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

| Submission date   | Recruitment status   | 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** Prof Abdul Dulloo

#### **Contact details**

Department of Medicine (Physiology) University of Fribourg Chemin du Musée 5 Fribourg Switzerland 1700

## 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