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MENSTRUAL HEALTH NEEDS AND EDUCATIONAL OUTCOMES AMONG ADOLESCENT GIRLS LIVING IN COUNTRIES IN SUB-SAHARAN AFRICA: SYSTEMATIC REVIEW PROTOCOL

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Keywords

Menstrual hygiene, menstrual health, educational performance, adolescents, teenage, girls, sub-Saharan Africa, systematic review

Abstract

Introduction

Poor menstrual health and unmet menstrual needs influence several aspects of adolescent girls' lives, including their educational outcomes. However, evidence on menstrual health needs and educational outcomes among these vulnerable girls living in countries across sub-Saharan Africa (SSA) is fragmented and inconclusive. The systematic review aims to explore the association between menstrual health needs and educational outcomes among adolescent girls (10-19 years) living in SSA.

Methods and analysis

Studies (published and unpublished) will be identified from relevant electronic databases including PubMed, CINAHL, ScienceDirect, Google Scholar and LILACS without language restriction. A comprehensive set of search terms and their alternate terms together with the names of countries in sub-Saharan Africa (Table 1) will be used for running the searches. We will also search, Scopus, Web of Science, African Index Medicus, HINARI, African Index Medicus, African Journals Online, Academic Search Premier, MedRXIV, ProQuest, EBSCO Open Dissertations, and reference lists of relevant studies. We will contact experts in the field for potentially relevant unpublished studies. All retrieved articles from the electronic databases and grey literature will be collated and deduplicated using Endnote and exported to Rayyan QCRI. The pre-defined eligibility criteria will be followed to screen papers for inclusion in the review using a validated study selection tool. The flow of studies will be reported using the PRISMA Flow Diagram. Given the anticipated volume of literature to be reviewed at least two reviewers will independently select studies, extract data and assess the quality of the included studies for risk of bias using validated tools. Any disagreements will be resolved through discussion between the reviewers. The Joanna Briggs Institute's Sumari Software will be used for citation management. Binary outcomes will be estimated using pooled proportions (for non-comparative studies) and odds ratio (OR) or risk ratio (RR) (for comparative studies), reported with their 95% confidence intervals (CIs). The mean difference will be used for reporting continuous outcomes with their 95% (CIs). In the case where different instruments have been used to report means, we will employ standardized mean difference (SMD). Heterogeneity will be assessed graphically for overlapping CIs and statistically

using the I^2 statistic and if heterogeneity is detected to be high (>50%), subgroup analysis will be performed to assess the impact of such variation.

Ethics and dissemination

Ethical approval is not required for a systematic review. The findings from this review will be published in a peer-reviewed journal and presented at relevant conferences. Additionally, the findings will be communicated to local stakeholders (e.g. adolescent girls, parents/guardians, school authorities) in appropriate formats and languages to support translation into policy and practice aiming to improve menstrual health and hygiene and education for adolescent girls in sub-Saharan Africa.

Registration

This protocol has been registered in the International Prospective Register of Systematic Reviews (PROSPERO) with registration number [CRD42024565296].

Strengths and limitations of this study

The strengths of this systematic review lie in the comprehensive search strategy and rigorous methodology. The broad geographical scope, coupled with planned subgroup analyses, offers both regional insights and country-specific differences. By focusing on quantitative studies, the review will provide robust statistical evidence, enhancing its relevance for policy-makers and practitioners. The commitment to disseminating findings in accessible formats to various stakeholders further increases its potential impact, bridging the gap between research and practice in adolescent health and education across the region. Despite the comprehensive search strategy, there is a potential for publication bias, particularly concerning unpublished studies that might be missed even with efforts to contact experts in the field. Where data permits, we will use Edger's formula to assess the likelihood of publication bias. Furthermore, the diverse contexts and anticipated methodologies used across sub-Saharan Africa are likely to result in significant heterogeneity between the included studies. Although subgroup analyses be performed to mitigate the effect of heterogeneity, the variability in study designs and settings might remain a challenge which when not considered carefully may limit the ability to draw definitive conclusions from the review findings.

Introduction

Girls often experience a variety of emotions, such as fear, shame, embarrassment, and guilt as a result of unmet menstrual health needs, including leakage of blood and body odour during menstruation [1], resulting in frequently missing school [2, 3]. When suitable and affordable menstrual care products are unavailable, some girls, even women, may struggle to meet their menstrual health needs [4] and resort to measures such as newspapers, old rags, dried leaves or socks [1], which may not provide adequate protection or maintain proper hygiene during menstruation [5].

