Acceptability and feasibility of a theory-based multicomponent intervention to reduce occupational sedentary behaviour in male workers: a study protocol of a cluster-randomised crossover trial

Abstract

Background: Prolonged sitting, an independent risk factor for increased morbidity and mortality, is accumulated mostly in the workplace. A recent study found that after controlling for individual, social and environmental correlates, professional males have the longest workplace sitting times. There is limited research targeting specific at-risk populations to reduce occupational sedentary behaviour. 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-component intervention to reduce workplace sitting.

Methods: Two companies in Dublin, Ireland will take part in a cluster-randomised crossover pilot study, and thirty office-based employees will be recruited (8 and 22 participants in each worksite) 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 to the pilot), the physical work environment (via provision of an under-desk pedal machine), and individual determinants (via mHealth technology to support behaviour change techniques). 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.

Keywords: under-desk pedal machine, mHealth, sedentary behaviour, active sitting, physical activity, occupational sedentary behaviour, socio-ecological model

Introduction

Background and rationale

Prolonged periods of daily sedentary behaviour (SB) are associated with increased mortality, and morbidities such as cardiovascular disease, diabetes (1–3), depression (4), and some cancers (5,6). Sedentary behaviour has been defined as any waking behaviour while in a sitting or lying position and that expends ≤1.5 metabolic equivalents (METs) of energy expenditure (EE) (7). Studies suggest that being sedentary for more than 7 hours per day is associated with increased all-cause and cardiovascular mortality rates (2,8). Although high levels of physical activity may attenuate these relationships, levels in excess of 5 times the World Health Organisation physical activity recommendations are required to eliminate the detrimental effects of SB (8).

Working adults spend more than 7.5 hours of their day being sedentary, and when individual, social and environmental factors are controlled for, professional males with high levels of education and who live in an urban

location have the longest sitting times (9). Reducing workplace sedentary behaviour is important to curtail the physical and mental health risks associated with prolonged SB (4,10–12). Individuals in private offices sit more and engage in more prolonged sitting than those in public office spaces (13).

Given the strong reinforcing and restrictive properties of the physical and social environment of the office workplace, allowing workers to continue with their favoured or required task (e.g. computer work), while breaking up prolonged SB may be most acceptable and effective in terms of workplace interventions (14). Studies examining sit-stand workstations have enabled the break-up of prolonged SB by replacing some SB with standing, however standing does not provide the metabolic benefits of light physical activity (15). A recent study using compositional analysis found that standing (and SB) was associated with increased body mass index (BMI), body fat and fat mass (16). It has also been found that standing for long periods may be detrimental to cardiovascular health, and has been associated with an increase in the risk of ischemic heart disease and varicose veins (17). Rempel and Krause (18) suggest that advising sedentary employees to increase standing time at work should not be recommended, and maintain if the basis for a reduction in SB is to improve cardiovascular health, promotion of increased standing is misguided. Results from studies using treadmill desks (19) and activity-permissive workstations (20) suggest that combining simultaneous, low intensity PA with sedentary practices could increase daily caloric expenditure and reduce cardio-metabolic risk factors. 'Active sitting' as opposed to 'reduced sitting' may be needed in workplace interventions where the preferences of employees and/or employers may be to remain seated in workplaces (21). Furthermore, combining PA with sedentary activities could reduce time-related costs of PA—a frequently cited barrier to regular PA in adults (22).

The socio-ecological model of SB emphasises the importance of intervening at the multiple interrelated influencing factors on behaviour in the workplace, and includes organisational structures, the physical and social interpersonal environment, and intrapersonal factors (23). Multicomponent interventions have reported the most success reducing workplace SB (24), while interventions that involve environmental restructuring (e.g. activity-permissive workstations) have shown the largest reductions in daily SB (25). When targeting the individual-level influences and determinants of SB in a multicomponent intervention, ensuring relevance and individualisation have been shown to be effective basic methods in health interventions, and this is traced especially to social cognitive theory (SCT) (26). The core determinants of health behaviour in SCT are knowledge of health risks, perceived self-efficacy, outcome expectations, health goals, perceived facilitators and barriers, and social and structural impediments to change. Pretesting the participants' knowledge, beliefs and circumstances and using this information as a basis for intervention development creates relevance (27). In a recent review of behaviour change strategies used in sedentary behaviour reduction interventions among adults, the most frequently used intervention functions were enablement (i.e. facilitating reduction in SB), education, and environmental restructuring, and the most commonly (and most promising) used techniques were setting behavioural goals, providing unspecified forms of social support, and adding objects to the environment (28). The feasibility of using under-desk pedal machines and some reduced SB has been reported in laboratory studies (29,30) and in studies of predominantly women (31). The rationale for providing sedentary employees working in professional environments with pedal machines at work is to allow

participants to engage in light-intensity activity (i.e. active sitting) that can be performed for long periods throughout the day without causing perspiration.

