosis of stage 1 HTN (BP >140-159/90-99 mmHg), which is based on the clinic and MOH definitions
2. Not currently taking HTN medication
3. Not having been on HTN medication in the past 3 months
4. Aged > 18 years and older

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
The total target number of participants is 250, with equal allocation of 125 participants to the intervention group (IHT and standard care) and the control group (standard care only).

Key exclusion criteria
1. Diagnosis of stage 1 HTN and currently taking HTN medication
2. Diagnosis of stage 2 HTN
3. Diabetes
4. History of recent myocardial infarction (in the past year)
5. Congestive heart failure
6. Complete heart block
7. Unstable angina
8. Glomerular Filtration rate of 90 or lower
9. Any pregnancy-associated HTN
10. Any limitation (e.g., limited hand mobility) preventing proper performance of IHT exercise
11. Any other condition that alters autonomic nervous system function

Date of first enrolment
26/08/2024

Date of final enrolment
02/02/2026

Locations

Countries of recruitment
Uganda

Study participating centre
Allan Stone Community Health Clinic, Soft Power Health
Kyabirwa
Uganda
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Sponsor information

Organisation
Center for Public Health Research

Sponsor details
Centre De Recherche en Santé Publique, Pavillon 7101 avenue du Parc, 3e étage
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Sponsor type
University/education

Website
https://www.cresp.ca/fr

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
The results of the project will be disseminated as group data. The information obtained by the research team will be analyzed and the results of this analysis will be available in peer-reviewed scientific journals, presentations at scientific conferences or seminars, and institutional reports. A summary report will be shared with participants. Individual results, such as blood pressure measures, will be provided to participants during the clinic visits and/or at the end of the study.

Intention to publish date

31/07/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from the principal investigator (Dr. Kate Zinszer, kate.zinszer@umontreal.ca), once the data have been published. Data will be anonymized and made available if consent from participants is obtained.

IPD sharing plan summary

Available on request