Cultural taboos further exacerbate the challenges faced by girls, as they hinder them from seeking the necessary assistance or support to meet their menstrual health needs [6–8]. To tackle these challenges, UNICEF and various non-governmental organizations (NGOs) have devised programs aimed at addressing the issues, predominantly within the Water, Sanitation, and Hygiene (WASH) sector [9]. Access to sanitary pads as menstrual hygiene products varies across low and middle-income countries (LMICs): women and girls in Democratic Republic of the Congo (17%), Kenya (14%), Ghana (10%) and Indonesia (9%) reported not using sanitary pads for menstrual health and hygiene respectively. Additionally, non-use of sanitary pads was even higher in India (54%), Ethiopia (41%), Nigeria (37%) and Uganda (36%) due to inequalities within countries according to demographics [10].

The lack of comprehensive policy direction to address menstrual health needs is concerning, although some countries like India, the Philippines, Kenya, South Africa, and Zambia have initiated efforts to address this issue [11, 12]. Government-led initiatives have the potential to challenge societal taboos by encouraging open discussions about menstruation and addressing the specific menstrual health needs of vulnerable schoolgirls. Some governments have collaborated with key stakeholders to establish national guidelines on menstrual health and hygiene [13]. At the grassroots level, numerous international and local non-governmental organizations (NGOs) have focused on improving school toilets, providing sanitary products (such as pads or menstrual cups), and offering puberty education including menstrual health and hygiene-related content. While these efforts are promising, further peer-reviewed evidence is needed to assess their effectiveness [14, 15]. This systematic review aims to strengthen the evidence base on the association between

menstrual health needs and educational outcomes among adolescent girls, potentially informing future policy decisions and interventions.

Rationale for this systematic review

The main purpose of the present review is to explore the association between menstrual health needs and educational outcomes (academic performance, absenteeism, and school dropouts) among adolescent girls aged 10-19 years in SSA. Educational outcomes are crucial to the overall development and future opportunities of adolescents [16, 17]. Understanding the association between menstrual health needs and educational outcomes is essential for addressing significant challenges such as high taxes on menstrual hygiene products, which affect affordability, and limited access to WASH facilities in schools.

Unmet menstrual health needs can lead to physical discomfort, infections, and psychosocial stress, causing adolescent girls to miss school, perform poorly academically, or drop out altogether. Cultural taboos and stigma surrounding menstruation further exacerbate these issues by making it difficult for girls to seek help or access necessary resources to meet their menstrual health needs [18, 19]. Therefore, examining how menstrual health needs impact educational outcomes can provide important information on the barriers that adolescent girls face in SSA.

The evidence generated from this review will be crucial for informing the planning of context-specific, culturally acceptable, and locally sustainable programs and policies. These interventions can mitigate the negative educational outcomes associated with unmet menstrual health needs among adolescent girls in SSA. By synthesizing existing quantitative evidence, this review aims to provide a comprehensive understanding of how menstrual health needs influence educational outcomes, thereby supporting efforts to improve both menstrual health and educational attainment for girls in this region.

Moreover, the findings from this review will contribute to achieving several Sustainable Development Goals (SDGs), including SDG 3 (Good Health and Well-being), SDG 4 (Quality Education), SDG 5 (Gender Equality), and SDG 6 (Clean Water and Sanitation). Highlighting the association between menstrual health needs and educational outcomes will advocate for integrated

approaches that ensure girls have access to affordable menstrual hygiene products and adequate WASH facilities in schools. This, in turn, will help reduce absenteeism, improve academic performance, and decrease school dropout rates, thereby promoting gender equality and enhancing the overall well-being of adolescent girls in SSA. [20]. By focusing on the intersection of menstrual health needs and education, the study aims to support efforts towards achieving these interconnected SDGs and their specific targets.

