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Does ethnicity affect our bodys response to passive physical activity?

Submission date
04/09/2014

Recruitment status
No longer recruiting

Registration date
20/10/2014

Overall study status
Completed

Last Edited
20/10/2014

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims:
The modern sedentary lifestyle has long been blamed as a major contributor to the present obesity epidemic. Recently, sitting down for long periods has been linked to cardiovascular disease, type 2 diabetes, and all-cause mortality, and new studies have suggested that reducing sitting time to less than 3 h per day may increase life expectancy by 2 years. So the search is on for effective methods to reduce the amount of time people sit down and increase the amount of energy we burn to try to prevent and treat these health issues. Intense exercise has been well studied, but it isnt always possible or practical in a real world situation. Passive exercise requires no voluntary effort that is, a device or an assistant (for example, a nurse) exerts force or causes the body to move; it is therefore of immense interest in individuals with reduced mobility. However, we still dont really understand how our bodies (especially our hearts and muscles) respond to this type of physical activity, and whether or not some people respond differently to others. So the aim of this study is to investigate if and how people differ in response to passive physical activity (whole body vibration and passive standing using a tilting table), and to determine the extent to which a persons ethnic background influences this response.

Who can participate?
Healthy men and women aged between 20-40 years.

What does the study involve?
We measure the energy expenditure (the amount of energy burned) by participants before, during and after two passive physical activities whole body vibration and passive standing using a clinical tilting table. This is done by measuring O2 and CO2 in the air that they breathe out. We also measure their heart rate and breathing with a wireless monitor strapped to their chest, and the activity of some of their muscles with small sensors stuck to their skin. All of these measurements are made once while they have fasted (having not eaten anything for 12 hours before the test), and repeated after they have eaten a small meal. Each participant is interviewed about their lifestyle in regards to diet and physical activity, and their body composition measured (height, weight, fat mass and muscle mass).To measure their normal, daily physical activity and body temperature, each participant is also given a wireless monitor which straps to their chest to wear continuously for one week.

What are the possible benefits and risks of participating?
There will be no direct benefit to participants from taking part in the study. However, the study will enable us to answer some questions about how the body responds to passive physical activity and what factors might determine how an individual will respond. In most healthy persons there should be no disadvantages or risks in taking part in this study. However, possible side effects do include feeling dizzy or lightheaded during the tilting table test, or neck/back pain during the whole body vibration.

Where is the study run?
Department of Medicine, University of Fribourg (Switzerland)

When is the study starting and how long is it expected to run for?
August 2013 to January 2019

Who is funding the study?
Department of Medicine, University of Fribourg (Switzerland)

Who is the main contact?
Professor Abdul Dulloo
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Variability in the metabolic and cardiovascular effect of passive physical activity; influence of ethnicity

Study objectives
The main aim of this study is to investigate the how and why individuals differ in their metabolic and cardiovascular response to passive physical activity (whole body vibration, and passive standing using a clinical tilting table).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethics Committee approval (025/13-CER-FR), 13/02/2014, ref. 025/13-CER-FR

Study design
Single centre randomized interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Passive physical activity

Interventions
1. Whole Body Vibration. The participant will stand on a vibrating platform. Vibrations will be intermittent, with 10 vibration periods of 30 seconds separated by equal non-vibration periods. The participant will be instructed to hold a hand-rail and semi-flex the knees to prevent transmission of vibrations to the upper body (above the waist).
2. Passive Standing. The participant will lie on a clinical tilting table, which will be slowly inclined in blocks of 20° (resting for 16 minutes at each level of incline) to a maximum of angle of 80 degrees to simulate the standing posture, but with little muscular effort being needed from the subject as their weight is supported by the tilting-table itself.

Each protocol will be conducted twice once when the participant is fasted and once after they have eaten a small standardized meal.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Energy expenditure will be measured by indirect calorimetry before, during, and after each intervention

Secondary outcome measures
1. Cardiovascular response (heart rate and blood pressure) and EMG activity will be measured by continuous physiological monitoring before, during and after whole body vibration
2. Body composition will be measured at the start the study
3. Dietary and lifestyle information will be collected by questionnaire
4. Body temperature and habitual physical activity will be measured by wireless physiological monitoring over a period of one week
5. The interaction between each intervention and food will be measured (the protocol will be conducted once in the fasted state, and once after participants have ingested a small, standardized meal)

Overall study start date
01/08/2013

Completion date
01/01/2019

Eligibility

Key inclusion criteria
1. 20 40 years old
2. Healthy as determined by medical history
3. European, Asian, African, or Indian ethnicity.
4. Signed consent given

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Pregnancy
2. History of eating disorders
3. History of metabolic diseases (e.g. diabetes)

4. History of cardiovascular disease
5. History of neurological or psychiatric disorders
6. History of gastro-intestinal disorders
7. Any other condition that might impair the subjects ability to participate in the study

Date of first enrolment
01/08/2013

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
Switzerland

Study participating centre
Department of Medicine (Physiology)
Fribourg
Switzerland
1700

Sponsor information

Organisation
Department of Medicine (Physiology), University of Fribourg (Switzerland)

Sponsor details
c/o Professor Jean-Pierre Montani
Chemin du Musée 5
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1700

Sponsor type
University/education

ROR
https://ror.org/022fs9h90

Funder(s)

Funder type

University/education

Funder Name
Department of Medicine, University of Fribourg (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration