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# **BMJ Open**

# Health promotion at the workplace setting: a protocol for a systematic review of effectiveness and sustainability of current practice in Sub-Saharan African countries

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#### Title

Health promotion at the workplace setting: a protocol for a systematic review of effectiveness and sustainability of current practice in Sub-Saharan African countries

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#### **Word Count**

Health promotion at the workplace setting: a protocol for a systematic review of effectiveness and sustainability of current practice in Sub-Saharan African countries

#### **ABSTRACT**

#### Introduction

Countries in sub-Saharan Africa (SSA) are experiencing a growing disease burden due to non-communicable diseases (NCDs). Changing behavioural practices such as, diets high in saturated fat, salt and sugar, sedentary lifestyles, have been linked to this chronic disease. Health promotion at the workplace setting is considered effective in the fight against this burden of disease, and has been reported to yield numerous benefits. However, there is need to generate evidence on effective and sustainable workplace health promotion (WHP) specific to SSA. We aim to synthesize the current literature on WHP in countries in SSA focusing on effectiveness and sustainability of the interventions.

# Methods and analysis

We will conduct a systematic review of published studies in SSA up to 30<sup>th</sup> September 2018. We will search the following databases: EMBASE, MEDLINE, PubMed, Web of Science, Scopus, ProQuest, and CINAHL. Two reviewers will independently screen potential articles for inclusion and disagreements will be resolved by consensus. We will appraise the quality and risk of bias of included studies using tools from Cochrane handbook for systematic reviews of interventions. We will carry out a descriptive synthesis of the results obtained to establish how effective and sustainable the interventions were. We will conduct a thematic analysis to identify the main focus areas of current interventions. This systematic review protocol has been prepared according to the Preferred Reporting Items for Systematic reviews and Meta- analyses for Protocols (PRISMA-P) 2015 statement.

#### **Ethics and dissemination**

This study does not require ethics approval. We will disseminate the results of this review through peer-reviewed publications and conference presentations.

#### Trial registration

This review protocol was submitted for registration in the PROSPERO International Prospective Register of systematic reviews on the 3<sup>rd</sup> of October, 2018.

## Keywords

Health promotion, workplace, systematic review, effectiveness, sustainability, Africa.

#### Strengths and limitations of this study

• This is a comprehensive review that examines multiple workplaces, across various industries in the sub- Saharan African region.

- The review search dates cover a long period of time providing for a comprehensive search for relevant articles.
- The methods of this review have been outlined in a protocol guarding against arbitrary decision making in the review process.
- Our search strategy is restricted by language where studies included will be limited to those that are published in the English language.
- The inclusion of diverse study designs, reporting on different intervention types
  makes this a heterogeneous study that may limit the extent to which the results are
  analysed.

# INTRODUCTION

#### Rationale

Globally, 41 million deaths (71% of all deaths) were due to non-communicable diseases (NCDs) [1]. The majority of these deaths were caused by: cardiovascular disease (44%); cancer (22%); chronic respiratory disease (9%); and diabetes (4%) [1]. In 2014, World Health Organisation (WHO) estimated a 17% increase of deaths from NCDs globally and a 27% increase for the African region, equivalent to 28 million additional deaths by 2030 [2]. WHO [3] estimated that by 2020, NCDs will be as prevalent as communicable diseases in sub-Saharan Africa (SSA). Already, NCDs are the main cause of adult deaths in Mauritius, Namibia and Seychelles [2].

The leading risks factors associated with the global increase in mortality are high blood pressure (responsible for 13% of death globally), tobacco use (9%), high blood glucose (6%), physical inactivity (6%), and overweight and obesity (5%) [4]. In SSA, changing behavioural practices has been linked to the chronic disease burden and the changes attributed to structural factors such as urbanisation, industrialisation [5], and food market globalisation [6]. The reversal or mitigation of this trend in SSA calls for the application of effective principles and practices of health promotion [7] and the mainstreaming of health promotion [8]. The current WHO health promotion strategy for the African region petitions governments to go beyond the focus on health behaviour which puts the burden of health improvement mainly on the individual, and address environmental, legislative, and policy changes [9].

Health promotion is described as "the process that enables people to increase control over (health determinants), and to improve their health" [10]. The 1997 Jakarta declaration affirmed that health promotion strategies were indeed effective in addressing health risk

factors [11], particularly lifestyle related risk factors which can be modified to prevent disease [3].

Nyamwaya [12] points out that the use of health promotion as a means of increasing societal responsibility for health now exists in all African countries. Laws and policies that facilitate adoption of healthy lifestyles and disease prevention such as tobacco legislation, have been put in place [12]. A focus on settings for health promotion has enabled the creation of supportive environments through the development of relevant, practical health promotion interventions that address a full range of health determinants at each setting [13]. The introduction of the settings approach for health promotion followed the 1986 Ottawa Charter's declaration that "health is created and lived by people within the settings of their everyday life, where they learn, work, play and love"[10]. The settings approach has translated to the utilisation of "the health potentials inherent in the social and institutional settings of everyday life" [14]. Settings identified in the Ottawa charter included: prisons, schools, universities, market places, hospitals, islands, districts, cities, regions and workplaces [10].

The workplace as a health promotion setting presents an opportunity to reach a large number of people within the adult population [15]. The working population is one that would not normally be engaged in organised health improvement initiatives [16]. WHO has estimated that workers are estimated to represent half of the world's population [17] and a majority of them spend a substantial portion of their waking hours at work [18]. Workplace health promotion (WHP) interventions are defined as employer initiatives directed at protecting the health of employees and thereby improving their productivity [19]. Beyond individual factors, a health promoting workplace adopts an ongoing process that addresses the multiple determinants of workers' health such as: organizational, environmental, and societal and community factors [16, 20-26].

WHP can help contain the current epidemic of lifestyle-related diseases [27]. When properly designed and implemented, WHP initiatives have been associated with multiple benefits such as: workers' positive lifestyle changes [16, 27], positive return on investment for the organisation [28-30], improved productivity and employee performance [31, 32], reduced medical costs [28, 31], reduced absenteeism costs [28, 33], lowered disease prevalence [34, 35], and increased organizational competitiveness [16]. The initiatives have also been observed to produce happier and loyal employees [30, 36-39]. Nonetheless, it is notable that reviews for health promotion interventions have limited their focus to individual interventions, leaving out interventions that focus on environmental, structural and social

determinants of health [38, 40]. With limited research on interventions focusing on multiple health determinants, employers have also shown reluctance to offer sufficiently comprehensive WHP programs because they are not fully persuaded of their benefits, and they also contend that there are few best practices for them to emulate [16, 41]. In addition, most of the published research in WHP has been reported from developed countries and there is scarcity of WHP reported in the low and middle income countries [31].

In SSA, there is a gap in the provision of evidence-based health promotion interventions at the workplace [42]. There is a need to generate evidence to justify strategic WHP choices and "best buy" interventions [7, 12]. A systematic review that synthesizes multiple published studies on WHP in SSA will help establish evidence for WHP effectiveness and sustainability specific to this region. With evidence on effective and sustainable WHP practice, a scale up of the implementation of effective, feasible interventions within SSA will be made possible. We therefore propose to carry out a systematic review that aims to synthesise published studies on current WHP practice in countries in Sub Saharan Africa focusing on effectiveness and sustainability of the interventions.

#### **Objective**

To conduct a comprehensive synthesis of the current WHP practice in countries within the Sub Saharan Africa focusing on effectiveness and sustainability of interventions, all through until 30<sup>th</sup> September 2018.

#### **Review Questions**

We aim to address the following questions:

- 1. How effective are the WHP interventions in countries within Sub Saharan Africa?
- 2. How sustainable is WHP in countries within Sub Saharan Africa?

#### **METHODS**

This review protocol was submitted for registration in the PROSPERO International Prospective Register of systematic reviews on the 3<sup>rd</sup> of October, 2018. The review has been prepared according to the Preferred Reporting Items for Systematic reviews and Meta-Analysis Protocols (PRISMA-P) 2015 statement [43].

In synthesis and description of current WHP practice in Sub Saharan Africa, the review will address the six priority action areas of the Ottawa Charter declaration [10]. Evidence of effectiveness of the WHP interventions will be limited to assessing whether set out

intervention goals were actually achieved as presented in the research papers. In line with the WHO framework for WHP, aspects of sustainability will also be assessed from the synthesized literature. Assessment for sustainability will be guided by; full integration or institutionalisation of a program within an organisation, inclusion of capacity building in the workplace, community involvement/participation in the program and maintenance of health benefits from the program [44, 45].

#### **Inclusion Criteria**

- a) Intervention type: health promotion at the workplace setting. Studies that do not report on WHP as whole will be excluded; for example, studies reporting on a standalone aspect such as safety, hospitals or treatment.
- b) Setting: workplaces within Sub- Saharan Africa.
- c) Publication: peer reviewed primary studies whose full text is publicly available. We will review the reference lists from past reviews and other non-primary studies for suitable studies that would meet the inclusion criteria. Duplicate publications of the same material will be excluded. For studies published in multiple journals, the most recent version will be considered.
- d) Study designs: all study designs will be included since HP interventions are evaluated using a wide variety of approaches and study designs [46-48].
- e) Language: English.

#### **Data Sources and Search Strategy**

We will search the following databases: Excerpta Medica Database (Embase), Medical Literature Analysis and Retrieval System Online (MEDLINE), PubMed, Web of Science, Scopus, ProQuest, Cumulative Index to Nursing and Allied Health Literature (CINAHL).

Table 1 shows the search strategy that we will use and we will adapt it to the different databases.

Table 1 Search strategy

#### Search terms

"Workplace" OR "occupational" OR "worksite" OR "organi\*ational" OR "industrial" OR "work" OR "worker" OR "employee"

AND

"Health\*" OR "health promotion" OR "Wellness" OR "Well-being" "wellbeing" OR

"health management" OR " Health protection" OR "

AND

"Program\*" OR "framework" OR "model" OR "intervention" OR "initiative"

AND

"Angola" OR "Benin" OR "Botswana" OR "Burkina Faso" OR "Burundi" OR "Cabo Verde" OR "Cameroon" OR "Central African Republic" OR "Chad" OR "Comoros" OR "Congo" OR "Democratic Republic of Congo" OR "Côte d'Ivoire" OR "Equatorial Guinea" OR "Eritrea" OR "Ethiopia" OR "Gabon" OR "Gambia" OR "The Gambia" OR "Ghana" OR "Guinea" OR "Guinea-Bissau" OR "Kenya" OR "Lesotho" OR "Liberia" OR "Madagascar" OR "Malawi" OR "Mali" OR "Mauritania" OR "Mauritius" OR "Mozambique" OR "Namibia" OR "Niger" OR "Nigeria" OR "Rwanda" OR "São Tomé and Principe" Or "Senegal" OR "Seychelles" OR "Sierra Leone" OR "Somalia" OR "South Africa" OR "South Sudan" OR "Sudan" OR "Swaziland" OR "Tanzania" OR "Togo" OR "Uganda" OR "Zambia" OR "Zimbabwe" OR "Africa" OR "sub-Saharan Africa"

AND NOT "Occupational Health and Safety"

### **Study Records**

# Data Management

We will import all identified studies to EndNote X8 software where duplicate records will be identified and excluded from record. In our study selection process, we will be guided by the inclusion criteria. We will use Rayyan QCRI [49], an internet based program to assist the screening and selection of studies.

#### Screening

Two reviewers (MW and LB) will independently select all studies that meet the inclusion criteria. The reviewers will screen the titles and abstracts of the studies for relevance based on the criteria set. They will then screen the full texts of potential eligible studies for inclusion and relevance. Any disagreements will be resolved by the two reviewers by consensus. The details of the excluded studies will be documented and presented in a flow chart.

#### Data Extraction

Using a predetermined data extraction sheet, two reviewers will independently extract data from final full texts of eligible studies and any inconsistencies will be resolved by consensus.

#### **Data Items**

We will extract the following data from our final selection: details of publication (author, author country of affiliation, year of publication, title of article, name of journal study published in), geographical location of intervention, study context (workplace/ industry type, single or multiple organisations studied), subjects of research (role/description of target population, if study is gender specific, employment type of participants, profession), aim of the study, program/intervention priority area focus, sustainability aspects of program, methods, study outcomes, study conclusions, limitations and future research areas proposed.

