ISRCTN16534102 https://doi.org/10.1186/ISRCTN16534102

How does the heart and cardiovascular system adapt to training in a hot environment?

Submission date
17/11/2021

Recruitment status
No longer recruiting

Registration date
24/12/2021

Overall study status
Completed

Last Edited
24/12/2021

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Heat acclimation is the controlled improvement in heat tolerance that comes from gradually increasing the intensity or duration of work performed in a heat chamber. This can protect an individual from heat injury as well as reduce the negative effect heat has on exercise capacity. The aim of this study is to test a new method of heat acclimation as well as understand the effects this has on the human body, specifically the heart and blood vessels.

Who can participate?
Healthy men and women aged 18-44 years who regularly compete in endurance based exercise at least 3 times a week and/or at least 5-hours a week. Participants must not been heat acclimated previously or been exposed to hypoxic conditions within the last 3 months (i.e. trained or competed in high environmental temperatures or high altitude. Participants must be non-smokers, with no history of cardiovascular or respiratory problems.

What does the study involve?
Preliminary testing (Visits 1-3: Everyone)
Upon arrival you will complete a medical assessment. This involves completing a screening questionnaire and consent form, along with an assessment of height, weight, resting blood pressure and body composition. In addition, you will complete an orthostatic tolerance 'tilt test' to assess how well your cardiovascular system responds to simulated prolonged standing. An echocardiogram will be performed (ultrasound of the heart) and repeated after visit 14. On the subsequent visit you will complete a sub-maximal exercise test on a cycle ergometer. This will be followed by a graded exercise test to determine your maximal oxygen uptake (V02max). On the third visit you will complete a warm-up followed by a familiarisation 20km time-trial on a bike. The purpose for this is to familiarise you with the heat chamber, the bike and the 20km time trial.

Pre-to-post-intervention measures (Everyone)
Performance time-trial (TT) (Visits 4 & 13)
A 20km cycling TT will be completed in the heat following a 10-minute warm-up on the bike. You will be asked to self-pace the effort, and be expected to complete the distance in the fastest time possible. Physiological and perceptual responses will be monitored throughout.

Heat stress test (Visit 5, 9 & 12)
All heat stress tests will involve 45-minutes, fixed intensity exercise on a cycle ergometer,under hot-humid conditions (32 & 70% RH). A finger-tip blood sample will be taken to Physiological (heart rate, core temperature, sweat rate) and perceptual responses (perceived exertion; RPE, thermal sensation; TSS) will be taken at rest and during exercise to understand your ability to tolerate the heat.

Orthostatic tolerance "Tilt-test" (Visit 1 & 14)
The purpose of this test is to determine the effect of the intervention (heat acclimation or temperate exercise) on how well your nervous system (autonomic nervous system) controls your heart rate and blood pressure. This will be measured as how long it takes for you to feel faint, in minutes. This will involve you being tilted upright to 60 degrees into a standing position on a table. After 20 minutes, if you have not yet felt faint, lower body negative pressure will be applied to your lower legs. This is painless. A strap will be placed over your knees so we can apply lower body negative pressure to the legs during the test. At any point if you feel faint or unwell the test will stop.

Heat acclimation intervention (Visits 5-12: Randomly assigned to this group)
Active heat acclimation
On these visits a rectal probe will be self-inserted (in-private) to measure core temperature. The aim of these sessions is raise and maintain your core temperature around 38.5 for around ~60-minutes through exercise (cycle ergometer or your own bike on a turbo trainer) and adjusting work rate to maintain the target core temperature. Physiological and perceptual responses will be taken at rest and during exercise. Total duration of heat exposure is 90 minutes/day. Conditions during these sessions will also be hot-humid (32 & 70% RH).
Passive heat acclimation
A heart rate strap will be fitted, and you will begin exercise (moderate intensity) for 30-minutes on a treadmill under temperate conditions (22 & 40% RH). Successively (<2-3min), still dressed in shorts you will enter a hot bath and be submerged to the neck in water maintained at 39.5. Immersion will last 30-40 minutes unless removal due to discomfort or gastrointestinal temperature reaching 39.7. Upon removal you will rest for 15-min in a temperate room 20. Body weight will be taken pre and post, while perceptual measures at 10-minute intervals. Additionally, core temperature and heart rate will be noted every 10-minutes. The aim of these sessions is to promote a heat adaptation response alongside normal training.

Temperate exercise group (Visits 5-12: Randomly assigned to this group)
During these sessions you will complete 90-minute sessions under temperate laboratory conditions (22 & 40% RH). The aim of these sessions is to mimic the exercise completed in the active heat acclimation intervention. As such, you will complete cycling exercise for 90-minutes (10-min warm-up, 20-minutes of high-intensity periods 1:1 work/rest, and 60-minutes steady-state cycling). Physiological and perceptual responses will be taken at rest and during exercise.

What are the possible benefits and risks of participating?
Benefits: By taking part you will help inform future investigations which may impact how athletes appropriately heat acclimate in preparation to competing in hot environments.
Possible risks: Participating in maximal exercise and exercise in the heat can be very strenuous and uncomfortable which can also result in increased heart rate, abnormal blood pressure or in some cases fainting. Participant care is the main priority and you will be monitored throughout the exercise trials.

