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

Submission date
27/02/2018

Recruitment status
No longer recruiting

Registration date
09/04/2018

Overall study status
Completed

Last Edited
30/06/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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Study website
http://www.gih.se/brainhealth

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures

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)

Overall study start date
01/01/2017

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
330, spread over a total of 24 clusters with 8 clusters per arm

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

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Sponsor type
University/education

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ROR
https://ror.org/046hach49

Funder(s)

Funder type
Industry

Funder Name
Stiftelsen för Kunskaps- och Kompetensutveckling

Alternative Name(s)
KK-Stiftelsen, Swedish Knowledge and Competence Development Foundation, Foundation for Knowledge and Development, Knowledge 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

Publication and dissemination plan
The trialists plan to submit the full study protocol for publication in spring 2018. Planned publication of the results in high-impact peer reviewed journals with the intent to publish around one year after finishing data collection.

Intention to publish date
31/12/2021

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