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Interventions outside the workplace for reducing sedentary behaviour in adults under 60 (Protocol)

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[Intervention Protocol]

Interventions outside the workplace for reducing sedentary behaviour in adults under 60

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of non-occupational interventions for reducing sedentary behaviour in adults under 60 years of age on sedentary time.

Secondary objectives are:

- to describe other health effects, and adverse events or unintended consequences of the interventions;
- to determine whether specific components of interventions are associated with changes in sedentary behaviour;
- to examine if there are any differential effects of interventions based on health inequalities (e.g. age, sex, income, employment).

BACKGROUND

Description of the condition

Research into sedentary behaviour is an emerging and rapidly growing field. Sedentary behaviour is defined as waking activity characterised by an energy expenditure of 1.5 or fewer metabolic equivalents and a sitting or reclining posture (Sedentary Behaviour Research Network 2012). A recent overview of systematic reviews of observational studies concluded that there is strong evidence for a positive relationship between sedentary behaviour and all-cause mortality, fatal and non-fatal cardiovascular disease, type 2 diabetes and metabolic syndrome, along with moderate evidence for increased incidence of ovarian, colon and endometrial cancers (De Rezende 2014). Conversely, interrupting sedentary time

and/or replacing it with light-intensity activity has been shown to improve several markers of cardiovascular disease risk (Dunstan 2012; Peddie 2013; Thorp 2014). Some research suggests that sedentary behaviour may be a distinct risk factor, independent of physical activity, for multiple adverse health outcomes (Chomistek 2013; Stamatakis 2011; Thorp 2011). Indeed, even people who are physically active at or above recommended levels experience the adverse effects of sedentary behaviour (Katzmarzyk 2009). Researchers estimate that people need approximately 60 to 75 minutes per day of moderate-intensity physical activity to eliminate the increased risk of death associated with high sitting time; however, this high activity level reduces but does not eliminate the increased risk associated with high TV-viewing time (Ekelund 2016). The mechanisms through which sedentary behaviours lead to cardiovascular morbidity and mortality are underexplored in the literature, but hypotheses point to defects in lipoprotein metabolism, early atherosclerosis, insulin resistance, and development of the metabolic syndrome (Same 2016). Obesity may act as a mediator between sedentary behaviours and negative health outcomes (Same 2016). Research from the genetics field has identified a genotype that is particularly susceptible to the adverse effects of excessive sedentary periods on glycaemic regulation (Alibegovic 2010), thus suggesting a potential gene-environment interplay that determines who is most susceptible to developing diabetes when exposed to excess sedentary time (Wilmot 2012).

Sedentary behaviour in adults is characterised as TV viewing and other screen-focused behaviours in domestic environments, prolonged sitting in the workplace, and time spent sitting in automobiles (Owen 2011). Accelerometer measured data from a representative sample of US adults shows that over 50% of waking hours are spent sedentary (Healy 2011). Weekday self-reported sitting time varies considerably across European countries, with adults in north-western European countries sitting the most (means 5.6 - 6.8 hours/day) (Bennie 2013). Accelerometer data suggest that UK men and women actually spend approximately 7.5 and 7 hours per day, respectively, being sedentary (Ekelund 2009). Many interventions to reduce sitting time in adults have focused on the workplace setting (Shrestha 2016); however, workplace sitting only represents one domain of sedentary behaviour, as adults spend approximately 70% of their non-work time being sedentary as well (Parry 2013). TV viewing is a major contributor to sedentary behaviour in the USA, with the average adult watching five hours of TV per day (Pettee 2009; The Nielsen Company 2009). In addition, inactive travel modes and other non-occupational behaviours such as leisure-time computer use are increasing (Brownson 2005; Chau 2012). There are several known individual correlates of sedentary behaviour, such as age, physical activity level, body mass index and socioeconomic status, and evidence relating to social and environmental factors is emerging (O'Donoghue 2016). A taxonomy of sedentary behaviours is currently under development to provide a structure for the current and future knowledge of sedentary behavior and a basis to distinguish different behaviors (Chastin 2013).

While no global guidelines on sedentary behaviour exist, several countries have made population-based recommendations. Much of the focus thus far is related to screen time for children. For example, since 2001 the American Academy of Pediatrics has recommended that parents limit children's total entertainment media time to no more than one to two hours of quality programming per day (American Academy of Pediatrics 2001). This two-hour limit for children is also consistent with the 2004 Australian guidelines (Australian Government 2004). Canada addressed general sedentary behaviour in their 2011 guidelines by recommending that children should minimise the time that they spend being sedentary each day (Tremblay 2011). In 2011 the UK Chief Medical Officers joined Australia (among others) in providing public health guidelines aimed specifically at highlighting the potential health risks associated with sedentary behaviour for adults (BHFNC Physical Activity and Health 2012). The UK guidelines recommend that all adults minimise the amount of time spent being sedentary (sitting) for extended periods (Department of Health 2011), without specifying a duration of time. The Australian guidelines recommend that adults minimise the amount of time spent in prolonged sitting and break up long periods of sitting as often as possible (Australian Government 2014). A recent academic paper led by UK researchers suggested that for predominantly desk-based occupations, workers should aim to initially progress towards accumulating two hours per day of standing and light activity during working hours, eventually progressing to a total accumulation of four hours per day (Buckley 2015); however, this is not an official guideline from the UK Chief Medical Officers.

While public health agencies have yet to present a quantified time limit on general sedentary behaviour, there is some evidence that a reduction of one to two hours of sedentary time per day could equate to substantial reductions in cardiovascular disease risk (Healy 2011). A study estimated that beneficial effects in cardiovascular disease risk biomarkers were associated with the reallocation of 30 minutes per day of sedentary time with an equal amount of either sleep, light-intensity physical activity or moderate-to-vigorous physical activity (Buman 2013). A recent review of experimental studies concluded that breaking up sitting time and replacing it with light-intensity ambulatory physical activity and standing may be sufficient stimulus to induce acute favourable changes in the postprandial (the period after eating a meal) metabolic parameters such as glucose and insulin response in people who are physically inactive and have type 2 diabetes, whereas a higher intensity or volume seems to be more effective in rendering such positive outcomes in young, regularly active people (Benatti 2015).

Description of the intervention

Our review will assess the effects of interventions that aim to reduce sedentary behaviour in adults in non-occupational settings. This will include studies that incorporate any component intending to reduce sedentary time, including if this is part of a larger

intervention. We define a component as any strategy that explicitly targets a reduction in sedentary behaviour and is reported as a component of the intervention. This approach allows our review to include not only studies that focus exclusively on sedentary behaviour but also those that take a combined approach to reduce sedentary behaviour and increase physical activity. It is likely that some studies will target a specific sedentary behaviour, such as TV viewing, or a collection of behaviours like overall screen time.

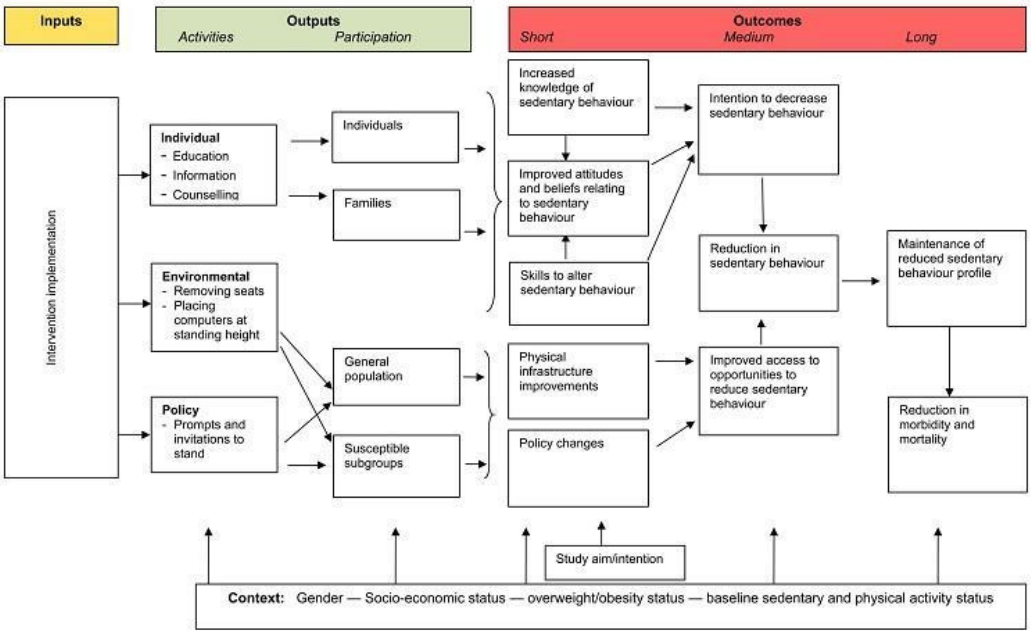
Interventions may be delivered at the individual, environmental or policy level. This includes interventions within domestic environments, transport and the wider community. Interventions include education and counselling sessions, where participants develop an implementation plan for behaviour change (De Greef 2010); self-monitoring of behaviour alongside goal-setting, where participants are encouraged to track their sitting time and set goals to increase break from sitting (Adams 2013); and multi-component lifestyle interventions. Interventions targeting the environmental level may include point-of-decision prompts to encourage adults to stand (Lang 2015), or they could consist of controls placed on screen-time, for example limiting TV viewing by installing an electronic lockout system (Otten 2009). We anticipate that those delivering the interventions will include counsellors, researchers, exercise physiologists, psychologists, GPs and other public health professionals. The delivery modes are likely to involve face-to-face individual and/or group sessions, telephone support, provision of written leaflets, and the use of online platforms. Many studies incorporate specific behaviour change strategies in the design, with self-monitoring behaviour, problem-solving, modifying social and physical environments, and giving information on the health impact of sitting - most closely associated with promising interventions (Gardner 2016).

How the intervention might work

Several frameworks have emerged from recent research for understanding sedentary behaviour and informing intervention development (Owen 2014; Prapavessis 2015). An ecologic model of sedentary behaviours highlights a behaviour- and context-specific approach to understand the multiple determinants (Owen 2011). The behaviours and contexts of primary concern are TV viewing and other screen-focused behaviours in domestic environments, prolonged sitting in the workplace, and time spent sitting in automobiles (Owen 2011). The authors suggest that change to sedentary behaviour in these domains may be altered by focusing on a specific setting with due consideration of the correlates of sedentary behavior for that setting along with understanding factors related to high levels of overall sedentary time. A recent review of behaviour change strategies used in interventions for sedentary behaviour concluded that the most promising interventions were based on environmental restructuring, persuasion or education (Gardner 2016). In addition, the following behaviour change techniques were particularly promising: self-monitoring, problem solving, and restructuring the social or physical environment.

We developed a logic model based on Baker 2015 to illustrate how the interventions might work and to describe the interactions between intervention activities and outcomes (Figure 1). We envisage several ways that interventions in non-occupational settings may reduce sedentary behaviour in adults aged under 60 years.

Figure 1. Logic Model for interventions targeted outside of workplace settings for reducing sedentary behaviour (adapted from Baker 2015)



1. *Individual, including education/information/counselling*: adults may be willing to alter behaviour after learning about the health risks of a sedentary lifestyle. To support efforts to change behaviour, counsellors could encourage adults to track their sitting time and set goals to increase breaks. Similarly, they may receive suggestions to reduce sitting time.

2. *Environmental*: for example, removing seats from certain carriages on a train would force commuters to stand for the journey. Similarly, studies could limit recreational TV viewing by installing a lockout system that engages after a specific usage period per day, thus promoting adults to change their usual behaviour. Placing computers at standing height would also prompt standing.

3. *Policy, including challenges to socials norms*: for example, by providing prompts and invitations to encourage standing in events, participants may be more likely to stand for some or all of the duration.

Why it is important to do this review

The evidence base reporting the health implications of sedentary behaviour and interventions to address this problem is rapidly expanding. Although studies first identified an increase in CVD risk experienced by people in highly sedentary jobs in the 1950s, only in recent years have the potential CVD risks from sedentary behaviour, as distinct from physical activity, come to be appreciated (Ford 2012). Recent observational and experimental evidence makes a compelling case for reducing and breaking up prolonged sitting time in both the primary prevention and disease management contexts (Dempsey 2014). The scale of the problem is evidenced by the fact that the adverse health effects of sedentary behaviour are present even in those who are physically active at or above recommended levels (Katzmarzyk 2009). An estimated 5.9% of deaths may be attributable to daily total sitting time, suggesting that its reduction in the population could produce comparable benefits to those achieved for reducing smoking, inactivity, and overweight and obesity (Chau 2013). In this comparison,

physical inactivity is defined as "doing no or very little physical activity at work, at home, for transport or in discretionary time" (Bull 2004; WHO 2009). See Published notes.

While there are several reviews in children and young people, only two systematic reviews of interventions to reduce sedentary time in adults have been published (Martin 2015; Prince 2014). However, these reviews include interventions designed to increase physical activity but also report changes in sedentary time as unintended or secondary outcomes, rather than solely focusing on interventions that purposely aimed to reduce sedentary behaviour. A recent review found that the most promising interventions targeted sedentary behaviour instead of physical activity (Gardner 2016). The key difference between our proposed review and existing reviews is that we will only examine the effects of interventions to reduce sedentary behaviour on sedentary time and health outcomes in non-occupational settings (Martin 2015; Prince 2014; Shrestha 2016). A recent Cochrane Review examined interventions to reduce sitting time in the workplace setting (Shrestha 2016), and two further Cochrane Reviews are underway to examine workplace interventions for increasing standing or walking for preventing and decreasing musculoskeletal symptoms in sedentary workers (Parry 2017a; Parry 2017b). However, there is no synthesis of evidence in non-occupational settings. As adults spend approximately 60% to 70% of their non-work time being sedentary (Clemes 2014; Parry 2013), there is great scope for intervention, and a synthesis of evidence on existing interventions will guide this task. We feel than non-occupational settings may offer greater scope to change sedentary behaviour than occupational settings, where individuals may have less control over their working environments and practices.

The need that policymakers and practitioners have for this Cochrane Review is evident in the focus on sedentary behaviour at governmental level worldwide. This is also reflected in much being written about the dangers of sitting in the media. Countries are expanding their public health guidelines to include recommendations on limiting sedentary time (for example see Healthy Ireland 2016 and Sedentary Behaviour and Obesity Working Group 2010). This review will also provide key evidence for countries that seek to update existing sedentary behaviour guidelines in future years (e.g. Australian Government 2014). The findings of the review will therefore aid evidence-based decision-making by policymakers and practitioners working to address sedentary behaviour worldwide. This rapidly growing field will inform the development of public health policy over the coming decade, and a regularly updated, robust, comprehensive review of the evidence is required to support this task.

OBJECTIVES

To assess the effects of non-occupational interventions for reducing sedentary behaviour in adults under 60 years of age on sedentary time.

Secondary objectives are:

- to describe other health effects, and adverse events or unintended consequences of the interventions;
- to determine whether specific components of interventions are associated with changes in sedentary behaviour;
- to examine if there are any differential effects of interventions based on health inequalities (e.g. age, sex, income, employment).

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and cluster-randomised controlled trials (cluster RCTs) aimed at changing sedentary behaviour. Given the growing volume of interventions targeting sedentary behavior, particularly RCTs, we feel that solely including RCTs and cluster RCTs will allow us to draw conclusions from the best available evidence.

Types of participants

We will include studies involving community-dwelling adults aged 18 to 59 years who are free from pre-existing medical conditions that may limit participation in the intervention.

Types of interventions

We will include interventions targeted outside of workplace settings. This may include interventions within domestic environments, transport, and the wider community. The following are examples of interventions that may be included in the review.

- Counselling/education to reduce and self-monitor sedentary behaviour.
- Limits/controls placed on screen time.
- Environmental change interventions, for example point-of-decision prompts to encourage standing.
- Multicomponent lifestyle interventions that include a sedentary behaviour element.
- Community-level interventions that specifically aim to address sedentary behaviour.

Interventions may be delivered at the individual, environmental or policy level. We will exclude interventions in workplace settings as they fall under the scope of a separate Cochrane Review (Shrestha

2016). We will also exclude studies that only aim to improve physical activity levels but happen to report sedentary time, as they do not specifically target sedentary behaviour in their design. Comparison will be between those receiving the intervention and those receiving no intervention or attention control.

Types of outcome measures

We will include studies that have sedentary behaviour as either a primary or secondary outcome of interest.

Primary outcomes

The primary outcome measure will be sedentary behaviour, assessed at baseline and postintervention. There is no international consensus on a gold standard measure of sedentary behaviour. With this in mind, we will include studies that utilise device-based (e.g. accelerometer and inclinometer) or self-report (e.g. self-report, diary or questionnaire) measures of sedentary time. This is likely to include studies that report sedentary behaviour in one domain only, for example sitting during transport or TV viewing at home, as well as total daily sedentary behaviour. We will consider both the total duration of sedentary behaviour reported and breaks in sedentary behaviour as primary outcome measures. We will check measures and timing of measures against published protocols and protocol registration documentation where available. We will summarise data collected regarding timing of measures and consider its potential impact on risk of bias.

Secondary outcomes

We will include the following secondary outcome measures.

- Energy expenditure.
- Body composition (e.g. body mass index, waist and hip circumference, body fat percentage).
- Cholesterol (e.g. total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol).
- Markers of insulin resistance (e.g. fasting blood glucose, liver transaminases, insulin levels or insulin resistance/impaired insulin sensitivity).
- Inflammatory markers (e.g. C-reactive protein (CRP), interleukin (IL)-6 and tumour necrosis factor (TNF)-α).
- Measures carotid intima media thickness (e.g. ultrasound).
- Measures of endothelial function (e.g. peripheral arterial tonometry).
- Measures of mental health (e.g. stress symptoms, anxiety, depression, self-image).
- Adverse events and symptoms (e.g. musculoskeletal injuries/pain or cardiovascular events).
- Unintended outcomes (e.g. social approval/disapproval by others, change in overall physical activity behaviour).

Search methods for identification of studies

Electronic searches

We will search the following electronic databases using a search strategy developed by NR and EM in liaison with the CPHG Trials Search Co-ordinator (see Appendix 1).

- Cochrane Public Health Group Specialised Register.
- CENTRAL.
- MEDLINE.
- Embase.
- Cochrane Database of Systematic Reviews.
- CINAHL.
- PsycINFO.
- SportDiscus.

We will not impose any language, publication status or date restrictions. We will contact authors and research groups for information about unpublished or ongoing studies.

Searching other resources

We will handsearch reference lists of included studies and key systematic reviews. We will also search trial registers such as ClinicalTrials.gov and contact authors of included studies and relevant systematic reviews to identify additional studies. In addition, we will contact experts in the field and ask them to identify further articles. We will search the websites of organisations involved in addressing and reporting research on sedentary behaviour (e.g. Sedentary Behaviour Research Network, World Health Organization, US Centers for Disease Control and Prevention).
NR and EM will carry out searches.

Data collection and analysis

Selection of studies

We will download the references retrieved from the electronic searches and handsearching to reference management software, Endnote, removing duplicates (Endnote 2015). Two review authors (EM and MM) will independently undertake an initial screening of titles and abstracts to exclude records outside the scope of the review. A third author (CF) will review any disagreement to reach a consensus. We will obtain full-text papers where we deem titles to be relevant or where eligibility is unclear. The inclusion decisions will be based on the full texts of potentially eligible studies. Two review authors working independently will determine whether each study meets the eligibility criteria (EM and MM). Where any disagreements occur, a third review author (CF) will examine the paper, and the three authors will reach a consensus. We will keep a record of reasons for excluding studies.

Should we identify papers detailing study design, study protocols or process evaluations, we will contact the authors to locate published or unpublished further work from the study. We will collate multiple reports of the same study and treat each study as the unit of interest.

Where we find a potentially relevant title of a paper in a language other than English, we will have the abstract translated to determine initial eligibility, and we will have the full text translated if we consider that it meets the scope of the review.

We will use the online software, Covidence, to manage the study selection process (Covidence 2016).

Data extraction and management

Two authors (EM and KM) will independently extract study characteristics and outcome data using a modified version of the Public Health Group Data Extraction and Assessment Form. We will consult a third author (CO'G) when disagreements occur and reach consensus among the three authors. All participating authors will pilot the Data Extraction and Assessment Form, modifying it where necessary to ensure comprehensiveness and comparability between results. We will complete the data extraction online using Covidence software and export the data directly to Review Manager 5 (Covidence 2016; RevMan 2014). Where there is missing information or where we need clarification, we will contact the authors of included studies. We will report relevant information in the 'Characteristics of included studies' table. Where there are multiple articles from the same study, we will compare them for completeness and possible contradictions.

We will extract the following data.

1. *Study objectives*: for example to decrease sedentary time or decrease sedentary time and increase physical activity.
2. *Study design*: RCT or cluster RCTs.
3. *Methods*: study location, study setting, date of study, duration of intervention and duration of follow-up. We will record how investigators measured sedentary behaviour, for example, questionnaire/accelerometer.
4. *Participants*: number randomised to each group, age, withdrawals. We will extract sociodemographic characteristics at baseline and endpoint using the PROGRESS framework (Place, Race, Occupation, Gender, Religion, Education, Socioeconomic status, Social status).
5. *Intervention*: content of intervention, description of comparison. We will note whether or not interventions included particular strategies to address diversity or disadvantage. We will classify any behaviour change strategies incorporated in the interventions according to version 1 of the Behaviour Change Technique Taxonomy (Michie 2013). We will categorise studies according to setting.
6. *Outcomes*: we will record outcomes measures at postintervention and follow-up if available. We will note whether clustering was taken in account in cluster RCTs. When there are available data on multiple measures of the same or similar outcomes, for example body composition measures of body mass index (BMI) and body fat percentage, we will record both.
7. *Notes*: funding received and conflicts of interest declared by the authors.

In addition to study characteristics and outcomes data, we will collect any available information about context, implementation factors, equity, cost and sustainability from included studies and report it in the 'Characteristics of included studies' table (CPHG 2011). We view sustainability of the interventions as a combination of intervention components (dose) and magnitude of effect over time. We will collect any available data related to sustainability (e.g. follow-up measures), assessing it using an adapted version of the approach adopted by Müller-Riemenschneider 2008. We will include potential moderators and confounders of study outcomes, such as age, race, gender, in the Data Extraction and Assessment Form.

Assessment of risk of bias in included studies

Two authors (EM and CO'G) will independently assess risk of bias using the Cochrane 'Risk of bias' tool. Where disagreements occur, a third author (MM) will review the studies, and together will reach consensus by discussion. The tool assesses:

- selection bias (sequence generation and allocation concealment);
- performance bias (blinding of participants and personnel);
- detection bias (blinding of outcome assessment);
- attrition bias (incomplete outcome data); and
- reporting bias (selective reporting).

We will grade each domain as being at 'low', 'high' or 'unclear' risk of bias.

We will consider blinding separately for different key outcomes where necessary; for example, the risk of bias for sitting measured by means of inclinometer may be very different than for a self-reported reduction in sitting time (Shrestha 2016). We will not consider blinding of participants and personnel for risk of bias assessment, as it is not possible to blind them in studies trying to modify activity behaviour (Shrestha 2014). We will consider the following additional criteria for cluster RCTs as recommended by section 16.3.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011): recruitment bias; baseline imbalance; loss of clusters; incorrect analysis; and comparability with individually randomised trials.

We will summarise risk of bias at the outcome level and judge each outcome as being at 'low', 'medium' or 'high' overall risk given the study designs and the potential impact of the identified risks noted in the table for each study that contributed results for that outcome (CPHG 2011).

Measures of treatment effect

For studies with continuous outcome measures, we will report mean scores and standard deviation. We will use the mean difference between the postintervention values of the intervention and control groups to analyse the size of the effects of the interventions. We will express dichotomous outcomes as risk ratios (RR) with 95% confidence intervals (CIs). We will also use RRs for categorical data (e.g. Likert scale).

Unit of analysis issues

For studies with multiple intervention groups, we will pool the intervention arms into one group to create a single pair-wise comparison, as recommended by section 16.5.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). This method avoids including a group of participants twice in the same meta-analysis. Where it is not appropriate to pool arms (for example if the arms are not sufficiently homogeneous) we will select the most relevant pair of arms and exclude the others.

For cluster-randomised trials that do not make allowance for the design effect of clustering, we will re-analyse data if possible. If appropriate we will employ statistical methods that allow analysis at the level of the individual while accounting for the clustering in the data. If successful, effect estimates and their standard errors (SEs) from correct analyses of cluster-randomised trials may be meta-analysed using the generic inverse-variance method in RevMan (O'Malley 2012).

Dealing with missing data

We will contact study authors via email where there are missing or unclear data (for e.g. missing information on methods, missing participants due to dropout and missing statistics). We will retrieve email addresses from author information provided on the study's publication and, where necessary, access contact directories from the author's documented affiliated organisation. We will note missing data in the data extraction form and report it in the 'Risk of bias' table. If numerical outcome data are missing, such as standard deviations (SDs) or correlation coefficients, and we cannot obtain them from the authors, we will calculate them from other available statistics such as P values according to the methods described Chapter 16 of the Cochrane Handbook (Higgins 2011; Shrestha 2014).

