# Increasing physical activity and reducing sedentary behaviour among office-workers in order to improve mental health and cognition

| Submission date   | Recruitment status No longer recruiting | <ul><li>Prospectively registered</li></ul> |  |  |
|-------------------|---|--|--|--|
| 27/02/2018        |   | Protocol                                   |  |  |
| Registration date | Overall study status                    | Statistical analysis plan                  |  |  |
| 09/04/2018        | Completed                               | [X] Results                                |  |  |
| Last Edited       | Condition category                      | [] Individual participant data             |  |  |
| 30/06/2025        | Other                                   |  |  |  |

## Plain English summary of protocol

Background and study aims

Physically inactive and sedentary lifestyles are negatively related to both mental health and cognition. For office workers, who spend two thirds of their workday sitting, it is important to improve these lifestyles. The aim of this study is to improve the mental health and cognition of office workers by either increasing physical activity or decreasing sedentary behaviour.

Who can participate?

Office workers employed at two large companies in Sweden

## What does the study involve?

Two interventions are tested, one aiming at increasing physical activity and the other at decreasing sedentary behaviour. Participants are randomly allocated to receive one of the two interventions, or to be put a waiting list. The counselling involves 3 individual and 2 group motivational counselling sessions. In addition, the physical activity intervention involves 6-months access to a commercial gym, as well as organized exercise sessions at work, lunch walks and online training possibilities. Team leaders encourage their employees to be physically active at work and outside work, including the commute to work. The sedentary behaviour intervention involves standing and walking meetings, and team leaders encourage employees to reduce sedentary behaviour at work, both in meetings and while working behind their desk. The waiting list group start one of the interventions 6 months later. Physical activity patterns, including sedentary behaviour, are measured in all groups with accelerometers and inclinometers at the start of the study and after the 6-month intervention.

What are the possible benefits and risks of participating?

It is not known whether sedentary behaviour or physical activity has the greatest impact on mental health and cognition. Potentially, office workers participating in the interventions increase their physical activity or reduce their sedentary behaviour which might result in better mental and physical health. There are no risks of participating in this study.

Where is the study run from?

GIH - The Swedish School of Sport and Health Sciences is responsible for the research and running the study. The study is a cooperation between GIH and five companies. The study will take place at two large companies in Sweden: Intrum and ICA-gruppen, both with mostly office workers as employees. The three other companies which contribute to the intervention are Itrim, SATS and Monark exercise.

When is study starting and how long is it expected to run for? January 2017 to December 2020

Who is funding the study? KK-Stiftelsen, ICA-gruppen, Intrum, SATS Elixia, Monark Exercise and Itrim Sweden

Who is the main contact? Dr Carla Nooijen carla.nooijen@gih.se

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Carla Nooijen

#### ORCID ID

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#### Contact details

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## Additional identifiers

## Protocol serial number

2017/2409-31/1

## Study information

#### Scientific Title

Improving office workers' mental health and cognition: a three-arm cluster randomized controlled trial targeting physical activity and sedentary behaviour in multi-component interventions

#### **Acronym**

## Healthy brain

## **Study objectives**

The primary hypothesis is that due to the multi-component interventions office-workers will favourably change their physical activity and sedentary behaviour as compared to the control group. The secondary hypotheses is that these changes in activity patterns will in turn have positive effects on mental health and cognition.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Regionala Etikprövningsnämnden i Stockholm, 02/02/2018, ref: 2017/2409-31/1

## Study design

Single-blinded three-arm clustered randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Sedentary office workers

#### **Interventions**

Two multicomponent interventions of 6 months will be studied. The interventions are both based on ecological frameworks suggesting that behaviour can be influenced on multiple levels including individual, social, organizational, environmental and policy. All participants will be randomized into receiving one of the two interventions, or to a waiting list control group. The waiting list group will start one of the interventions 6 months later to compare the effects of the interventions to a group receiving no intervention during that period. In order to control contamination and to limit interaction between the different groups, randomisation will be done on a cluster level. The aim is to have 24 clusters (8 clusters per arm), 10 at Company A and 14 at Company B. Clusters will be composed while considering: 1) having a team or line manager, 2) having regular group meetings, 3) limited regular meetings with other teams. Block randomisation will be performed using a computer-generated random number list prepared by an investigator with no clinical involvement in the trial. Groups will be randomly allocated (1:1) with stratification for company and cluster size (large vs small).

The physical activity intervention aims to promote physical activity of moderate to vigorous intensity and includes:

- 1. Individual: motivational counselling towards improving their time spent in moderate to vigorous physical activity, based on cognitive behavioral therapy (CBT). Counselling consists of 3 individual and 2 group sessions and focuses on both work and leisure time. The counselling includes feedback on individual moderate to vigorous physical activity
- 2. Environmental: access to a commercial gym (6 months) with possibility to go during working hours, as well as organized exercise sessions at work, lunch walks, online training possibilities,

and provision of company bikes

3. Organizational: team leaders encourage employees to be physically active during and outside working hours, including commuting to work

The sedentary behaviour intervention aims to reduce sedentary behaviour, including breaking up prolonged sitting and includes:

- 1. Individual: motivational counselling towards reducing their time in sedentary behaviour and breaking up prolonged sitting, based on CBT. Counselling consists of 3 individual and 2 group sessions and focuses on both work and leisure time. The counselling includes feedback on individual sedentary behaviour
- 2. Environmental: implementation of standing and walking meetings. Note that companies already provided their employees with sit-stand desks
- 3. Organizational: team leaders encourage employees to reduce sedentary behaviour at work, both in meetings and while sitting behind desk

The waiting list control will be a passive control group that will be measured again after 6 months. After this measurement they will start the assigned intervention.

This 24-month study includes 5 measurement timepoints, with measurements every 6 months. The 5th measurement point will only be performed provided that drop-out rate is not higher than 30% and sufficient resources are available. The outcomes of the randomized controlled trial are based on the first two measurement points. After that, the study continues as a cohort study with long-term follow-up measurements of up to 1.5 years after the end of the intervention.

## Intervention Type

Behavioural

## Primary outcome(s)

Physical activity patterns, including sedentary behaviour, objectively measured with accelerometers (Actigraph) and inclinometers (ActivPAL) at baseline and after the 6-month intervention

## Key secondary outcome(s))

This 24-month study includes 5 measurement timepoints, with measurements every 6 months

#### Proximal outcomes:

1. Physical activity patterns, including sedentary behaviour, objectively measured with accelerometers (Actigraph) and inclinometers (ActivPAL), at long-term follow-up

Distal outcomes (all measured at all specified timepoints):

- 1. Mental health: including self-reported measures of anxiety and depression (The Hospital Anxiety and Depression Scale, stress (single-item), recovery (self-rating of recovery from work), burnout (Shirom and Melamed burnout measure), general mental health (single-item), life satisfaction (WHO-5 and single-item), and sickness absence
- 2. Cognition: a comprehensive cognitive test battery assessing the following cognitive domains: processing speed (Digit symbol), attention (Trail Making Test-A), working memory (Capacity: Automated Operation Span; Backward Digit Span), executive functions (Trail Making Test-B, Stroop, n-back), episodic memory (free recall; recognition), semantic memory (SRB:1), and visuospatial ability (Form Board Test). Additionally, self-reported subjective memory complaints (Cognitive Dysfunction Questionnaire) will be assessed.

Secondary outcomes (all measured at all specified timepoints, unless otherwise stated):

- 1. Cardiovascular fitness: participants undergo a submaximal cycle ergometer test. Heart rate response to a submaximal rate of work will be used to estimate maximal oxygen consumption
- 2. Body composition: body mass index calculated from measured weight and height. Waist circumference (WC) measured in duplicate with participants standing dressed in underwear and exhaled. WC measured at the minimum circumference between the iliac crest and the rib cage
- 3. Sleep: during night time, participants wear the accelerometer on the non-dominant wrist and additionally self-reported sleep will be assessed (Karolinska Sleep Questionnaire)
- 4. Self-reported data for physical activity (including active transport) and sedentary behaviour (Workforce Sitting Questionnaire)
- 5. Other health habits: including smoking, drinking and diet (national guidelines)
- 6. Physical health: self-reported physical health (single-item) and self-reported health conditions
- 7. Feasibility and acceptability of the intervention (only measured after intervention)

