Explorative study to investigate effects of reduced sitting intervention on total sitting time

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

Summary

ID

NL-OMON43403

Source
ToetsingOnline

Brief title
Sit less, move more study

Condition

- Lifestyle issues

Synonym
inactivity, seated behaviour

Research involving
Human

Sponsors and support

Primary sponsor: Integratieve Fysiologie, Radboudumc
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: inactivity, reduced sitting intervention

Outcome measures

Primary outcome

Total sitting time per day.

Secondary outcome

Sitting to standing transitions

Study description

Background summary

Over the last years, physical inactivity has been identified as the major cause of death in Western society. Since exercise training does not improve fitness and cardiovascular risk in all subjects or may not be feasible for all patients, we have searched for alternatives to reduce physical inactivity. Interestingly, a 2.8-year prospective study in 222,497 individuals found that >11h of sitting/day is associated with 40% higher risk for all-cause mortality compared to <4h sitting/day. Importantly, the detrimental impact of sitting time is not altered after correcting for exercise training time. Therefore, the benefits from *reduce sitting time* and exercise training seem independent from each other, and seem to work via distinct protective pathways. Consequently, prolonged sitting is a logical target to improve fitness and cardiovascular risk factors via *reduce sitting time*. In this study, we will explore the efficacy of a novel *reduce sitting time*-intervention to reduce total sitting time per day and increasing sit to stand transitions. Understanding the ability of this device for prolonged and sustainable changes in behaviour seems prerequisite for subsequent effects on health outcomes.

Study objective

In this study we examine the effect of a 4-week reduced sitting time intervention on physical activity pattern (i.e. total sitting time per day as primary parameter). As a secondary objective, we re-examine behavioural patterns 4 weeks after the intervention to explore longer-term adherence to the intervention.

Study design

Intervention pilot study

Intervention

4 weeks reduced sitting intervention, adopting a widely adopted and RIVM-approved intervention.

Study burden and risks

Subjects will wear a pedometer throughout the day in order to record physical activity patterns. Based on established algorithms, this device enables the identification of prolonged periods of sitting or physical inactivity, which will lead to notification of the participant that she/he has to break up his/her sitting behaviour. In addition, a widely used physical activity monitor (i.e. Sensewear armband) will be worn to assess physical activity levels.6 Participants will report 3 times to the research centre (before, after and 4-weeks after the intervention) to measure physical activity patterns (to examine the primary research question), but also cardiovascular risk factors (e.g. blood pressure, blood lipid profile, BMI and waist-to-hip circumference) to explore whether the changes in physical activity patterns relate to changes in cardiovascular risk. Taken together, the nature and extent of burden and risks associated with the intervention and measurements are negligible, whilst the study potentially leads to significant health benefits.

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

- >= 18 years of age
- Mentally able/allowed to give informed consent
- seated behaviour > 40 hours per week

Exclusion criteria

- Persons who are not physically able to perform light-intensity physical activity such as standing and walking.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2016

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	14-03-2016
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL55880.091.15

Study results

Date completed:	14-07-2016
Actual enrolment:	10

Summary results
Trial ended prematurely