#### Risk of Bias and Quality Appraisal

Two reviewers will independently rate the quality and risk of bias of included studies using tools from Cochrane handbook for systematic reviews of interventions and the results will be presented in a table format. To assess the quality of studies included, the reviewers will use the criteria from Cochrane Handbook for Systematic reviews on international version 5.1.0 [50]. To assess the risk of bias, the reviewers will use the Cochrane tool (table 2) commonly used for Random Controlled Trials adapting it to this review as per the guidelines [51]. We will assign a judgement of 'low', 'high' or 'unclear risk' of bias in the review authors' judgement column. We will report a summary assessment of risk of bias showing the proportion of information that comes from selected studies at low, unclear or high risk of bias for each item in the tool.

Domain	Support for	Review authors'			
	Judgement	judgement			
Selection bias					
Random sequence generation: selection bias					
(biased allocation to interventions) due to					
inadequate generation of a randomised sequence.					
Allocation concealment: selection bias (biased					
allocation to interventions) due to inadequate					
concealment of allocations prior to assignment.					
Performance bias	1	1			
Blinding or participants and personnel:					

performance bias due to knowledge of the							
allocated interventions by participants and							
personnel during the study.							
Blinding of outcome assessment: detection bias							
due to knowledge of the allocated interventions by							
outcome assessors.							
Attrition bias							
Incomplete outcome data: attrition bias due to							
amount, nature or handling of incomplete outcome							
data.							
Reporting bias							
Selective reporting: reporting bias due to selective							
outcome reporting.							
Other bias							
Bias due to problems not covered elsewhere in the							
table.							

#### **Data Synthesis**

We will use descriptive analysis to present and discuss the studies by geographical regions, regional spread of study authors, number of studies per year, journals that have published these studies, type of workplaces studied, and description of research participants, methods and study outcomes. We will draw out summaries and comparisons from data extracted.

The reviewers will carry out a thematic analysis to present and discuss the Ottawa Charter priority action areas reflected in the synthesized studies with the main themes across different workplace types, time periods and geographical distribution presented and discussed. We will also run a comparison of these aspects across the four country classification by income. In addition to the manual coding and analysis, we will complement the thematic analysis with the use of Leximancer Version 4 software.

#### **Patient and Public Involvement**

We will not involve patients and the public in this review.

#### Reporting this review

We will report the systematic review according to the checklist of items to include when reporting a systematic review as per the PRISMA 2009 statement [52]. We will present a flow diagram to show the study selection process, specifying reasons for exclusion at each stage. The study quality appraisal tool will be availed as online supplementary material.

#### Potential amendments

In case of any changes to this protocol, we will outline the details of the changes in the final report. However, no further amendments to this protocol are foreseen.

#### Conclusion

To heed to the WHO's clarion call to implement and scale—up effective health promotion interventions in Africa [2], there is a need to assess what has been effective and sustainable in the context of the workplace setting. There is need to "...establish what has worked...and what should be done here and now, to improve the health of the people of this Region" [2]. Previous reviews on WHP focused on the effectiveness of specific interventions; for example, on physical activity [53, 54], nutrition promotion [55] and smoking cessation [37]. Through this comprehensive review, we will provide new insights by presenting a holistic outline of current WHP practice in sub-Saharan Africa, with a focus on effectiveness and sustainability.

#### **Ethics and dissemination**

Since systematic reviews are based on available published data, this review will therefore not require any formal ethical approval. We will disseminate the results of this systematic review through peer-reviewed publications and conference presentations.

#### **Authors' Contributions**

MNW conceived the paper and wrote the first draft. BZD and JLV provided revisions to the manuscript. All authors read and approved the final manuscript. MNW is the guarantor of the review.

## **Data sharing Statement**

All data for this manuscript are included in the submission.

#### **Funding Statement**

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#### **Competing interests Statement**

None declared.

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Developing criteria for including non-randomized studies > Table 13.2.a: List of study design features (studies with allocation to interventions at the Table 13.2.a: List of study design features (studies with allocation to interventions at the individual level)												
	RCT	Q-RCT	NRCT	СВА	PCS	RCS	HCT	NEC	CC	XS	ВА	CR/CS
Was there a comparison:								•://b				
Between two or more groups of								<u> 3</u> .				
participants receiving different								mjopen.bm <del>f.</del> com/				
nterventions?	Y	Υ	Y	Υ	Y	Υ	Υ	<u>≌</u> Y	Υ	Υ	N	N
Within the same group of participants over time?	Р	Р	N	V	N	N	N	ja,	N	N	Υ	N
·	r	г	IN	'//	N N	IN	IN	 8	IN	IN	ī	IN
Were participants allocated to groups								Ž				
oy:	V	N	N	N.	NI NI	N.	N.	9.	N.	NI.		
Concealed randomization?	Y	N Y	N	N	N	N	N	orfa <i>f</i> ril <sup>A</sup> 9,	N	N	na	na
Quasi-randomization?	N N	Y N	N Y	N P	N N	N N	N	₹.	N N	N N	na	na
By other action of researchers? Time differences?	N	N N	r N	N N	N N	N	Y	1ΣΙ	N N	N N	na	na
Location differences?	N	N N	IN P	P	N P	IN P	P	28			na	na
Treatment decisions?	N	N	r N	P	P	P	N	924 24	na N	na P	na na	na na
Participants' preferences?	N	N	N	P	P	, P	N	282 <b>⊈</b> b₹	N	P	na	na
On the basis of outcome?	N	N	N	N	N	N	N	ġ,	Y	P	na	na
Some other process? (specify)	.,	,,		.,	11	.,	11	guest.	•	•	Πα	Πα
Which parts of the study were prospective:								:. Protected				
Identification of participants?	Υ	Υ	Υ	Р	Υ	N	P*	e 2}⁄	N	N	Р	Р
Assessment of baseline and		•	-	•	•		-	e d	• •		-	-
allocation to intervention?	Υ	Υ	Υ	Р	Υ	N	P*	₹	Ν	N	na	na
Assessment of outcomes?	Υ	Υ	Υ	Р	Υ	Р	Р	čopyright.	Ν	N	Р	Р

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Generation of hypotheses?	Υ	Υ	Υ	Υ	Υ	Υ	Υ	270	Р	Р	Р	na
On what variables was comparability between groups assessed:								)50 oı				
Potential confounders?	Р	Р	Р	Р	Р	Р	Р	75	Р	Р	Ν	na
Baseline assessment of outcome variables?	Р	Р	Р	Υ	Р	Р	Р	2 Maj	N	N	N	na

Y=Yes; P=Possibly; P\*=Possible for one group only; N=No; na=not applicable. NB:. Note that 'possibly' is used in the table to indicate cells where either 'Y' or 'N' may be the case. It should not be used as a response option when applying the checklist; if uncertain, the response should be 'can't tell' (see Box 13.4.a).

RCT=Randomized controlled trial; Q-RCT=Quasi-randomized controlled trial; NRCT=Non-randomized controlled trial; CBA=Controlled before-and-ager study; PCS=Prospective cohort study; RCS=Retrospective cohort study; HCT=Historically controlled trial; NCC=Nested case-control study; CC=Case-control study; XS=Cross-sectional study; BA=Before-and-after comparison; CR/CS=Case report/Case series

Table 13.2.b: List of study design features (studies with allocation to interventions at the group

Table 13.2.b: List of study design features (studies with allocation to interventions at the group leve

	CIRCT	CIQ-RCT	CINRT	CITS	CChBA	) ITS	ChBA	EcoXS
Was there a comparison:			),			ope		
Between two or more groups of clusters receiving different interventions?	Y	Y	Y	Υ	Υ	n.bmj. N	N	Υ
Within the same group of clusters over time?	Р	Р	N	Υ	N	og Y	Υ	N
Were clusters allocated to groups by:						n/ on		
Concealed randomization?	Υ	N	Ν	N	N	₽ N	N	N
Quasi-randomization?	N	Υ	N	N	N	N N N Y N P P  April 19, 2024 by gues	N	N
By other action of researchers?	N	N	Υ	Р	P	N $^{\overline{\Theta}}$	N	N
Time differences?	N	N	Ν	Υ	Υ	202 Y	Υ	N
Location differences?	N	N	Р	Р	Р	N ę.	N	Р
Policy/public health decisions?	Na	na	Р	Р	Р	ဖွဲ့ P	na	na
Cluster preferences?	Na	na	Р	Р	Р	est P	na	na
Some other process? (specify)						Pro		
Which parts of the study were prospective:						otect		
Identification of participating clusters?	Υ	Υ	Υ	Р	Р	cted_P	Р	N
Assessment of baseline and allocation to						by c		
intervention?	Υ	Υ	Υ	Р	Р	P Copyrig	Р	N
						yright		

					)   o			
Assessment of outcomes?	Υ	Υ	Υ	Р	Р	P	Р	N
Generation of hypotheses?	Y	Υ	Υ	Υ	Υ	S Y	Υ	Р
On what variables was comparability between groups assessed:					on 22			
Potential confounders?	Р	Р	Р	Р	P §	Р	Р	Р
Baseline assessment of outcome variables?	Р	Р	Р	Υ	Y	Υ	Υ	N

Note that 'cluster' refers to an entity (e.g. an organization), not necessarily to a group of participants; 'group' refers to one or more clusters; see Box 13.4.a.

Note that 'possibly' is used in the table to indicate cells where *either* 'Y' or 'N' may be the case. It should not be used a response option when applying the checklist; if uncertain, 'can't tell' should be used (see Box 13.4.a).

Y=Yes; P=Possibly; P\*=Possible for one group only; N=No; NR=Not required. CIRCT=Cluster randomized controlled trial; CIQ-RCT=Cluster quasi-randomized controlled trial; CINRT=Cluster non-randomized controlled trial; CITS=Controlled interrupted time series (Shadish 2002); CChBA=Controlled cohort before and after study (Shadish 2002); EcoXS=Ecological cross-sectional study.

# Box 13.4.a: User guide for data collection/study assessment using checklist in Table 13.2.a or Table 3.2.a

Note: Users need to be very clear about the way in which the terms 'group' and 'cluster' are used in these tables. Table 13.2.a only refers to groups, which is used in its conventional sense to mean a number of individual participants. With the exception of allocation on the basis of outcome, 'group' can be interpreted synonymously with 'intervention group'. Table 13.2.b refers to both clusters and groups. In this table, 'clusters' are typically an organizational entity such as a family health practice, or administrative area, not an individuals As in Table 13.2.a, 'group' is synonymous with 'intervention group' and is used to describe a collection of allocated units, but in Table 13.2.b these units are clusters rather than individuals. Furthermore, although individuals are nested in clusters, a cluster does not necessarily represent a fixed collection of individuals. For instance, in cluster-allocated studies, clusters are often studied at two or more time-points periods) with different collections of individuals contributing to the data collected at each time-point.

Was there a comparison?

Typically, researchers compare two or more groups that receive different interventions; the groups may be studied over the same time period, or over different time periods (see below). Sometimes researchers compare outcomes in just one group but at two time points. It is also possible that researchers may have done both, i.e. studying two or more groups and measuring outcomes at more that one time-point.

Were participants/clusters allocated to groups by?

These items aim to describe how groups were formed. None will apply if the study does not compare two or more groups of subjects. The information is often not reported or is difficult to find in a paper. The items provided cover the main ways in which groups may be formed. More than one option may apply to a single study, although some options are mutually exclusive (i.e. a study is either randomized or not).

