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

Submission date 17/11/2021	Recruitment status No longer recruiting	Prospectively registered			
		<pre>Protocol</pre>			
Registration date 24/12/2021	Overall study status Completed	Statistical analysis plan			
		Results			
Last Edited	Condition category Other	Individual participant data			
24/12/2021		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)

Passive heat acclimation

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).

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 steadystate 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

https://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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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

Intervention Type

Behavioural

exercise.

Primary outcome(s)

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

Key secondary outcome(s))

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.

Completion date

01/11/2021

Eligibility

Key inclusion criteria

- 1. Aged 18-44 years
- 2. Regularly compete in endurance based exercise (\geq 3 times a week and/or \geq 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 \geq 25°C or altitude \geq 2500m)
- 3. A non-smoker, with no history of cardiovascular or respiratory problems

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

44 years

Sex

All

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

United Kingdom

England

Study participating centre Leeds Beckett University

Carnegie School of Sport Headingley Campus Leeds United Kingdom LS63QT

Sponsor information

Organisation

Leeds Beckett University

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes