Effect of Patient-centred Care on Quality Nursing Care, Nurse-sensitive Indicators and Satisfaction of Nurses and Patients in Adult Medical Inpatients Setting: A Mixed Methods Systematic Review Protocol

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Authors' contributions

This work was carried out in collaboration between all authors. All authors read and approved the final manuscript.

Systematic Review Article

ABSTRACT

Background: The Institute of Medicine (IOM) in the USA proposed Patient-centred care (PCC) as a quality health care model that relies on partnerships among health practitioners, patients and their families whereby patients' values, needs and preferences are factored into the health care process. This allows for patients' input in their health education, support to make decisions on their care and participation in their own care. Patient-centred care (PCC) is projected as the gold standard for quality health care with positive effect on quality of nursing care, patient satisfaction, nurse satisfaction and nurse-sensitive indicators. Even though many studies have been done on the subject of patient centred care, fewer reviews exists on the effect of Patient-centred care on

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outcomes such as quality nursing care, nurse satisfaction, patient satisfaction and nurse-sensitive outcomes.

Aim: The aim of this review is to identify PCC models in literature and examine their effect on quality nursing care (QNC), nurse satisfaction (NS) patient satisfaction (PS) and on nurse-sensitive indicators.

Methods: This study adopts principles of systematic literature review to do a search on the effect of patient-centred care (PCC) models on selected health outcomes. These outcomes include quality nursing care (QNC), nurse sensitive indicators (NSI) and satisfaction of nurses and patients in the hospital setting with emphasis on medical inpatient setting. Papers published in English language between 1990 and 2018 from the selected databases will be searched. To identify eligible studies, keywords search and where possible MeSH terms related to "patient-centred care", quality nursing care, nurse satisfaction, nurse-sensitive outcomes and patient satisfaction will be used. These terms will be searched individually first and then combined with "OR". To situate the search within the nursing context and impatient setting, the keywards or MeSH terms will be used with "nursing", "nursing care", "nursing services", "inpatients".

Discussion: The review seeks to provide evidence on existing models of PCC in literature and how they affect the quality of nursing delivery, nurse-sensitive outcomes and satisfaction of both nurses and patients in the hospital setting.

Conclusion: This review seeks to provide the international perspective on the effects of Patient-centred care (PCC) on quality nursing and satisfaction of nurses and medical inpatients on nursing services delivery during admission. Dimensions or attributes and barriers of PCC delivery will be identified and incorporated into a context-driven PCC model for implementation in the Ghanaian setting.

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1. INTRODUCTION

Many countries face quality health care (QHC) problems and efforts at mitigating these problems have been ongoing for decades. Quality health care issues were highlighted in the seminal work of Donabedian, "Evaluating the Quality of Medical Care"[1] and was reinforced by "Crossing the Quality Chasm" report in the United States of America (USA). "Crossing the Quality Chasm" report identified a great disparity between the health care being received and what the optimal care should be [2] and thus proposed Patient-centred care (PCC) as one of the quality aims. Hence PCC as a core quality health care model has gained worldwide attention and so is measurement of outcomes of clinical interventions that facilitate PCC delivery across various care settings [3]. Implementation of patient-centred care (PCC) appears to promote high quality health care (QHC), better health outcomes including nurse-sensitive indicators (NSI) and efficient health delivery [4]. Generally, literature suggests that the implementation of PCC model is associated with better perceptions of health care quality, patient satisfaction, staff satisfaction and improved outcomes [5,6]. Patient-centred care (PCC) is therefore projected

as the gold standard for quality health care [7]. This review seeks to appraise the effect of PCC models on quality nursing care, nurse satisfaction, Nurse-sensitive indicators and patient satisfaction as a part of a project for PCC implementation effort in Ghana.

1.1 Background to the Review

The concept of quality health care (QHC) has been described by Mitchell [8] as an abstraction which does not exist discreetly but is socially constructed among relevant actors based on agreed upon norms and values (standards) and available possibilities. The Institute of Medicine (IOM) defined quality of health care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" [9 p4].

Patient-centred care is defined by the Committee on Quality of Health Care in America, Institute of Medicine as being "respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient's values guide all clinical decisions" [2 p6]. The IOM proposed model of PCC is one that relies on partnerships

among health practitioners, patients and their families. These partnerships seek to incorporate patients' wants, needs and preferences, allowing for patients' input in their health education, support for patients to make decisions on their care and participation in their own care process [2]. PCC in the Nursing context has been defined as "the degree to which the patient's wishes, needs and preferences are taken into account by nurses when the patient requires professional nursing care" [10 p106].

Patient satisfaction (PS) represents the patient's subjective and dynamic perception of the level of expected care received [11]. Patient Satisfaction with nursing care is the patients' subjective evaluation of their cognitive and emotional reaction as a result of the interaction between their expectations regarding ideal nursing care and their perceptions of the actual nursing care delivered [12]. Job satisfaction is defined as "the degree of positive affect towards a job or its components [13 p536] or job satisfaction is the degree or level that employees like their work [14]. Job satisfaction in this study is looked at as a positive concept describing work attitudes, abilities and positive factors promoting quality nursing care [14]. Nurse satisfaction is influenced by the nature of interpersonal relationship among nurses, the service environment, mode of organization of nursing services and the nature and process of patient care [14]. A health outcome denotes change in a patient's current or future health status, patient's attitudes, knowledge, health related behaviour and satisfaction that may be attributable to health care [15]. Patient care outcomes that are significantly affected by nursing care are referred to as Nurse-sensitive indicators [16]. Nurse-sensitive indicators (NSI) are affected by system-centred measures such as nurse turnover and nurse staffing levels as well as process factors such as the process of service delivery such as PCC or PCNC [17].

Many health services in both developed and developing countries do not meet minimum standards for clinical effectiveness or patient satisfaction [18]. Evidence of poor health care concerns still exists even in the well-developed and well-resourced health systems with corresponding growing awareness and pressure for improvement of health care quality and performance of the health system worldwide [19]. Though health care reforms have been undertaken in Africa, care in many countries remains poor [20]. In the Ghanaian context, the World Bank report [21] revealed an improvement in the number of health workers but health care quality still suffers with low patients' rating of Health workers' competencies and performance, widespread deficiencies in technical skills culminating in substandard clinical care quality.

PCC appears to significantly impact on quality health care. A recent report by the Health Innovation Network (HIN), South London, intimated that PCC can impact positively on health care quality, satisfaction and health outcomes [22]. This is in concordance with the acknowledgement of the World Health Organisation (WHO) that people-centred services (for example, PCC) are the catalysts for successful outcomes [23]. The role of nurses in providing PCC or PCNC has been illuminated by the International Council of Nursing (ICN) that "nurses are the cornerstone of health care delivery that is focused on person-centeredness, continuity of care, comprehensiveness and integration of services which are fundamental to holistic care" [24 p16]. Lusk and Fader [25] suggested that the characteristics, behaviours or attributes of PCC are fundamental to the core and essence of nursing practice.

Despite the perceived beneficial effects of PCC, its implementation presents mixed results in literature. While McCormack and McCance [26] suggest PCC is widely used; Gallo, Hoagwood and Olin [27] contend that implementation of PCC has not been vigorously pursued. A recent report confirms that fewer studies about PCC outcomes exist [23]. Similarly, it argued that up to date, limited PCC conceptualization and implementation in African countries (including Ghana) exists especially in low income African countries as well as Sub-Saharan countries [28]. Consequently, this study seeks to appraise literature on the effect of PCC on QNC, NS, NSI, and PS. This review will serve as the first phase in a larger study that seeks to develop and implement an evidence-based contextualised PCC model in the Ghanaian adult medical inpatient setting.

1.2 Purpose of the Review

The purpose of this review is to identify PCC models in literature and examine their effect on quality nursing care (QNC), nurse satisfaction (NS) patient satisfaction (PS) and on nurse-sensitive indicators. The review is purposefully a first phase towards developing and implementing a contextualised evidence-based PCC model in the Ghanaian context.

1.3 Review Objectives

The objectives of this review are to ascertain the best available evidence among adult medical inpatients by:

1. Identifying existing PCC models in literature
2. Examining how the existing PCC models were implemented
3. Examining how the implementation of PCC models affect:

   a) Quality Nursing care (QNC),
   b) Nurse satisfaction (NS),
   c) Nurse-sensitive Indicators (NSI)
   d) Patient Satisfaction (PS)

4. Identifying what tools are used to measure the effects of PCC on nursing outcomes from literature.

1.4 Review Question(S)

The main questions of the review are as follows:

1. What are the existing PCC models in literature?
2. How are the existing PCC models implemented?
3. What are the effects of the PCC models with regards to:

   a) QNC?
   b) PS?
   c) NS?
   d) NSI?

4. What tools are used to measure the effect of PCC on nursing outcomes?

2. CONCEPTUAL MODEL FOR SYSTEMATIC REVIEW

The review seeks to identify structural, process and outcome characteristics of patient-centred care models in literature related to nursing care in inpatient medical setting. The Nursing Role Effectiveness Model proposed by Irvine, Sidani, and Hall [29] has been adapted and modified for this review. The study emphasis is the "independent nursing role" where Patient-centred care (PCC) as regards to nursing care (Patient-centred Nursing care [PCNC]) is the principal focus. The PCC interventions to be reviewed will include existing PCC models (dimensions), PCC principles, activities, enablers and barriers. The "interdependent role" involves nursing team communication and care coordination complementing the patient-centred activities as shown in Fig. 1.
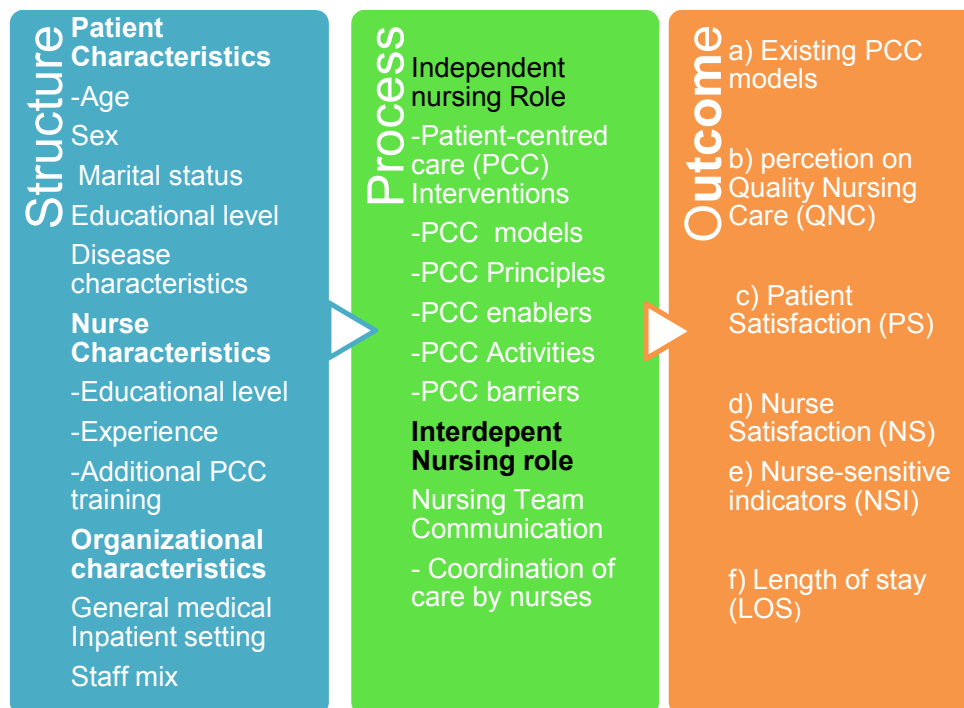

Fig. 1. Conceptual framework for the systematic review
Source: Adapted from Nursing Role Effectiveness Model (Irvine, Sidani, & McGillis Hall, 1998) and modified under the Donabedian (1966) Structure-Process-Outcome (SPO) model

2.1 Information Sources

Studies will be retrieved by searching the following databases - from 1990 to 2018 and by hand searching references in the studies included
• MEDLINE • PubMed • CINAHL • EMBASE • Cochrane Library • Google scholar • SCOPUS • PsychINFO • Joanna Brigs • EMCARE

2.2 The Search Strategy

Using keywords, MESH terms and free text words, ten databases will be searched. The free text words will be related to the themes of the review. In order to cater for differences in terminologies and words truncation appropriate Boolean Operators will be included into the search strategy. Limitations will be set in accordance with the inclusion and exclusion criteria of the review. A MEDLINE search strategy will be developed (as shown in Table 1) and subsequently adapted to the syntax and subject headings of other databases.

Table 1. Search strategy from medline

Search ID	Searches
1	Patient-Centered Care/ or Nurse-Patient Relations/ or Patient Participation/ or patient-centred care.mp. or "Attitude of Health Personnel"/ or Patient Care Team/
2	patient-centered care.mp. or Patient-Centered Care/
3	person-centred care.mp.
4	patient-centredness.mp.
5	individualised care.mp.
6	Patient Care Planning/ or negotiated care.mp.
7	patient-centred nursing care.mp.
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	Nursing Care/ or quality nursing care.mp.
10	nursing.mp. or NURSING/
11	9 or 10
12	Nursing Staff/ or Interprofessional Relations/ or Job Satisfaction/ or Nurses/ or nurse satisfaction.mp.
13	Nurse-sensitive indicators.mp. or Quality Indicators, Health Care/
14	nursing outcomes.mp.
15	12 or 13 or 14
16	patient satisfaction.mp. or Patient Satisfaction/
17	client satisfaction.mp.
18	satisfaction.mp. or Personal Satisfaction/
19	16 or 17 or 18
20	adults.mp. or Adult/
21	middle-age.mp. or Middle Aged/
22	In patient.mp. or Aged/
23	Medical in patient.mp.
24	Medical in patient.mp.
25	in-patient setting.mp.
26	20 or 21 or 22 or 23 or 24 or 25
27	8 and 11 and 15 and 19 and 26
28	limit 27 to (yr="1990 -Current" and "all adult (18 plus years)" and English)

2.3 Design/ Methods of the Review

This is a mixed method systematic review aimed at identifying PCC models in literature and their effects on perceptions of quality nursing care (QNC), nursing-sensitive indicators (NSI), patient' satisfaction (PS) and nurse satisfaction (NS). Database searches and selection of studies for inclusion will be done by two reviewers independently and verified by a third independent reviewer. This systematic review will employ the guidelines of the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) format to report the study findings. [30] Qualitative data will be synthesized using Thematic Network Analysis tool proposed by Attride-Stirling [31] or meta-analysis if sufficient articles are retrieved.

2.4 The Study Population/Participants

1. The target population for this study will comprise all quantitative, qualitative and mixed methods PCC studies related to nursing care among adult (18 years and above) medical inpatients and nurses working in medical impatient setting.

2. These PCC studies would have examined at least one of the following:

   a) Quality nursing care (QNC)
   b) Nurse-sensitive Indicators (NSI)
   c) Patient Satisfaction (PS)
   d) Nurse Job Satisfaction (NS)

2.4.1 Inclusion criteria

1. PCC records from January, 1990 to 30th September, 2018 related to nursing care in the following databases CINAHL, PubMed, MEDLINE, EMBASE, PsychInfo, Joanna Brigs, EMCARE, Cochrane Library, google scholar and SCOPUS.
2. Citations are deemed eligible for inclusion if they are quantitative, qualitative or mixed methods PCC studies in English and among adult (18 years and above) medical inpatients setting.
3. Studies which evaluated the effect of PCC on at least one of the following:

   a) Quality Nursing Care (QNC)
   b) Nurse-sensitive Indicator (NSI)
   c) Patient Satisfaction (PS)
   d) Nurse Satisfaction (NS)

4. Hand searching of references from citations retrieved that meet the inclusion criteria.
5. Searching grey literature including dissertations and thesis.

2.4.2 Exclusion criteria

The exclusion criteria delimit individuals from taking part in the study [32] and for this review, the exclusion criteria for this review are:

1. PCC Citations that fall out the time limit (1990-2018)
2. Studies which did not evaluate PCC for at least one of the following:

   a) Quality nursing care,
   b) Nurse-sensitive indicators
   c) Patient satisfaction
   d) Nurse Job-satisfaction.

3. PCC studies outside medical inpatient setting
4. RCTs without random allocation of participants

2.4.3 Intervention(S)/Exposure(S)

The review will consider studies that evaluate the effects of the patient-centred care model on quality nursing care, nurse satisfaction, patient satisfaction and nurse-sensitive indicators amongst adult medical inpatients. Studies to be considered are PCC interventions among adult medical inpatients that include:

a. Randomised controlled Trials (RCTs)
b. Quasi experimental studies (QES)
c. Additional PCC training for providers (ATP).
d. Descriptive studies
e. Qualitative PCC studies

2.5 Comparator/Control

Traditional Nursing Care: standard nursing care for medical inpatients that employ nursing services without incorporating individual patient preferences, needs, and values. Traditional nursing care also includes generalized patient education.

2.6 Primary Outcome(S)

This review will consider studies that include the following outcome measures:

a. Existing PCC models in literature
b. Patient Perception on Quality Nursing Care (QNC)
c. Nurse Perception on Quality Nursing Care (QNC)
d. Patient Satisfaction (PS)
e. Nurse Satisfaction (NS)
f. Nurse-sensitive indicators (NSI)

3. DATA MANAGEMENT, SCREENING AND SELECTION

For the purposes of screening and management of the data, all search results will be downloaded into the reference manager ENDNOTE version X7. The titles, abstracts and subject headings of all searched articles will be screened in accordance with the eligibility criteria. Eligible PCC studies identified will be categorized according to structural factors such as background characteristics of nurses, patients and the care environment. The second category includes PCC processes or activities such as RCTs, non-randomized control trials, quasi-experimental studies, observational studies and qualitative studies. The third categorisation of identified studies is based on outcomes such as the effect of PCC on QNC, NS, PS and NSI. Two independent reviewers will work on this review which will then be verified by a third reviewer.

3.1 Data Extraction (Selection and Coding)

Data will be extracted from PCC quantitative, qualitative and mixed methods studies included in the review. Data extracted will include specific details about the population, interventions, study methods, and outcomes related to the specific objectives and the review questions.

4. RISK OF BIAS (QUALITY) ASSESSMENT

Two independent reviewers will assess the validity and methodological quality of the papers selected for retrieval prior to inclusion of such studies in the review. The two independent reviewers will resolve any disagreement that may arise between them through discussion or with a third reviewer until consensus is reached. The quality of papers will be assessed using the Mixed Methods Appraisal Tool (MMAT) – Version 2011 [33] (see appendix 1) and the quality of papers that report meta-analysis will be assessed using the GRADE tool [34]. Taking

cognizance of the fact that studies with statistically significant ($p < 0.05$) findings are more likely to be published than those with non-significant findings [35,36,37]; publication bias will be evaluated using funnel plots and assessment of funnel plot asymmetry, if applicable. This method has been widely used previously [36,38,39,40] and recommended to investigate publication bias [41]. Reporting bias from RCTs will be evaluated by checking the time of publication of the trial protocol and recruitment of patients. For trials published after 1st July 2005; the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organization will be screened. The outcomes specified in the screened protocol will be compared against those in the published report to assess selective outcome reporting bias.

5. STRATEGY FOR DATA SYNTHESIS

The review will seek to synthesise the quantitative PCC papers included through pooled in statistical meta-analysis. All results will be subject to double data entry. Odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed using the standard Chi-square. Assessment of heterogeneity will be done to confirm our expectation by adopting the method of Whitehead et al. [38]. Methodological heterogeneity will be determined by comparing the findings of the different study designs of the included studies, and the outcome discussed among the review team to arrive at a consensus. Where statistical pooling is not possible, the findings will be presented in narrative form. The qualitative papers will be analysed using Thematic Network Analysis as proposed by Attride-Stirling [31]. Thematic network analysis "is a method for identifying, analyzing and reporting patterns (themes) within data" [42 p79] and also provides detail and thick description of the data set.

6. DISCUSSION

This systematic review will provide evidence of what models of PCC exist in literature with regards to adult medical inpatient setting. The study will contribute to knowledge on how these PCC models affect the quality of nursing care, nurse-sensitive indicators, nurse satisfaction and patient satisfaction. Factors that promote or

hinder PCC implementation will be identified to serve as lessons for improving PCC design and evidence-based PCC implementation activities. The mixed method design will allow for comprehensiveness of the review of literature and triangulation of findings.

7. CONCLUSION

This review seeks to provide the international perspective on the effects of Patient-centred care (PCC) on quality nursing and satisfaction of nurses and medical inpatients on nursing services delivery during admission. Dimensions or attributes and barriers of PCC delivery will be identified and incorporated into a context-driven PCC model for implementation in the Ghanaian setting.

CONSENT AND ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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APPENDIX 1

Mixed Methods Appraisal Tool (MMAT) – Version 2011

Types of mixed methods study components or primary studies	Methodological quality criteria (see tutorial for definitions and examples)	Responses			
		Yes	No	Can't tell	comment
Screening questions (for all types)	. Are there clear qualitative and quantitative research questions (or objectives*), or a clear mixed methods question (or objective*)?				
	. Do the collected data address the research question (objective)? E.g., consider whether the follow-up period is long enough for the outcome to occur (for longitudinal studies or study components).				
	Further appraisal may be not feasible or appropriate when the answer is 'No' or 'Can't tell' to one or both screening questions.				
1. Qualitative	1.1. Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question (objective)?				
	1.2. Is the process for analyzing qualitative data relevant to address the research question (objective)?				
	1.3. Is appropriate consideration given to how findings relate to the context, e.g., the setting, in which the data were collected?				
	1.4. Is appropriate consideration given to how findings relate to researchers' influence, e.g., through their interactions with participants?				
2. Quantitative randomized controlled (trials)	2.1. Is there a clear description of the randomization (or an appropriate sequence generation)?				
	2.2. Is there a clear description of the allocation concealment (or blinding when applicable)?				
	2.3. Are there complete outcome data (80% or above)?				
	2.4. Is there low withdrawal/drop-out (below 20%)?				
3. Quantitative nonrandomized	3.1. Are participants (organizations) recruited in a way that minimizes selection bias?				
	3.2. Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups when appropriate) regarding the exposure/intervention and outcomes?				
	3.3. In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls), are the participants comparable, or do researchers take into account (control for) the difference between these groups?				

	3.4. Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?				
4. Quantitative Descriptive	4.1. Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)?				
	4.2. Is the sample representative of the population understudy?				
	4.3. Are measurements appropriate (clear origin, or validity known, or standard instrument)?				
	4.4. Is there an acceptable response rate (60% or above)?				
5. Mixed methods	5.1. Is the mixed methods research design relevant to address the qualitative and quantitative research questions (or objectives), or the qualitative and quantitative aspects of the mixed methods question (or objective)?				
	5.2. Is the integration of qualitative and quantitative data (or results*) relevant to address the research question (objective)?				
	5.3. Is appropriate consideration given to the limitations associated with this integration, e.g., the divergence of qualitative and quantitative data (or results*) in a triangulation design?				

Criteria for the qualitative component (1.1 to 1.4), and appropriate criteria for the quantitative component (2.1 to 2.4, or 3.1 to 3.4, or 4.1 to 4.4), must be also applied.

*These two items are not considered as double-barreled items since in mixed methods research, (1) there may be research questions (quantitative research) or research objectives (qualitative research), and (2) data may be integrated, and/or qualitative findings and quantitative results can be integrated.

Adopted from: Pluye P, Robert E, Cargo M, Bartlett G, O'Cathain A, Griffiths F. et al. Proposal: A mixed methods appraisal tool for systematic mixed studies reviews.2011. Retrieved on [30th Sep 2018] from http://mixedmethodsappraisaltoolpublic.pbworks.com .

APPENDIX 2

PRISMA-P 2015 Checklist
This checklist has been adapted 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 Yes	No	Line number(s)
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☑	☐	
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☑	
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☑	☐	
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☑	☐	
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☑	☐	
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	☐	☑	
Support					
Sources	5a	Indicate sources of financial or other support for the review	☑	☐	
Sponsor	5b	Provide name for the review funder and/or sponsor	☑	☐	
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☐	☑	No role
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☑	☐	
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to 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	☑	☐	
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	☑	☐	
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned	☑	☐	

Section/topic	#	Checklist item	Information reported Yes	No	Line number(s)
		limits, such that it could be repeated			
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☑	☐	
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)	☑	☐	
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	☑	☐	
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	☑	☐	
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☑	☐	
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	☑	☐	
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☑	☐	
	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)	☐	☑	Not applicable
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☐	☑	Not applicable
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☑	☐	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☐	☑	Not applicable
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☑	☐	

Peer-review history:
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