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Workplace interventions for cardiovascular diseases: protocol of a systematic review and meta-analysis

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ABSTRACT

Introduction Cardiovascular diseases (CVDs) are the number one cause of death globally, impacting on public and private sectors. Current traditional interventions to prevent CVDs are mainly provided in healthcare centres and even when they are effective, they are not enough to reduce the rising prevalence; therefore, additional strategies are needed. Evidence suggests that health interventions in the workplace supply numerous benefits improving cardiovascular risk factor profiles in individuals. Hence, the aim of this systematic review and meta-analysis is to collate the evidence from randomised controlled trials, cluster randomised trials and quasi-experimental studies of workplace interventions to determine their effectiveness in terms of improving cardiovascular risk factors and preventing CVDs.

Methods and analysis EMBASE, PsycINFO, PubMed, the Cochrane Central Register of Controlled Trials, LILACS, Scopus, Web of Science, WHO International Clinical Trials Registry Platform, ClinicalTrials.gov and ProQuest Dissertations & Theses Global will be searched to include articles on workplace interventions in adults for CVDs events, cardiometabolic risk factors or behavioural risk factors. The study selection, data extraction, risk of bias and the assessment of the quality of the body of evidence will be conducted by two reviewers working in parallel and disagreements will be resolved by consensus or consultations with a third reviewer. Data synthesis will be done by meta-analysis using random-effects models when possible, otherwise the vote counting method will be applied. Statistical heterogeneity will be assessed by a χ^2 test and I^2 statistics. The quality of the body of evidence for each outcome will be assessed by applying the Grading of Recommendations, Assessment, Development and Evaluation approach.

Ethics and dissemination Ethical approval is not required for this systematic review protocol. The results of the systematic review will be published in a peer-reviewed journal and will be publicly available.

PROSPERO registration number CRD42021276161.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The protocol is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol checklist.
⇒ The proposed review will be conducted by applying the latest Cochrane recommendations and tools for systematic reviews of interventions.
⇒ The protocol incorporates a comprehensive search strategy to include all eligible studies that match the inclusion criteria, with no limit on language or date of publication.
⇒ The screening, selection, data extraction and quality assessment will be done by two reviewers independently. Any discrepancies will be resolved by consensus or consultations with a third reviewer.
⇒ Only individually randomised controlled trials, cluster randomised trials and quasi-experimental studies will be included, which could limit the evidence by excluding observational studies.

INTRODUCTION

The number of people with chronic diseases is growing due to modern lifestyles[1] coupled with an increase in life expectancy.[2] In this context, cardiovascular diseases (CVDs) have become the number one cause of death globally,[3] triggering a substantial impact on individuals' health and also affecting companies, in terms of loss of productivity, staff turnover, absenteeism and increased healthcare costs at the workplace.[2 4]

Several risk factors have shown an association with the development and clinical manifestation of CVDs, such as excess body weight and fat, an elevated blood pressure, disturbed blood glucose and an abnormal serum lipid profile,[3 5] all of them related to lifestyle behaviours,[6] including smoking, insufficient physical activity, unhealthy diet and excessive alcohol intake.[3 5] In addition, studies have found that work exposures are associated with the development of CVDs.[5] Job strain, effort-reward imbalance, long working hours, job insecurity,[7] shift work[8] and occupational noise[9] are considered to be possible risk factors for CVDs; however, the causal connection is still subject to debate.[7]

It is estimated that approximately 80% of premature ischaemic heart disease and stroke could be prevented by addressing modifiable risk factors.[4 10] Current traditional interventions to prevent CVDs are mainly provided in healthcare centres and even when they are effective, they are not enough to reduce the rising prevalence; therefore, additional strategies are needed. Most adults spend about half of their waking hours at work; therefore, the workplace offers an ideal environment to promote the health and well-being of employed populations.[2 7 11] Evidence suggests that health and wellness interventions in the workplace supply numerous benefits improving cardiovascular risk factor profiles in individuals.[12 13]

It is possible to classify workplace interventions for CVD into three groups, health promotion programmes, stress management and organisational prevention strategies.[14]

Health promotion programmes

These interventions are generally aimed at healthy workers, and workers at risk of CVD to help them make lifestyle changes to reduce traditional behavioural risk factors.[14] Workplace health promotion programmes offer the possibility of continually involving a group of workers to make a positive and sustainable change in their lifestyle choices,[12] but most of these initiatives address problems only from an individual perspective, regardless of the work exposures.[15]

Workplace health promotion programmes may improve workers' cardiovascular risk markers, increase their self-esteem and job satisfaction, reduce stress, strengthen skills for health protection and improve their health and sense of well-being.[4] These programmes have been shown also to improve work productivity, corporate image and reduce medical expenses.[4]

Stress management

Psychosocial factors play an important role in workers' health and well-being.[4] One of the key underlying psychosocial determinants of CVDs is stress,[3] and the most studied source of acute and chronic stress is work.[14]

Worksite stress management interventions are individual strategies to relieve or to cope with the stress that can be produced by environmental, physical or psychosocial sources.[14] Examples include conflict management, communication skills, assertiveness training, progressive muscle relaxation, mindfulness and meditation, among others.[14 16 17] These interventions have shown an effect on reducing some cardiovascular risk factors such as high blood pressure[18] and improving outcomes related to work stress and well-being.[19]

Organisational strategies

Recent approaches to improving health and well-being in the workplace propose diverting attention from individual risk factors to environmental/policy changes in the workplace.[20]

Organisational strategies are interventions that focus on reducing or eliminating the source of the problem in the workplace rather than reducing traditional cardiovascular risk factors and modifying people's perception and ability to manage stress.[14] Examples include balanced working time arrangements,[21] control of occupational noise,[22] strategic light/dark exposure,[8] training in technical skills,[23] extrinsic reward (monetary and non-monetary, esteem, career opportunity and others)[24] among others.

Health and wellness programmes in the workplace are effective in reducing modifiable cardiovascular risk factors in healthy individuals and those with CVDs.[12] In a review of 72 papers, it is estimated that worksite health and wellness interventions could produce 26% reductions in healthcare costs and 30% reductions in workers' compensation and disability management claims costs.[12] Workplaces offer the possibility to perform health interventions at the individual and environmental levels.[2] The detection and management of cardiovascular risk factors in the workplace are still unexploited,[25] and the optimal models for the implementation of worksite intervention programmes for CVDs have not yet been elucidated.[12] There are some prevention guidelines, but they have so far limited their recommendations to interventions that promote individual health-related behaviours.[10] This is partly explained because of the lack of comprehensive reviews about the effectiveness of worksite interventions on CVDs.[2]

Therefore, the aim of the systematic review and meta-analysis in this protocol is to collate the evidence from randomised controlled trials (RCTs), cluster randomised trials (CRTs) and quasi-experimental studies of workplace interventions to determine their effectiveness in terms of improving cardiovascular risk factors and preventing CVDs.

METHODS AND ANALYSIS

Protocol and registration

This protocol has been registered in PROSPERO and reported according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) guidelines[26] (online supplemental material 1). The study is planned to start in December 2021 and end in October 2022. Any amendment made to the protocol will be updated in PROSPERO and reported in the study results paper itself.

Eligibility criteria

For the study selection, the population, intervention, comparison and outcome framework will be applied.

Population

Studies conducted with adult populations (18 years of age and older), men and women regardless of their ethnicity and occupation, working full-time or part-time, with and without pre-existing CVDs will be included. Studies including individuals under 18 years old and non-working populations will be excluded.

Interventions

Any individual, group or organisational workplace/worksite intervention that can be classified as a health promotion programme, stress management or organisational strategy that seeks to prevent CVDs (clinical health events) or improve cardiovascular risk factors (cardiometabolic and behavioural risk factors).

'Workplace' or 'worksite' will be understood as 'any place where people are employed and receive a wage or salary for their labour. Worksites could differ in size, type, work schedule and location'.[27]

Comparators

Control groups that received no intervention, standard care or with other interventions not linked with the workplace.

Outcomes

The selected studies should include at least one of the following outcomes.

Primary outcomes

- Clinical Health Event: morbidity or mortality of ischaemic heart disease and cerebrovascular disease according to the International Classification of Diseases 11th Revision, 2019 (ICD11)[28] Studies that used older ICD revisions will be homologated according to the WHO equivalences.
- Cardiometabolic risk factors: changes to the measure of body weight and body mass index, body fat, high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol, triglycerides, systolic and diastolic blood pressure and blood glucose.[3 5]

For primary outcomes, only medical or professional reports will be included. Self-report measures of cardiovascular events or cardiometabolic risk factors will not be considered.

Secondary outcomes

- Behavioural risk factors: changes to diet (salt, and fruit and vegetable intake), levels of physical activity, smoking habits and alcohol consumption.[3]

Study design

Individually.

Search strategy

A comprehensive literature search will be conducted using the following electronic academic databases for potentially relevant records from published and unpublished studies regardless of the publication date or publication language:

- EMBASE via Ovid (1947 to 21 December 2021).
- PsycINFO via Ovid (1880 to 21 December 2021).
- PubMed (1946 to 21 December 2021).
- The Cochrane Central Register of Controlled Trials (until 21 December 2021).
- LILACS (1986 to 21 December 2021).
- Scopus (1788 to 21 December 2021).
- Web of Science (1945 to 21 December 2021).
- WHO International Clinical Trials Registry Platform (https://trialsearch.who.int/).
- ClinicalTrials.gov (www.clinicaltrials.gov).
- ProQuest Dissertations & Theses Global.

In addition, a hand search will be carried out to obtain records from the following sources: reference lists of included papers, citing reference searching of included papers, collections of the review authors and reference lists of previous systematic reviews.

The search will be conducted in English words, without a language filter. If an article is written in a different language than English or Spanish, the document will be translated into one of these languages.

An example of the proposed search strategy for EMBASE via Ovid is in online supplemental material 2. This search will be adapted to the other databases.

Selection of studies

The search results will be downloaded and added to the reference management software Endnote.[29] Afterwards, the study record references will be uploaded to the web-based software platform Covidence,[30] which will be used to support the selection, data extraction and risk of bias (RoB) assessment of the studies. Duplicates will be identified and deleted.

Two review authors will independently screen the titles and abstracts of the studies retrieved during the searches to identify relevant articles. Two reviewers will then assess in parallel the full texts of articles identified as being potentially eligible against the predefined inclusion criteria. Any discrepancies will be resolved by consensus or consultations with a third reviewer. For screening, selection, data extraction and quality assessment, the roles of the reviewers working in parallel and the third for consensus would be assumed by any of the authors. The process of study selection will be illustrated in a PRISMA-based flow diagram.[31]

If the full text of the article is not available in the databases used, a more extensive search will be conducted in other sources. If the full text is not found after that second search, authors will be contacted and asked for the document. References will be excluded if full text and contact information are not available after the extensive search.

Data extraction

Data will be extracted by two reviewers independently from the included studies. For the extraction, a structured data extraction form will be designed and piloted by all the reviewers on at least 10 references to be then applied in Covidence by the reviewers. Data will be extracted based on intention-to-treat if these results are available, however, we will go with per-protocol if they are not. The proposal extract form will include the following information.

1. General information: study ID, reviewer name, date of extraction, title, year (publication), lead author

name, email, address, country in which the study was conducted.
2. Study methods: aim of the study, study design, unit of allocation (by individuals or cluster/groups), single or multicentre, if multicentre number of recruiting centres, start date, end date, length of participants follow-up, ethical approval needed/obtained for study, details about allocation (randomisation), study funding sources, possible conflicts of interest for study authors, likelihood of reporting other biases, methods used to prevent and address missing data.
3. Participants: age (mean with SD, range), sex, if both sex percentages, race/ethnicity, comorbidities, inclusion criteria, exclusion criteria, method of recruitment of participants, total number of participants, clusters (number of clusters and the average (mean) size of each cluster), intracluster (or intraclass) correlation coefficient (ICC), the international standard classification of occupations, industrial setting (sector), full or part-time work.
4. Intervention: type of intervention (health promotion programmes, stress management, organisational prevention strategies), name of the intervention, timing of intervention, frequency, intervention protocol, staff qualification, resources for the intervention (eg, tools), integrity of implementation (compared with the plan), definition of control group.
5. Outcome: type of outcome (clinical health event, cardiometabolic risk factor, behavioural risk factor), outcome name, measurement tool or instrument, specific metric (eg, change in blood pressure from baseline to the postintervention time point), methods of aggregation, power (eg, power and sample size calculation, level of power achieved) timing of outcome measurements, adverse outcome.
6. Results of intervention and control groups: n° of participants randomly assigned, n° of participants included in the analysis (intervention and control), n° of participants who withdrew were lost to follow-up, or excluded, dichotomous data (table 2x2), mean (continuous data), SD (continuous data).
7. Results between-groups: risk ratio (RR) (95% CI), OR (95% CI), mean difference (95% CI), standardised mean difference (95% CI), other effect measurement, direction of effect (+, 0, −) (no statistical significance), key conclusions of the study authors.

Discrepancies on the extracted information will be resolved by consensus or by a third reviewer. Any update in the form will be registered on PROSPERO and reported in the systematic review itself.

Missing data will be requested from the corresponding author in the study; if we receive no response, the available data will be considered.

RoB of individual studies

Randomised Studies

Two reviewers will separately assess the RoB for each study at the outcome level by applying V.2 of the Cochrane tool for assessing the RoB in randomised trials, which comprises: bias arising from the randomisation process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, bias in selection of the reported result and other bias.[32]

For cluster-randomised trials, an adaptation of RoB2 for cluster-randomised trials will be used, which includes: bias arising from the randomisation process, bias arising from the identification or recruitment of participants into clusters, bias due to deviations from intended intervention, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result.[33]

Applying the RoB 2 criteria, each study result will be judged as 'low RoB', 'some concerns' or 'high RoB'

Quasi-experimental studies

For non-randomised studies of interventions, two reviewers will independently assess RoB using the ROBINS-I tool, considering seven domains: bias due to confounding (sex, age, socioeconomic status), bias in selection of participants into the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes and bias in selection of the reported result.[33]

With the results, an overall judgement on the RoB for the outcome will be reached. The levels will be 'low', 'moderate', 'serious' or 'critical'.

Data synthesis

First, a qualitative assessment of all the included studies will be done. The conceptual similarity of the included studies will be evaluated based on their population (sexes and age groups), interventions, controls, outcomes, design and follow-up. Then, similar trials will be pooled and plotted together in forest plots for a visual evaluation of any sign of heterogeneity.

Cluster-randomised trials will be analysed along with individually RCTs. Their sample sizes will be adjusted using the ICC.[32] If the trial does not report the ICC value, the ICC will be estimated from a similar trial. Otherwise, cluster-randomised trials that have not adjusted for clustering would not be included in the meta-analysis, although the results will be analysed separately or in the qualitative analysis.

The presence of statistical heterogeneity will be assessed by a χ^2 test, where a p value<0.10 provides evidence of heterogeneity of intervention effects. To quantify the inconsistency across studies, the I^2 statistic will be used, which 'describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error'.[32] An I^2 value greater than 75% will be interpreted as indicative of considerable heterogeneity.[32] If considerable heterogeneity is identified, it will be reported, and possible reasons will be explored through subgroup analysis.

Where applicable, a pairwise meta-analysis will be conducted according to the Cochrane Handbook for Systematic Reviews of Interventions.[32] The Cochrane Collaboration's software Review Manager (RevMan V.5) will be uised to analyse the data. As heterogeneity is anticipated, random-effects models will be used.

For dichotomous data, RR or OR with their 95% CI will be pooled. For continuous outcome data, mean differences (MD) or standardised MD with their 95% CI will be pooled.

To explore the possible existence of meta-biases a funnel plot will be created and examined for each group of studies.

If meta-analyses are not possible due to considerable heterogeneity across the group of studies (I^2 over 75%), the vote counting method will be applied, which is an alternative synthesis method, validated and recommended by Cochrane.[32] Those results will be represented in an effect direction plot.[34]

In addition to the primary analyses, subgroup analyses will be conducted if sufficient data are available. To evidence possible differences in the results by sex, subgroup analyses of studies with mainly male participants versus studies with mainly female participants will be carried out.

Considering the different physical and mental demands between jobs from different economic sectors, subgroup analysis will be executed by primary (extraction of raw materials), secondary (manufacturing) and tertiary (services) sectors.

Outcome measures could vary at different time points, due to adherence issues and the minimal time to develop CVDs or to improve or worsen cardiometabolic risk factors. That is why, if possible, subgroup analysis by the length of follow-up is planned (3 months vs 6 and 12 months, 6 months vs 12 months and 24 months or more).

Sensitivity analyses

To prove that our findings are not affected by arbitrary or unclear decisions, the following sensitivity analyses are planned:

- Analysis of only studies with an overall low RoB.
- Analysis of only studies with individuals between 18 and 65 years old.
- Analysis of only studies with individuals free of CVDs at the baseline.
- Analysis of only RCTs.
- Analysis of only studies with control groups with no intervention.

Other analyses will be included if during the review process other issues suitable for sensitivity analysis are identified.

Quality of the evidence

The assessment of the quality of the body of evidence for each outcome will be done by applying the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.[32] Two reviewers will independently judge the RoB, consistency of effect, imprecision, indirectness and publication bias of the evidence. Then, depending on those results, the reviewers will score the evidence as high certain of the evidence, moderate certain of the evidence, low certain of the evidence or very low certain of the evidence.[32] Any disagreement will be resolved by consensus or consultation with a third reviewer.

Summary of the finding will be produced using the GRADEpro Guideline Development Tool software in tables showing all our decisions about the certain of the evidence and their justifications.

Reaching conclusions

The conclusions of our systematic review will be based only on findings from the quantitative and qualitative syntheses of included studies. With our results, we will suggest priorities for future research and report the remaining uncertainties on the subject. The findings of the systematic review will be available through publication in a peer-reviewed journal.

Patient and public involvement

Patients or the public were not involved in the development of this protocol.

DISCUSSION

CVDs are a big threat to the health of the population, and even when governments are making some efforts, these have been not enough to reduce their increasing prevalence.[25] Most of the current strategies for CVDs are executed in healthcare provider centres such as general practice services (GPs) and hospitals, but complementary approaches propose the workplace as a convenient place for interventions for cardiovascular risk factors.[2]

Governments are primarily responsible for public health strategies; however, employers are also accountable for providing a safe and hazard-free workplace. Workplace exposures could harm and also improve physical and mental health.[4] Workplace health interventions offer employers the opportunities to promote a healthy work environment and reduce direct and indirect costs[35] and could support current strategies implemented by national and international health entities. The worksite is an ideal setting for the prevention and control of CVDs.[2] Some of the reasons for that are the length of time that most adults spend working[2 7 11] and the possibility to perform interventions on an individual, group and environmental scale.[2] Many companies are already providing wellness programmes in the workplace; however, these can be optimised. More robust and transparent research is needed to develop the optimal programme delivery models[12] considering the impact and effectiveness of the interventions.[4]

Budgets for health are limited, so investment decisions should be guided by the evidence on the effectiveness of interventions and considerations of their costs in

relation to these effects.[36] Currently, an essential source of evidence for public health policy decisions is systematic reviews with strong methods.[37] The number of studies on interventions in the workplace for lifestyles changes are increasing as well as the systematic reviews and meta-analysis that aim to summarise and analyse the results of those individual studies. However, most systematic reviews focused on limited types of interventions and outcomes. Furthermore, guidelines on how to conduct and report systematic reviews are constantly being developed.[38] Therefore, the systematic review of this protocol aims to define the effectiveness of a broad range of workplace interventions to prevent CVDs and improve cardiovascular risk factors, by incorporating the latest recommendations and the best practices for systematic reviews.

To avoid biases for publication status and language, we will include published and unpublished studies in all languages. Bias in the selection, data extraction, individual studies bias assessment and analysis will be reduced by incorporating two researchers working in parallel independently at each of these stages. The research team includes professionals from different areas, including psychology, occupational therapy, ergonomics, physiotherapy, medicine, biochemistry and researchers with broad experience in epidemiology and public health.

To make meta-analysis more feasible, just individually RCTs, CRTs and quasi-experimental studies will be included, which could limit the evidence by excluding observational studies. We have included CVD events (morbidity or mortality from ischaemic heart disease and cerebrovascular disease) as a primary outcome but considering the state of the art of research in worksite interventions for CVDs, we project to find a reduced number of studies with that outcome, which could limit the analysis. Other limitations detected in the process will be reported in the paper of the systematic review itself.

By providing this detailed protocol, we aspire to improve the understanding, the transparency and the value of our review methodology as well as detecting and informing deviances from the original plan.[26]

With the finding of this systematic review, we expect to later carry out a qualitative study to explore the experiences and opinions of employers, employees and experts about the workplace interventions here included. With the results of both studies, we aim to build a toolkit of workplace interventions for CVDs, including quantitative evidence of effectiveness and qualitative information about the applicability of each intervention.

Ethics and dissemination

Ethical approval is not required for this systematic review protocol. The results of the systematic review will be published in a peer-reviewed journal and will be publicly available.

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Contributors CMA is the guarantor of the review. CMA presented the idea for the systematic review. AB, JH and JR contributed to the development of the idea. CMA worked with AB, JH, JR, CTF, FPR, FCC and CSU to define search strategy, study eligibility criteria, create a plan for study selection, data extraction, risk of bias assessment, data synthesis and graduate the quality and strength of evidence. This manuscript was critically appraised and approved by all participating authors.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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