Preparing for heat waves - enhancing human thermophysiological resilience.

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Primary objective: To assess the effect of passive heat acclimation, in combination with low-to-moderate intensity exercise, on cardiovascular and thermophysiological responses in overweight, older individuals.Secondary objective: To assess the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56773

Source
ToetsingOnline

Brief title
Prep4heat

Condition

- Other condition

Synonym
heat stress, hyperthermia

Health condition

thermoregulation

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiovascular, heat acclimation, heat exposure, thermoregulation

Outcome measures

Primary outcome

Primary study parameters include thermophysiological parameters (core temperature, skin temperature, and local sweat rate) and cardiovascular markers (heart rate, blood pressure, blood flow).

Secondary outcome

Secondary study parameters include metabolic parameters (substrate oxidation, energy expenditure, plasma glucose, insulin, total cholesterol, and free fatty acid concentrations), brain blood flow, endothelial function, and thermal perception (thermal sensation and comfort), and gastrointestinal tolerance.

Study description

Background summary

As the ongoing progression of climate change exposes individuals to elevated temperatures and an escalating frequency of extreme heat events, the risk of more intense and prolonged heat waves raises significant concerns for public health, particularly among vulnerable populations. The physiological response to acute heat stress involves involuntary thermolytic reactions that may strain the cardiovascular system, especially in individuals with pre-existing vulnerabilities. Heat acclimation has been identified as a potential strategy to enhance thermoregulation and mitigate the adverse effects of heat stress. While existing research primarily focuses on athletes and military, this study aims to investigate the impact of a practical heat acclimation strategy, combining passive and active heat exposure, on thermophysiological,

cardiovascular and metabolic parameters in healthy overweight adults. The study targets a population at increased risk for heat-related complications, seeking to provide realistic guidelines for broader application when a heat wave appears on the weather forecast.

Study objective

Primary objective: To assess the effect of passive heat acclimation, in combination with low-to-moderate intensity exercise, on cardiovascular and thermophysiological responses in overweight, older individuals.
Secondary objective: To assess the effect of passive heat acclimation, in combination with low-to-moderate exercise on metabolic health in overweight, older individuals.

Study design

A non-randomized, within-subject experimental trial.

Intervention

Passive heat exposure (29-35ºC; 6h/day for 7 days) in combination with 30min/day low-to-moderate intensity cycling.

Study burden and risks

The burden and risks involved in participating in this experiment are minimal. Insertion of the catheters in a vein is comparable to a routine blood draw, with the only risk being a small local hematoma. The experimental trial involves a total of 33 blood samples (390 mL) in the entire study duration. The collected blood volume is less than the standard quantity for a blood donation and will be fully replenished in approximately one month. Heat exposure might cause minor discomfort for some individuals. The necessary frequent consecutive visits may pose a challenge for some participants, requiring a commitment of time. The participation contributes to scientific knowledge, but no direct benefit for the participants is expected. Participants will receive a compensation for their time investment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy males and females
60 to 80 years
BMI 25-30 kg/m2
Sedentary (<2h exercise/week)

Exclusion criteria

• Presence of uncontrolled chronic cardiovascular disease, as determined by medical history and physical examination
• Participating in a structured exercise program
• Taking hot baths/saunas regularly
• Travelled for a prolonged time to destinations with elevated temperatures the last 3 months
• Pre-existing T2DM
• Blood donation within a month of study initiation
• People with low hemoglobin concentration (males: Hb = 13.5-17.5 g/dL, females: Hb = 11.5-15.5 g/dL)
• Recent participation in biomedical study (less than 1 month)
• Using any medication that may influence glucose or lipid metabolism

(beta-blockers, thyroid medications, stimulants, antidepressants, anticoagulants)
• Smoking or abuse of alcohol
• People with lactose intolerance

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-07-2024
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	22-05-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86367.068.24