Assessment of heterogeneity

We will consider methodological heterogeneity by assessing differences in included studies in terms of study design. We will consider clinical heterogeneity by assessing variability in the participants, interventions and outcomes, as recorded in the 'Characteritics of included studies' table. We will visually inspect the forest plots to assess statistical heterogeneity and use the I^2 statistic to quantify the level of heterogeneity present ($P < 0.10$). This describes the percentage of the variability in effect estimates due to heterogeneity rather than sampling error (chance) (Deeks 2011).We will perform sensitivity analyses to investigate heterogeneous results.

Assessment of reporting biases

If at least 10 studies are available for meta-analysis, we will investigate reporting bias using funnel plots. As publication bias may be one of a number of possible explanations for small-study effects, we will attempt to understand the sources and consider their implications in sensitivity analyses. For continuous outcomes with intervention effects measured as mean differences, we will use Egger's test to evaluate funnel plot asymmetry (Egger 1997).

When there are fewer than 10 studies, we would not use funnel plots to assess reporting bias, as the power of the tests would be too low to distinguish chance from real asymmetry (Sterne 2011).

Data synthesis

If the participants, interventions and comparisons are sufficiently similar, we will conduct a meta-analysis using RevMan 5. We will use the random-effects model, as it allows for a greater level of natural heterogeneity between studies. The appropriate method of meta-analysis will depend on the nature of the data, and we will follow the guidelines presented in Chapter 9, 'Analysing data and undertaking meta-analyses' of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011). We will include data from cluster-randomised trials in meta-analyses if trial authors have taken clustering into account or if we can undertake approximately correct analyses as outlined above in Chapter 16: 'Special topics in statistics' of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will examine the effects of interventions according to types of intervention, for example environmental changes, education and policy.

If it is not possible to conduct a meta-analysis, we will report effect sizes of each study. We will group the data based on the category of intervention (e.g. individual, environmental, policy). If this is not possible we will group the data by the category that best explores the heterogeneity of studies and makes most sense to the reader (for example by populations or outcomes). Within each category we will present the data in tables and narratively summarise the results. We will identify the theoretical frameworks and models identified in the primary studies. We will also consider costs and sustainability of the studies in the synthesis.

We will create a 'Summary of findings' table for the main comparisons. The 'Summary of findings' table will include the number of participants and studies for the primary outcomes (device-based and self-report measures of sedentary behaviour), summarise the intervention effect, and include a measure of the quality of evidence (see Quality of Evidence section below).

Subgroup analysis and investigation of heterogeneity

Where sufficient data are available we will carry out the following subgroup analyses for our primary outcome to see if there is any evidence of differential responses to intervention.

- *Gender*: given the unique sedentary behaviour profiles of men and women (Bennie 2013; Matthews 2008), and the fact that interventions to reduce sedentary behaviour seem to have limited effects when targeting women only (Martin 2015), we will examine outcomes by gender (men, women, men and women).
- *Socio-economic group* (education or income): since variations in response to public health interventions according to socioeconomic status are frequent (White 2009), we will compare outcomes by socioeconomic group. It has been noted that high levels of education are associated with higher levels of sitting (Bennie 2013).
- *Age*: we will carry out subgroup analysis to consider the influence of the age of participants.
- *Intensity of the intervention*: where the data are available, we will assess the intensity of the interventions using an adapted version of the approach used by Baker 2015.
- C*ategory of study setting*: as interventions may be setting-specific, we will consider the influence of study setting, e.g. schools/universities, transport, home.
- *BMI or another measure of overweight/obesity*: we will carry out subgroup analysis to consider the influence of body composition given the evidence that associations between prolonged sitting and risk of cardiovascular disease are stronger in overweight vs normal weight adults (Chomistek 2013).
- *Study aim*: as previous reviews have demonstrated differential effects between interventions that solely aim to reduce sedentary behaviour or take combined approach of reducing sedentary behaviour and increasing physical activity (Gardner 2016; Martin 2015), we will carry out subgroup analysis to compare outcomes by study intention.
- *Baseline sedentary status*: as daily sedentary time for adults varies across studies (Bennie 2013), we will investigate if baseline sedentary level has an influence on outcomes.
- *Baseline physical activity*: we will consider the influence of baseline physical activity level in our subgroup analyses.

Where appropriate, we will assess subgroup heterogeneity through examination of the forest plots and quantification using the I^2 statistic.