- Randomization: Allocation was carried out on the basis of truly random sequence. Such studies are covered by the standard guidance elsewhere in this *Handbook*. Check carefully whether allocation was adequately concealed until subjects were definitively recruited.
- Quasi-randomization: Allocation was done on the basis of a pseudo-random sequence, e.g. odd/even hospital number date of birth, alternation. Note: when such methods are used, the problem is that allocation is rarely concealed. These studies are often included in systematic reviews that only include randomized trials, using assessment of the risk of bias to distinguish them from properly randomized trials.
- By other action of researchers: This is a catch-all category and further details should be noted if the researchers reported hem. Allocation happened as the result of some decision or system applied by the researchers. For example, subjects managed in particular 'units' of provision (e.g. wards, general practices) were 'chosen' to receive the intervention and subjects managed in other units to receive the control intervention.
- Time differences: Recruitment to groups did not occur contemporaneously. For example, in a historically controlled study subjects in the control group are typically recruited earlier in time than subjects in the intervention group; the intervention is then introduced and subjects receiving the intervention are recruited. Both groups are usually recruited in the same setting. If the design was under the control of the researchers, both this option and 'other action of researchers' must be ticked for a single study. If the design 'came about' by the introduction of a new intervention, both this option and 'treatment decisions' must be ticked for a single study.
- Location differences: Two or more groups in different geographic areas were compared, and the choice of which area (3) received the intervention and control interventions was not made randomly. So, both this option and other action of researchers could be ticked for a single study.
- Treatment decisions: Intervention and control groups were formed by naturally occurring variation in treatment decisions. This option is intended to reflect treatment decisions taken mainly by the clinicians responsible; the following option is intended to reflect treatment decisions made mainly on the basis of subjects' preferences. If treatment preferences are uniform for particular provider 'units', or switch over time, both this option and 'location' or 'time' differences should be ticked.
- Patient preferences: Intervention and control groups were formed by naturally occurring variation in patients' preferences. This option is intended to reflect treatment decisions made mainly on the basis of subjects' preferences; the previous option is intended to reflect treatment decisions taken mainly by the clinicians responsible.
- On the basis of outcome: A group of people who experienced a particular outcome of interest were compared with a gioup of people who did not, i.e. a case-control study. Note: this option should be ticked for papers that report analyses of multiple risk factors for a particular outcome in a large series of subjects, i.e. in which the total study population is divided into those who experienced the outcome and those who did not. These studies are much closer to nested case-control studies than cohort studies, even when longitudinal data are collected prospectively for consecutive patients.

Additional options for cluster-allocated studies.

\_ocation differences: see above.

Policy/public health decisions: Intervention and control groups were formed by decisions made by people with the responsibility for implementing policies about public health or service provision. Where such decisions are coincident with clusters, on where such people are the researchers themselves, this item overlaps with 'other action of researchers' and 'cluster preferences'.

Cluster preferences: Intervention and control groups were formed by naturally occurring variation in the preferences of lusters, e.g. preferences made collectively or individually at the level of the cluster entity. ≤

Which parts of the study were prospective?

These items aim to describe which parts of the study were conducted prospectively. In a randomized controlled trial, altour of these items would be prospective. For NRS it is also possible that all four are prospective, although inadequate detail may be presented to discern this, particularly for generation of hypotheses. In some cohort studies, participants may be identified, and have been allocated to treatment retrospectively, but outcomes are ascertained prospectively.

On what variables was comparability of groups assessed?

These questions should identify 'before-and-after' studies. Baseline assessment of outcome variables is particularly useful when outcomes are measured on continuous scales, e.g. healthstatus or quality of life.

Response options

Try to use only 'Yes', 'No' and 'Can't tell' response options. 'N/a' should be used if a study does not report a comparison between groups.

Reeves BC, Deeks JJ, Higgins JPT, Wells GA. Chapter 13: Including non-randomized studies. In: Higgins JPT, Green (editors), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from <a href="https://www.handbook.cochrane.org">www.handbook.cochrane.org</a>.

# Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

# Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-P reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

•	,		
		Reporting Item	Page Number
Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
Update	<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	n/a not an update
	<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the guarantor of the review	10
	<u>#4</u>	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a not an amendment

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	10
Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	10
Role of sponsor or funder	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a- has no funder
Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	3-5
Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6
Information sources	<u>#9</u>	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6
Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6-7
Study records - data management	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records and data throughout the review	7
Study records - selection process	#11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	7
Study records - data collection process	<u>#11c</u>	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	7
Data items	#12 For pe	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned er review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	7-8

		data assumptions and simplifications	
Outcomes and prioritization	<u>#13</u>	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5,9
Risk of bias in individual studies	<u>#14</u>	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8-9
Data synthesis	<u>#15a</u>	Describe criteria under which study data will be quantitatively synthesised	9
	<u>#15b</u>	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's T)	n/a
	<u>#15c</u>	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	9
	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	9
Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	8-9
Confidence in cumulative evidence	<u>#17</u>	Describe how the strength of the body of evidence will be assessed (such as GRADE)	8-9

The PRISMA-P checklist is distributed under the terms of the Creative Commons Attribution License CC-BY 4.0. This checklist can be completed online using <a href="https://www.goodreports.org/">https://www.goodreports.org/</a>, a tool made by the <a href="EQUATOR Network">EQUATOR Network</a> in collaboration with <a href="Penelope.ai">Penelope.ai</a>

# **BMJ Open**

# Health promotion at the workplace setting: a protocol for a systematic review of effectiveness and sustainability of current practice in low- and middle- income countries.

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Secondary Subject Heading:	Occupational and environmental medicine
Keywords:	PUBLIC HEALTH, Health Promotion, sustainability, workplace, effectiveness, low- and middle- income countries

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#### Title

Health promotion at the workplace setting: a protocol for a systematic review of effectiveness and sustainability of current practice in low- and middle- income countries.

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#### **Word Count**

Health promotion at the workplace setting: a protocol for a systematic review of effectiveness and sustainability of current practice in low- and middle- income countries.

#### **ABSTRACT**

#### Introduction

LMICs are experiencing a growing disease burden due to NCDs. Changing behavioural practices such as, diets high in saturated fat, salt and sugar and sedentary lifestyles, have been associated with the increase in NCDs. Health promotion at the workplace setting is considered effective in the fight against NCDs and has been reported to yield numerous benefits. However, there is a need to generate evidence on the effectiveness and sustainability of WHP practice specific to LMICs. We aim to synthesize the current literature on WHP in LMICs focusing on interventions effectiveness and sustainability.

# Methods and analysis

We will conduct a systematic review of published studies from LMICs up to the 31st of March 2019. We will search the following databases: EMBASE, MEDLINE, PubMed, Web of Science, Scopus, ProQuest, and CINAHL. Two reviewers will independently screen potential articles for inclusion and disagreements will be resolved by consensus. We will appraise the quality and risk of bias of included studies using two tools from the Cochrane handbook for systematic reviews of interventions. We will present a narrative overview and assessment of the body of evidence derived from the comprehensive review of the studies. The reported outcomes will be summarised by study design, duration, intensity / frequency of intervention delivery, and by the six priority health promotion action areas set out in the Ottawa Charter. We will conduct a thematic analysis to identify the focus areas of current interventions. This systematic review protocol has been prepared according to the Preferred Reporting Items for Systematic reviews and Meta- analyses for Protocols (PRISMA-P) 2015 statement.

#### **Ethics and dissemination**

This study does not require ethics approval. We will disseminate the results of this review through peer-reviewed publications and conference presentations.

Trial registration number: (PROSPERO: CRD42018110853).

# **Keywords**

Health promotion, workplace, systematic review, effectiveness, sustainability, LMICs.

#### Strengths and limitations of this study

 This will be a comprehensive review that examines multiple workplaces, across various industries in LMICs.

- The review search dates and search strategy will ensure a comprehensive search for relevant articles.
- The methods of this review have been outlined in a protocol to guard against arbitrary decision making in the review process.
- Our search strategy is restricted by language; studies included will be limited to those in English.
- The inclusion of studies with diverse study designs, intervention types and workplace settings makes this a broad, heterogeneous study; this may limit the depth of the analysis.

# INTRODUCTION

#### Rationale

Globally, 41 million deaths (71% of all deaths) were due to non-communicable diseases (NCDs) [1]. The majority of these deaths were caused by: cardiovascular disease (44%); cancer (22%); chronic respiratory disease (9%); and diabetes (4%) [1]. In low- and middle- income countries (LMICs) 85% of premature deaths are attributable to NCDs [2]. In 2014, the World Health Organisation (WHO) estimated a 17% increase of deaths from NCDs globally and a 27% increase for the African region, equivalent to 28 million additional deaths by 2030 [3]. In sub- Saharan Africa (SSA) region, where majority of the LMICs are located, the WHO [4] estimated that by 2020, NCDs will be as prevalent as communicable diseases. Already, NCDs are the main cause of adult deaths in Mauritius, Namibia and Seychelles [3].

The leading risks factors associated with the global increase in mortality are high blood pressure (responsible for 13% of death globally), tobacco use (9%), high blood glucose (6%), physical inactivity (6%), and overweight and obesity (5%) [5]. Changes in lifestyle; adoption of sedentary behaviours and nutrition transition have been identified as some of the modifiable risk factors that increase the risk of NCDs [2]. The reversal or mitigation of this trend calls for the application of effective principles and practices of health promotion [6] and the mainstreaming of health promotion [7]. The current WHO strategy towards the prevention of NCDs incorporates the reduction of health risks and promotion of healthy lifestyles through health promotion [8].

Health promotion is described as "the process that enables people to increase control over (health determinants), and to improve their health" [9]. The 1997 Jakarta declaration affirmed

that health promotion strategies were indeed effective in addressing health risk factors [10], particularly lifestyle related risk factors which can be modified to prevent disease [4].

Globally, the health promotion approach has been adopted by many countries including the LMICs. For instance, Nyamwaya [11] points out that the use of health promotion as a means of increasing societal responsibility for health now exists in all African countries. Laws and policies that facilitate adoption of healthy lifestyles and disease prevention such as tobacco legislation, have been put in place [11]. A focus on settings for health promotion has enabled the creation of supportive environments through the development of relevant, practical health promotion interventions that address a full range of health determinants at each setting [12]. The introduction of the settings approach for health promotion followed the 1986 Ottawa Charter's declaration that "health is created and lived by people within the settings of their everyday life, where they learn, work, play and love"[9]. The settings approach has translated to the utilisation of "the health potentials inherent in the social and institutional settings of everyday life" [13]. Settings identified in the Ottawa charter included: prisons, schools, universities, market places, hospitals, islands, districts, cities, regions and workplaces [9].

The workplace as a health promotion setting presents an opportunity to reach many people within the adult population [14]. The working population is one that would not normally be engaged in organised health improvement initiatives [15]. WHO has estimated that workers are estimated to represent half of the world's population [16] and majority of them spend a substantial portion of their waking hours at work [17]. Workplace health promotion (WHP) interventions are defined as employer initiatives directed at protecting the health of employees and thereby improving their productivity [18]. The Center for Disease Control and Prevention [19] has described the three components to comprehensive WHP programs as: screening, lifestyle or risk factor management, and disease management. Workplaces may implement programs that include one component or a combination of components. Examples of screening programs include blood pressure and body weight measurement, and blood cholesterol level assessment [20]. The majority of the WHP programs target lifestyle or risk factor management at the individual level. Examples of these include: physical activity and nutrition programs [21, 22], reduction in smoking [23, 24], and use of stairs [25].

WHP contributes to improvement of employee health and can help contain the current epidemic of lifestyle-related diseases [26]. When properly designed and implemented, WHP interventions have been associated with multiple benefits. For instance, in a systematic review of literature carried out by Cancelliere, Cassidy [27], the results from 21% of the studies show preliminary evidence that WHP programs can positively affect presenteeism. Authors of a

review that looked at WHP interventions for smoking cessation tested in controlled studies conclude that they found strong evidence that interventions which target individual smokers increase the likelihood of quitting smoking [28]. A prospective cohort study that aimed to evaluate the impact of a 6- year WHP program reported a decrease in systolic blood pressure in the hypertension subgroup [29]. In an evaluation of a WHP program, Oberlinner, Lang [20] demonstrate that the program yielded benefits in reduction of employee's body mass index. Results from a cluster randomised controlled trail investigating effectiveness of a WHP intervention showed that there were positive changes in job performance and psychological health of the employees [30]."

It is notable that reviews for health promotion interventions have limited their focus to individual level interventions, leaving out interventions that focus on environmental, structural and social determinants of health [31, 32]. With limited research on interventions focusing on multiple health determinants, employers have also shown reluctance to offer sufficiently comprehensive WHP programs because they are not fully persuaded of their benefits, and they also contend that there are few best practices for them to emulate [15, 33]. Moreover, most of the published research in WHP has been reported from high- income countries [33] and there is scarcity of WHP reported in the LMICs [29]. There is a gap in the provision of evidence-based health promotion interventions at the workplace. This review will yield a narrative overview and assessment of the body of evidence. The results of this review will provide additional information to guide strategic WHP choices and help identify "best buy interventions". Sustainability of WHP programs refers to the continuation of interventions or the effects [34]. Some studies have sighted employee participation rates as an example for indication of sustainability of the WHP interventions [35, 36]. There is limited information on the long-term effectiveness and continuation of the WHP programs [34, 36].

Overall, a systematic review that synthesizes multiple published studies on WHP from LMICs will provide a comprehensive summary of evidence available in WHP practice in these countries. Like the publication of primary research studies mentioned earlier, most of the literature reviews carried out on WHP also focus on studies done in high- income countries [37-39]. Results from this review will provide preliminary evidence for WHP effectiveness and sustainability specific to LMICs. Such evidence will facilitate the scaling up of the implementation of effective, feasible interventions within LMICs. We therefore propose to carry out a systematic review that aims to synthesise published studies on current WHP practice in LMICs countries focusing on effectiveness and sustainability of the interventions.

#### **Objective**

To assess the effectiveness and sustainability of interventions for health promotion in the workplace setting in LMICs.

We aim to address the following questions:

- 1. How effective are interventions for health promotion at the workplace setting in LMICs?
- 2. How sustainable are interventions for health promotion at the workplace setting in LMICs?

#### **METHODS**

This review protocol is registered on the International prospective register of systematic reviews (PROSPERO: CRD42018110853). The review will be prepared according to the Preferred Reporting Items for Systematic reviews and Meta-Analysis Protocols (PRISMA-P) 2015 statement [40].

#### **Inclusion Criteria**

- a) Population: This review will include studies done in adult populations; 18 years of age and above, within the workplace settings in LMICs.
- b) Intervention characteristics: interventions for health promotion at the workplace setting. Study designs: all study designs will be included since WHP interventions are evaluated using a wide variety of approaches and study designs [41-43].

Publication status: published studies whose full text is publicly available. We will review the reference lists from past reviews for suitable studies that would meet the inclusion criteria. Duplicate publications of the same material will be excluded. For studies published in multiple papers, the most recent version will be considered.

Timeline: Studies published from LMICs up to 31st of March 2019.

Language: English.

- c) Comparison: Studies on WHP will present multiple research designs. An intervention to promote health at the workplace will be compared with no intervention. To help answer our research questions, other comparisons involving interventions will be assessed on a case to case basis as encountered in the literature.
- d) Outcomes measured either objectively or subjectively will be included in the review. This will include primary outcomes; employee participation rates, duration of intervention, objectively or subjectively measured effects of the intervention on

employee's physical, mental, financial or social health measures. As a secondary outcome, operational indicators and factors for sustainability will be considered.

#### **Exclusion Criteria**

Workplace related studies that do not report on WHP interventions will be excluded; for example, studies reporting on a standalone aspect such as occupational safety and health, hospitals or treatment.

#### **Data Sources and Search Strategy**

We will search the following databases: Excerpta Medica Database (Embase), Medical Literature Analysis and Retrieval System Online (MEDLINE), PubMed, Web of Science, Scopus, ProQuest, Cumulative Index to Nursing and Allied Health Literature (CINAHL). Table 1 shows the search strategy that we will use. We will adapt the strategy to the different databases.

Table 1 Search strategy

#### Search terms

"Workplace" OR "occupational" OR "worksite" OR "organi\*ational" OR "industrial" OR "work" OR "worker" OR "employee"

AND

"Health\*" OR "health promotion" OR "Wellness" OR "Well-being" "wellbeing" OR "health management" OR "Health protection"

AND

"Program\*" OR "framework" OR "model" OR "intervention" OR "initiative"

AND

"Afghanistan" OR "Albania" OR "Algeria" OR "American Samoa" OR "Angola" OR "Armenia" OR "Azerbaijan" OR "Bangladesh" OR "Belarus" OR "Belize" OR "Benin" OR" "Bhutan" OR "Bolivia" OR "Bosnia and Herzegovina" OR "Botswana" OR "Brazil" OR "Bulgaria" OR "Burkina Faso" OR "Burundi" OR "Cabo Verde" OR "Cambodia" OR "Cameroon" OR "Central African Republic" OR "Chad" OR "China" OR "Colombia" OR "Comoros" OR "Democratic Republic of Congo" OR "Congo" OR "Costa Rica" OR "Cote d'Ivoire" OR "Ivory Coast" OR "Cuba" OR "Djibouti" OR "Dominica" OR "Dominican Republic" OR "Ecuador" OR "Egypt" OR "Arab Republic" OR "El Savador" OR "Equatorial Guinea" OR "Eritrea" OR "Eswatini" OR "Ethiopia" OR "Fiji" OR "Gabon"

OR "The Gambia" OR "Georgia" OR "Ghana" OR "Grenada" OR "Guatamela" OR "Guinea" OR "Guinea Bissau" OR "Guyana" OR "Haiti" OR "Honduras" OR "India" OR "Indonesia" OR "Iran" OR "Islamic Republic" OR "Iraq" OR "Jamaica" OR "Jordan" OR "Kazakhastan" OR "Kenya" OR "Kiribati" OR "Democratic People's Republic of Korea" OR "Korea" OR "Kosovo" OR "Kyrgyz Republic" OR "Lao PDR" OR "Lebanon" OR "Lesotho" OR "Liberia" OR "Libya" OR "Madagascar" OR "Malawi" OR "Malaysia" OR "Maldives" OR "Mali" OR "Marshall Islands" OR "Mauritania" OR "Mauritius" OR "Mexico" OR "Micronesia" OR "Moldova" OR "Mongolia" OR "Montenegro" OR "Morocco" OR "Mozambique" OR "Myanmar" OR "Namibia" OR "Nauru" OR "Nepal" OR "Nicaragua" OR "Niger" OR "Nigeria" OR "North Macedonia" OR "Pakistan" OR "Papua New Guinea" OR "Paraguay" OR "Peru" OR "Philippines" OR "Romania" OR "Russian Federation" OR "Rwanda" OR "Samoa" OR "Sao Tome and Principe" OR "Senegal" OR "Serbia" OR "Sierra Leonne" OR "Solomon Islands" OR "Somalia" OR "South Africa" OR "South Sudan" OR "Sri Lanka" OR "St Lucia" OR "St Vincent and the Grenadines" OR "Sudan" OR "Suriname" OR "Syrian Arab Republic" OR "Tajikistan" OR "Tanzania" OR "Thailand" OR "Timor-Leste" OR "Togo" OR "Tonga" OR "Tunisia" OR "Turkey" OR "Turkmenistan" OR "Tuvalu" OR "Uganda" OR "Ukraine" OR "Uzbekistan" OR "Vanuatu" OR "Venezuela" OR "Vietnam" OR "West Bank of Gaza" OR "Yemen" OR "Zambia" OR "Zimbabwe" OR Africa OR "sub-Saharan Africa" OR "low and middle income countr\*" OR "low income countr\*" OR "Low OR middle income countr\*" OR "Low and middle income countr\*" OR "LMIC\*" OR "developing country" OR "underdeveloped country" OR "resource limited"

#### Grey literature

To allow for the inclusion of as much evidence as possible, we will use Google web search (<a href="www.google.com">www.google.com</a>) to look for grey literature. We will contact the first and senior author of included articles for relevant material. We will do this through email communication. **Study** 

#### Records

#### Data Management

We will import all identified studies to EndNote software where duplicate records will be identified and excluded from record. In our study selection process, we will be guided by the inclusion criteria. We will use Rayyan QCRI [44], an internet based program to assist the screening and selection of studies.

#### Screening

Two reviewers (MW and BZ) will independently select all studies that meet the inclusion criteria. The reviewers will screen the titles and abstracts of the studies for relevance based on the criteria set. They will then screen the full texts of potential eligible studies for inclusion and relevance. Any disagreements will be resolved by consensus. The details of the excluded studies outlining reasons for exclusion will be documented and presented in a flow chart.

#### **Data Extraction**

Using a predetermined data extraction sheet, two reviewers will independently extract data from final full texts of eligible studies and any inconsistencies will be resolved by consensus.

#### **Data Items**

We will extract the following data from our final selection: details of publication (author, author country of affiliation, year of publication, title of article, name of journal study published in), geographical location of intervention, study context (workplace/ industry type, single or multiple organisations studied), subjects of research (role/description of target population, if study is gender specific, employment type of participants, profession), aim of the study, program/intervention priority area focus, sustainability aspects of program, methods, study outcomes, study conclusions, limitations and future research areas proposed.

### Risk of Bias and Quality Appraisal

Two reviewers will independently rate the quality and risk of bias in included studies using two tools from Cochrane handbook for systematic reviews of interventions. To assess the quality of studies included, the reviewers will use the criteria from Cochrane handbook for systematic reviews on international version 5.1.0 [45]. To assess the risk of bias, the reviewers will use the Cochrane tool (table 2) commonly used for random controlled trials. This will be adapted to this review to accommodate the multiple research designs anticipated in the included studies. The adaptation will be done as per the guidelines and criteria for judging risk of bias in the 'risk of bias' assessment tool [46]. We will assign a judgement of 'low', 'high' or 'unclear risk' of bias in the review authors' judgement column. Additional categories indicating either uncertainty or lack of information over the potential for bias will be incorporated.

For all non- randomised studies, we will incorporate an assessment of risk of bias due to confounders. We will compile a list of confounders and determine which of these confounders were considered in the selected studies. The assessment will include determining if the most important confounders were considered, how precisely each confounder was measured,

whether they were distributed similarly in intervention and control cohorts, how carefully they were controlled for and how the researchers controlled for confounding [45].

Towards the detection of reporting biase, the authors will use funnel plots to demonstrate the intervention estimates from individual studies against a measure of each study's size.

Table 2 The Cochrane tool for assessing risk of bias		
Domain	Support for	Review authors'
	Judgement	judgement
Selection bias		
Random sequence generation: selection bias		
(biased allocation to interventions) due to		
inadequate generation of a randomised sequence.		
Allocation concealment: selection bias (biased		
allocation to interventions) due to inadequate		
concealment of allocations prior to assignment.		
Performance bias		
Blinding or participants and personnel:		
performance bias due to knowledge of the allocated	•	
interventions by participants and personnel during	0	
the study.	4	
Blinding of outcome assessment: detection bias		
due to knowledge of the allocated interventions by		
outcome assessors.		
Attrition bias		I
Incomplete outcome data: attrition bias due to		
amount, nature or handling of incomplete outcome		
data.		
Reporting bias		
Selective reporting: reporting bias due to selective		
outcome reporting.		
Other bias	1	1
Bias due to problems not covered elsewhere in the		
table.		
	1	l

#### **Data Synthesis**

We will present a narrative overview and assessment of the body of evidence derived from the comprehensive review of the included studies. The studies will be presented and described by geographical region, regional spread of study authors, number of studies per year, journals that have published these studies. Additional characteristics of included studies will include; study design, duration of study, type of workplaces setting, and description of research participants and intervention, study outcomes and any additional notes by the authors.

The summary assessment of risk of bias will be considered for each important outcome within each study (across domains) and across studies presented in summary tables. We will use the summaries to make judgements about the quality of evidence. We will create additional tables listing the identified confounders as columns and the studies as rows, indicating the results of assessments of each confounder for every study. We will also develop a table of comparisons and outcomes. A comparison of results will be done between results from studies assessed at high or unclear risk of bias and from those studies at low risk of bias. Comparison will further be drawn between outcomes for the various study designs, durations of delivery for each study, frequency of intervention delivery reported, and priority health promotion action area that each WHP program focuses on. The six health promotion priority areas outlined in the Ottawa Charter [9] will be applied.

Assessment for sustainability will be adopted from the conceptual frameworks developed by Shediac-Rizkallah and Bone [47] and adopted by Cochrane handbook for systematic reviews in public health and health promotion. The operational indicators that will be assessed will be categorised as follows; maintenance of health benefits achieved through an initial program, level of institutionalisation of a program within an organisation and measures of capacity building in the workplace setting. To evaluate specific conditions or strategies that favour sustainability in the LMICs context, a criterion assessing three groups of factors will be applied; project design and implementation factors, factors within the organisational setting and factors in the broader community environment such as cultural factors [47].

Additionally, the reviewers will carry out a thematic analysis to present and discuss the main themes across different workplace types, time periods and geographical distribution of included studies. In addition to the manual data entry and summary, we will complement this analysis with the use of Leximancer Version 4 software.

#### **Patient and Public Involvement**

We will not involve patients and the public in this review.

#### Reporting this review

We will report the systematic review according to the checklist of items to include when reporting a systematic review as per the PRISMA 2009 statement [48]. We will present a flow diagram to show the study selection process, specifying reasons for exclusion at each stage. The study quality appraisal tool will be availed as online supplementary material.

#### **Potential amendments**

In case of any changes to this protocol, we will outline the details of the changes in the final report. However, no further amendments to this protocol are foreseen.

#### **Conclusion**

To heed to the WHO's clarion call to implement and scale—up effective health promotion interventions in Africa [3], there is a need to assess what has been effective and sustainable in the context of the workplace setting. There is need to "...establish what has worked...and what should be done here and now, to improve the health of the people in Africa" [3] and the rest of the LMICs.

Previous reviews on WHP focused on the effectiveness of specific interventions; for example, on physical activity [49, 50], nutrition promotion [51] and smoking cessation [28]. Through this comprehensive review, we will provide new insights by presenting a holistic outline of current WHP practice in LMICs, with a focus on effectiveness and sustainability.

#### **Ethics and dissemination**

Since systematic reviews are based on available published data, this review will therefore not require any formal ethical approval. We will disseminate the results of this systematic review through peer-reviewed publications and conference presentations.

#### **Authors' Contributions**

MNW conceived the paper and wrote the first draft. BZD and JLV provided revisions to the manuscript. All authors read and approved the final manuscript. MNW is the guarantor of the review.

#### **Data sharing Statement**

All data for this manuscript are included in the submission.

#### **Funding Statement**

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#### **Competing interests Statement**

None declared.

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Developing criteria for including non-randomized studies > Table 13.2.a: List of study design features (studies with allocation to interventions at the Table 13.2.a: List of study design features (studies with allocation to interventions at the individual level)												
	RCT	Q-RCT	NRCT	СВА	PCS	RCS	НСТ	NEC	CC	XS	ВА	CR/CS
Was there a comparison:								a://b				
Between two or more groups of								mjopen.bn∓com/orFABriPG;282∓bF				
participants receiving different			<b>,</b>		V	<b>V</b>		ope,	V	V		
nterventions?	Y	Υ	Y	Y	Y	Υ	Y	57	Y	Υ	N	N
Within the same group of participants over time?	Р	P	N	Y	N	N	N	, j	N	N	Υ	N
•	'	•	14		<b>V</b> ,	.,		8	.,	.,	•	
Were participants allocated to groups by:								₹				
Concealed randomization?	Y	N	N	N	N	N	N	₽.	N	N	na	na
Quasi-randomization?	Ň	Y	N	N	N	N	N	₽	N	N	na	na
By other action of researchers?	N	N	Y	P	N	N	N /	=;`	N	N	na	na
Time differences?	N	N	N	N	N	N	Y	. <del>9</del>	N	N	na	na
Location differences?	N	N	P	P	P	Р	P	20 100 100 100 100 100 100 100 100 100 1	na	na	na	na
Treatment decisions?	N	N	N	Р	Р	Р	N	27	N	Р	na	na
Participants' preferences?	N	N	N	Р	Р	Р	N	Ş۷	N	Р	na	na
On the basis of outcome?	N	N	N	N	N	N	N	9	Υ	Р	na	na
Some other process? (specify)								guest.				
Which parts of the study were prospective:								. Protected				
Identification of participants?	Υ	Υ	Υ	Р	Υ	Ν	P*	g⁄	N	N	Р	Р
Assessment of baseline and				_			D#	a pe				
allocation to intervention?	Y	Y	Y	Р	Y	N	P*	\$₹	N	N	na	na
Assessment of outcomes?	Υ	Υ	Υ	Р	Υ	Р	Р	čopyright.	N	N	Р	Р

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		BMJ Open

Generation of hypotheses?	Y	Y	Υ	Υ	Υ	Υ	Υ	8-027	Р	Р	Р	na
On what variables was comparability between groups assessed:								)50 oı				
Potential confounders?	Р	Р	Р	Р	Р	Р	Р	75. O	Р	Р	N	na
Baseline assessment of outcome variables?	Р	Р	Р	Υ	Р	Р	Р	2 Mag	N	N	N	na

Y=Yes; P=Possibly; P\*=Possible for one group only; N=No; na=not applicable. NB:. Note that 'possibly' is used in the table to indicate cells where either 'Y' or 'N' may be the case. It should not be used as a response option when applying the checklist; if uncertain, the response should be 'can't tell' (see Box 13.4.a).

RCT=Randomized controlled trial; Q-RCT=Quasi-randomized controlled trial; NRCT=Non-randomized controlled trial; CBA=Controlled before-and-ager study; PCS=Prospective cohort study; RCS=Retrospective cohort study; HCT=Historically controlled trial; NCC=Nested case-control study; CC=Case-control study; XS=Cross-sectional study; BA=Before-and-after comparison; CR/CS=Case report/Case series

Table 13.2.b: List of study design features (studies with allocation to interventions at the group

Table 13.2.b: List of study design features (studies with allocation to interventions at the group leves

	CIRCT	CIQ-RCT	CINRT	CITS	CChBA	ITS	ChBA	EcoXS
Was there a comparison:					7			
Between two or more groups of clusters receiving different interventions?	Y	Y	Y	Y	Y	N B	N	Y
Within the same group of clusters over time?	Р	Р	N	Υ	N	Y	Υ	N
Were clusters allocated to groups by:					9	2		
Concealed randomization?	Υ	N	N	N	N 3	A N	N	N
Quasi-randomization?	N	Υ	N	N	N	<u>.</u> N	N	N
By other action of researchers?	N	N	Υ	Р	P	N N	N	N
Time differences?	N	N	N	Υ	Υ	ŠΥ	Υ	N
Location differences?	N	N	Р	Р	Р ,	Y N P P	N	Р
Policy/public health decisions?	Na	na	Р	Р	Р	_ P	na	na
Cluster preferences?	Na	na	Р	Р	Р	P P	na	na
Some other process? (specify)					;	D T		
Which parts of the study were prospective:						TECHE P		
Identification of participating clusters?	Y	Υ	Υ	Р	Р	<u>P</u> P	Р	N
Assessment of baseline and allocation to						<b>*</b> '		
intervention?	Υ	Υ	Υ	Р	P	g P	Р	N

Assessment of outcomes? Generation of hypotheses?	Y Y	Y Y	Y Y	P Y	P :	P Y	P Y	N P
On what variables was comparability between groups assessed:					<u>.</u>	on 22		
Potential confounders?	Р	Р	Р	Р	Р	May P	Р	Р
Baseline assessment of outcome variables?	Р	Р	Р	Υ	Y	è Y	Υ	N

Note that 'cluster' refers to an entity (e.g. an organization), not necessarily to a group of participants; 'group' refers to one or more clusters; see Box 13.4.a.

Note that 'possibly' is used in the table to indicate cells where *either* 'Y' or 'N' may be the case. It should not be used a response option when applying the checklist; if uncertain, 'can't tell' should be used (see Box 13.4.a).

Y=Yes; P=Possibly; P\*=Possible for one group only; N=No; NR=Not required. CIRCT=Cluster randomized controlled trial; CIQ-RCT=Cluster quasi-randomized controlled trial; CINRT=Cluster non-randomized controlled trial; CITS=Controlled interrupted time series (Shadish 2002); CChBA=Controlled cohort before and after study (Shadish 2002); EcoXS=Ecological cross-sectional study.

#### Box 13.4.a: User guide for data collection/study assessment using checklist in Table 13.2.a or Table 3.2.a

Note: Users need to be very clear about the way in which the terms 'group' and 'cluster' are used in these tables. Table 13.2.a only refers to groups, which is used in its conventional sense to mean a number of individual participants. With the exception of allocation on the basis of outcome, 'group' can be interpreted synonymously with 'intervention group'. Table 13.2.b refers to both clusters and groups. In this table, 'clusters' are typically an organizational entity such as a family health practice, or administrative area, not an individual As in Table 13.2.a, 'group' is synonymous with 'intervention group' and is used to describe a collection of allocated units, but in Table 13.2.b these units are clusters rather than individuals. Furthermore, although individuals are nested in clusters, a cluster does not necessarily represent a fixed collection of individuals. For instance, in cluster-allocated studies, clusters are often studied at two or more time-points periods) with different collections of individuals contributing to the data collected at each time-point.

Was there a comparison?

Typically, researchers compare two or more groups that receive different interventions; the groups may be studied over the same time period, or over different time periods (see below). Sometimes researchers compare outcomes in just one group but at two time-points. It is also possible that researchers may have done both, i.e. studying two or more groups and measuring outcomes at more than one time-point.

Were participants/clusters allocated to groups by?

These items aim to describe how groups were formed. None will apply if the study does not compare two or more groups of subjects. The information is often not reported or is difficult to find in a paper. The items provided cover the main ways in which groups may be formed. More than one option may apply to a single study, although some options are mutually exclusive (i.e. a study is either randomized or not).

 Randomization: Allocation was carried out on the basis of truly random sequence. Such studies are covered by the standard guidance elsewhere in this *Handbook*. Check carefully whether allocation was adequately concealed until subjects were definitively recruited.

- Quasi-randomization: Allocation was done on the basis of a pseudo-random sequence, e.g. odd/even hospital number date of birth, alternation. Note: when such methods are used, the problem is that allocation is rarely concealed. These studies are often included in systematic reviews that only include randomized trials, using assessment of the risk of bias to distinguish them from properly randomized trials.
- By other action of researchers: This is a catch-all category and further details should be noted if the researchers reportenem. Allocation happened as the result of some decision or system applied by the researchers. For example, subjects managed in particular 'units' of provision (e.g. wards, general practices) were 'chosen' to receive the intervention and subjects managed in other units to receive the control intervention.
- Time differences: Recruitment to groups did not occur contemporaneously. For example, in a historically controlled study subjects in the control group are typically recruited earlier in time than subjects in the intervention group; the intervention is then introduced and subjects receiving the intervention are recruited. Both groups are usually recruited in the same setting. If the design was under the control of the researchers, both this option and 'other action of researchers' must be ticked for a single study. If the design 'came about' by the introduction of a new intervention, both this option and 'treatment decisions' must be ticked for a single study.
- Location differences: Two or more groups in different geographic areas were compared, and the choice of which area (s) received the intervention and control interventions was not made randomly. So, both this option and 'other action of researchers could be ticked for a single study.
- Treatment decisions: Intervention and control groups were formed by naturally occurring variation in treatment decisions. This option is intended to reflect treatment decisions taken mainly by the clinicians responsible; the following option is intended to reflect treatment decisions made mainly on the basis of subjects' preferences. If treatment preferences are uniform for particular provider 'units', or switch over time, both this option and 'location' or 'time' differences should be ticked.
- Patient preferences: Intervention and control groups were formed by naturally occurring variation in patients' preferences. This option is intended to reflect treatment decisions made mainly on the basis of subjects' preferences; the previous option is intended to reflect treatment decisions taken mainly by the clinicians responsible.
- On the basis of outcome: A group of people who experienced a particular outcome of interest were compared with a gioup of people who did not, i.e. a case-control study. Note: this option should be ticked for papers that report analyses of *multiple risk factors for a particular outcome* in a large series of subjects, i.e. in which the total study population is divided into those who experienced the outcome and those who did not. These studies are much closer to nested case-control studies than cohort studies, even when longitudinal data are collected prospectively for consecutive patients.

Additional options for cluster-allocated studies.

\_ocation differences: see above.

Policy/public health decisions: Intervention and control groups were formed by decisions made by people with the responsibility for implementing policies about public health or service provision. Where such decisions are coincident with clusters, on where such people are the researchers themselves, this item overlaps with 'other action of researchers' and 'cluster preferences'.

Which parts of the study were prospective?

These items aim to describe which parts of the study were conducted prospectively. In a randomized controlled trial, altour of these items would be prospective. For NRS it is also possible that all four are prospective, although inadequate detail may be presented to discern this, particularly for generation of hypotheses. In some cohort studies, participants may be identified, and have been allocated to treatment retrospectively, but outcomes are ascertained prospectively.

On what variables was comparability of groups assessed?

These questions should identify 'before-and-after' studies. Baseline assessment of outcome variables is particularly useful when outcomes are measured on continuous scales, e.g. healthstatus or quality of life.