Contemporary technological advances in digital tools such as mobile phones, the internet and wearable technology provide a platform to intervene on an individual level to change behaviours. A review and meta-analysis of interventions using computer, mobile and wearable technology to reduce sedentary behaviour reported a mean reduction of 41 minutes per day in interventions that used computer, mobile and wearable technology tools, with the most frequent BCTs being prompts/cues, self-monitoring of behaviour, unspecified social support and goal-setting (32).

Mobile health (mHealth) technology has rapidly gained popularity in the general population. mHealth technology includes wearable physical activity monitors and trackers that connect to smartphone applications (apps). These apps allow individuals to manage their own health and wellbeing at a relatively low cost and offer potential to tailor interventions to the needs of individuals or specific groups. A recent review to investigate the use of mHealth in interventions found reasonable evidence that mHealth may be an effective and feasible method to increase PA, with some evidence for effectiveness in reducing SB (33). Studies using mHealth to promote physical activity and reduce sedentary behaviour in the workplace found significant reductions in sedentary time in women (34), where the outcomes were increasing daily steps (35,36), or reductions in computer use as a proxy for SB (37). Team-based competition as opposed to individual monitoring has also been found to increase compliance with wearing activity monitors (33).

Adopting a participatory approach to intervention development and evaluation benefits the development of effective interventions (38,39). For interventions to be acceptable, feasible and effective, participant involvement provides important information on the individual, organisational and cultural contexts into which SB reduction strategies must be embedded.

The present study

Previous research attests to the potential efficacy of combining pedal machines and motivational behaviour change strategies. However, to our knowledge no studies have combined BCTs of goal-setting, social comparison, self-monitoring and prompt/cues in a multicomponent intervention using mHealth technology, and a newly refined ergonomic under-desk pedal machine, as well as targeting organisational support, in a male only sample. This paper outlines the protocol for a pilot study to explore the acceptability and feasibility of a prototype of a multicomponent intervention. This pilot study will employ a cluster-randomised controlled wait-list crossover design, and has been designed to inform subsequent refinement of intervention content, in terms of acceptability and feasibility of the intervention components and measures, so that the format may be suitable for real-world implementation and evaluation in a trial.

Aims and objectives

The study aims to investigate the acceptability and feasibility of an intervention to reduce SB, by promoting active sitting and light physical activity in professional male office workers.

The objectives are:

1. to investigate the acceptability of the intervention using semi-structured interviews and focus group data which will explore participants' views of acceptability and usefulness as well as expectations and experiences of the intervention overall
2. to measure intervention acceptability, appropriateness and feasibility using a questionnaire (40)
3. to ascertain if participants in the intervention period differ in overall SB and PA compared to the control period. This will be answered by collecting accelerometry data, which will provide information on minutes spent sedentary, standing and moving.

Methods

Setting and context

The proposed feasibility study will be conducted in two private-sector professional organisations in Dublin, Ireland (a legal firm and an online medical education provider).

Management approval has been obtained for employee recruitment, permission to make environmental changes in the office setting, and for study contacts to occur during work-time. All participants will provide written informed consent before inclusion in the study. Ethical approval has been obtained from the Research Ethics Committee of the School of Medicine, Trinity College Dublin (ref. 20190702). The Standard Protocol Items Recommendations for Intervention Trials reporting guidelines (appendix 1) were used to guide the preparation of this pilot study protocol (41).

Design

Intervention development process

This intervention was developed using guidance from the Medical Research Council (MRC) (42,43) and encompasses three distinct phases. The first preclinical stage was a literature review of workplace interventions to reduce SB and application of socioecological theory to the design of the current intervention.