Where is the study run from?
The Carnegie School of Sport, Leeds Beckett University (UK)

When is the study starting and how long is it expected to run for?
October 2020 to November 2021

Who is funding the study?
UK Triathlon
Ministry of Defence (UK)

Who is the main contact?
Dan Snape, d.snape@leedsbeckett.ac.uk

Contact information

Type(s)
Public

Contact name
Mr Dan Snape

Contact details
Carnegie School of Sport
Leeds Beckett University
Leeds
United Kingdom
LS6 3QT
+44 (0)113 812 0000
d.snape@leedsbeckett.ac.uk

Type(s)
Scientific

Contact name
Dr Iain Parsons

ORCID ID
http://orcid.org/0000-0002-8577-8289

Contact details
School of Cardiovascular Medicine and Life Sciences
King's College London
London
United Kingdom
SE1 7EH
+44 (0)20 7188 7188
iain.parsons@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The cardiac physiological responses to combined active and passive heat acclimation

Study objectives
Combined active and passive heat acclimation improves orthostatic tolerance compared to temperate exercise. Combined active and passive heat acclimation induces demonstrable physiological changes in comparison to temperate exercise. Lower limb muscle mass is inversely proportional to the magnitude of post-exercise hypotension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/06/2021: Leeds Beckett University Research and Ethics Committee (Leeds Beckett University, City Campus, Leeds, LS1 3HE, UK; +44 113 81 28603; t.ispoglou@leedsbeckett.ac.uk), ref: 84895

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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
Prolongation of orthostatic tolerance in patients with reflex syncope

Interventions

Randomisation via an online tool to heat acclimation or controlled temperate exercise.

Heat acclimation intervention (Visits 5-12: Randomly assigned to this group)
Active heat acclimation
On these visits a rectal probe will be self-inserted to measure core temperature. The aim of these sessions is raise and maintain core temperature around 38.5 for around ~60-minutes through exercise and adjusting work rate to maintain the target core temperature. Physiological and perceptual responses will be taken at rest and during exercise. Total duration of heat exposure is 90 minutes/day. Conditions during these sessions will also be hot-humid (32 & 70% RH).

Passive heat acclimation
A heart rate strap will be fitted, and participants will begin exercise (moderate intensity, RPE 13) for 30-minutes on a treadmill under temperate conditions (22 & 40% RH). Successively (<2-3min), still dressed in shorts participants will enter a hot bath (Contrast Spa Duo) and be submerged to the neck in water maintained at 39.5. Immersion will last 30-40 minutes unless removal due to discomfort or gastrointestinal temperature reaching 39.7. Upon removal participants will rest for 15-min in a temperate room 20. Body weight will be taken pre and post, while perceptual measures at 10-minute intervals. Additionally, core temperature and heart rate will be noted every 10-minutes. The aim of these sessions is to promote a heat adaptation response alongside normal training.

Temperate exercise group (Visits 5-12: Randomly assigned to this group)
During these sessions participants will complete 90-minute sessions under temperate laboratory conditions (22 & 40% RH). The aim of these sessions is to mimic the exercise completed in the active heat acclimation intervention. As such, participants will complete cycling exercise for 90-minutes (10-min warm-up, 20-minutes of high-intensity periods 1:1 work/rest, and 60-minutes steady-state cycling). Physiological and perceptual responses will be taken at rest and during exercise.

Intervention Type
Behavioural

Primary outcome measure
Orthostatic tolerance using a tilt test with lower body negative pressure at Visit 1 (baseline) and Visit 14

Secondary outcome measures
1. Performance time trial (TT) (20km completed as quickly as possible) Visits 4 (baseline) and 13
2. Physiological and perceptual responses measured by a heat stress test ((45 minutes of fixed intensity (2.5W.kg-1) exercise on a cycle ergometer, under hot-humid conditions (32 & 70% RH) with measurement of heart rate, core temperature, sweat rate, perceived exertion and thermal sensation)) at visit 5(baseline) 9 and 12.

Overall study start date
01/10/2020

Completion date
01/11/2021

Eligibility

Key inclusion criteria
1. Aged 18-44 years
2. Regularly compete in endurance based exercise (≥3 times a week and/or ≥5-hours a week). Have not been heat acclimated or been exposed to hypoxic conditions within the last 3 months (i. e. trained or competed in environmental temperatures of ≥25°C or altitude ≥2500m)
3. A non-smoker, with no history of cardiovascular or respiratory problems

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
44 Years

Sex
Both

Target number of participants
25

Total final enrolment
22

Key exclusion criteria
1. Suffered previously from heat illness (i.e. nausea, loss of consciousness or dizziness)
2. Any ankle, knee, leg, hip or back problems
3. History of cardiovascular or respiratory problems such as severe asthma.
4. Diagnosed with medical conditions such as diverticulitis, inflammatory bowel disease, gag reflex disorders or impairments.
5. Suffering from diarrhoea, haemorrhoids, bleeding tendencies, constipation, or intestinal complications.

Date of first enrolment
08/06/2021

Date of final enrolment
01/10/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Beckett University
Carnegie School of Sport
Headingley Campus
Leeds
United Kingdom
LS63QT

Sponsor information

Organisation
Leeds Beckett University

Sponsor details
Carnegie School of Sport
Headingley Campus
Leeds
England
United Kingdom
LS6 3QT
+44 (0)113 812 0000
s.backhouse@leedsbeckett.ac.uk

Sponsor type
University/education

Website
http://www.leedsbeckett.ac.uk/

ROR
https://ror.org/02xsh5r57

Funder(s)

Funder type
Government

Funder Name
Ministry of Defence

Alternative Name(s)
MOD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
British Triathlon

Results and Publications

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

Intention to publish date
01/11/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon reasonable request from Dan Snape (d.snape@leedsbeckett.ac.uk). This will involve anonymised patient data for at least 2 years following completion of the trial. Data availability is for the purposes of academic endeavour only (e.g. for the purposes of meta-analysis) and may be subject to further participant consent.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Methodology flowchart		26/11/2021	No	No