Response options

Try to use only 'Yes', 'No' and 'Can't tell' response options. 'N/a' should be used if a study does not report a comparisc between groups.

Reeves BC, Deeks JJ, Higgins JPT, Wells GA. Chapter 13: Including non-randomized studies. In: Higgins JPT, Green (editors), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from <a href="https://www.handbook.cochrane.org">www.handbook.cochrane.org</a>.

# Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

#### Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-P reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
Update	<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	n/a not an update
	<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the guarantor of the review	10
	<u>#4</u>	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a not an amendment

Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	10
Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	10
Role of sponsor or funder	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a- has no funder
Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	3-5
Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6
Information sources	<u>#9</u>	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6
Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6-7
Study records - data management	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records and data throughout the review	7
Study records - selection process	<u>#11b</u>	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	7
Study records - data collection process	<u>#11c</u>	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	7
Data items	<u>#12</u>	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned	7- 8

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		data assumptions and simplifications	
Outcomes and prioritization	<u>#13</u>	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5,9
Risk of bias in individual studies	<u>#14</u>	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8-9
Data synthesis	<u>#15a</u>	Describe criteria under which study data will be quantitatively synthesised	9
	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's T)	n/a
	<u>#15c</u>	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	9
	<u>#15d</u>	If quantitative synthesis is not appropriate, describe the type of summary planned	9
Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	8-9
Confidence in cumulative evidence	<u>#17</u>	Describe how the strength of the body of evidence will be assessed (such as GRADE)	8-9

The PRISMA-P checklist is distributed under the terms of the Creative Commons Attribution License CC-BY 4.0. This checklist can be completed online using <a href="https://www.goodreports.org/">https://www.goodreports.org/</a>, a tool made by the <a href="EQUATOR Network">EQUATOR Network</a> in collaboration with <a href="Penelope.ai">Penelope.ai</a>

### **BMJ Open**

## Health promotion at the workplace setting: a protocol for a systematic review of effectiveness and sustainability of current practice in low- and middle- income countries.

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Secondary Subject Heading:	Occupational and environmental medicine, Public health
Keywords:	Health Promotion, sustainability, workplace, effectiveness, low- and middle- income countries

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#### Title

Health promotion at the workplace setting: a protocol for a systematic review of effectiveness and sustainability of current practice in low- and middle- income countries.

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#### **Word Count**

Health promotion at the workplace setting: a protocol for a systematic review of effectiveness and sustainability of current practice in low- and middle- income countries.

#### **ABSTRACT**

#### Introduction

Low- and middle- income countries (LMICs) are experiencing a growing disease burden due to non- communicable diseases (NCDs). Changing behavioural practices such as, diets high in saturated fat, salt and sugar and sedentary lifestyles, have been associated with the increase in NCDs. Health promotion at the workplace setting is considered effective in the fight against NCDs and has been reported to yield numerous benefits. However, there is a need to generate evidence on the effectiveness and sustainability of workplace health promotion practice specific to LMICs. We aim to synthesize the current literature on workplace health promotion in LMICs focusing on interventions effectiveness and sustainability.

#### Methods and analysis

We will conduct a systematic review of published studies from LMICs up to the 31st of March 2019. We will search the following databases: EMBASE, MEDLINE, PubMed, Web of Science, Scopus, ProQuest, and CINAHL. Two reviewers will independently screen potential articles for inclusion and disagreements will be resolved by consensus. We will appraise the quality and risk of bias of included studies using two tools from the Cochrane handbook for systematic reviews of interventions. We will present a narrative overview and assessment of the body of evidence derived from the comprehensive review of the studies. The reported outcomes will be summarised by study design, duration, intensity / frequency of intervention delivery, and by the six-priority health promotion action areas set out in the Ottawa Charter. We will conduct a thematic analysis to identify the focus areas of current interventions. This systematic review protocol has been prepared according to the Preferred Reporting Items for Systematic reviews and Meta- analyses for Protocols (PRISMA-P) 2015 statement.

#### Ethics and dissemination

This study does not require ethics approval. We will disseminate the results of this review through peer-reviewed publications and conference presentations.

Trial registration number: CRD42018110853.

#### **Keywords**

Health promotion, workplace, systematic review, effectiveness, sustainability, LMICs.

#### Strengths and limitations of this study

 This will be a comprehensive review that examines multiple workplaces, across various industries in LMICs.

- The review search dates and search strategy will ensure a comprehensive search for relevant articles.
- The methods of this review have been outlined in a protocol to guard against arbitrary decision making in the review process.
- Our search strategy is restricted by language; studies included will be limited to those in English.
- The inclusion of studies with diverse study designs, intervention types and workplace settings makes this a broad, heterogeneous study; this may limit the depth of the analysis.

#### INTRODUCTION

#### Rationale

In 2016, an estimated 41 million deaths globally (71% of all deaths) were due to non-communicable diseases (NCDs) [1]. The majority of these deaths were caused by: cardiovascular disease (44%); cancer (22%); chronic respiratory disease (9%); and diabetes (4%) [1]. In low- and middle- income countries (LMICs) 85% of premature deaths are attributable to NCDs [2]. In 2014, the World Health Organisation (WHO) estimated a 17% increase of deaths from NCDs globally and a 27% increase for the African region, equivalent to 28 million additional deaths by 2030 [3]. In sub- Saharan Africa (SSA) region, where majority of the LMICs are located, the WHO [4] estimated that by 2020, NCDs will be as prevalent as communicable diseases. Already, NCDs are the main cause of adult deaths in Mauritius, Namibia and Seychelles [3].

The leading risks factors associated with the global increase in mortality are high blood pressure (responsible for 13% of death globally), tobacco use (9%), high blood glucose (6%), physical inactivity (6%), and overweight and obesity (5%) [5]. Changes in lifestyle; adoption of sedentary behaviours and nutrition transition have been identified as some of the modifiable risk factors that increase the risk of NCDs [2]. The reversal or mitigation of this trend calls for the application of effective principles and practices of health promotion [6] and the mainstreaming of health promotion [7]. The current WHO strategy towards the prevention of NCDs incorporates the reduction of health risks and promotion of healthy lifestyles through health promotion [8].

Health promotion is described as "the process that enables people to increase control over (health determinants), and to improve their health" [9]. The 1997 Jakarta declaration affirmed

that health promotion strategies were indeed effective in addressing health risk factors [10], particularly lifestyle related risk factors which can be modified to prevent disease [4].

Globally, the health promotion approach has been adopted by many countries including the LMICs. For instance, Nyamwaya [11] points out that the use of health promotion as a means of increasing societal responsibility for health now exists in all African countries. Laws and policies that facilitate adoption of healthy lifestyles and disease prevention such as tobacco legislation, have been put in place [11]. A focus on settings for health promotion has enabled the creation of supportive environments through the development of relevant, practical health promotion interventions that address a full range of health determinants at each setting [12]. The introduction of the settings approach for health promotion followed the 1986 Ottawa Charter's declaration that "health is created and lived by people within the settings of their everyday life, where they learn, work, play and love"[9]. The settings approach has translated to the utilisation of "the health potentials inherent in the social and institutional settings of everyday life" [13]. Settings identified in the Ottawa charter included: prisons, schools, universities, market places, hospitals, islands, districts, cities, regions and workplaces [9].

The workplace as a health promotion setting presents an opportunity to reach many people within the adult population [14]. The working population is one that would not normally be engaged in organised health improvement initiatives [15]. WHO has estimated that workers are estimated to represent half of the world's population [16] and majority of them spend a substantial portion of their waking hours at work [17]. Workplace health promotion (WHP) interventions are defined as employer initiatives directed at protecting the health of employees and thereby improving their productivity [18]. The Center for Disease Control and Prevention [19] has described the three components to comprehensive WHP programs as: screening, lifestyle or risk factor management, and disease management. Workplaces may implement programs that include one component or a combination of components. Examples of screening programs include blood pressure and body weight measurement, and blood cholesterol level assessment [20]. The majority of the WHP programs target lifestyle or risk factor management at the individual level. Examples of these include: physical activity and nutrition programs [21, 22], reduction in smoking [23, 24], and use of stairs [25].

WHP contributes to improvement of employee health and can help contain the current epidemic of lifestyle-related diseases [26]. When properly designed and implemented, WHP interventions have been associated with multiple benefits. For instance, in a systematic review of literature carried out by Cancelliere, Cassidy [27], the results from 21% of the studies show preliminary evidence that WHP programs can positively affect presenteeism. Authors of a

review that looked at WHP interventions for smoking cessation tested in controlled studies conclude that they found strong evidence that interventions which target individual smokers increase the likelihood of quitting smoking [28]. A prospective cohort study that aimed to evaluate the impact of a 6- year WHP program reported a decrease in systolic blood pressure in the hypertension subgroup [29]. In an evaluation of a WHP program, Oberlinner, Lang [20] demonstrate that the program yielded benefits in reduction of employee's body mass index. Results from a cluster randomised controlled trail investigating effectiveness of a WHP intervention showed that there were positive changes in job performance and psychological health of the employees [30]."

It is notable that reviews for health promotion interventions have limited their focus to individual level interventions, leaving out interventions that focus on environmental, structural and social determinants of health [31, 32]. With limited research on interventions focusing on multiple health determinants, employers have also shown reluctance to offer sufficiently comprehensive WHP programs because they are not fully persuaded of their benefits, and they also contend that there are few best practices for them to emulate [15, 33]. Moreover, most of the published research in WHP has been reported from high- income countries [33] and there is scarcity of WHP reported in the LMICs [29]. There is a gap in the provision of evidence-based health promotion interventions at the workplace. This review will yield a narrative overview and assessment of the body of evidence. The results of this review will provide additional information to guide strategic WHP choices and help identify "best buy interventions". Sustainability of WHP programs refers to the continuation of interventions or the effects [34]. Some studies have sighted employee participation rates as an example for indication of sustainability of the WHP interventions [35, 36]. There is limited information on the long-term effectiveness and continuation of the WHP programs [34, 36].

Overall, a systematic review that synthesizes multiple published studies on WHP from LMICs will provide a comprehensive summary of evidence available in WHP practice in these countries. Like the publication of primary research studies mentioned earlier, most of the literature reviews carried out on WHP also focus on studies done in high- income countries [37-39]. Results from this review will provide preliminary evidence for WHP effectiveness and sustainability specific to LMICs. Such evidence will facilitate the scaling up of the implementation of effective, feasible interventions within LMICs. We therefore propose to carry out a systematic review that aims to synthesise published studies on current WHP practice in LMICs countries focusing on effectiveness and sustainability of the interventions.

#### **Objective**

To assess the effectiveness and sustainability of interventions for health promotion in the workplace setting in LMICs.

We aim to address the following questions:

- 1. How effective are interventions for health promotion at the workplace setting in LMICs?
- 2. How sustainable are interventions for health promotion at the workplace setting in LMICs?

#### **METHODS**

This review protocol is registered in the PROSPERO International prospective register of systematic reviews (Registration Number:CRD42018110853). The review will be prepared according to the Preferred Reporting Items for Systematic reviews and Meta-Analysis Protocols (PRISMA-P) 2015 statement [40].

#### **Inclusion Criteria**

- a) Population: This review will include studies done in adult populations; 18 years of age and above, within the workplace settings in LMICs.
- b) Intervention characteristics: interventions for health promotion at the workplace setting. Study designs: all study designs will be included since WHP interventions are evaluated using a wide variety of approaches and study designs [41-43].

Publication status: published studies whose full text is publicly available. We will review the reference lists from past reviews for suitable studies that would meet the inclusion criteria. Duplicate publications of the same material will be excluded. For studies published in multiple papers, the most recent version will be considered.

Timeline: Studies published from LMICs up to 31st of March 2019.

Language: English.

- c) Comparison: Studies on WHP will present multiple research designs. An intervention to promote health at the workplace will be compared with no intervention. To help answer our research questions, other comparisons involving interventions will be assessed on a case to case basis as encountered in the literature.
- d) Outcomes measured either objectively or subjectively will be included in the review. This will include primary outcomes; employee participation rates, duration of intervention, objectively or subjectively measured effects of the intervention on employee's physical, mental, financial or social health measures. As a secondary outcome, operational indicators and factors for sustainability will be considered.

#### **Exclusion Criteria**

Workplace related studies that do not report on WHP interventions will be excluded; for example, studies reporting on a standalone aspect such as occupational safety and health, hospitals or treatment.

#### **Data Sources and Search Strategy**

We will search the following databases: Excerpta Medica Database (Embase), Medical Literature Analysis and Retrieval System Online (MEDLINE), PubMed, Web of Science, Scopus, ProQuest, Cumulative Index to Nursing and Allied Health Literature (CINAHL).

Table 1 shows the search strategy that we will use. We will adapt the strategy to the different databases.

Table 1 Search strategy

#### Search terms

"Workplace" OR "occupational" OR "worksite" OR "organi\*ational" OR "industrial" OR "work" OR "worker" OR "employee"

AND

"Health\*" OR "health promotion" OR "Wellness" OR "Well-being" "wellbeing" OR "health management" OR "Health protection"

**AND** 

"Program\*" OR "framework" OR "model" OR "intervention" OR "initiative"

AND

"Afghanistan" OR "Albania" OR "Algeria" OR "American Samoa" OR "Angola" OR "Armenia" OR "Azerbaijan" OR "Bangladesh" OR "Belarus" OR "Belize" OR "Benin" OR" "Bhutan" OR "Bolivia" OR "Bosnia and Herzegovina" OR "Botswana" OR "Brazil" OR "Bulgaria" OR "Burkina Faso" OR "Burundi" OR "Cabo Verde" OR "Cambodia" OR "Cameroon" OR "Central African Republic" OR "Chad" OR "China" OR "Colombia" OR "Comoros" OR "Democratic Republic of Congo" OR "Congo" OR "Costa Rica" OR "Cote d'Ivoire" OR "Ivory Coast" OR "Cuba" OR "Djibouti" OR "Dominica" OR "Dominican Republic" OR "Ecuador" OR "Egypt" OR "Arab Republic" OR "El Savador" OR "Equatorial Guinea" OR "Eritrea" OR "Eswatini" OR "Ethiopia" OR "Fiji" OR "Gabon" OR "The Gambia" OR "Georgia" OR "Ghana" OR "Grenada" OR "Guatamela" OR "Guinea" OR "Guinea Bissau" OR "Guyana" OR "Haiti" OR "Honduras" OR "India" OR "Indonesia" OR "Iran" OR "Islamic Republic" OR "Iraq" OR "Jamaica" OR "Jordan" OR "Kazakhastan" OR "Kenya" OR "Kiribati" OR "Democratic People's Republic of Korea"

OR "Korea" OR "Kosovo" OR "Kyrgyz Republic" OR "Lao PDR" OR "Lebanon" OR "Lesotho" OR "Liberia" OR "Libya" OR "Madagascar" OR "Malawi" OR "Malaysia" OR "Maldives" OR "Mali" OR "Marshall Islands" OR "Mauritania" OR "Mauritius" OR "Mexico" OR "Micronesia" OR "Moldova" OR "Mongolia" OR "Montenegro" OR "Morocco" OR "Mozambique" OR "Myanmar" OR "Namibia" OR "Nauru" OR "Nepal" OR "Nicaragua" OR "Niger" OR "Nigeria" OR "North Macedonia" OR "Pakistan" OR "Papua New Guinea" OR "Paraguay" OR "Peru" OR "Philippines" OR "Romania" OR "Russian Federation" OR "Rwanda" OR "Samoa" OR "Sao Tome and Principe" OR "Senegal" OR "Serbia" OR "Sierra Leonne" OR "Solomon Islands" OR "Somalia" OR "South Africa" OR "South Sudan" OR "Sri Lanka" OR "St Lucia" OR "St Vincent and the Grenadines" OR "Sudan" OR "Suriname" OR "Syrian Arab Republic" OR "Tajikistan" OR "Tanzania" OR "Thailand" OR "Timor-Leste" OR "Togo" OR "Tonga" OR "Tunisia" OR "Turkey" OR "Turkmenistan" OR "Tuvalu" OR "Uganda" OR "Ukraine" OR "Uzbekistan" OR "Vanuatu" OR "Venezuela" OR "Vietnam" OR "West Bank of Gaza" OR "Yemen" OR "Zambia" OR "Zimbabwe" OR Africa OR "sub-Saharan Africa" OR "low and middle income countr\*" OR "low income countr\*" OR "Low OR middle income countr\*" OR "Low and middle income countr\*" OR "LMIC\*" OR "developing country" OR "underdeveloped country" OR "resource limited"

#### Grey literature

To allow for the inclusion of as much evidence as possible, we will use Google web search (<a href="www.google.com">www.google.com</a>) to look for grey literature. We will contact the first and senior author of included articles for relevant material. We will do this through email communication.

#### **Study Records**

#### Data Management

We will import all identified studies to EndNote software where duplicate records will be identified and excluded from record. In our study selection process, we will be guided by the inclusion criteria. We will use Rayyan QCRI [44], an internet based program to assist the screening and selection of studies.

#### Screening

Two reviewers (MW and BZ) will independently select all studies that meet the inclusion criteria. The reviewers will screen the titles and abstracts of the studies for relevance based on the criteria set. They will then screen the full texts of potential eligible studies for inclusion and

relevance. Any disagreements will be resolved by consensus. The details of the excluded studies outlining reasons for exclusion will be documented and presented in a flow chart.

#### **Data Extraction**

Using a predetermined data extraction sheet, two reviewers will independently extract data from final full texts of eligible studies and any inconsistencies will be resolved by consensus.

#### **Data Items**

We will extract the following data from our final selection: details of publication (author, author country of affiliation, year of publication, title of article, name of journal study published in), geographical location of intervention, study context (workplace/ industry type, single or multiple organisations studied), subjects of research (role/description of target population, if study is gender specific, employment type of participants, profession), aim of the study, program/intervention priority area focus, sustainability aspects of program, methods, study outcomes, study conclusions, limitations and future research areas proposed.

#### Risk of Bias and Quality Appraisal

Two reviewers will independently rate the quality and risk of bias in included studies using two tools from Cochrane handbook for systematic reviews of interventions. To assess the quality of studies included, the reviewers will use the criteria from Cochrane handbook for systematic reviews on international version 5.1.0 [45]. To assess the risk of bias, the reviewers will use the Cochrane tool (table 2) commonly used for random controlled trials. This will be adapted to this review to accommodate the multiple research designs anticipated in the included studies. The adaptation will be done as per the guidelines and criteria for judging risk of bias in the 'risk of bias' assessment tool [46]. We will assign a judgement of 'low', 'high' or 'unclear risk' of bias in the review authors' judgement column. Additional categories indicating either uncertainty or lack of information over the potential for bias will be incorporated.

For all non- randomised studies, we will incorporate an assessment of risk of bias due to confounders. We will compile a list of confounders and determine which of these confounders were considered in the selected studies. The assessment will include determining if the most important confounders were considered, how precisely each confounder was measured, whether they were distributed similarly in intervention and control cohorts, how carefully they were controlled for and how the researchers controlled for confounding [45].

Towards the detection of reporting biase, the authors will use funnel plots to demonstrate the intervention estimates from individual studies against a measure of each study's size.

Table 2 The Cochrane tool for assessing risk of bia	S	
Domain	Support for	Review authors'
	Judgement	judgement
Selection bias		
Random sequence generation: selection bias		
(biased allocation to interventions) due to		
inadequate generation of a randomised sequence.		
Allocation concealment: selection bias (biased		
allocation to interventions) due to inadequate		
concealment of allocations prior to assignment.		
Performance bias		
Blinding or participants and personnel:		
performance bias due to knowledge of the allocated		
interventions by participants and personnel during		
the study.		
Blinding of outcome assessment: detection bias		
due to knowledge of the allocated interventions by		
outcome assessors.	•	
Attrition bias	0.	
Incomplete outcome data: attrition bias due to	4	
amount, nature or handling of incomplete outcome		
data.	0,	
Reporting bias	7/	
Selective reporting: reporting bias due to selective		
outcome reporting.		
Other bias		
Bias due to problems not covered elsewhere in the		
table.		

#### **Data Synthesis**

We will present a narrative overview and assessment of the body of evidence derived from the comprehensive review of the included studies. The studies will be presented and described by geographical region, regional spread of study authors, number of studies per year, journals that

have published these studies. Additional characteristics of included studies will include; study design, duration of study, type of workplaces setting, and description of research participants and intervention, study outcomes and any additional notes by the authors.

The summary assessment of risk of bias will be considered for each important outcome within each study (across domains) and across studies presented in summary tables. We will use the summaries to make judgements about the quality of evidence. We will create additional tables listing the identified confounders as columns and the studies as rows, indicating the results of assessments of each confounder for every study. We will also develop a table of comparisons and outcomes. A comparison of results will be done between results from studies assessed at high or unclear risk of bias and from those studies at low risk of bias. Comparison will further be drawn between outcomes for the various study designs, durations of delivery for each study, frequency of intervention delivery reported, and priority health promotion action area that each WHP program focuses on. The six health promotion priority areas outlined in the Ottawa Charter [9] will be applied.

Assessment for sustainability will be adopted from the conceptual frameworks developed by Shediac-Rizkallah and Bone [47] and adopted by Cochrane handbook for systematic reviews in public health and health promotion. The operational indicators that will be assessed will be categorised as follows; maintenance of health benefits achieved through an initial program, level of institutionalisation of a program within an organisation and measures of capacity building in the workplace setting. To evaluate specific conditions or strategies that favour sustainability in the LMICs context, a criterion assessing three groups of factors will be applied; project design and implementation factors, factors within the organisational setting and factors in the broader community environment such as cultural factors [47].

Additionally, the reviewers will carry out a thematic analysis to present and discuss the main themes across different workplace types, time periods and geographical distribution of included studies. In addition to the manual data entry and summary, we will complement this analysis with the use of Leximancer Version 4 software.

#### **Patient and Public Involvement**

We will not involve patients and the public in this review.

#### Reporting this review

We will report the systematic review according to the checklist of items to include when reporting a systematic review as per the PRISMA 2009 statement [48]. We will present a flow

diagram to show the study selection process, specifying reasons for exclusion at each stage. The study quality appraisal tool will be availed as online supplementary material.

#### **Potential amendments**

In case of any changes to this protocol, we will outline the details of the changes in the final report. However, no further amendments to this protocol are foreseen.

#### Conclusion

To heed to the WHO's clarion call to implement and scale—up effective health promotion interventions in Africa [3], there is a need to assess what has been effective and sustainable in the context of the workplace setting. There is need to "...establish what has worked...and what should be done here and now, to improve the health of the people in Africa" [3] and the rest of the LMICs.

Previous reviews on WHP focused on the effectiveness of specific interventions; for example, on physical activity [49, 50], nutrition promotion [51] and smoking cessation [28]. Through this comprehensive review, we will provide new insights by presenting a holistic outline of current WHP practice in LMICs, with a focus on effectiveness and sustainability.

#### **Ethics and dissemination**

Since systematic reviews are based on available published data, this review will therefore not require any formal ethical approval. We will disseminate the results of this systematic review through peer-reviewed publications and conference presentations.

#### **Authors' Contributions**

MNW conceived the paper and wrote the first draft. BZD and JLV provided revisions to the manuscript. All authors read and approved the final manuscript. MNW is the guarantor of the review.

#### **Data sharing Statement**

All data for this manuscript are included in the submission.

#### **Funding Statement**

This research received no specific grant from any funding agency in the public, commercial or not-for profit sectors.

#### **Competing interests Statement**

None declared.

