The effect of low intensity physical activity on insulin sensitivity; an exploratory study into a possible link between insulin sensitivity and mood and cognitive performance

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To assess the effect of low intensity physical activity on plasma insulin levels, cognition and mood in subjects with overweight/obesity

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

Summary

ID

NL-OMON42156

Source
ToetsingOnline

Brief title
SIT LESS 3

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
blood sugar values, insulin sensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Unilever

Intervention

Keyword: cognition, insulin, low intensity physical activity, sitting less

Outcome measures

Primary outcome

• To assess the effect of low intensity physical activity (LIPA) on plasma insulin levels (as measured as area under the curve during an oral glucose tolerance test)

Secondary outcome

Secondary objectives:

• To assess the effect of LIPA on insulin sensitivity

• To assess the effect of LIPA on plasma C-peptide and glucose levels

• To assess the effect of LIPA on lipid metabolism

• To assess the effect of LIPA on mood and cognitive performance

• To assess the effect of LIPA on Quality of Life and sleep

• To explore the association between plasma glucose, plasma insulin, insulin sensitivity and mood, cognitive performance, Quality of Life and sleep

• To assess the effect of LIPA on inflammation and endothelium

• To assess the effect of LIPA on blood pressure

• Insulin like growth factor 1 (IGF-1) and growth hormone (GH)

Study description

Background summary

A sedentary lifestyle and obesity are well known risk factors of type 2 diabetes. The major focus of current guidelines for type 2 diabetes prevention is on energy balance. Physical activity guidelines recommend at least 30 minutes/day of moderate to vigorous physical activity (MVPA). However, no advice is given how the other 23.5 hours of the day should be spent. Several recent epidemiologic studies suggest that excessive sitting, independent of moderate to vigorous physical activity, has detrimental health effects. Another possibility to sit less is by increasing low intensity physical activities as slowly walking and standing. A recent published study of our research group (Duvivier et al. PLOS ONE 2013) suggests that sitting less and replacing it by slowly walking and standing has a better effect on insulin action and cardiovascular risk factors than the combination of one hour MVPA per day and sitting the rest of the day. Until now this research is not performed in subjects with overweight/obesity.

Study objective

To assess the effect of low intensity physical activity on plasma insulin levels, cognition and mood in subjects with overweight/obesity

Study design

intervention study

Intervention

2 activity regimes of 4 days: a sitting regime and a "sit less" regime

Study burden and risks

The blood samples taken during the oral glucose tolerance test are relatively non-invasive with little risks. Risks are: bruising, fainting and vomiting after insertion of the needle.

During the test day the subjects will be asked to drink a glucose drink (75 gram glucose) and to fill in/complete cognition tests and questionnaires (sleep, mood, quality of life).

The following activities will strongly affect daily activities of the subjects:
- Noting down the activities each hour in a diary
- Following the number of hours walking/sitting/standing/sleeping of the

activity regimes
- Following the same diet as during the first activity regime
- Visiting the university 8 times during 5 weeks

The subjects will be informed that the study will strongly affect daily activities.

Contacts

Public
Universiteit Maastricht

Olivier van Noortlaan 120
Vlaardingen 3133 AT
NL
Scientific
Universiteit Maastricht

Olivier van Noortlaan 120
Vlaardingen 3133 AT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

o Signed informed consent
o Men and postmenopausal women: 40-80 years old
o BMI: 25.0 - 35.0 kg/m2
o Maximum 2.5 hours of MVPA per week (during last 3 months)

o Having a general practitioner
o Agreeing to be informed about medically relevant personal test-results by a physician
o Accessible veins on arms as determined by examination at screening

Exclusion criteria

o Reported participation in another biomedical trial which may have an effect on insulin sensitivity one month before the pre-study examination or during the study
o Blood donation in the past three months
o Reported participation in night shift work 2 weeks prior to pre-study investigation or during the study. Night work is defined as working between midnight and 6.00 AM.
o Consumption of >14 (women) or > 21 (men) alcoholic units per week
o Reported dietary habits: medically prescribed diet, slimming diet;
o Reported weight loss (>2kg) in the last three months prior to the screening;
o Not being able to execute at least three (out of four) cognition tests in the training session
o Not being able to execute the sit less try-out day
o Being an employee of Unilever or the collaborating research departments in Maastricht University Medical Centre
o Experimental drug use (during the last 3 months)
o Use of insulin, oral blood glucose lowering medication (metformin and/or SU-derivatives and/or DPP-IV inhibitors), corticosteroids or vitamin K antagonists in the last 3 months
o Fasting plasma glucose level > 6.9 mmol/L
o Medical conditions which make participation in the study not responsible which will be decided by a medical doctor during screening
o Other clinically relevant abnormalities in clinical chemistry at screening (to be judged by a medical doctor)
o Mental or physical disability which interferes with physical activity

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2015
Enrollment:	27
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-06-2015
Application type:	Amendment
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	NL50688.068.14
Other	volgt (www.clinicaltrials.gov)