Phase I involved the identification of intervention components and the underlying mechanisms by which the outcomes will be influenced. The development of the intervention followed the principles of the integrated approach of socioecological theory: a method that emphasises the need to consider multiple levels of influence on behaviour. Qualitative testing and the adoption of a participatory approach through focus groups and semi-structured interviews with both employees and employers has been conducted to help understand the relevance of the intervention components as well as potential barriers to behaviour change.

This protocol outlines Phase II of the approach that tests the acceptability and feasibility to develop an optimum intervention.

Participants

Participants will be office-based employees from two companies in Dublin, Ireland.

Inclusion criteria

- Are male
- Spend most of their working week performing desk-related activities

Exclusion criteria

- Have limitations with or contraindications to physical activity as indicated by the Physical Activity Readiness Questionnaire (44)
- Do not have use of their own personal desk
- Are female
- Are under 18 years of age
- Are planning to be absent from the workplace for more than two days during the study period
- Are involved in another programme or intervention to reduce sedentary behaviour

Convenience sampling has been used to recruit the organisations, comprising of two private corporate organisations, a legal firm and an online medical training company, in Dublin locations – who have been involved in the development of this pilot study. The organisations were initially approached through the lead researcher's personal networks. Purposive sampling will be used to recruit eligible participants within each company via an email sent by a contact within each company.

Sample size

No formal sample size calculations are produced for this feasibility study. Sample size is pragmatic and chosen based on resources. Thirty male desk-based workers will be recruited to the feasibility trial, a sample size of n=30 is conventionally deemed adequate for pilot studies as it permits collection of sufficient useful data while minimising research costs (45).

Focus groups comprising separate management and employee participants in each worksite will be recruited (four in total). This is appropriate in qualitative research of this kind, with diversity of sampling (i.e. all stakeholder groups) more important than numbers of focus groups (46).

Procedure

An open call will be given to all staff who meet inclusion criteria, regardless of area/department to take part in the research. When preliminary agreement to the study has been obtained, the lead researcher will meet potential participants at their workplace, where they will be provided with a consent form, participant information leaflet (PIL) and a verbal explanation of the study. Participants who are interested in taking part in the study will be asked to peruse the consent form and PIL for a 24-hour period. Arrangements to meet all participants who are willing to participate will then be made and they will be then sign the consent form. The Physical Activity Readiness Questionnaire (rPARQ) health screening tool (44) will be administered to participants at the information/briefing stage to ensure participants' physical capability to safely participate in the study. Following the baseline period, all participants will be provided with a report via email on their weekly sedentary behaviour and physical activity derived from their baseline accelerometer data. Participants randomised to the intervention group will then be

trained by the lead researcher in a face-to-face session at their workplace on how to use the intervention equipment.

Intervention

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 (47). Social-comparison, focusing on the masculine ideal and gender influences (48,49), 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 (50).

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.

Assessments

At baseline, participants will wear the thigh-based accelerometer (activPAL3) monitor for 24 h/day, for 7 consecutive days (and 14 days each for control and intervention arms), and will be instructed that they can wear the monitor for showering but to remove the monitor if they will be submerged in water for a prolonged period (e.g. bathing or swimming). All device removals will be documented in a wear diary. Prior to being attached to the participant, the device will be set to record at 20 Hz. The activPAL3 will be set to start recording at 1500 h on the day the participant receives the device. Each device will be attached to the anterior aspect of the midline of the right thigh using a nitrile sleeve and waterproof Tegaderm dressing. Sleep, sedentary time, standing time, LPA and MVPA will be derived from the activPAL3 data. Under-desk pedalling time will be calculated using the sitting postural function, together with prolonged bouts showing counts of >290 (SD +/- 46) to signify physical activity while seated. Sedentary time and standing time are calculated using the postural function of the monitor, through the associated software (activPAL v8.10.8.75).

Contextual information on SB will be measured using self-report via Ecological Momentary Assessment (EMA). The use of EMA has been recommended to collect ecologically valid and context-specific outcome data alongside objective measures in studies (56,57). EMA involves repeated sampling of participants' current behaviours and experiences in real time and in their natural environments, and is useful to specify the type of activity or contextual factors (e.g., physical, social, temporal, affective) surrounding these behaviours which are important factors to consider when developing interventions, and that cannot be provided by objective measures (58). Studies that focus on decreasing sedentary time specifically in the workplace must examine if sedentary time increases or decreases outside of work (i.e. compensatory or transfer effects) (59). EMA has been reported as a valid and reliable to measure SB and PA in adults (60), and for use in a workplace setting (61). Each day six notifications will appear on participants' own mobile smartphones at random times between 8am and 10pm, using the application P.I.E.L. survey app version 1.2.4.2 (62). The notifications are scheduled at random times to obtain a representative sample of participants' activities over the course of their study participation. The questions have been found to be valid and feasible (appendix 3) (63).