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Developing criteria for including non-randomized studies > Table 13.2.a: List of study design features (studies with allocation to interventions at the Table 13.2.a: List of study design features (studies with allocation to interventions at the individual level)												
	RCT	Q-RCT	NRCT	СВА	PCS	RCS	НСТ	NEC	CC	XS	ВА	CR/CS
Was there a comparison:								a://b				
Between two or more groups of								mjopen.bn∓com/orFABriPG;282∓bF				
participants receiving different			<b>,</b>		V	<b>V</b>		ope,	V	V		
nterventions?	Y	Υ	Y	Y	Y	Υ	Y	57	Y	Υ	N	N
Within the same group of participants over time?	Р	P	N	Y	N	N	N	, j	N	N	Υ	N
•	'	•	14		<b>V</b> ,	.,		8	.,	.,	•	
Were participants allocated to groups by:								₹				
Concealed randomization?	Y	N	N	N	N	N	N	₽.	N	N	na	na
Quasi-randomization?	Ň	Y	N	N	N	N	N	₽	N	N	na	na
By other action of researchers?	N	N	Y	P	N	N	N /	=;`	N	N	na	na
Time differences?	N	N	N	N	N	N	Y	. <del>9</del>	N	N	na	na
Location differences?	N	N	P	P	P	Р	P	20 100 100 100 100 100 100 100 100 100 1	na	na	na	na
Treatment decisions?	N	N	N	Р	Р	Р	N	27	N	Р	na	na
Participants' preferences?	N	N	N	Р	Р	Р	N	Ş۷	N	Р	na	na
On the basis of outcome?	N	N	N	N	N	N	N	9	Υ	Р	na	na
Some other process? (specify)								guest.				
Which parts of the study were prospective:								. Protected				
Identification of participants?	Υ	Υ	Υ	Р	Υ	Ν	P*	g⁄	N	N	Р	Р
Assessment of baseline and				_			D#	a pe				
allocation to intervention?	Y	Y	Y	Р	Y	N	P*	\$₹	N	N	na	na
Assessment of outcomes?	Υ	Υ	Υ	Р	Υ	Р	Р	čopyright.	N	N	Р	Р

23		
	Generation of hypotheses?	Y
	On what variables was comparability between groups assessed:	
	Potential confounders?	Р

Generation of hypotheses?	Υ	Υ	Υ	Y	Y	Υ	Υ	8-027	Р	Р	Р	na
On what variables was comparability between groups assessed:								050 oı				
Potential confounders?	Р	Р	Р	Р	Р	Р	Р	n <del>2</del> 2	Р	Р	N	na
Baseline assessment of outcome variables?	Р	Р	Р	Υ	Р	Р	Р	2 Maj	N	N	N	na

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Y=Yes; P=Possibly; P\*=Possible for one group only; N=No; na=not applicable. NB:. Note that 'possibly' is used in the table to indicate cells where either 'Y' or 'N' may be the case. It should not be used as a response option when applying the checklist; if uncertain, the response should be 'can't tell' (see Box 13.4.a).

RCT=Randomized controlled trial; Q-RCT=Quasi-randomized controlled trial; NRCT=Non-randomized controlled trial; CBA=Controlled before-and-ager study; PCS=Prospective cohort study; RCS=Retrospective cohort study; HCT=Historically controlled trial; NCC=Nested case-control study; CC=Case-control study; XS=Cross-sectional study; BA=Before-and-after comparison; CR/CS=Case report/Case series

Table 13.2.b: List of study design features (studies with allocation to interventions at the group

Table 13.2.b: List of study design features (studies with allocation to interventions at the group level)

	CIRCT	CIQ-RCT	CINRT	CITS	CChBA	ITS	ChBA	EcoXS
Was there a comparison:					7			
Between two or more groups of clusters receiving different interventions?	Y	Y	Y	Y	Y	N Y	N	Y
Within the same group of clusters over time?	Р	Р	N	Υ	N	Y	Υ	N
Were clusters allocated to groups by:					9	07		
Concealed randomization?	Υ	N	N	N	N 3	Aprii N	N	N
Quasi-randomization?	N	Υ	N	N	N	<u>-</u> N	N	N
By other action of researchers?	N	N	Υ	Р	P	19 N	N	N
Time differences?	N	N	N	Υ	Υ	Š Y	Υ	N
Location differences?	N	N	Р	Р	Р ,	Y N P P	N	Р
Policy/public health decisions?	Na	na	Р	Р	Р	_ P	na	na
Cluster preferences?	Na	na	Р	Р	Р	P P	na	na
Some other process? (specify)					;	D		
Which parts of the study were prospective:						offected P		
Identification of participating clusters?	Y	Υ	Υ	Р	Р	<u>р</u> Р	Р	N
Assessment of baseline and allocation to						₹ '		
intervention?	Υ	Y	Υ	Р	Р	P P	Р	N

Assessment of outcomes? Generation of hypotheses?	Y Y	Y Y	Y Y	P Y	P 50	18-037050 P Y	P Y	N P
On what variables was comparability between groups assessed:					<u> </u>	3 3		
Potential confounders?	Р	Р	Р	Р	Р	P	Р	Р
Baseline assessment of outcome variables?	Р	Р	Р	Υ	Y	ે Y	Υ	N

Note that 'cluster' refers to an entity (e.g. an organization), not necessarily to a group of participants; 'group' refers to one or more clusters; see Box 13.4.a.

Note that 'possibly' is used in the table to indicate cells where *either* 'Y' or 'N' may be the case. It should not be used a response option when applying the checklist; if uncertain, 'can't tell' should be used (see Box 13.4.a).

Y=Yes; P=Possibly; P\*=Possible for one group only; N=No; NR=Not required. CIRCT=Cluster randomized controlled trial; CIQ-RCT=Cluster quasi-randomized controlled trial; CINRT=Cluster non-randomized controlled trial; CITS=Controlled interrupted time series (Shadish 2002); CChBA=Controlled cohort before and after study (Shadish 2002); EcoXS=Ecological cross-sectional study.

#### Box 13.4.a: User guide for data collection/study assessment using checklist in Table 13.2.a or Table 3.2.a

Note: Users need to be very clear about the way in which the terms 'group' and 'cluster' are used in these tables. Table 13.2.a only refers to groups, which is used in its conventional sense to mean a number of individual participants. With the exception of allocation on the basis of outcome, 'group' can be interpreted synonymously with 'intervention group'. Table 13.2.b refers to both clusters and groups. In this table, 'clusters' are typically an organizational entity such as a family health practice, or administrative area, not an individual As in Table 13.2.a, 'group' is synonymous with 'intervention group' and is used to describe a collection of allocated units, but in Table 13.2.b these units are clusters rather than individuals. Furthermore, although individuals are nested in clusters, a cluster does not necessarily represent a fixed collection of individuals. For instance, in cluster-allocated studies, clusters are often studied at two or more time-points periods) with different collections of individuals contributing to the data collected at each time-point.

Was there a comparison?

Typically, researchers compare two or more groups that receive different interventions; the groups may be studied over the same time period, or over different time periods (see below). Sometimes researchers compare outcomes in just one group but at two time-points. It is also possible that researchers may have done both, i.e. studying two or more groups and measuring outcomes at more than one time-point.

Were participants/clusters allocated to groups by?

These items aim to describe how groups were formed. None will apply if the study does not compare two or more groups of subjects. The information is often not reported or is difficult to find in a paper. The items provided cover the main ways in which groups may be formed. More than one option may apply to a single study, although some options are mutually exclusive (i.e. a study is either randomized or not).

 Randomization: Allocation was carried out on the basis of truly random sequence. Such studies are covered by the standard guidance elsewhere in this *Handbook*. Check carefully whether allocation was adequately concealed until subjects were definitively recruited.

- Quasi-randomization: Allocation was done on the basis of a pseudo-random sequence, e.g. odd/even hospital number date of birth, alternation. Note: when such methods are used, the problem is that allocation is rarely concealed. These studies are often included in systematic reviews that only include randomized trials, using assessment of the risk of bias to distinguish them from properly randomized trials.
- By other action of researchers: This is a catch-all category and further details should be noted if the researchers reportenem. Allocation happened as the result of some decision or system applied by the researchers. For example, subjects managed in particular 'units' of provision (e.g. wards, general practices) were 'chosen' to receive the intervention and subjects managed in other units to receive the control intervention.
- Time differences: Recruitment to groups did not occur contemporaneously. For example, in a historically controlled study subjects in the control group are typically recruited earlier in time than subjects in the intervention group; the intervention is then introduced and subjects receiving the intervention are recruited. Both groups are usually recruited in the same setting. If the design was under the control of the researchers, both this option and 'other action of researchers' must be ticked for a single study. If the design 'came about' by the introduction of a new intervention, both this option and 'treatment decisions' must be ticked for a single study.
- Location differences: Two or more groups in different geographic areas were compared, and the choice of which area (s) received the intervention and control interventions was not made randomly. So, both this option and 'other action of researchers could be ticked for a single study.
- Treatment decisions: Intervention and control groups were formed by naturally occurring variation in treatment decisions. This option is intended to reflect treatment decisions taken mainly by the clinicians responsible; the following option is intended to reflect treatment decisions made mainly on the basis of subjects' preferences. If treatment preferences are uniform for particular provider 'units', or switch over time, both this option and 'location' or 'time' differences should be ticked.
- Patient preferences: Intervention and control groups were formed by naturally occurring variation in patients' preferences. This option is intended to reflect treatment decisions made mainly on the basis of subjects' preferences; the previous option is intended to reflect treatment decisions taken mainly by the clinicians responsible.
- On the basis of outcome: A group of people who experienced a particular outcome of interest were compared with a gioup of people who did not, i.e. a case-control study. Note: this option should be ticked for papers that report analyses of *multiple risk factors for a particular outcome* in a large series of subjects, i.e. in which the total study population is divided into those who experienced the outcome and those who did not. These studies are much closer to nested case-control studies than cohort studies, even when longitudinal data are collected prospectively for consecutive patients.

Additional options for cluster-allocated studies.

\_ocation differences: see above.

Policy/public health decisions: Intervention and control groups were formed by decisions made by people with the responsibility for implementing policies about public health or service provision. Where such decisions are coincident with clusters, on where such people are the researchers themselves, this item overlaps with 'other action of researchers' and 'cluster preferences'.

Which parts of the study were prospective?

These items aim to describe which parts of the study were conducted prospectively. In a randomized controlled trial, altour of these items would be prospective. For NRS it is also possible that all four are prospective, although inadequate detail may be presented to discern this, particularly for generation of hypotheses. In some cohort studies, participants may be identified, and have been allocated to treatment retrospectively, but outcomes are ascertained prospectively.

On what variables was comparability of groups assessed?

These questions should identify 'before-and-after' studies. Baseline assessment of outcome variables is particularly useful when outcomes are measured on continuous scales, e.g. healthstatus or quality of life.

Response options

Try to use only 'Yes', 'No' and 'Can't tell' response options. 'N/a' should be used if a study does not report a comparisc between groups.

Reeves BC, Deeks JJ, Higgins JPT, Wells GA. Chapter 13: Including non-randomized studies. In: Higgins JPT, Green (editors), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from <a href="https://www.handbook.cochrane.org">www.handbook.cochrane.org</a>.

# Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

#### Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-P reporting guidelines, and cite them as:

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		Reporting Item	Page Number
Identification	<u>#1a</u>	Identify the report as a protocol of a systematic review	1
Update	<u>#1b</u>	If the protocol is for an update of a previous systematic review, identify as such	n/a not an update
	<u>#2</u>	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Contact	<u>#3a</u>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	<u>#3b</u>	Describe contributions of protocol authors and identify the guarantor of the review	10
	<u>#4</u>	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	n/a not an amendment

Sources	<u>#5a</u>	Indicate sources of financial or other support for the review	10
Sponsor	<u>#5b</u>	Provide name for the review funder and / or sponsor	10
Role of sponsor or funder	<u>#5c</u>	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	n/a- has no funder
Rationale	<u>#6</u>	Describe the rationale for the review in the context of what is already known	3-5
Objectives	<u>#7</u>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
Eligibility criteria	<u>#8</u>	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6
Information sources	<u>#9</u>	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	6
Search strategy	<u>#10</u>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6-7
Study records - data management	<u>#11a</u>	Describe the mechanism(s) that will be used to manage records and data throughout the review	7
Study records - selection process	<u>#11b</u>	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	7
Study records - data collection process	<u>#11c</u>	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	7
Data items	<u>#12</u>	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned	7- 8

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		data assumptions and simplifications	
Outcomes and prioritization	<u>#13</u>	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5,9
Risk of bias in individual studies	<u>#14</u>	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8-9
Data synthesis	<u>#15a</u>	Describe criteria under which study data will be quantitatively synthesised	9
	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I2, Kendall's T)	n/a
	<u>#15c</u>	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	9
	<u>#15d</u>	If quantitative synthesis is not appropriate, describe the type of summary planned	9
Meta-bias(es)	<u>#16</u>	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	8-9
Confidence in cumulative evidence	<u>#17</u>	Describe how the strength of the body of evidence will be assessed (such as GRADE)	8-9

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