A preliminary literature search has identified several existing systematic reviews relating to menstruation, for example, menstrual cup usage [18], menstrual hygiene management [3, 21] and menstrual experiences of adolescent girls [22] and the effectiveness of menstrual health interventions in low-and-middle-income countries in East Asia and the Pacific region [23] but none assessed the outcomes of interest in our review. Systematic reviews on this topic in the African context have focussed mostly on other issues such as knowledge, attitudes, and practices of menstrual health and hygiene across English-speaking West African countries [24], and the prevalence of good menstrual hygiene practices and associated factors among adolescent girls in sub-Saharan Africa [25] or focused on a specific country's context [5]. A closely related systematic review addressed menstrual hygiene management interventions' ability to improve education and psychosocial outcomes for women and girls in low and middle-income countries (not SSA context). The review found insufficient evidence to establish the effectiveness of menstruation management interventions due to the high risk of bias and clinical heterogeneity in the included studies [15]. The review authors recommended further studies to establish the role of menstrual health and hygiene in educational performance, psychosocial outcomes and employment. Given the significant time elapsed since this review and the potential emergence of new evidence, there is a need to revisit this topic with a specific focus on adolescent girls in the sub-Saharan African region. By narrowing the scope to this population and geographical area, and considering only the most recent and relevant literature, this systematic review aims to provide a more comprehensive and updated synthesis of the evidence on the association between menstrual health needs and educational outcomes.

The findings from this review will help address the gap identified in the previous review and contribute to informing effective policies and interventions to support menstrual health and

education for adolescent girls in sub-Saharan Africa. This review will answer the question, is there an association between menstrual health needs and academic performance among adolescent girls in SSA? A secondary research question is what is the relationship between menstrual health needs and truancy among adolescent girls in SSA? By comprehensively reviewing and synthesizing the available evidence, this review will contribute to the existing knowledge base, identify gaps in the literature, and provide insights for future research and interventions.

Methods and Analysis

This systematic review will be prepared following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Protocols (PRISMA-P) guidelines (online supplementary file 1) [26]. We have followed the Cochrane guidelines specified in the Cochrane Handbook for preparing systematic reviews [27] and methods used in published works [28–39]. The full systematic review will be reported following the checklist specified in PRISMA [40] and the study flow encompassing the searches and selection will be reported using the PRISMA flow diagram (online supplementary file 2). The full review is expected to start on 1st November, 2024 and be completed by 31st May 2025.

Patient and public Involvement

This review recognizes the importance of involving the public, including stakeholders and relevant communities, in the research process particularly to ensure evidence is co-produced. The insights and perspectives of relevant stakeholders in menstrual health research have informed the research question, preliminary search strategies and protocol development. This review aims to address the specific needs, concerns, and menstrual health challenges faced by adolescent girls. To ensure relevance and applicability, we have involved teenage and adolescent girls to understand outcomes that are important to them, the general public, and key stakeholders such as educators, health professionals and community leaders through stakeholder consultations.

Criteria for Considering Studies for this review

Types of studies

Observational studies such as cohort, case-control and cross-sectional studies that assessed the association between menstrual health needs and educational outcomes among adolescent girls

living in a country in Sub-Saharan Africa will be eligible for inclusion. Reviews, commentaries, case studies, or opinions, will not be eligible for inclusion. If the study was part of a review of global focus which included SSA, the review itself will not be included but we will go through it to identify studies conducted in SSA. If the study reported a country or regional data without a well-defined sample (representative sample or sub-sample within the source population), or multi-country studies that included primary studies from countries in SSA and elsewhere and reported separately for each of the countries, only the studies from countries in SSA context will be selected for inclusion.

Participants

This review will include studies that involve adolescent girls (aged 10-19 years) residing in sub-Saharan Africa. In this systematic review, we define an adolescent girl as a girl aged 10 to 19 years. Eligible participants will include in-school or out-of-school girls, or both, as well as those from urban and rural areas. We will consider studies involving participants from various settings such as schools, communities, and healthcare facilities. If adolescent and adult data have been lumped there is no way we could disaggregate the data, such datasets will also be excluded.

Interventions

This systematic review is not an intervention review.

Comparison:

This is a non-comparative review but where outcomes or variables permit comparison, we will attempt to compare.

Outcomes

Primary outcomes

- Academic performance: measured by grades, standardized test scores and overall GPA
- School enrolment: measured by the number of girls enrolled during the study period

Secondary outcomes

- School attendance: measured by the number of school days attended versus days missed due to menstrual issues
- School engagement: measured by the extent to which students are involved, attached, and committed to the academic and social activities provided in school.

Search strategy.

A comprehensive search terms were identified from the PICOS-formulated review title and used to develop the search strategy (Table 1). The search will involve electronic databases and other sources. Studies will be identified from relevant electronic databases including PubMed, CINAHL, ScienceDirect, Google Scholar and LILACS from 1st January 2012 (when WHO/UNICEF Joint Monitoring Programme provided a formal definition for menstrual hygiene management) to 31st October 2024, without language restriction. The search will use a combination of keywords and controlled vocabulary terms (e.g., MeSH terms) related to menstrual hygiene, educational achievement, adolescent girls, and sub-Saharan Africa (see Table 1 for further details). We will also search, Scopus, Web of Science, African Index Medicus, HINARI, African Index Medicus and African Journals Online. Grey literature sources, such as conference proceedings, Academic Search Premier, MedRXIV, ProQuest, EBSCO Open Dissertations and institutional repositories will also be searched. The reference lists of relevant articles will be screened to identify additional studies and experts in the field will be contacted for additional studies published but missed by our searches and unpublished studies they may know the subject of discussion.

Table 1: PubMed Search Strategy (to be adapted for the other databases)

Search	Query
#1	Search: ((((((((("menstrual cycle") OR (menstruation[MeSH Terms])) OR (menses)) OR (period)) OR (menstrual)) OR ("menstrual products")) OR ("menstrual hygiene")) OR ("menstrual hygiene products")) OR ("menstrual hygiene management")) OR ("period products")
#2	Search: ((((((adolescent) OR (adolescence)) OR (teens)) OR (teenager)) OR ("young adults")) OR (youth)) OR (girls)
#3	(#1 AND #2)
#4	Search: ((((((((((((((((("Educational status"[MeSH Terms]) OR (education)) OR (school)) OR (schooling)) OR (learning)) OR ("school attendance")) OR ("academic performance")) OR ("academic achievement")) OR ("academic engagement")) OR ("school dropout")) OR ("school disengagement")) OR ("school drop out")) OR ("school absenteeism")) OR ("school absence")) OR ("school avoidance")) OR ("school refusal behavior")) OR ("academic failure")) OR ("academic underachievement")) OR ("subpar performance")
#5	(#3 AND #4)
#6	Search: ((Africa) OR ("sub-Saharan Africa")) OR (Algeria)) OR (Angola)) OR (Benin)) OR (Bostwana)) OR ("Burkina Faso")) OR (Burundi)) OR ("Cabo Verde")) OR ("Cape Verde")) OR (Cameroon)) OR ("Central African Republic")) OR (Chad)) OR (Comoros)) OR ("Democratic Republic of Congo")) OR ("DR Congo")) OR (Congo)) OR (Djibouti)) OR (Egypt)) OR ("Equatorial Guinea")) OR (Eritrea)) OR (Eswatini)) OR (Ethiopia)) OR (Gabon)) OR (Gambia)) OR (Ghana)) OR (Guinea)) OR ("Guniea-Bissau")) OR ("Ivory Coast")) OR ("Cote d'Ivoire")) OR (Niger)) OR (Nigeria)) OR ("Sao Tome and Principe")) OR (Senegal)) OR (Seychelles)) OR ("Sierra Leone")) OR (Somalia)) OR (Kenya)) OR (Lesotho)) OR (Liberia)) OR (Libya)) OR (Madagascar)) OR (Malawi)) OR (Mali)) OR (Mauritania)) OR (Mauritius)) OR (Morocco)) OR (Mozambique)) OR (Namibia)) OR ("South Africa")) OR ("South Sudan")) OR (Tanzania)) OR (Togo)) OR (Tunisia)) OR (Uganda)) OR (Zambia)) OR (Zimbabwe)
#7	(#5 AND #6)

Managing the search results and study selection

Studies retrieved from the electronic databases, grey literature and other sources will be uploaded into Endnote where duplicates will be removed. The deduplicated studies will then be exported into Rayyan where study screening and selection will be performed. The study selection process will involve two stages: title and abstract screening, followed by full-text review. Depending on the search output, at least two reviewers will independently screen the identified articles against the predetermined inclusion and exclusion criteria using a pre-tested study selection flow chart

(Fig. 1). Any disagreements will be resolved through discussion between the independent reviewers or by involving a third reviewer.

