Cold-induced thermogenesis in adults from Siberia and Western Europe

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To compare the effect of cold exposure on energy expenditure in a population of adults of Western European origin with adults living in Siberia

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON51034

Source
ToetsingOnline

Brief title
Energy expenditure during cold exposure

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Energy balance. Overweight.

Research involving
Human

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Cold adaptation, Cold-induced thermogenesis

Outcome measures

Primary outcome

Main study parameters/endpoints:

* The energy expenditure during the whole-body cold exposure

Secondary outcome

Exploratory parameters:

o Shivering activity (using surface electromyography) during the cold exposure

o Core (using a telemetric pill) and skin temperatures (using iButtons) during the cold exposure

o Thermal sensation and comfort (via questionnaires) during the cold exposure

o Heart rate (via polar chest strap) and blood pressure (via automatic blood pressure device) during the cold exposure

o 6 days daily-living measurement of skin temperature (iButtons) and physical activity (actigraph)

o Cold-induced vasodilation (assessed during cold-finger test)

o Body composition (via skinfold thickness and deuterium dilution)

o Glucose, triglycerides and cholesterol (via fingertip capillary blood sample)

Study description

Background summary

The effect of a single cold exposure on metabolic parameters will be studied, and in addition a comparison between different populations will be made. Specifically, during January 2020, the proposed daily activity and temperatures measurements, cold-finger test, and whole-body cold exposure were performed in

a population who lives in Siberia in extreme conditions where the environmental temperature is frequently -30 °C in the winter. Thus, this research will allow a comparison between the non-cold acclimated Western Europeans with the cold acclimated Siberian population. Specifically, determining the metabolic response (change in energy expenditure and onset of shivering thermogenesis) to the whole- body cold exposure in both the Siberian population and our proposed Western European population will have important implications to the research line investigating the effects of cold exposure on glucose metabolism. For example, if the metabolic response to the matched cold exposure is blunted or non-existent after generations of cold acclimation, then one type of cold exposure may not be effective for all individuals.

Study objective

To compare the effect of cold exposure on energy expenditure in a population of adults of Western European origin with adults living in Siberia

Study design

The research involving the Siberian population has already been completed in Siberia in January 2020. We will now replicate the same measurements with a Western European population. A design combining observational and quasi-experimental methods will be applied. Each participant will attend the university on 3 occasions. The first visit will be a screening, lasting approximately 1 hour. During the next visit a cold-induced vasodilation test of the finger will be performed, along with attaching skin temperature sensors and a physical activity monitor for daily living measurements, this visit will last approximately 1 hour 30 min. The final visit will involve a cold exposure test, with the visit lasting approximately 3 hours.

Intervention

During the first test day (second visit) a cold-induced vasodilation (CIVD) test of the finger will be performed. Cold-induced vasodilation is a mechanism that may prevent the occurrence of local cold injuries (Daanen, 2003). The CIVD reaction measures the cold-protection blood perfusion response to cold. During the test, the participant*s middle finger is immersed in ice water for 30 min. The magnitude of the CIVD reaction is measured by the skin temperature response during the cold exposure. Additionally, participants will be attached with skin temperature sensors and a physical activity monitor for monitoring their daily-living for 6 days.
During the final visit a whole-body cold exposure test will be performed. Subjects will be exposed to air temperature of ~9°C, for which the cold-exposure duration will be a maximum of 1 h.

Study burden and risks

* The cold finger test and whole-body cold exposure are likely to be uncomfortable.
* During the whole-body cold test, the participant will likely experience shivering, which may feel uncomfortable.
* During the whole-body cold test, men will wear shorts and women will wear shorts and a t-shirt.
* The fingertip capillary blood sample involves a pinprick to the fingertip
* Because the skin temperature sensors are attached for a long duration (6 days) this may cause some irritation. If skin irritation does occur then it is advised to remove the temperature sensor and replace in a location 2-3 centimetres away from the original location.

This study will provide more insight into the effects of cold exposure on energy metabolism and may contribute to future research in this area regarding thermoregulation and the treatment of metabolic disease.

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

Signed informed consent, White western European, Healthy Man or Woman, Age 18 * 70 years at the start of the study, BMI * 18.5 and <35 kg/m2, Participants must meet all the of the following: same sex, within ± 8 years of age, and within ± 5 % body mass and ± 5 % height of a previous cold-acclimated participant

Exclusion criteria

Smoking.
Active uncontrolled cardiovascular disease.
Raynaud*s disease.
Cold-acclimated, such as takes daily cold baths, or works in a refrigerated environment, within 1 month previous to the start of the study.
Abuse of alcohol or drugs.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2021
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	29-03-2021
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	NL76012.068.20