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Is a multi-component intervention to reduce workplace sedentary behaviour acceptable and feasible to professional males?

Submission date
07/10/2019

Recruitment status
No longer recruiting

Registration date
27/02/2020

Overall study status
Completed

Last Edited
28/03/2023

Condition category
Other

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

Plain English summary of protocol
Methods: Male staff will be invited to take part. Primary outcomes are acceptability and feasibility and secondary outcomes include levels of sedentary behaviour, physical activity and work engagement.
Discussion: The findings are expected to inform the design of a future trial assessing the impact of an intervention using pedal machines and mHealth on short and longer-term occupational sedentary behaviour, work-related outcomes such as productivity and cost effectiveness.

Background and study aims
Prolonged sitting, an independent risk factor for increased death and disease, occurs mostly in the workplace. A recent study found that professional males have the longest workplace sitting times. Current evidence supports the use of multi-level interventions developed using participative approaches. This study aims to explore the acceptability and feasibility of a multi-level intervention to reduce workplace sitting.

Who can participate?
Males over 18 working in full-time sedentary and professional occupations

What does the study involve?
Two companies in Dublin, Ireland will take part in a cluster-randomised crossover pilot study, and office-based employees will be recruited. The components of the intervention target multiple levels of influence including organisational structures (via management consultation and recruitment), the physical work environment (via provision of an under-desk pedal machine), and individual determinants (via mHealth technology to support behaviour change techniques).

What are the possible benefits and risks of participating?
The benefits of the study are that the participants involved are contributing to the understanding of the acceptability and feasibility of an intervention to reduce sedentary behaviour in a workplace setting. People taking part will potentially reduce their daily sedentary behaviour and may thereby benefit from taking part in the study. There are minimal risks to taking part in this study.

Where is the study run from?
Public Health and Primary Care, Trinity College, Dublin

When is the study starting and how long is it expected to run for?
September 2019 to December 2019

Who is funding the study?
Dean of the Faculty of Health Sciences, Trinity College Dublin, Ireland

Who is the main contact?
Gail Nicolson
nicolsg@tcd.ie

Contact information

Type(s)
Scientific

Contact name
Ms Gail Nicolson

ORCID ID
https://orcid.org/0000-0002-5580-8635

Contact details
Institute of Population Health
Tallaght Cross
Belgard Square West
Dublin
Ireland
D24 DH74
+353 1 8963739
nicolsg@tcd.ie

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Study3

Study information

Scientific Title

Pilot study to test the acceptability and feasibility of a theory-led multicomponent intervention to reduce sedentary behaviour in the workplace

Study objectives
A multicomponent theory-led intervention to reduce workplace sedenatry behaviour will be acceptable and feasible to professional males

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/09/2019, School of Medicine, Trinity College Dublin (Trinity College, 152-160 Pearse St, Dublin 2, Ireland; +353 1 896 1476; SOMREC@tcd.ie), ref: 20190702

Study design
Randomised wait-list crossover design

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Reduction of risk factor sedenatry behaviour

Interventions
Two companies in Dublin, Ireland will take part in a cluster-randomised crossover pilot study, and office-based employees will be recruited and randomised to the control or the intervention arms.

The components of the intervention target multiple levels of influence including organisational structures (via management consultation and recruitment), the physical work environment (via provision of an under-desk pedal machine), and individual determinants (via mHealth technology to support behaviour change techniques).

The intervention comprises the provision of three components:
1. An under-desk pedal machine (DeskCycle2; 3D Innovations LLC., Greeley, CO, USA)
2. Garmin Forerunner 35 activity tracker
3. Access to a Garmin Connect application (app) and website (Garmin.com)

The intervention will communicate the key message: “Cycle at work”. As highlighted from prior qualitative work determinants of goal-setting, self-monitoring, and social-comparison will be targeted using behaviour change techniques provided within the Garmin Connect app/website. Social-comparison, focusing on the masculine ideal and gender influences, such as individual or team-based competition will be used as a strategy in this study. This BCT will be targeted by the lead researcher creating a graph displaying each team’s participants’ weekly progress to enable social comparison. Participants will also be prompted to move every 60 minutes of accumulated sedentary behaviour using the move prompt on the Garmin Forerunner 35 wrist-worn device. Based on randomisation, either the first or fourth week will involve an active intervention to use

an under-desk pedal machine to interrupt sedentary behaviour every hour and accumulate ≥30 minutes of light physical activity during the working day. There will be a washout period of one week between the intervention and control arms. In circumstances where a participant suffers any adverse outcome such as pain or discomfort while taking part in the study, they will be advised to immediately discontinue participation in the study.

