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## Parent and caregiver perspectives on home-based newborn care in low-income settings: protocol for a systematic review of qualitative studies

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# Parent and caregiver perspectives on home-based newborn care in low-income settings: protocol for a systematic review of qualitative studies

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## Abstract

**Introduction:** Newborn health and survival are closely linked to essential newborn care provided within the first days and weeks of an infant's life by parents and caregivers at home and within the community. Newborn care practices are often socially and culturally determined and have been explored in qualitative and formative research related to improving neonatal survival. We aim to provide a comprehensive review of qualitative studies on parent and caregiver experiences of newborn care practices with a view to identifying barriers and facilitators that may impact on newborn health. The rationale is that providing this information will be useful for intervention design and program scale-up for newborn survival.

**Methods and analysis:** We will systematically review qualitative studies reporting on newborn care practices. The ENTREQ statement will be used for reporting the stages of the review and dissemination. The search period will include all studies published from 2006-2016. Study selection will incorporate both the ENTREQ and PRIMSA guidelines and quality assessment will be done in two phases using the COREQ and CASP guidelines as well as those identified by Carroll et al. If sufficient data of good quality are available, we will conduct a full synthesis of the studies identified by the review.

**Ethics and dissemination:** The results will be disseminated through peer-reviewed publications, conference presentation, and directly to organizations involved in newborn health. Formal ethical approval from the author's institution is not required, as no primary data or identifying data will be collected.

Review registration number: (Prospero) CRD42016035674

## Strengths and limitations

Strengths of the proposed study include:

- A comprehensive search strategy
- Use of multiple reviewers
- Quality assessment verification
- Comprehensive description of the findings

Limitations include:

- English language studies only
- Exclusion of studies prior to 2006
- Potential for missing material that may be relevant but is not found by the search strategy

## Background

Community-based or home-based care of the newborn infant is a crucial component of survival, healthy growth, and optimal development for all children [1]. Following delivery, parents and caregivers play the most important role in protecting and providing for newborns in the most vulnerable period of their young lives, the twenty-eight days following birth [2]. Despite strong evidence for the effectiveness of feasible interventions to reduce newborn mortality [3], which continues to be unacceptably high [4], coverage of these interventions is low [5].

In evaluating research priorities for improving newborn health and birth outcomes, researchers and key stakeholders have identified a significant number of domains related to caregiver perceptions and behaviors, and related to home and community newborn care practices [6]. Providing data on these topics is key for scale up of coverage and effective implementation of interventions aimed at improving newborn health.

Our rationale in conducting this review is that while many individual qualitative and formative research studies have been conducted on newborn care practices in the home and community [7-10], to date there has not been a systematic review or synthesis of the existing qualitative research. Conducting a systematic review will provide comprehensive and useful data for programming and policy related to both facility and community care for newborns as well as guidance for intervention design and scale up of existing programs.

The primary objective is to systematically review qualitative literature related to newborn care practices with a focus on parent and caregiver perceptions and experiences of in low-income settings, focusing on information related to barriers and facilitators that may affect interventions for newborn survival.

## Methods and analysis

This systematic review has been registered with the International Prospective Register of Systematic Reviews (PROSPERO): registration number CRD42016035674.

### *Study design*

The review to be undertaken will follow the ENTREQ statement (Enhancing Transparency in Reporting the Synthesis of Qualitative Research) in reporting the stages of the review and dissemination. In view of the unique nature of qualitative research, the review will employ both the ENTREQ guidelines [11] and the Preferred Reporting Items for Systemic Reviews and Meta-Analyses (PRISMA) guidelines, as the latter is more closely related to reviews of quantitative literature and may not be sufficient alone [12].

Studies will be included where data are presented as having been directly obtained from participants who are parents or caregivers of newborns (infants under 28 days of age, including low birth weight or small babies), whether born at home or at a facility, with or without skilled attendance. Caregivers will be defined as mothers/fathers or other adult family or community members who provide physical and psychological support to meet the basic needs of newborn infants.

Studies will be included if they use widely accepted qualitative data collection methods (interviews, focus groups, direct observation, participatory action research, etc...) and analysis methods. Studies involving mixed methods where the qualitative data will be difficult to extract will be excluded, as will studies with heterogeneous participant groupings or studies with settings where perceptions of parents/caregivers cannot be extracted. Commentaries and conference proceedings will not be included. Additionally, studies from countries other than those defined by the World Bank as Low-income and Lower-middle-income Countries will be excluded [13].

For the purpose of this systematic review, newborn care practices will be defined as all actions taken by parents/caregivers that provide for the essential biological, physiological, and psychological needs of the newborn infant following delivery up to 28 days of life. These will include, but are not limited to, the essential newborn care practices as defined in the international reference literature [14] such as cord care, drying and wrapping after delivery, initiation of breastfeeding, bathing, thermal control, breastfeeding, and care seeking for newborn illness.

Given that newborn mortality is highest in areas of low socioeconomic status and with poor health infrastructure [2, 15], only studies from low-income and lower-middle-income settings, as defined by World Bank, will be included.

*Search strategy*

The following electronic databases which are considered to be the most relevant for the topic will be searched: MEDLINE (PubMed), Embase, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) through EBSCO. The initial search strategy will be developed for MEDLINE and then adapted for other databases. Medical subject headings (MeSH) will initially be used, followed by free-text terms using controlled vocabulary (see Annex 1 for a detailed description of the search strategy). Results will be restricted to English language publications from the last ten years. In addition to the aforementioned search strategy, we will manually search reference lists of included studies to identify any additional studies that fit the inclusion criteria.

Systematic reviews of published literature may inflate estimates of health intervention effects, as negative or inconclusive findings are less likely to be published [16]. To minimize publication bias, this systematic review will include grey and unpublished literature. An iterative process will be used to identify the grey and unpublished literature, including manual review of internal reports; websites of relevant organizations working in the field of maternal/neonatal health in low-income countries; bibliographies of published and unpublished articles included in the study; and reports from scientific meetings. Internet searches will be conducted using search strings adapted from those described above. Experts working in the field may also be contacted to identify relevant literature. Results will be limited to publications in English from the last ten years.

*Study selection*

Search results will be imported into Endnote software [Thomson Reuters (Scientific LLC)]. Duplicates and irrelevant studies will be removed. Two independent reviewers will first screen study titles and abstracts for eligibility. Eligibility will be tested against pre-determined inclusion criteria and quality assessment guidelines. Three Endnote folders will be created: one for studies that meet initial search criteria (where agreed by both reviewers), one for studies that do not meet criteria (where agreed by both reviewers), and one for further full-text review to determine eligibility. In all cases, the decision to

include or exclude a study must be agreed on by both reviewers. If a decision cannot be reached, a third reviewer will make the final decision.

A flow diagram using PRISMA guidelines for reporting of systematic reviews will be used in reporting of the selection process and results. [17]

### *Quality appraisal*

To improve the internal validity of the review, each study will be assessed for quality according to Carroll and colleagues' guidelines [18, 19] and the CASP checklist [20]. Studies must meet minimum objective criteria to be considered of sufficient quality. The criteria will include domains such as appropriateness of study design, sampling methodology, as well as data collection techniques and analysis methods used in each study. The authors will document studies that were excluded on the basis of quality. Descriptive information of these studies will be available as requested.

A further quality assessment will be conducted using the consolidated criteria for reporting of qualitative research checklist (COREQ) [21]. The COREQ checklist consists of 32 quality measures. Two reviewers will independently review each study against the checklist to reach consensus. In cases of non-consensus, a third reviewer will decide the outcome. A quality assessment table will be created to facilitate comparisons among the reviewed studies.

### *Data Extraction*

Specific characteristics from included studies will be extracted, and compiled into a unified data matrix. A single reviewer will complete abstract review and a second reviewer will check for accuracy. Extracted data will include, but not be limited to, reference details (author/data/publication), methodological approach (e.g. interviews/focus groups), conceptual theory underlying the study (e.g. Grounded Theory), objectives or aims of the study, sampling methodology, sociodemographic characteristics of participants, country/region, and analysis method.

### *Analysis*

The final analysis plan will be dependent on the results of the review. If results are relevant and meet the stated objectives, data from the Results, Discussion and Conclusion sections of included studies, will be extracted into NVivo 11 qualitative software [NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 11, 2015] for further synthesis. Thematic analysis, whereby themes that are descriptive of the data will be developed, analyzed, and presented. Tables and visual representations of the thematic analysis will be provided.

### *Discussion*

To our knowledge, this will be the first study to systematically review and synthesize qualitative data on newborn care practices in low-income countries from the perspective of caregivers. The findings will provide insight about the barriers and facilitators that hinder or enable implementation of newborn-care best practices

Abbreviations

N/A

Competing interests statement

The authors declare they have no competing interests.

Authors' contributions

AB drafted and finalized the manuscript. EFK, AK, and LS contributed sections to the draft manuscript and search strategy. All authors read and approved the final version.

Acknowledgement

N/A

Annex 1. Sample search strategies

1. "Infant" [MeSH] OR "Infant" [All Fields] OR "Newborn" [MeSH] OR "Newborn" [All Fields]
2. ("infant, newborn" [MeSH] OR ("infant" [All Fields] AND "newborn" [All Fields]) OR "newborn infant" [All Fields] OR "newborn" [All Fields]) AND care [All Fields] AND practices
3. (("infant, newborn [MeSH] OR ("infant" [All Fields] AND "newborn" [All Fields]) OR "newborn infant" [All Fields] OR "newborn" [All Fields] AND care [All Fields] AND practices [All Fields] AND ("2006/03/28"[PDat]: "2016/03/28" [PDat])

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mothers, newborn babies, and stillbirths, and at what cost? *Lancet* 2014, **384**(9940):347-370.

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9. Group NMFRW: **Developing community-based intervention strategies to save newborn lives: lessons learned from formative research in five countries.** *J Perinatol* 2008, **28**(Suppl 2):S2 - S8.

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12. Fleming PS, Koletsi D, Pandis N: **Blinded by PRISMA: are systematic reviewers focusing on PRISMA and ignoring other guidelines?** *PLoS One* 2014, **9**(5):e96407.

13. **Country and Lending Groups** [<http://data.worldbank.org/about/country-and-lending-groups>]

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## PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 4:1

Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	x	<input type="checkbox"/>	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	<input type="checkbox"/>	x	N/A
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	x	<input type="checkbox"/>	1
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	x	<input type="checkbox"/>	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	x	<input type="checkbox"/>	5
Amendments	4	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	<input type="checkbox"/>	x	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	x	<input type="checkbox"/>	5
Sponsor	5b	Provide name for the review funder and/or sponsor	x	<input type="checkbox"/>	5
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	x	<input type="checkbox"/>	5
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	x	<input type="checkbox"/>	2
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to	x	<input type="checkbox"/>	2

Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
		participants, interventions, comparators, and outcomes (PICO)			
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	x	<input type="checkbox"/>	2-3
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	x	<input type="checkbox"/>	3
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	x	<input type="checkbox"/>	5
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	x	<input type="checkbox"/>	3-4
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	x	<input type="checkbox"/>	3-4
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	x	<input type="checkbox"/>	3-4
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	x	<input type="checkbox"/>	4
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	x	<input type="checkbox"/>	4
Risk of bias in individual studies	14	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	x	<input type="checkbox"/>	4
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	x	<input type="checkbox"/>	4
	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 (e.g., $I^2$ , Kendall's tau)	x	<input type="checkbox"/>	4
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-	<input type="checkbox"/>	x	N/A

Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
		regression)			
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	X	<input type="checkbox"/>	4
<b>Meta-bias(es)</b>	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	X	<input type="checkbox"/>	4
<b>Confidence in cumulative evidence</b>	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	X	<input type="checkbox"/>	4

# BMJ Open

## Parent and caregiver perspectives on home-based newborn care in low-income settings: protocol for a systematic review of qualitative studies

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<b>Primary Subject Heading</b>:	Global health
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# Parent and caregiver perspectives on home-based newborn care in low-income settings: protocol for a systematic review of qualitative studies

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## Abstract

**Introduction:** Newborn health and survival are closely linked to essential newborn care provided within the first days and weeks of an infant's life by parents and caregivers at home and within the community. Newborn care practices are often socially and culturally determined and have been explored in qualitative and formative research related to improving neonatal survival. We aim to provide a comprehensive review of qualitative studies on parent and caregiver experiences of newborn care practices with a view to identifying barriers and facilitators that may impact on newborn health. The rationale is that providing this information will be useful for intervention design and program scale-up for newborn survival.

**Methods and analysis:** We will systematically review qualitative studies reporting on newborn care practices. The ENTREQ statement will be used for reporting the stages of the review and dissemination. The search period will include all studies published from 2006-2016. Study selection will incorporate both the ENTREQ and PRIMSA guidelines and quality assessment will be completed using CASP guidelines. Pending the identification of sufficient data of good quality, we will conduct a full synthesis of the studies identified by the review.