Work Engagement will be measured at baseline, post control arm and post intervention arm using the Utrecht Work Engagement Scale (UWES-9) (64). The perceived benefits of reducing sedentary behaviour in the workplace will also be assessed at these time points using a questionnaire. Immediately upon finishing the study, participants will be asked to complete a questionnaire to assess the acceptability, appropriateness and feasibility of the intervention.

Focus groups and semi-structured interviews will be carried out at 2-weeks post intervention follow up. An interview schedule has been designed based on existing literature. The interview schedule (appendix 3) for the focus groups will be guided by Orsmond et al (65). The interview schedule will be pre-piloted on a small number of employees within the Public Health and Primary Care Department.

Primary Outcomes

The following outcomes will be assessed using a pen and paper questionnaire:

- Appropriateness of the intervention
- Acceptability of the intervention
- Feasibility of the intervention

The outcomes will also be assessed via focus groups and/or semi-structured interviews:

- 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)
- Experiences of the other intervention components
- Organisational-level and management perspectives of using the pedal machine
- Acceptability of the intervention
- Acceptability of the assessments and burden
- Acceptability of the study procedures

Feasibility outcomes

Recruitment process

- Number of people recruited to the study recorded by the researcher at the beginning of the study.

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.

Secondary outcomes

Trial-related outcomes, assessed at baseline (before randomisation) and throughout the control and intervention periods:

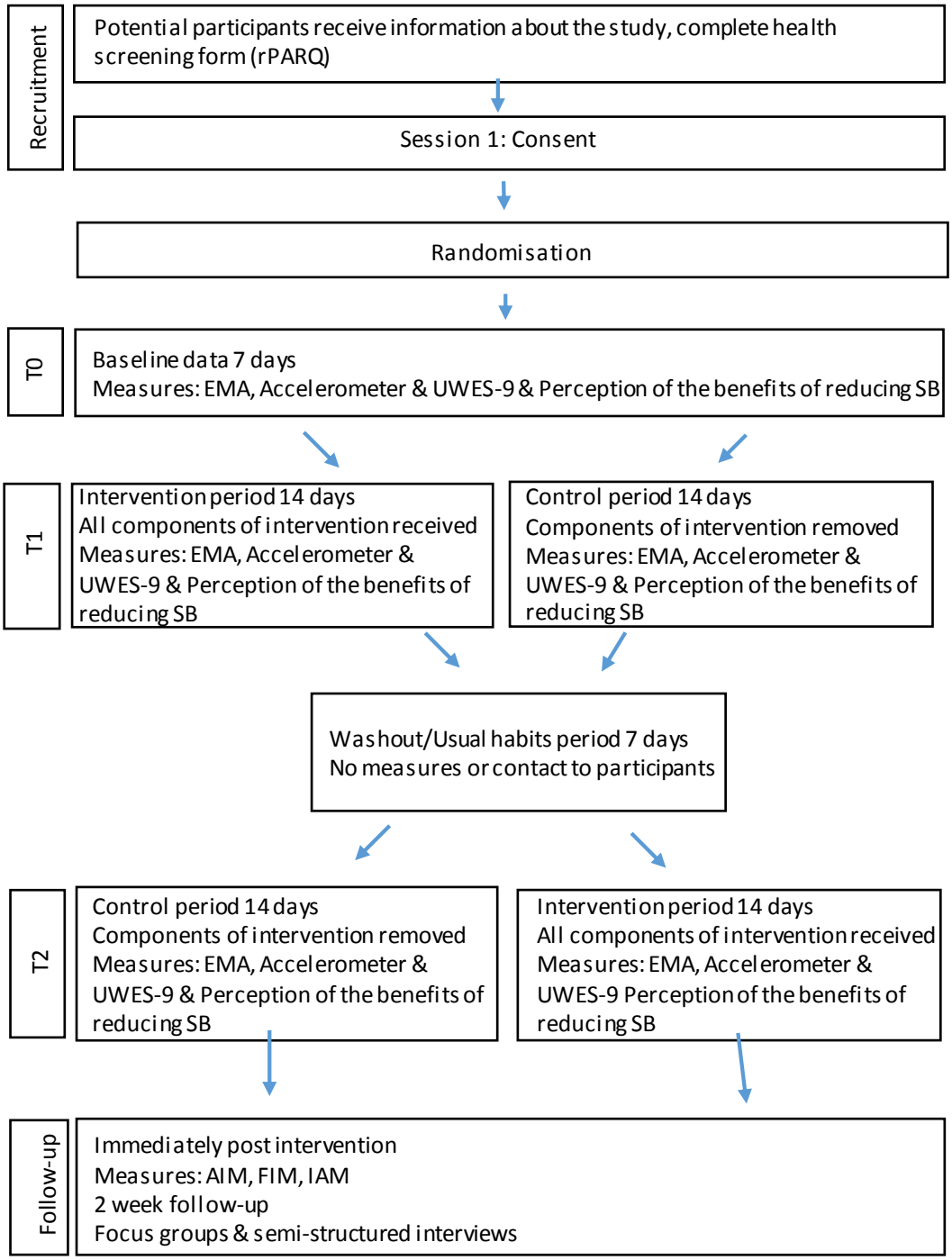
- Sedentary behaviour and physical activity measured using ActivPal3 accelerometers:

-Sedentary behaviour during working hours (workplace sedentary behaviour) and all waking hours (total sedentary behaviour)

-Physical activity during working hours (workplace activity) and all waking hours (total physical activity)

- 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 interventions arms.
- Work Engagement will be measured at baseline, post control arm and post intervention arm using the UWES-9 (66) using pen and paper.
- Perception of the benefits of reducing workplace sedentary behaviour will be assessed using 3-point questionnaire.

Figure 1 Flow chart of study based on CONSORT reporting guidelines for pilot and feasibility studies



Data analysis

From a feasibility perspective, descriptive analysis will account for the number of participants participating in the intervention and the numbers unwilling to participate. Participant experience of acceptability and satisfaction with the intervention will be assessed using analysis of the focus groups and semi-structured interviews. Transcriptions of audio recorded interviews will be analysed using thematic analysis (67). At each stage, findings will be verified and discussed in order to assess the accuracy of the interpretation, promote reliability and ensure rigour (68). The main analysis of this study will include thematic analysis and no software package will be used to analyse the data.

Quantitative analyses will be carried out using Statistical Package for the Social Sciences V.25 (IBM Corp., Armonk, New York, USA). Descriptive statistics (daily mean SB and PA in minutes, SD) will be provided of overall SB and PA as derived from the objective measure and from the EMA information. Mixed-model repeated measures linear regression will be used to analyse continuous outcomes data. Statistical adjustment for order and period effects will be made. The advantage of a crossover design means that adjustment for other covariates, such as age will not be necessary because in a cross-over design, each participant serves as their own control, thus reducing the influence of confounding covariates. All tests of statistical significance will be two-tailed, with $\alpha = 0.05$.

Discussion

This paper describes the design of a cluster randomised wait-list crossover study that will test the acceptability and feasibility of a theory-led multicomponent intervention to reduce sedentary behaviour in professional males. The design builds on previous developmental work of the participating worksites. The current study, to our knowledge will be the first study to target professional males in an intervention that combines a new ergonomic version of an under-desk pedal machine, the utilisation of mHealth to target specific BCTs such as self-monitoring, social comparison and goal-setting, as well as management recruitment to the study. This makes a unique combination of components that aims to reduce sedentary behaviour and increase light physical activity during participants' working day.

The time spent in sedentary behaviour is increasing rapidly in middle- to high-income countries in recent years and is set to continue to do so without intervention (69). Given the detrimental health impact of prolonged and uninterrupted daily sedentary behaviour, this presents a serious public health concern. The longest sedentary behaviour occurs in the workplace, therefore reducing and/or breaking up long periods of occupational sedentariness could significantly attenuate the risk of disease among desk-bound workers (70,71). Office workers are one of the largest occupational groups in high-income areas, and are sedentary for a large proportion of their day, therefore reducing their SB could have important public health implications (9).