Sensitivity analysis

We will use sensitivity analysis for primary outcomes to explore the impact of risk of bias on study findings, excluding studies at high or unclear risk of bias. As we may only be able to identify additional issues suitable for sensitivity analysis during the review process, once we observe the individual peculiarities of the studies under investigation (Deeks 2011), we anticipate the possibility of including other study characteristics.

Summary of findings table

We will use the GRADE system to assess the quality of the body of evidence for each outcome, and to draw conclusions about it within the text of the review. The quality of a body of evidence as assessed by GRADE is understood as the extent to which one can be confident in the estimate of effect (Guyatt 2008). We will summarise the assessment with a 'Summary of findings' table created with the GRADEpro software (GRADEpro GDT).
We will rate evidence as very low, low, moderate or high quality by considering the GRADE domains. Table 1 presents definitions for these ratings (Balshem 2011). The GRADE approach to rating the quality of evidence begins with the study design (randomised trials start as high quality) and then addresses five reasons to possibly downgrade the quality of evidence (Balshem 2011). The five factors that may lead to downgrading the quality of evidence are:

- study limitations - risk of bias;
- publication bias - when available evidence comes from a number of small studies;
- imprecision - random error;
- inconsistency - inconsistency in the magnitude of effect in studies of alternative management strategies (Guyatt 2011a);
- indirectness - indirect participants, interventions, outcomes or comparisons.

If one of these factors is found to exist, it is classified either as serious (rating down by one level) or as very serious (rating down by two levels).

Table 1: Definitions for quality ratings in GRADE

Quality level	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

(*Continued*)

Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect
Very low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1	randomised controlled trial.pt.
2	controlled clinical trial.pt.
3	randomized.ab.
4	placebo.ab.
5	clinical trials as topic.sh.
6	randomly.ab.
7	trial.ti.
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	exp animals/ not humans.sh.
10	8 not 9
11	Sedentary Lifestyle/
12	(sedentary or sitting or seated).ti.
13	((sedentary or sitting or seated) adj5 (behavio* or lifestyle or life-style)).ti,ab
14	(sedentary adj3 (adult? or men or women or males or females or individuals or people or population?)).ti,ab
15	((sedentary or sitting or seated) adj5 time).ti,ab.
16	((sedentary or sitting or seated or inactiv* or underactiv* or under activ*) and (computer* or television or tv or video game? or videogame? or gaming)).ti,ab
17	(time adj5 (computer* or television or tv or video game? or videogame? or gaming or screen or media)).ti,ab
18	((watch* or view*) adj5 (television or tv)).ti,ab.
19	(play* adj5 (video game? or videogame? or computer game?)).ti,ab
20	11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21	adult/ or middle aged/ or young adult/
22	(adult* or men or women or males or females).ti,ab.

(*Continued*)

23	21 or 22
24	10 and 20 and 23
25	(occupational or workplace or work place).ti.
26	24 not 25

CONTRIBUTIONS OF AUTHORS

Draft the protocol: EM, MM, CF, KM, NR, CO'G.

Study selection: EM, MM (CF as arbiter).

Extract data from studies: EM, KM (CO'G as arbiter).

Enter data in RevMan: EM, KM.

Carry out the analysis: EM, CF.

Interpret the analysis: EM, CF.

Draft the final review: EM, MM, CF, KM, NR, CO'G.

Disagreement resolution: as noted above.

Update the review: EM, MM, CF, KM, NR, CO'G.

DECLARATIONS OF INTEREST

Elaine M Murtagh: none known.

Marie H Murphy: together with another Ulster University colleague, the Sport & Exercise Sciences Research Institute at UU has received 20 standing desks from Ergotron to allow us to undertake a small research project on the use of sit-stand desks in office workers. This work is at feasibility stage and will not feature in the review.

Charles Foster: none known.

Karen Milton: none known.

Nia W Roberts: none known.

Clodagh SM O'Gorman: none known.

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- Bodleian Health Care Libraries, University of Oxford, UK.

NR works at the Bodleian Health Care Libraries

- Graduate Entry Medical School, University of Limerick, Ireland.

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External sources

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NOTES

'Physical inactivity' and 'insufficient physical activity' are sometimes used to refer to failing to meet physical activity guidelines. In both cases it is distinct from sedentary behaviour, for which a definition already exists (See Sedentary Behaviour Research Network 2012).