The effectiveness of the SMArT Work & Life intervention for reducing sitting time in office workers

Submission date	Recruitment status	[X] Prospectiv	
20/12/2017	No longer recruiting	[X] Protocol	
Registration date	Overall study status Completed	[] Statistical	
24/01/2018		[X] Results	
Last Edited 05/02/2025	Condition category Other	[_] Individual	

X] Prospectively registered

] Statistical analysis plan

] Individual participant data

Plain English summary of protocol

Background and study aims

People whose job primarily involves desk-based work spend a large proportion of their day sitting down at work and many of these individuals also sit a lot when they are at home. High levels of sitting have been linked to diseases such as type 2 diabetes, heart disease, and some cancers. This makes office workers an 'at-risk' group and who should be targeted for lifestyle intervention. An intervention has been developed called SMArT Work & Life that is designed to reduce the time that office workers spend sitting both inside and outside of work, emphasising a 'whole-of-day' preventive approach. Previous interventions have only focused on sitting at work. The SMArT Work & Life intervention involves multiple strategies to encourage a reduction in sitting time both in and out of the workplace, including strategies at the organisational level (e. g., provision for standing meetings, competitions), environmental level (e.g., relocating waste bins, printers) and group/individual level (education, goal setting, progress sessions, technology to track and provide feedback on their own sitting time). Workplace champions within local councils will deliver some of these strategies. This intervention will be delivered with and without the provision of a height adjustable workstation (allows the user to either stand or sit to work). This is important because although previous studies have achieved substantial reductions in workplace sitting, there are cost implications associated with these workstations so it is also important to also evaluate the impact of the intervention without this resource. The aim of this study is to test how effective the SMArT Work & Life intervention is, with and without a heightadjustable workstation.

Who can participate?

Office workers at local councils in Leicester, Manchester and Liverpool areas (UK)

What does the study involve?

Participating office groups are randomly allocated to one of three groups. One third of the office groups receive the intervention and a height-adjustable workstation, one third receive the intervention without a height-adjustable workstation, and one third act as a comparison group (carry on as normal). The research team measure how much office workers sit during the day (inside and outside of work) using a physical activity device worn on the thigh for 7 days. This

monitor also provides an accurate measure of daily steps taken, time standing, and time being active. A number of measures of health are also taken, including weight, body fat, waist circumference, blood pressure, and a finger prick blood sample to analyse levels of blood sugar and cholesterol. Participants are asked to answer some questions about their health and work. These measurements are taken from all participants before the intervention begins and again at 3, 12 and 24 months after the first set of measurements. No interventions targeting sitting have followed participants over this length of time before. This will show whether participants maintain any behaviour change over the long term. The research team also talk to a number of office workers and workplace champions throughout the intervention delivery period about their experiences of the various strategies. The research team also test whether the intervention, with and without a height-adjustable desk, is value for money.

What are the possible benefits and risks of participating?

Benefits of taking part in this study include receiving feedback on health following a health assessment, receiving a £10 voucher for each assessment completed, and participants receiving intervention may experience health benefits and feel better. The research team are promoting regular posture change and not prolonged time in any one behaviour as this may lead to discomfort such as sore feet and lower back pain.

Where is the study run from? University of Leicester (UK)

When is the study starting and how long is it expected to run for? January 2018 to March 2021

Who is funding the study? NIHR Public Health Research Programme (UK)

Who is the main contact? Dr Charlotte Edwardson, ce95@le.ac.uk Dr Alex Clarke-Cornwell, a.m.clarke-cornwell@salford.ac.uk

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers PHR 16/41/04

Study information

Scientific Title

A three arm cluster randomised controlled trial to test the effectiveness and cost-effectiveness of the SMArT Work & Life intervention for reducing daily sitting time in office workers

Acronym SMArT Work & Life

Study objectives

This study aims to determine the long term effectiveness and cost-effectiveness of the multicomponent SMArT Work & Life intervention (when provided with and without a heightadjustable desk) for reducing daily sitting time in office workers compared with no intervention. If both interventions are shown to be effective, a secondary aim will be to determine if one intervention is more effective than the other.