Reallocating just 30 minutes of SB, sleep time or standing time with LPA has been found to beneficially affect body composition, including BMI and fat mass (16), therefore restructuring the physical environment to enable LPA is an important strategy.

The current feasibility study is designed to inform subsequent refinement of intervention content, in terms of acceptability and feasibility of the intervention components and measures, so that the format may be suitable for real-world implementation and evaluation in a trial. Its primary purpose is to address key design uncertainties, including the feasibility of recruiting eligible participants, as well as the appropriateness, acceptability and feasibility of the intervention. The qualitative component of the study will allow for exploration of any issues surrounding the acceptability of the under-desk pedal machines, as well as the mHealth component from the perspectives of the users, which will include employees and management. It will also allow for exploration of the study procedures and assessment methods.

By also assessing the secondary outcomes of SB and PA, and work engagement and perceived benefits of reducing workplace SB, the current feasibility study will clarify the design of a future larger trial that will extend the current knowledge regarding the effectiveness of this type of multicomponent intervention to reduce occupational SB.

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Authors' contributions

All authors contributed to the design of the study. The manuscript was drafted by GN with contributions from CD and CH. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Author details

[1]Public Health & Primary Care, Trinity College Dublin, Institute of Population Health, Russell Centre, Tallaght Cross, D24 DH74, Ireland

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Page Number on which item is reported
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	ISRCTN Registry
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	Original
Funding	4	Sources and types of financial, material, and other support	11
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	11
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	11
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A/
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	1-3

	6b	Explanation for choice of comparators	2-3
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	6
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	6
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	5
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	5
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			6
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	6
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-8

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	8
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	26-28
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	8
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	4

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	4
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	25-28
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	11
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	25-28
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	25-28
	31b	Authorship eligibility guidelines and any intended use of professional writers	11
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	25-28
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Appendix 2 Ecological momentary assessment

1. What were you doing right before the phone went off?
   Response options: Reading, Using computer, watching TV/movies, Eating/drinking, Socialising, Doing hobbies, Physical activity/exercising, Other
2. What type of physical activity/exercise?
   Response options: Running/jogging, Walking, Weightlifting/strength training, Using cardiovascular equipment, Elliptical machine, Cycling, Other
3. What was this other activity?
   Response options: Cooking/chores, Riding in a car, Childcare, Attending meeting/appointment, Volunteering, Something else
4. Were you sedentary while doing that activity?
   Response option: Yes, No

Appendix 3 Focus group schedule

(a) Acceptability of intervention components

To start, could you tell me what are your thoughts of the intervention, overall? *What was your experience of it?*

What did you think of the individual components of the intervention? *What was your experience of using the pedal machine? How did you find wearing the Garmin watch? What about the challenge aspect of the intervention?*

What are your thoughts on the measures used within the study? *How did you find wearing the accelerometer?*

What are your thoughts on the text messages asking about your physical activity and sedentary behaviour? *The number of messages throughout the day – too many? Was it acceptable to you? Were there any other outcomes of using this that you were not expecting?*

(b) Randomisation

What are your thoughts on the fact that you were in the control group or the intervention group to begin the study? *How might it have affected your participation in the study?*

(c) Appropriateness of the intervention

Do you think that the intervention was appropriate in helping you to be less sedentary and move more in your working day? *Do you think the components used in the intervention were appropriate in enabling you to reduce your workplace sedentary behaviour?*

(d) Effectiveness of the intervention

Do you think that the intervention was effective in its aims of reducing your sedentary behaviour and increasing your physical activity in work? *Do you feel that the intervention achieved its goal in reducing your workplace sedentary behaviour? Do you think this is sustainable in the long-term?*

(e) Barriers to reducing workplace sitting not addressed by the intervention

Was there something that impeded you taking part in the intervention that we did not take into consideration? *Was there a factor that stopped you taking part in the intervention as much as you would have liked?*

(f) Other benefits/harms of the intervention

Were there other benefits or improvements that you felt because of the intervention?

Were there disadvantages taking part in the intervention?

