Building Bridges between Physical Activity and Diet to improve postprandial (cognitive) health

Published: 15-02-2018
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To get insights into how the composition of the meal can affect the effects of prolonged sitting and sitting interrupted with physical activity on cognitive function and other health outcomes.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lifestyle issues
Study type	Interventional

Summary

ID

NL-OMON48965

Source
ToetsingOnline

Brief title
BridgePAD

Condition

- Lifestyle issues

Synonym
prolonged sitting, sedentary behavior

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognition, Nutrition, Physical activity, Sitting

Outcome measures

Primary outcome

Cognitive function

Secondary outcome

1) Cerebrovascular health

2) Metabolic health

3) Perceivable benefits

Study description

Background summary

Sedentary behaviour is an independent risk factor for cardiovascular disease, type II diabetes and all-cause mortality and has also been related to impaired cognitive function. In society today, often unhealthy meals are consumed (e.g. high fat/high calorie) followed by prolonged periods of sitting. Resultantly, people are exposed to the negative effects of sitting and of the meal. Much research has been done to determine if reducing sitting can improve metabolic health and results suggest that breaking up sitting with low-intensity or moderate physical activity can modulate cardiovascular risk factors. However, less is known about how a meal could interfere with the acute effects of sitting and/or breaking up sitting on cardiovascular and cognitive health. Yet it is known that one meal can acutely affect cognitive function and that the meal composition influences the outcome.

Study objective

To get insights into how the composition of the meal can affect the effects of prolonged sitting and sitting interrupted with physical activity on cognitive function and other health outcomes.

Study design

Cross-over design

Intervention

On the assessment days participants will receive a breakfast of a specific composition after which they will be required to either sit for four consecutive hours or to sit interrupted with physical activity bouts.

Study burden and risks

Participants will visit the research center five times for a total of 28.5 hours. All measurements are non-invasive, except for the drawing of venous blood. Venous blood sampling only poses a low risk. Short discomfort (3 minutes) is expected during emersion of the hand in ice-cold water during the Cold Pressure Test (to measure vascular function). If the discomfort is experienced as unbearable by a participant the test will be stopped. Together, the nature and extent of the burden and risks associated with participation have been evaluated as negligible. Yet, the study could give insight into improving health in a large part of the general population which is at risk for adverse health outcomes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Overweight or obese (BMI * 25 kg/m2 * 35 kg/m2)
* Sedentary and physically inactive (sitting > 40 hours per workweek; not meeting recommended aerobic physical activity levels of the WHO)
* Age * 45 years
* Ability to give informed consent
* Proficiency of the Dutch language

Exclusion criteria

Dietary habits/conditions that interfere with diet intervention, including following of a vegetarian diet
physical/mental conditions that interfere with diet/ physical activity intervention
MoCA score * 25
Diabetes mellitus, cardiovascular disease, gastrointestinal disease, cancer, epilepsy, unstable and/or untreated thyroid disease, untreated hypertension, major chronic disease or injury
Glucose/lipid lowering medication, anti-inflammatory medication, anti-depressant use with depression symptoms
Smoking, more than three alcohol consumptions per day
Currently participating in other research
Pregnant or lactating women, planned pregnancy

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):	26-03-2018
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	15-02-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-04-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-10-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-03-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-05-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 25025
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64153.091.17
OMON	NL-OMON25025