Ethics approval required

Old ethics approval format

Ethics approval(s) College of Life Sciences University of Leicester, 23/01/2018, ref: 14372-ce95diabetesresearchcentre

Study design Cluster 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

General chronic disease prevention

Interventions

Clusters (different office spaces) will be randomised to receive one of the following conditions: 1. The multi-component SMArT Work & Life intervention with a height-adjustable workstation (intervention group 1) 2. The multi-component SMArT Work & Life intervention without a height-adjustable workstation (intervention group 2)

3. Usual practice (control condition)

The SMArT Work & Life intervention is a multicomponent intervention promoting positive changes in sitting (at work and in leisure time) and movement in office workers. The intervention includes organisation (manager buy in, workshop for managers), environmental (small scale restructuring in the office and at home, display of posters/reminders at work and at home) and individual (action planning, goal setting, free apps and prompts) and group (education workshops, regular coaching, competitions (colleagues and family) based components.

The research team will measure how much office workers sit during the day (inside and outside of work) using a physical activity device worn on the thigh for 7 days. This monitor also provides an accurate measure of daily steps taken, time standing, and time being active. We will also take a number of measures of health including weight, body fat, waist circumference, blood pressure, and take a finger prick blood sample to analyse levels of blood sugar and cholesterol. Participants will be asked to complete some questions about their health and work. These measurements will be taken from all participants before the intervention begins, and again at 3, 12 and 24 months after the first set of measurements. No interventions targeting sitting have

followed participants over this length of time before. This will allow the research team to assess whether participants maintain any behaviour change over the long term. They will also talk to a number of office workers and workplace champions throughout the intervention delivery period about their experiences of the various strategies. The research team will also test whether our intervention, with and without a height-adjustable desk, is value for money.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 21/09/2020: Objectively measured daily sitting time, measured using activPAL at 12 months

Previous primary outcome measure as of 02/08/2018: Objectively measured daily sitting time, measured using activPAL at 24 months

Previous primary outcome measure: Objectively measured sitting time, measured using activPAL at baseline, 3, 12, and 24 months

Secondary outcome measures

Current secondary outcome measures as of 21/09/2020:

1. Objectively measured sitting during work hours at 3 and 12 months and daily sitting at 3 months

2. Objectively measured prolonged sitting time (daily and during work hours) at 3 and 12 months 3. Objectively measured standing and movement (daily and during work hours), measured using activPAL and Axivity at baseline, 3 and 12 months

4. Self-reported sitting, assessed using an adapted version of the Occupational Sitting and Physical Activity Ouestionnaire (Chau et al 2012) and an adapted version of the past day recall of sedentary time (PAST) questionnaire (Clarke et al 2015) at baseline, 3 and 12 months 5. Adiposity (BMI, percent body fat [measured with body composition scales], waist circumference), blood pressure and blood markers [HbA1c, fasting glucose, cholesterol, triglycerides measured with finger prick blood samples]), measured at baseline, 3 and 12 months 6. Fatigue (Fatigue Scale, Chalder 1993), stress (Perceived Stress Scale, Cohen et al 1983), anxiety and depression (Hospital Anxiety and Depression Scale (HADS), Zigmond et al, 1983), wellbeing (WHO-5 scale, Bech 1998), emotion (Positive and Negative Affect Schedule), work engagement (Utretcht Work Engagement Scale (UWES) Schaufeli et al, 2002), job performance (single-item 7-point likert scale, Bond et al 2001) and satisfaction (single-item 7-point likert scale, Nagy, 2002), occupational fatigue (Need for Recovery Scale), musculoskeletal issues (Standardised Nordic Questionnaire), presenteeism (Work Limitations Questionnaire, Lerner et al, 2001), work load and relations (Health and Safety Executive Management Standards Indicator Tool), sickness absence (self-reported and organisation records), and quality of life (EQ5D-5L, Herdman et al 2011), measured at baseline, 3 and 12 months

7. Self-reported sleep (Pittsburgh Sleep Quality Index (PSQI), Buysse et al 1989) and objectively measured sleep (Axivity), measured at baseline, 3 and 12 months

8. Social norms, cohesion and support for sitting less:

8.1. Social norms measured using eight items (e.g., 'My workplace is committed to supporting staff choices to stand or move more at work') on a 5-point Likert (Dunstan et al 2013) measured at baseline,3 and 12 months

