What influences our response to low level physical activity and how do people differ?

Submission date		Prospectively registered
18/09/2013	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
15/10/2013	Completed	Results
Last Edited	Condition category	Individual participant data
15/10/2013	Other	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, excessive sitting 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 sitting time 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. Low intensity exercise and small movements are more relevant to daily life, but we still dont really understand how our bodies (especially our hearts and muscles) respond, and why some people respond differently to others. So the aim of this study is to investigate how and why people differ in response to low level physical activity (leg presses, cycling and simple posture change and maintenance), and to determine the extent to which (i) body composition and gender, (ii) ethnicity, and (iii) normal, daily physical activity and body temperature influence this response.

Who can participate?

Healthy men and women aged between 20-40 years.

What does the study involve?

All participants will receive the same treatment. We will measure your energy expenditure (the amount of energy you burn) before, during and after three simple, low level physical activities leg press, cycling, and posture maintenance (lying, sitting and standing) by measuring O2 and CO2 in the air you breathe out. We will also measure your heart rate and breathing with a wireless monitor strapped to your chest, and the activity of some of your muscles with small sensors stuck to your skin. All of these measurements will be made once while you have fasted (having not eaten anything for 12 hours before the test), and repeated after you have had a small meal.

You will be interviewed you about your lifestyle in regards to diet and physical activity, and we will measure your body composition (your height, weight, fat mass and muscle mass). To measure your normal, daily physical activity and body temperature you will be given a wireless monitor which straps to your chest to wear continuously for one week.

What are the possible benefits and risks of participating?

There will be no personal benefit to you from taking part in the study. However, the study will enable us to answer some questions about how the body responds to low level physical activity and what factors might determine how an individual will respond.

In most healthy persons there should be no disadvantage in taking part in this study. However, possible side effects include feeling dizzy or lightheaded after changing posture. Should you experience these or any other reactions you should inform the researcher.

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? The study will start in January 2013 and is expected to run for 5 years.

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

Who is the main contact? Professor Abdul Dulloo abdul.dulloo@unifr.ch

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 energy cost of low level physical activity

Study objectives

The main aim of this study is to investigate how and why individuals differ in their metabolic and cardiovascular response to different low-level physical activities (low intensity dynamic and isometric exercise and posture maintenance).

With such immense interest in methods to increase our daily physical activity in the modern sedentary environment, the results of these investigations will open new avenues for research by bettering our understanding the metabolic basis of variability in the energetics of low-level physical activities relevant to daily life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Review Board of the University of Fribourg, 30.11.2012

Study design

Single centre randomised interventional study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

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

Low level physical activity

Interventions

- 1. Low level intermittent isometric exercise (leg press at less than 25kg of force). The participant will press against a fixed platform for 8 repetitions of 30 second rest / 30 second relaxation.
- 2. Low level dynamic exercise (cycling at no more than 50W). The participant will cycle for 5 minutes at each intensity, with the resistance level changing incrementally to a maximum of 50W
- 3. Simple posture change and maintenance. The subject will be instructed to transition between and maintain three basic postures (lying, sitting and standing), remaining in the lying and sitting postures for at least 30 minutes and the standing posture for a maximum of 10 minutes.

All study participants will undergo all three types of exercise with their metabolic and cardiovascular response measured before, during and after each exercise. The order of the three exercises will be randomised for each participant. The entire protocol will be conducted twice (in all participants) 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 each intervention
- 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 and once following the ingestion of a small, standardised meal).

Overall study start date

01/01/2013

Completion date

01/01/2018

Eligibility

Key inclusion criteria

- 1. 20 40 years old
- 2. Healthy as determined by medical history
- 3. Signed consent given

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

100

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

Date of first enrolment

01/01/2013

Date of final enrolment

01/01/2018

Locations

Countries of recruitment

Switzerland

Study participating centre Department of Medicine (Physiology)

Fribourg Switzerland 1700

Sponsor information

Organisation

University of Fribourg (Switzerland)

Sponsor details

c/o Professor Jean-Pierre Montani Department of Medicine (Physiology) Chemin du Musée 5 Fribourg Switzerland 1700

Sponsor type

University/education

Website

http://www.unifr.ch/

ROR

https://ror.org/022fs9h90

Funder(s)

Funder type

Hospital/treatment centre

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