(g) Suggested improvements to the intervention

What do you think would improve the intervention going forward if it was run on a larger scale? *What would you change if you were to take part again in the intervention? Would you stick to it over a long period?*

Appendix 4 Participant Information leaflet and consent form

Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

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

Research Team

Gail Nicolson, Dr Catherine Darker and Dr Catherine Hayes

We are inviting you to take part in a research study. Before you decide that you want to take part, it is important for you to understand why it is being done and what it will involve. Please take you time to read the information in this information sheet before deciding to take part. If you have any questions or do not understand the information, you can ask the research team. Their details are at the end of this information sheet.

What is the aim of this research?

The aim of the research is to undertake a pilot study to investigate if a multicomponent intervention to reduce sedentary behaviour in a workplace setting is acceptable and feasible.

Who is organising the research?

The study is being conducted by Gail Nicolson as part of her PhD project to test a pilot intervention to reduce sedentary behaviour in the workplace. The PhD is funded by the Dean of the Faculty of Health Sciences, Trinity College Dublin.

Can I take part in this study?

We are looking for men aged 18 or over with sedentary occupations, who are physically healthy to engage in light-moderate physical activity, and who would like to reduce their sedentary in their working day.

How many people will take part in the research?

Thirty people will take part in this pilot study.

What are the possible risks to taking part in the study?

There are minimal risks to taking part in this study.

What are the possible benefits of taking part in this study?

Participants in this study 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.

Do I have to take part?

You do not have to take part in this study. You may decide if you would like to take part. You are free to refuse to take part in the pilot study, refuse to answer have any measurements taken at any time. You are free to withdraw from the study at any time and your details will be deleted if you decide to withdraw or request that your information is deleted.

What will happen if I take part?

If you decide to take part in the research, you must sign a consent form. We would like to see if an intervention to reduce sedentary behaviour at your workplace is acceptable and feasible, and also if it is effective in reducing your sedentary behaviour and increasing your physical activity.

Firstly, to get your baseline daily activity information we will ask you to wear a thigh-worn accelerometer to measure your sedentary behaviour and physical activity for 24 hours a day for 7 days. From this information we will provide you of a graph illustrating a breakdown of your sedentary behaviour and physical activity for the week. We will also ask you to download an app that will notify you 6 times a day every day to complete a short survey (each survey takes approximately 10 to 30 seconds to complete) to help us to gain real-time information about what you are doing throughout the day. The questions ask what you are doing right before the notification went off – such as if you are working on your computer, reading or engaging in physical activity.

Your worksite will then be randomised to start the study either in the control period which means that you will not receive the intervention but you will continue to wear the accelerometer data and you will be sent the text messages asking about your daily activities. At the end of each week the researcher will come to your workplace to upload the accelerometer data onto a laptop. Alternatively, your worksite will begin with the intervention period, followed by the control period depending on the randomisation. The control periods and intervention periods will take place over 14 days each. In between the control and intervention periods will be what is called a 'washout period/usual habits' for 7 days where you have no measurements taken and you will not be contacted by the researcher.

In the intervention period you will receive an under-desk pedal machine (Desk-Cycle™) to use as well as a wrist-worn physical activity tracker (e.g. Garmin Forerunner 35) so that you can track your daily use of the pedal machine and monitor your activity using the associated app/website (e.g. Garmin Connect). You will take part in a challenge to cycle at your desk every day and upload your activity to the website where you can see yours -, and others in your worksites' progress. The activity tracker will also prompt you to move every hour that you have been sedentary, and by engaging in some physical activity such as a short walk or uploading a cycling activity, you will clear this 'move bar'.

In summary, there is a 7 day baseline measure period, then you will then either be in the intervention period or the control period (14 days each); with a 7 day washout period in between; followed by whichever period you did not receive. At the end of the baseline, control and intervention periods we will ask you to complete a questionnaire on your work engagement. This questionnaire takes approximately 5-10 minutes to complete.

At the end of the study, we would like you know how you found the study and what your experience and thoughts of participating were. We would like you to complete a short questionnaire (takes about 5 minutes to complete) on whether you thought that the intervention was acceptable, feasible and appropriate. We would also like you to take part in a focus group to tell us about your experience of being in the study. We will convene in a place suitable to you to carry out the focus group. The focus group will consist of 6-8 of your fellow co-workers to discuss your views on the pilot study in your workplace. The discussion will be audio-recorded and will take 30 - 40 minutes. The recording will be sent to a transcriber who will put it into writing word for word. Your name or any identifying information will not be included in the transcript and the audio recording will then be destroyed. Your information will not be disclosed to anyone outside of the research team. You can request a transcript of the interview.