**Ethics and dissemination:** The results will be disseminated through peer-reviewed publications, conference presentation, and directly to organizations involved in newborn health. Formal ethical approval from the author's institution is not required, as no primary data or identifying data will be collected.

Review registration number: (Prospero) CRD42016035674

## Strengths and limitations

Strengths of the proposed study include:

- Focus on lower income countries
- Synthesis of qualitative findings where currently none exists in the published literature

Limitations include:

- English language studies only will be included
- Potential for missing material that may be relevant but is not found by the search strategy

## Background

Community-based or home-based care of the newborn infant is a crucial component of survival, healthy growth, and optimal development for all children [1]. Following delivery, parents and family caregivers play the most important role in protecting and providing for newborns in the most vulnerable period of their young lives, the twenty-eight days following birth [2]. Despite strong evidence for the effectiveness of feasible interventions to reduce newborn mortality [3], which continues to be unacceptably high [4], coverage of these interventions is low [5].

In evaluating research priorities for improving newborn health and birth outcomes, researchers and key stakeholders have identified a significant number of domains related to caregiver perceptions and behaviors, and related to home and community newborn care practices [6]. Providing data on these prioritized research topics is key for scale up of coverage and effective implementation of interventions aimed at improving newborn health.

Our rationale in conducting this review is that while many individual qualitative and formative research studies have been conducted on newborn care practices in the home and community [7-10], to date there has not been a systematic review or synthesis of the existing qualitative research. Conducting a systematic review will provide comprehensive and useful data for programming and policy related to both facility and community care for newborns, as well as guidance for intervention design and scale up of existing programs.

Newborn care practices comprise a multifaceted group of behaviors, thus qualitative methodologies and the data obtained from qualitative research are especially appropriate for gaining information about these practices, particularly in low-income countries where such behaviors will vary based on the sociocultural context [9].

The primary objective of the proposed study is to systematically review qualitative literature related to newborn care practices with a focus on parent and caregiver perceptions and experiences in low-income settings, focusing on information related to barriers and facilitators that may affect interventions for newborn survival.

## Methods and analysis

This systematic review has been registered with the International Prospective Register of Systematic Reviews (PROSPERO): registration number CRD42016035674.

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Studies will be included where data are presented as having been directly obtained from participants who are parents or caregivers of newborns (infants under 28 days of age,

including low birth weight or small babies), whether born at home or at a facility, with or without skilled attendance. Caregivers will be defined as mothers/fathers or other adult family or community members who provide day to day physical and psychological support to meet the basic needs of newborn infants. Community health workers will not be considered as caregivers for the purposes of this review, though we acknowledge that they may be involved in caring for newborn infants at specific points in time.

Studies will be included if they use widely accepted qualitative data collection methods (interviews, focus groups, direct observation, participatory action research, etc...) and analysis methods. Studies involving mixed methods where the qualitative data will be difficult to extract will be excluded, as will studies with heterogeneous participant groupings or studies with settings where perceptions of parents/caregivers cannot be extracted. Commentaries will not be included. Additionally, studies from countries other than those defined by the World Bank as Low-income and Lower-middle-income Countries will be excluded [13].

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Given that newborn mortality is highest in areas of low socioeconomic status and with poor health infrastructure [2, 15], only studies from low-income and lower-middle-income settings, as defined by World Bank, will be included.

*Search strategy*

The following electronic databases which are considered to be the most relevant for the topic will be searched: MEDLINE (PubMed), Embase, and Cumulative Index to Nursing and Allied Health Literature (CINAHL) through EBSCO. The initial search strategy will be developed for MEDLINE and then adapted for other databases. Medical subject headings (MeSH) will initially be used, followed by free-text terms using controlled vocabulary (see Annex 1 for a detailed description of the search strategy). A library and information scientist specialized in public health will assist in further piloting of search strategies, will finalize the search strategy, and will perform the database searches for the review.

Results will be restricted to English language publications from the last ten years. In addition to the aforementioned search strategy, we will manually search reference lists of included studies to identify any additional studies that fit the inclusion criteria. Experts working in the field may also be contacted to identify relevant literature that has not been obtained through the database and manual search of reference lists. Results from these searches will again be limited to publications in English from the last ten years.

