How sickening is sitting: experimental evidence

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18-22 YEAR OLD MALES WIHT A NORMAL WEIGHTExamine the possible attenuating cardiometabolic health effects of (A) hourly, 10-min standing interruptions, when compared to a single bout of prolonged sitting, and (B) sitting on a stability ball, when...

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

Summary

ID

NL-OMON44870

Source
ToetsingOnline

Brief title
SOS experimental evidence

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
c-peptide, C-peptide., Indicators of dysfunction of glucose and triglyceride metabolism: 18-22yr old males with a normal body weight: elevated blood plasma levels of glucose, insulin, triglyceride and cortisol; 14-18yr old males with overweight/obesity: elevated levels of plasma glucose

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Metabolic health indicators, Overweight/obesity, Sitting, Young adults

Outcome measures

Primary outcome

18-22 YEAR OLD MALES WIHT A NORMAL WEIGHT

The main outcomes of this study are the post-prandial responses of plasma levels of C-peptide, glucose, triglycerides and high-sensitive C-reactive protein and pre/post values of cortisol plasma levels.

14-18 YEAR OLD MALES WITH OVERWEIGHT/OBESITY

The main outcomes of this study are the post-prandial responses of plasma levels of C-peptide, glucose, and high-sensitive C-reactive protein.

For details see document "C2. Amendement".

Secondary outcome

18-22 YEAR OLD MALES WIHT A NORMAL WEIGHT

Secondary outcomes of this study are functioning of the autonomic nervous system, sleep-wake patterns, attention/concentration and mood.

14-18 YEAR OLD MALES WITH OVERWEIGHT/OBESITY

Secondary outcomes of this study are functioning of the autonomic nervous system and "C2. Amendement".

For details see document "C2. Amendement".

Study description

Background summary

Recent experimental studies demonstrated that, when compared to prolonged sitting, interruptions during prolonged sitting significantly reduced postprandial glucose, insulin and C-peptide in healthy young adults. One study could not establish this in children. Thus far, no studies have examined the possible positive effects of standing interruptions to prolonged sitting or active sitting. Moreover, to date, no studies are performed in overweight/obese children, who may be at increased risk for cardiometabolic ill-health. This information is essential to inform preventive interventions and guidelines on sedentary behaviour in children.

Study objective

18-22 YEAR OLD MALES WIHT A NORMAL WEIGHT
Examine the possible attenuating cardiometabolic health effects of (A) hourly, 10-min standing interruptions, when compared to a single bout of prolonged sitting, and (B) sitting on a stability ball, when compared to a single bout of prolonged sitting, in healthy young males.

14-18 YEAR OLD MALES WITH OVERWEIGHT/OBESITY
Examine the possible attenuating cardiometabolic health effects of (A) 10-min standing interruptions every 30 min, when compared to a single bout of prolonged sitting, and (B) 4-min cycling interruptions every 30 min, when compared to a single bout of prolonged sitting, in overweight/obese young males.

For details see document "C2. Amendement".

Study design

18-22 YEAR OLD MALES WIHT A NORMAL WEIGHT
Experimental study with a cross-over design, including three experimental conditions, lasting 5 hours each:
1) prolonged sitting on a lounge chair;
2) prolonged sitting on a lounge chair with hourly 10-min standing interruptions;
3) active sitting on a stability ball.

14-18 YEAR OLD MALES WITH OVERWEIGHT/OBESITY
Experimental study with a cross-over design, including three experimental

conditions, lasting 5 hours each:
1) prolonged sitting on a lounge chair;
2) prolonged sitting on a lounge chair with 10-min standing interruptions every 30 min;
3) prolonged sitting on a lounge chair with 4-min cycling interruptions every 30 min, at a moderate intensity.

For details see document "C2. Amendement".

Study burden and risks

There are no expected risk or benefits in the present study. Participants will visit the laboratory three times in a fasted state. After the first venous blood sample is collected, they will receive a standardized meal. Venous blood samples (6 samples in total) will be collected hourly using an in-dwelling catheter. Additionally, autonomic functioning (non-invasive; pre, halfway, post), attention/concentration (pre, halfway, post) and mood (hourly) will be measured. Muscle activity will be measured hourly using surface electrodes at the belly of the indicated muscles. These methods are safe, frequently used and will be executed by trained and qualified researchers. The experimental conditions include very common daily activities and do not possess any potential risk either. There is minimal risk for the participants. Nevertheless, vial broaching can induce pain for the participants. Additionally, the time investment (5,5 * 6 hours per visit) can be a burden for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

NORMAL WEIGHT MALES:
Apparently healthy normal weight (20 subjects) males aged 18-22 years; or overweight/obese (BMI *25/30; 20 subjects) males aged 14-18 years; Dutch or English speaking; Signed informed consent from the participant (males aged 16-18 years) and signed informed consent from the participant and one of his parents (males aged 14-15 years).

Exclusion criteria

Major acute illness/injury; Physical problems that may limit the ability to perform the experiment (i.e. the standing or cycling interruptions or sitting on a stability ball); having diabetes mellitus type II.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	12-05-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20679
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL51407.029.15
OMON	NL-OMON20679