What will happen to the information that I provide?

We will keep all of your information confidential. Your name and contact details will only be seen by the research team.

The information (data) collected from the accelerometer will be uploaded to a secure laptop that is password encrypted. The accelerometer device only collects data on your activities such as lying, sitting, standing, stepping and cycling in minutes per day. Your name will not be attached to any of this data and each information file will be have a code when uploaded.

The PIEL Survey app is only used to collect the survey data and send you notifications. The PIEL Survey app does not use a remote server or database. Your data is stored on your own phone. At the end of each study period you will email your data file to the researcher. The email account on your devices is set up to use SSL/TLS security using settings from the email provider ensuring encryption.

The questionnaires used in this study will be completed using pen and paper and your name will not be attached to them. All completed questionnaires will be stored in a locked bag during transportation to the researcher's place of work, where they will be stored in a locked cabinet.

We will replace your name with a code and store your name separately from your other information. Only the researcher will hold the key to the code. The researcher will enter the information that you provide on a password-protected computer using the code. The data will then be analysed by the researcher. Trinity College Dublin is the Data Controller. The means that the College controls and is responsible for the keeping and use of your personal information. The transcriber of the focus group data is the Data Processor - that is they process your data. They must only process your data on the instructions of the Data Controller. The responsibilities of the Data Processor include the necessity to keep personal data secure from unauthorised access, disclosure, destruction or accidental loss. The Data Processor will destroy the audio recording when it is transcribed. Your data will not be used in future unconnected research without your consent. If you would like to have more information about how your data are protected please ask for the Privacy Notice. You can ask for a copy of the Privacy Notice from Gail Nicolson (details below). In line with Trinity College Dublin Data Protection guidelines all data will be stored securely for ten years. Your information will be destroyed securely after that time.

If you need to make a complaint, you can contact the Data Protection Officer at dataprotection@tcd.ie.

What will happen to the study results?

The results of the study will be used in the write-up of the researcher's PhD thesis. Research results may also be published in a journal or presented at a conference. Your information will not be linked to you in any way.

Has this study been approved?

The study will not begin until approval is received from Research Ethics Committee of the School of Medicine at Trinity College Dublin.

Further information: If you would like any further information, or have questions about the study and your participation in the focus group, you can contact Gail Nicolson on 01-8963739.

Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Interview Participant Consent Form

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

PhD Candidate: Gail Nicolson, Trinity College Dublin.

Tel: 01-8963739 Email: nicolsg@tcd.ie

Primary supervisor: Dr Catherine Darker, Trinity College Dublin.

Tel: 01-8968510 Email: Catherine.darker@tcd.ie

Secondary Supervisor: Dr Catherine Hayes, Trinity College Dublin.

Tel: 01-8961385 Email: hayesc9@tcd.ie

If you would like any more information about the study or if you have any further questions, please refer to the attached participant information leaflet or contact the research team.

Please initial each box to confirm that you have read, understood and agreed to each of the points of the form.

1. I confirm that I have read and understood the attached Participant Information Leaflet. I have had the opportunity to think about the information and to ask questions. The research team has answered any questions that I have had. ☐

2. I agree to take part in the research study. ☐

3. I agree that my personal details will not be shared with anyone outside of the research team. A professional transcriber will have access to the focus group data I provide, and will sign a legally binding ☐

   Data Processing Contract governing the data processing as outlined in Article 28 of the General Data Protection Regulation (GDPR). I understand that my data will be anonymised i.e. my name or personal details will not appear, prior to any publication of the results. I understand that I can get a copy of the Privacy Notice from the researcher if I want to find out more about how my data are protected.

4. I agree to my data being stored securely for ten years after the study ends, by Trinity College Dublin researchers ☐

5. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. I understand that if I withdraw from the study, any data collected from me can still be used unless I state otherwise. I understand if I need to make a complaint, I can contact the Data Protection Officer at dataprotectionofficer@tcd.ie. ☐

6. I agree to being part of a pilot study and understand that survey information that I provide will be confidential to the research team and the focus group will be audio-recorded and put into writing word ☐

   for word by a transcriber, and the voice recording will then be destroyed.

_____ _____ _____

(Please print name of participant here) Date (Please sign here)

_____ _____ _____

Researcher's name Date Researcher's signature