*Study selection*

Search results will be imported into Endnote software [Thomson Reuters (Scientific LLC)]. Duplicates and irrelevant studies will be removed. Two independent reviewers will first screen study titles and abstracts for eligibility. Eligibility will be tested against pre-determined inclusion criteria and quality assessment guidelines. Three Endnote folders

will be created: one for studies that meet initial search criteria (where agreed by both reviewers), one for studies that do not meet criteria (where agreed by both reviewers), and one for further full-text review to determine eligibility. In all cases, the decision to include or exclude a study must be agreed on by both reviewers. If a decision cannot be reached, a third reviewer will make the final decision.

A flow diagram using PRISMA guidelines for reporting of systematic reviews will be used in reporting of the selection process and results. [16]

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Two reviewers will independently review each study against the checklist to reach consensus. In cases of non-consensus, a third reviewer will decide the outcome. A quality assessment table will be created to facilitate comparisons among the reviewed studies.

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### *Analysis*

The final analysis plan will be dependent on the results of the review. If results are relevant and meet the stated objectives, data from the Results, Discussion and Conclusion sections of included studies, will be extracted into NVivo 11 qualitative software [NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 11, 2015] for further synthesis. Thematic analysis, whereby themes that are descriptive of the data will be developed, analyzed, and presented. Tables and visual representations of the thematic analysis will be provided.

### *Discussion*

To our knowledge, this will be the first study to systematically review and synthesize qualitative data on newborn care practices in low-income countries from the perspective of caregivers. The focus on qualitative findings will allow for rich data on complex and often heterogeneous care practices in lower income countries where newborn mortality is most prevalent to be made more widely available. The findings will provide insight about the barriers and facilitators that hinder or enable implementation of newborn-care best practices.

Abbreviations

N/A

Competing interests statement

The authors declare they have no competing interests.

Authors' contributions

Per ICMJE criteria, AB was responsible for the overall conception and design of the work and drafted and revised it for important intellectual content. EFK also drafted and revised for important intellectual content. AK, and LS assisted with the acquisition, analysis, and interpretation of data for the work. All authors reviewed and agreed on final approval of the version to be published. All authors have agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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N/A

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**Annex 1. Sample search strategies**

1. “Infant” [MeSH] OR “Infant” [All Fields] OR “Newborn” [MeSH] OR “Newborn” [All Fields]
2. (“infant, newborn” [MeSH] OR (“infant” [All Fields] AND “newborn” [All Fields]) OR “newborn infant” [All Fields] OR “newborn” [All Fields]) AND care [All Fields] AND practices
3. ((“infant, newborn” [MeSH] OR (“infant” [All Fields] AND “newborn” [All Fields]) OR “newborn infant” [All Fields] OR “newborn” [All Fields] AND care [All Fields] AND practices [All Fields] AND (“2006/03/28” [PDat]: “2016/03/28” [PDat]))

For peer review only

## PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 4:1

Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	x	<input type="checkbox"/>	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	<input type="checkbox"/>	x	N/A
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	x	<input type="checkbox"/>	1
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	x	<input type="checkbox"/>	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	x	<input type="checkbox"/>	5
Amendments	4	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	<input type="checkbox"/>	x	N/A
Support					
Sources	5a	Indicate sources of financial or other support for the review	x	<input type="checkbox"/>	5
Sponsor	5b	Provide name for the review funder and/or sponsor	x	<input type="checkbox"/>	5
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	x	<input type="checkbox"/>	5
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	x	<input type="checkbox"/>	2
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to	x	<input type="checkbox"/>	2

Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
		participants, interventions, comparators, and outcomes (PICO)			
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	x	<input type="checkbox"/>	2-3
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	x	<input type="checkbox"/>	3
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	x	<input type="checkbox"/>	5
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	x	<input type="checkbox"/>	3-4
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	x	<input type="checkbox"/>	3-4
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	x	<input type="checkbox"/>	3-4
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	x	<input type="checkbox"/>	4
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	x	<input type="checkbox"/>	4
Risk of bias in individual studies	14	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	x	<input type="checkbox"/>	4
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	x	<input type="checkbox"/>	4
	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 (e.g., $I^2$ , Kendall's tau)	x	<input type="checkbox"/>	4
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-	<input type="checkbox"/>	x	N/A

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Section/topic	#	Checklist item	Information reported		Page number(s)
			Yes	No	
		regression)			
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	X	<input type="checkbox"/>	4
<b>Meta-bias(es)</b>	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	X	<input type="checkbox"/>	4
<b>Confidence in cumulative evidence</b>	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	X	<input type="checkbox"/>	4