8.2. Social cohesion measured using the 'social community' sub-scale of the Copenhagen
Psychosocial Questionnaire-II (CPS2) (Kristensen, 2001) measured at baseline, 3 and 12 months
8.3. Support, measured using questions on support from the organisation, manager, colleagues

and family for sitting less and moving more often will be adapted from Brackenridge et al 2016 measured at baseline, 3 and 12 months

9. Self-reported health resource use (for cost-effectiveness analysis), measured at baseline, 3 and 12 months

10. Process evaluation: attendance at workshops and coaching (workplace champion logs), opinions of, and engagement with different intervention components (questionnaires and focus groups), intervention fidelity and receipt (workshop and coaching observations), barriers and facilitators focus groups). These measures are ongoing throughout the study

Previous secondary outcome measures as of 02/08/2018:

1. Objectively measured sitting during work hours at 3, 12 and 24 months and daily sitting at 3 and 12 months

2. Objectively measured prolonged sitting time (daily and during work hours) at 3, 12 and 24 months

3. Objectively measured standing and movement (daily and during work hours), measured using activPAL and Axivity at baseline, 3, 12 and 24 months

4. Self-reported sitting, assessed using an adapted version of the Occupational Sitting and Physical Activity Questionnaire (Chau et al 2012) and an adapted version of the past day recall of sedentary time (PAST) questionnaire (Clarke et al 2015) at baseline, 3, 12 and 24 months 5. Adiposity (BMI, percent body fat [measured with body composition scales], waist circumference), blood pressure and blood markers [HbA1c, fasting glucose, cholesterol, triglycerides measured with finger prick blood samples]), measured at baseline, 3, 12 and 24 months

6. Fatigue (Fatigue Scale, Chalder 1993), stress (Perceived Stress Scale, Cohen et al 1983), anxiety and depression (Hospital Anxiety and Depression Scale (HADS), Zigmond et al, 1983), wellbeing (WHO-5 scale, Bech 1998), emotion (Positive and Negative Affect Schedule), work engagement (Utretcht Work Engagement Scale (UWES) Schaufeli et al, 2002), job performance (single-item 7-point likert scale, Bond et al 2001) and satisfaction (single-item 7-point likert scale, Nagy, 2002),occupational fatigue (Need for Recovery Scale), musculoskeletal issues (Standardised Nordic Questionnaire), presenteeism (Work Limitations Questionnaire, Lerner et al, 2001), work load and relations (Health and Safety Executive Management Standards Indicator Tool), sickness absence (self-reported and organisation records), and quality of life (EQ5D-5L, Herdman et al 2011), measured at baseline, 3, 12 and 24 months

7. Self-reported sleep (Pittsburgh Sleep Quality Index (PSQI), Buysse et al 1989) and objectively measured sleep (Axivity), measured at baseline, 3, 12 and 24 months 8. Social norms, cohesion and support for sitting less:

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8.2. Social cohesion measured using the 'social community' sub-scale of the Copenhagen Psychosocial Questionnaire-II (CPS2) (Kristensen, 2001) measured at baseline, 3, 12 and 24 months

8.3. Support, measured using questions on support from the organisation, manager, colleagues and family for sitting less and moving more often will be adapted from Brackenridge et al 2016 measured at baseline, 3, 12 and 24 months

9. Self-reported health resource use (for cost-effectiveness analysis), measured at baseline, 3, 12 and 24 months

10. Process evaluation: attendance at workshops and coaching (workplace champion logs), opinions of, and engagement with different intervention components (questionnaires and focus groups), intervention fidelity and receipt (workshop and coaching observations), barriers and facilitators focus groups). These measures are ongoing throughout the study Previous secondary outcome measures:

1. Objectively measured standing and movement, measured using activPAL and Axivity at baseline, 3, 12 and 24 months

2. Adiposity (BMI, percent body fat [measured with body composition scales], waist circumference), blood pressure and blood markers [HbA1c, cholesterol, triglycerides measured with finger prick blood samples]), measured at baseline, 3, 12 and 24 months 3. Fatigue (Fatigue Scale, Chalder 1993), stress (Perceived Stress Scale, Cohen et al 1983), anxiety and depression (Hospital Anxiety and Depression Scale (HADS), Zigmond et al, 1983), wellbeing (WHO-5 scale, Bech 1998), work engagement (Utretcht Work Engagement Scale (UWES) Schaufeli et al, 2002), job performance (single-item 7-point likert scale, Bond et al 2001) and satisfaction (single-item 7-point likert scale, Nagy, 2002), presenteeism (Work Limitations Questionnaire, Lerner et al, 2001), sickness absence (organisation records), and quality of life (EQ5D-5L, Herdman et al 2011), measured at baseline, 3, 12 and 24 months 4. Self-reported sleep (Pittsburgh Sleep Quality Index (PSQI), Buysse et al 1989) and objectively measured sleep (Axivity), measured at baseline, 3, 12 and 24 months

5. Self-reported health resource use (for cost-effectiveness analysis), measured at baseline, 3, 12 and 24 months

6. Process evaluation: attendance at workshops and coaching (workplace champion logs), opinions of, and engagement with different intervention components (questionnaires and focus groups), intervention fidelity and receipt (workshop and coaching observations), barriers and facilitators (focus groups). These measures are ongoing throughout the study

Overall study start date

02/01/2018

Completion date

01/03/2021

Eligibility

Key inclusion criteria

1. Office-based employees within the Councils in Leicester, Manchester and Liverpool areas (UK) (Liverpool added on 20/03/2019)

2. Spend the majority of their day sitting

3. They must also work for the council at least 3 days/week

4. Participant is willing and able to give informed consent to take part in the study

5. Able to walk without the use of an assistive device or requiring assistance form another person

Participant type(s)

Healthy volunteer

Age group Adult

Sex Both

Target number of participants 660

Total final enrolment

Key exclusion criteria
1. Currently pregnant
2. Currently using a height-adjustable workstation at their primary work location
3. Unable to communicate in English
4. Unable to provide written informed consent

Date of first enrolment 01/04/2018

Date of final enrolment 28/02/2019

Locations

Countries of recruitment England

United Kingdom

Study participating centre Diabetes Research Centre (University of Leicester) United Kingdom LE5 4PW

Sponsor information

Organisation University of Leicester

Sponsor details Research Governance Office Fielding Johnson Building Leicester England United Kingdom LE1 7RH

Sponsor type University/education

ROR https://ror.org/04h699437

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Funder(s)

Funder type Government

Funder Name Public Health Research Programme

Alternative Name(s) NIHR Public Health Research Programme, PHR

Funding Body Type Government organisation

Funding Body Subtype National government

Location United Kingdom

Results and Publications

Publication and dissemination plan

The full trial protocol will be published in 2018 in an open access journal. The main results paper will be published within one year of completing the trial.

Intention to publish date

01/07/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Charlotte Edwardson (ce95@le.ac.uk).

Type of data: Study protocol data including Inclusion/Exclusion Criteria, England Sample Size, Type and registration details (online), and the publication will include anonymised full datasets and baseline characteristics.

When will the data become available and for how long: Study final data analysis will be available approximately 24 months from official study closure and for as long as legislation requires it to be available.

By what access criteria data will be shared: Accessed over the internet by anyone having access to the Web portal (for ISRCTN data), other data will be shared on request to Chief Investigator via email, which will be for anonymised datasets only. Data can be downloaded by anyone for use with Microsoft Excel (or equivalent) for ISRCTN anonymised online datasets, request via Chief Investigator for anonymised datasets. Data will be transferred via secure data transfer methods.

Consent from participants: The study has obtained informed consent from all participants, as part of this there is implicit consent for use for anonymised data sets by the research team

(under the secondary use policy). Data anonymization: All published data will be anonymised. Ethical or legal restrictions: No.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>		14/09/2018	04/03/2022	Yes	No
<u>Results article</u>		17/08/2022	05/01/2023	Yes	No
<u>Results article</u>	Cost-effectiveness	11/11/2022	28/06/2023	Yes	No
<u>Results article</u>	secondary process evaluation measures	30/11/2023	05/12/2023	Yes	No
<u>Results article</u>	intervention effectiveness	19/12/2023	08/01/2024	Yes	No
<u>Results article</u>		01/09/2023	05/02/2025	Yes	No