Working mechanisms (all measured at all specified timepoints, unless otherwise stated):

- 1. Blood analyses: per measurement point, three blood samples (each 5 ml) will be drawn to determine blood glucose, plasma and serum levels of inflammatory markers, BDNF, VEGF, and IGF-1, as well as genetic profiling of BDNF genes (baseline only)
- 2. Self-reported: including self-efficacy (Exercise Self-Efficacy Scale), motivation and self-regulation (BREQ-4)

## Completion date

31/12/2020

## **Eligibility**

## Key inclusion criteria

- 1. Between 18-70 years of age
- 2. Have the capability of standing and exercising

## Participant type(s)

Other

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

70 years

## Sex

All

## Total final enrolment

263

## Key exclusion criteria

- 1. Not be working for the full duration of the first 6 months of the study (i.e. retirement, maternity leave)
- 2. Very high physical activity level: more than 30 min/day in prolonged bouts (≥10 min) moderate to vigorous physical activity. This exclusion criteria will be checked by assessing physical activity with accelerometers. Note that because we have found that almost all office-workers working at the involved companies have high levels of sedentary behavior, sedentary behavior will not be used as an exclusion criterion

# Date of first enrolment 15/03/2018

Date of final enrolment 31/12/2018

## Locations

## **Countries of recruitment**Sweden

## Study participating centre Intrum Hesselmans torg 14 Stockholm Sweden 10524

## Study participating centre Intrum Södra Hamngatan 53 Göteborg Sweden 41106

Study participating centre ICA Gruppen Svetsarvägen 16 Solna Sweden 17141

## Sponsor information

## Organisation

The Swedish School of Sport and Health Sciences, GIH

#### **ROR**

https://ror.org/046hach49

## Funder(s)

## Funder type

Industry

## **Funder Name**

Stiftelsen för Kunskaps- och Kompetensutveckling

## Alternative Name(s)

Foundation for Knowledge and Development, Knowledge Foundation, KK-Stiftelsen, Swedish Knowledge and Competence Development Foundation, KKS

## **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

## Location

Sweden

## **Funder Name**

ICA-gruppen

#### **Funder Name**

Intrum

## **Funder Name**

SATS Elixia

## **Funder Name**

Monark Exercise

#### **Funder Name**

Itrim Sweden

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Carla Nooijen (carla.nooijen@gih.se). Anonymised data will be available after ending data collection and publishing the main results.

## IPD sharing plan summary

Available on request

## **Study outputs**

| Output type                   | Details  | Date<br>created | Date<br>added  | Peer<br>reviewed? | Patient-<br>facing? |
|-------------------------------|--|-----------------|----------------|-------------------|---------------------|
| Results article               | results  | 01/09<br>/2020  | 04/09<br>/2020 | Yes               | No                  |
| Results article               | cognitive function results                       | 31/05<br>/2022  | 08/06<br>/2022 | Yes               | No                  |
| Results article               | effects on mental health                         | 09/01<br>/2024  | 10/01<br>/2024 | Yes               | No                  |
| Results article               | 24-hour behavior                                 | 15/04<br>/2021  | 30/06<br>/2025 | Yes               | No                  |
| Results article               | Role of executive function                       | 27/12<br>/2021  | 30/06<br>/2025 | Yes               | No                  |
| Results article               | Self-efficacy, motivation and perceived barriers | 02/06<br>/2021  | 30/06<br>/2025 | Yes               | No                  |
| Participant information sheet | Participant information sheet                    | 11/11<br>/2025  | 11/11<br>/2025 | No                | Yes                 |
| Study website                 | Study website                                    | 11/11<br>/2025  | 11/11<br>/2025 | No                | Yes                 |