Randomisation
Following baseline assessments, worksites will be randomised to either the intervention or control arms of the trial. Simple cluster randomisation will be determined by a statistician not associated with the project, who will use randomisation software to allocate each worksite to begin with either the intervention or control period.

Allocation concealment
Participants will not be advised of their group allocation until after baseline assessments have been made. The allocation concealment mechanism is important to reduce selection bias as it prevents foreknowledge of the period (control/intervention) in which participants are enrolling, which negatively affect recruitment.

Blinding
Due to the nature of the study, neither the participants nor research team will be blinded to group assignments. This lack of blinding introduces biases such as performance bias and outcome assessment bias. However, the use of objective and reliable measures of the secondary outcomes have been included in terms of measurement of the secondary outcomes which reduces the risks associated with a lack of blinding.

Control arm
Participants in the control arm will be informed that they have been randomised to a delayed intervention that will begin after three weeks, and will be asked to continue their normal workplace habits. All measures collected in the intervention group will be collected in the control arm.

Intervention Type
Behavioural

Primary outcome(s)
The following outcomes will be assessed using a pen and paper questionnaire:
1. Appropriateness of the intervention
2. Acceptability of the intervention
3. Feasibility of the intervention

The outcomes will also be assessed via focus groups and/or semi-structured interviews:
4. Experience of using the under-desk pedal machines, including factors perceived as affecting the pedal machine, issues (contextual, practical, individual or others), and adverse consequences (work, health or otherwise related)
5. Experiences of the other intervention components
6. Organisational-level and management perspectives of using the pedal machine
7. Acceptability of the intervention
8. Acceptability of the assessments and burden
9. Acceptability of the study procedures

Feasibility outcomes:
10. Recruitment process - number of people recruited to the study recorded by the researcher at

the beginning of the study.
11. Feasibility of measurement tools - missing data from questionnaires. This information will be recorded by the researcher in a separate report at the end of the study

Key secondary outcome(s))
Trial-related outcomes, assessed at baseline (before randomisation) and throughout the control and intervention periods:
1. Sedentary behaviour and physical activity measured using ActivPal3 accelerometers
1.1 Sedentary behaviour during working hours (workplace sedentary behaviour) and all waking hours (total sedentary behaviour)
1.2 Physical activity during working hours (workplace activity) and all waking hours (total physical activity)

2. Context-specific sedentary behaviour measured using EMA with notifications of survey, completion sent six times a day at random times throughout the baseline, control and intervention arms.
3. Work Engagement will be measured at baseline, post control arm, and post-intervention arm using the UWES-9 using pen and paper.
4. Perception of the benefits of reducing workplace sedentary behaviour will be assessed using a 3-point questionnaire

Completion date
20/12/2019

Eligibility

Key inclusion criteria
For participants
1. Male
2. Adult (i.e. 18 years and older) currently in full-time sedentary and professional occupation
3. Must be present for the duration of the study period
4. rPARQ will be used as a screening tool to ensure physical capability in the study. Individuals who answer no to all of the questions can be included in the study

For worksites:
1. Professional company in the Dublin region with >5 male employees

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

Male

Total final enrolment
22

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
18/09/2019

Date of final enrolment
11/10/2019

Locations

Countries of recruitment
Ireland

Study participating centre
Trinity College Dublin
Public Health and Primary Care
Dublin
Ireland
D24 DH74

Sponsor information

Organisation
Trinity College Dublin

ROR
https://ror.org/02tyrky19

Funder(s)

Funder type
University/education

Funder Name
Dean of the Faculty of Health Sciences, Trinity College Dublin

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/09/2021	09/09/2021	Yes	No
Protocol article		10/11/2020	28/03/2023	Yes	No
Participant information sheet		07/10/2019	27/02/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		10/10/2019	27/02/2020	No	No