

What are the most effective behaviour change techniques to promote physical activity and/or reduce sedentary behaviour in inactive adults? A systematic review protocol

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Keywords: Sedentary lifestyle; health behaviour; exercise; intervention studies; review

Word Count: 2950

ABSTRACT

Introduction: A large proportion of the population are not meeting recommended levels of physical activity and have increasingly sedentary lifestyles. Low levels of physical activity are predictive of poor health outcomes and time spent sedentary is related to a host of risk factors independently of physical activity levels. Building an evidence base of the best approaches to intervene in the lifestyles of inactive individuals is crucial in preventing long-term disease, disability, and higher mortality rates.

Methods and Analysis: Systematic searches will be conducted on all relevant databases (e.g. PubMed, Scopus, CINAHL, PsycINFO). Studies will be included if they assess interventions aimed at changing physical activity or sedentary behaviour levels in adults (over 18) who are inactive and do not suffer from chronic conditions. Studies must also be randomised controlled trials (RCT), have a primary outcome of physical activity or sedentary behaviour, and measure outcomes at least six months after intervention completion. Studies will be coded using the Behaviour Change Technique (BCT) taxonomy v1 and TIDieR guidelines. Two reviewers will independently screen full-text articles and extract data on study characteristics, participants, BCTs, intervention features, and outcome measures. Study quality will also be assessed independently by two reviewers using the Cochrane risk of bias tool. A meta-analysis will be considered if there is sufficient homogeneity across outcomes. GRADE criteria will be used to assess quality of evidence.

Dissemination: This will be the first review to systematically appraise interventions aimed at changing the physical activity or sedentary behaviour of inactive individuals using RCT designs with a six-month follow-up post intervention. This review will better inform

intervention designers targeting inactive populations and inform the design of a future complex intervention.

Review registration: This protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 17th October 2014 (registration number: CRD42014014321).

Strengths and Limitations

- This review will provide a unique contribution by being the first to evaluate the most effective behaviour change techniques (BCT) used in randomised controlled trials of interventions promoting physical activity and/or decreasing sedentary behaviour in inactive adults using the BCT taxonomy v1 and TIDieR reporting guidelines.
- This review will also be the first to appraise these studies in inactive populations free of chronic conditions with a minimum of six months post-intervention follow-up. This will provide researchers, clinicians, and the wider public with evidence of sustainable ways in which to reduce the risk factors that accompany inactive lifestyles.
- The main limitation is that there is always a possibility that the review does not identify every piece of evidence relevant to the research question, especially due to the strict inclusion criteria. Every effort will be made to search all appropriate resources to minimise this risk.

**WHAT ARE THE MOST EFFECTIVE BEHAVIOUR CHANGE TECHNIQUES TO PROMOTE
PHYSICAL ACTIVITY AND/OR REDUCE SEDENTARY BEHAVIOUR IN INACTIVE ADULTS? A
SYSTEMATIC REVIEW PROTOCOL**

Background

Physical inactivity is the fourth leading risk factor for mortality around the world[1]. Walking, moderate and vigorous physical activity have a beneficial effect on the risk factors associated with cardiovascular disease (CVD), type 2 diabetes, and cancer[2]. Participating in 150 minutes per week of vigorous intensity physical activity is related to better survival rates and better physical and cognitive health in older age[3]. When compared to subjects who participate in low levels of activity, highly active (men, 22%; women 31%) and moderately active (men, 19%; women 24%) people have a reduced risk of all-cause mortality[4]. Even relatively low amounts of leisure-time physical activity (92 minutes per week) have been associated with a 14% reduction in risk of mortality and increased life expectancy of three years compared to no activity[5]. The evidence is clear that physical activity is highly beneficial, yet only 67% of men and 55% of women in England report participating in the recommended levels of physical activity in 2012[6], with corresponding figures of 52% and 43% from the US in 2008[7]. Objectively-measured levels in 2008 from the UK data show much lower levels - just 6% of men and 4% of women performed the recommended amount[6], demonstrating the over-reporting inherent in self-report measures of this type (e.g.[8]).

The latest research also suggests that alongside the negative health outcomes related to low physical activity levels, sedentary behaviour is an independent risk factor for a range of health problems. Sedentary behaviour (in this case watching television) is related

to obesity even after controlling for levels of leisure-time physical activity and diet[9]. Daily sitting time is linked to all-cause mortality[10] and risk of mortality through CVD[11] after factoring in physical activity levels. Higher levels of sedentary behaviour are also predictive of insulin resistance[12] and strongly associated with diabetes[13]. Despite these unequivocal data, many people report sitting for longer than 5 hours per day, with objective measurements suggesting that sedentary activities comprise 57% of daily behaviour in Australian adults [14], and between 52% (30-39 year olds) and 67% (70-85 year olds) in US adults [15]. Interventions aimed at increasing physical activity and/or reducing sedentary behaviour are clearly of paramount importance, yet are often described poorly and have shown modest results, particularly in the long term (e.g. over 12 months follow-up;[16]).

There have been a wide range of systematic reviews of interventions in this area that have had a narrow focus, for instance, on only one approach such as pedometer provision[17], one mode of delivery such as telephone-based[18] or mobile technology[19], or community-based approaches only[20]. Others have included non-randomised and non-controlled designs[21], included a mixture of inactive and active populations[22] or did not analyse the behaviour change techniques (BCT) that may have been related to effectiveness (e.g.[23-24]). Even those reviews that have included only RCTs have not analysed BCTs[25]. When BCTs have been analysed, non-randomised designs have been included, older, less exhaustive taxonomies have been applied, and studies that did not measure outcomes for at least six months post-intervention have been included (e.g.[16, 26]).

Other reviews that have included inactive participants have done so as part of highly heterogeneous intervention samples including those with diabetes, CVD, and depression (e.g.[25, 23]). The behaviour change techniques that are effective with a person suffering

with diabetes may be different than those used with a participant suffering from CVD or cancer. For this reason only inactive participants who are not suffering from major or chronic diseases or conditions will be included in this review.

The biggest problem in evaluating complex interventions that attempt to change behaviour is establishing the effectiveness of various components due to the imprecise nature of the intervention content and BCT descriptions. A group of international experts have recently collaborated to produce an exhaustive taxonomy of BCTs, which names active behaviour change intervention techniques that cannot be reduced to smaller components, such as goal setting or self-monitoring of behaviour[27]. The BCT taxonomy v1 is a 93 item list which allows all behaviour change interventions to be systematically described, reviewed, and replicated.

Since previous systematic reviews of physical activity and sedentary behaviour interventions have been published[16, 26], the list of BCTs that can be investigated has become broader and more nuanced. It is, therefore, important to find out whether the other BCTs included in this enhanced taxonomy are used and effective in physical activity and/or sedentary behaviour interventions. Another major problem in assessing the effectiveness of physical activity interventions is that details other than the BCTs have often been poorly reported. This includes vague descriptions of rationale, materials, mode, intensity, and duration of delivery, providers or fidelity. This review will, therefore, also code intervention descriptions using the 'Template for Intervention Description and Replication' (TIDieR;[28]). TIDieR is a 12-item checklist detailing how to report the why, what, who, and where of intervention delivery. It is designed to help ensure that health professionals and

researchers can accurately implement and replicate interventions and will be used alongside the BCT taxonomy v1 to evaluate included studies.

Objectives:

This is the first review to systematically identify and evaluate the effectiveness of the BCTs used in randomised controlled trials of interventions aimed at increasing physical activity and/or reducing sedentary behaviour in inactive adults with a six month follow-up measurement that considers all settings and modes of delivery. The aim of this systematic review is to answer the following two questions:

- What are the commonly used and most effective BCTs in RCTs of behavioural interventions to promote physical activity and/or reduce sedentary behaviour in inactive adults?
- Which intervention features are associated with intervention effectiveness, including mode of delivery, theoretical framework, dose, intensity, and frequency?

METHODS AND ANALYSIS

This protocol has been reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines[29].

Eligibility criteria

Study characteristics

This review will include published, unpublished and in-progress intervention studies from January 1990 to December 2014, in English language only.

Participants

This review will include only studies with adult participants (18 or older) who are identified as inactive prior to the intervention. Inactivity may be defined differently by each study but an upper limit will be set for inclusion at less than 150 minutes of moderate or 75 minutes of vigorous-intensity activity per week, or less than 10000 steps per day. Those that are inactive due to serious injury or long term physical incapacity will be excluded.

Participants suffering or rehabilitating from serious/chronic disease will be excluded. Those that are recovered from serious illness or injury will be considered in sub-group analysis if appropriate. Athlete participants and participants engaging in other health/fitness related programmes will also be excluded from the review. Studies in which there is a mixture of participants (e.g. some classified as inactive, and others obese or at risk), will only be considered if at least 70% are classified as inactive, making a clear distinction with any previous reviews that have used a more heterogeneous samples (e.g.[24]).

Intervention

Studies will be included if they evaluate an RCT intervention that aims to increase physical activity and/or reduce sedentary behaviour as one of its primary aims. Intervention approaches must include at least one BCT from the BCT taxonomy v1[27] but do not need to have a specified theoretical basis. Interventions can be delivered in a variety of settings (e.g. community centre, hospital, clinic, private residence), modes of delivery (e.g. face-to-face, online, text message, phone call) or frequency, duration or intensity (anywhere from single contact point of five minutes to intensive year-long or more interventions). Excluded are studies that do not attempt to directly change physical activity and/or sedentary behaviour. For example, interventions that only measure change in intentions and not behaviour itself.

Comparator or control

This review will include studies that compare a physical activity and/or sedentary behaviour intervention that contains at least one behaviour change technique to any of the following controls: passive control group (e.g. usual care, waiting list control, no treatment) or active control group (e.g. alternative cognitive or behavioural approaches).

Outcome measures

Primary outcomes: Studies will only be included if one of the primary outcomes is objective or self-reported physical activity and/or sedentary behaviour assessed by standardised subjective or objective tools, between baseline, post intervention, and six month follow-up. This review will not include studies reporting only on changes in weight or wellbeing. Outcomes should be measured for a minimum of six months after intervention completion.

Secondary outcomes: For the studies that meet the principal inclusion criteria the following outcomes will also be assessed if available: objectively measured health indicators (e.g. Body Mass Index; BMI), subjective wellbeing (life satisfaction, health-related quality of life, positive and negative affect), self-efficacy, and metabolic health (e.g. blood pressure, lipids, insulin resistance). Adverse effects will also be reported where available (e.g. injury risk, worsening health inequalities).

Information Sources

This review will include comprehensive searches on the following electronic databases: PubMed; Scopus; CINAHL; Applied Social Sciences Index (ASSIA); PsycINFO; Web of Science; SPORTDiscus; EMBASE; Cochrane Central Register of Controlled Trials (CENTRAL);

British Nursing Index (BNI); Google Scholar; Health Technology Assessment (HTA) database.

All databases will be searched between January 1990 and December 2014.

In addition to the electronic database searches we will search for published systematic reviews of physical activity interventions to identify relevant RCTs; reference lists of relevant articles and books; the Database of Abstracts of Reviews of Effects (DARE); the Cochrane systematic review database; National Institute of Health Research (NIHR) portfolio for recently completed or ongoing studies; the current controlled trials register; the System for Information on Grey Literature (SIGLE). Furthermore, we will hand search the bibliographies of all included studies and request from experts in the field any relevant information on unpublished and ongoing research, and key related journals.

Search Strategy

Searches will include a combination of terms from medical subject headings (MeSH) and keywords in the title, abstract, and text for the population, intervention, comparator, and outcomes. A PubMed search is included in Table 1 – this will be adapted to the syntax and subject headings of the remaining databases.

Table 1: Search Terms

Concept	Search terms
Population	MeSH terms: adult (exp), body weight, body mass index, sedentary lifestyle, overweight (exp) Free text terms: BMI, inactive, sedentary
Intervention	MeSH terms: behaviour, behavior therapy, exercise, exercise therapy (exp), health behaviour, health education, health promotion (exp), intervention

studies, lifestyle (exp), physical education and training, primary health care, social environment (exp)

Free text terms: BCT*, behaviour*, behaviour* change*, behaviour change strateg*, behaviour change technique*, behaviour* intervention*, behaviour* modification*, behaviour* therapy, behavior* change*, behavior change strateg*, behavior change technique*, behavior* intervention*, behavior* modification*, exercise activit*, exercise fitness, exercise intervention*, exercise prescribe*, exercise program*, exercise promot*, exercise referral*, exercise supervis*, exercise train*, health* behaviour*, lifestyle change*, lifestyle intervention*, lifestyle modification*, lifestyle train*, MVPA, MVPA intervention*, Peer support*, physical activit*, physical activity intervention*

Comparator MeSH terms: clinical trials

Free text terms: Clinical trial [pt], placebo [ab], randomly [ab], randomized [ab], trial [ti]

Outcomes MeSH terms: exercise, physical fitness, resistance training, sports, walking

Free text terms: MVPA, physical activit*, physical inactivit*, sedentary behaviour*, sedentary behavior*, fitness

Data Management

The results from all literature searches will be imported into Endnote reference management software. Duplicates will be removed by the software and then the main reviewer will manually remove any other examples.

Selection Process

One reviewer will screen all retrieved records by title and abstract for all inclusion and exclusion criteria. A second reviewer will also screen a random 10% of the total titles and abstracts. Any disagreements at this stage will be included for further assessment. Following initial screening full text versions of all potentially relevant studies will be retrieved and reviewed independently for suitability by two reviewers. Study authors will be contacted where necessary if relevant information on eligibility is missing. Reasons for inclusion and exclusion will be recorded, and a group discussion will resolve any discrepancies following a blind review by a third author.

Data Extraction

Data from included studies will be extracted into Excel using a data extraction form independently by two authors. The form will be piloted on a sample of studies external to the review to ensure consistency of extraction between authors. Any disagreements will be resolved by discussion with a third author and/or by seeking further clarification from study authors.

Data Items

Two reviewers will code and extract data independently using the following categories:

- General: date of data extraction, author/s, article title, type of publication, country of origin, source of funding.

- Study characteristics: aims/objectives of the study, study design (including control groups), inclusion and exclusion criteria, recruitment and sampling methods (including unit of randomization and blinding), unit of allocation.
- Participants: population type and setting, inclusion and exclusion criteria, number of participants, baseline characteristics (e.g. age, gender, weight status, ethnicity, socioeconomic status, health/risk factors).
- Features of interventions: intervention setting, care provider, code BCTs based on the BCT taxonomy v1[27], code for the TIDieR[28] guidelines for reporting of interventions, theoretical basis.
- Measurement description: unit of measurement, type of measurement used (objective/subjective), additional outcomes measured (e.g. mood, life satisfaction), follow-up duration, and frequency.

When possible we will include results that have used intention-to-treat analysis and if effect sizes cannot be calculated further information will be sought from study authors.

Outcomes and Prioritisation

The primary outcomes are physical activity and sedentary behaviour. Physical activity outcomes may include objectively measured pedometer steps (per day/week), or accelerometer data. Cardiorespiratory fitness is also acceptable as an objective outcome of changes in physical activity (e.g. VO₂ max;[30]). Self-report physical activity outcomes may include walking (steps per day/week), vigorous, moderate, and/or light-intensity activity (minutes per day/week), proportion of participants achieving recommended physical activity levels (e.g. 150 minutes per week of moderate-intensity activity). Sedentary behaviour outcomes may include objectively measured sedentary behaviour or sitting time

using accelerometers or inclinometers. Self-report sedentary behaviour outcomes may include time spent watching TV, computer usage, total screen time (TV, computer, and phone/iPad use combined), or sitting (travel, relaxing, and workplace). This review will not include studies reporting only on changes in weight or wellbeing. Outcomes should be measured for a minimum of six months after intervention completion.

For the studies that meet the principal inclusion criteria the following outcomes will also be assessed if available: objectively measured Body Mass Index (BMI) and metabolic health (e.g. blood pressure, lipids, insulin resistance), subjective wellbeing using validated questionnaires such as life satisfaction (e.g. SWLS,[31]), health-related quality of life (e.g. MOS SF-36,[32]), positive and negative affect (e.g. PANAS,[33]), and self-efficacy (e.g. GSES,[34]).

Risk of bias in individual studies

Two reviewers will independently assess methodological quality of the studies using the Cochrane tool for assessing risk of bias[35]. This tool evaluates the quality of allocation sequence generation and concealment, blinding of participants, intervention providers and outcome assessors, completeness of data, the extent to which outcomes are selectively reported, and any other potential sources of bias. Each domain will be assigned a risk of bias category from the following: 'low risk for bias', 'unclear risk for bias' and 'high risk for bias'. Information on quality for each study will be accompanied by a description of the assessment and decision-making process.

Data Synthesis

Differences in effectiveness will be analysed according to outcomes and number and type of BCTs used[36]. Appropriate statistical techniques will be used for each type of continuous (weighted mean differences if outcomes are consistent or standard mean difference if different outcomes are used, with 95% confidence interval, CI) and dichotomous variable (risk ratios, with 95% CI). This review will also include a meta-analysis (if there is sufficient homogeneity of outcomes) to calculate pooled effect sizes across studies, using a random or fixed effect model depending on level of heterogeneity of intervention effects. Heterogeneity will be investigated using Chi Square (significance level: 0.1) and Higgins I^2 statistics, with high levels (as specified by guidance in the Cochrane Handbook for Systematic Reviews of Interventions) being considered suitable for subgroup analysis to determine the source of the heterogeneity.

Subgroups and Sensitivity Analysis

Analysis by subgroups will include (if possible or appropriate) the following: mode of delivery (e.g. face-to-face or internet-delivered); type of physical activity/sedentary behaviour measurement (self-report vs objective); BCTs; theoretical basis; targeting single versus multiple health behaviours; age of participants (over 65 vs under 65). Sensitivity analysis will be carried out to determine the effects of studies with a high risk of bias on the overall results with and without these studies.

If a meta-analysis is not possible a narrative synthesis of all relevant studies will be conducted supported by tables of study characteristics, participant and intervention details, settings, and outcomes.

Meta-bias

This review will assess study protocols for outcome reporting bias by judging whether authors have selectively reported outcomes using the Cochrane tool for assessing risk of bias[35]. Reporting bias will be analysed using funnel plots.

Confidence in cumulative evidence

The quality of evidence for primary outcomes will be assessed using the Grading of Recommendations Assessment, Development and Evaluation guidelines[37], which includes the following domains: design; study limitations; consistency; directness; precision; publication bias. Quality will be judged as 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), low (Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect), or 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)[38].

DISCUSSION

Inactive populations are a key intervention target as they are at risk of a host of negative health outcomes, even when controlling for physical activity levels. To date, no review of physical activity or sedentary behaviour interventions has focused exclusively on inactive populations, RCTs or coded BCTs exhaustively using the most recent BCT taxonomy v1. This review will be the first to evaluate the effectiveness of BCTs used in RCTs of physical activity and/or sedentary behaviour interventions in populations of inactive adults using the latest and most comprehensive taxonomies and reporting guidelines with a six-month

follow up. It is highly important to use the latest coding guidelines to assess the effectiveness of previous interventions, and to inform future interventions for people with inactive lifestyles before they develop chronic conditions that place such a large burden on individuals and society in terms of personal, social, and economic costs. This review also represents preliminary work for the development and evaluation of a future complex intervention, consistent with the guidelines from the Medical Research Council[39].

Contributions

All authors contributed to the development of the selection criteria. NH developed the search strategy. AC provided expertise on the physical activity literature, BCT taxonomy, and TIDiER framework considerations. DT provided expertise on systematic review methodology and the risk of bias assessment. NT contributed to the data extraction criteria. All authors read and provided feedback on the draft, and approved the final manuscript.

Competing interests

None

Funding sources/sponsor

The review is part of a doctoral thesis.

Data sharing statement

This systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 17th October 2014 (registration number: CRD42014014321). This protocol has been reported using the Preferred Reporting Items for

Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines. The final review and data will be published later.

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