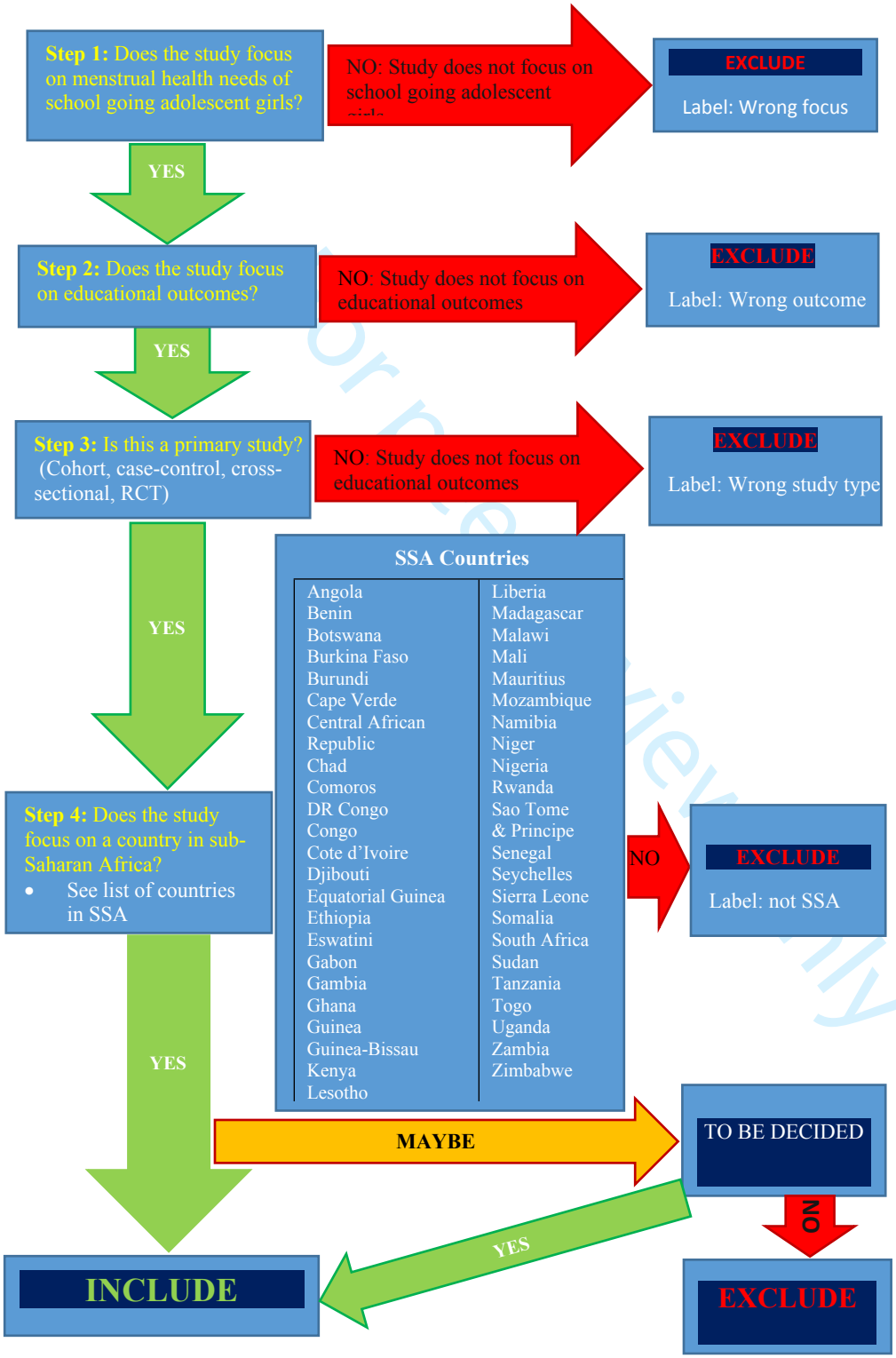

Fig. 1: Study selection flow chart

Data extraction and management

A standardized data extraction form will be developed to elicit relevant information from the included studies. The data extraction form will capture details such as study characteristics (e.g., author, year and country the study was conducted), study design (RCTs, quasi-RCTs and cluster RCTs, etc.), participant demographics (age, rural or urban setting, in-school or out of school including school dropouts), menstrual information, intervention details including type (provision of menstrual hygiene products such as sanitary pads, menstrual cups etc., menstrual hygiene education and awareness programs, access to appropriate facilities for example, clean and private toilets, and other supportive measures. The characteristics of the comparison group will also be extracted, as well as data on outcome measures (academic performance, school attendance and enrolment), school drop-out, menstrual hygiene practices and menstrual hygiene knowledge. We will extract adverse events data and classify them as serious and non-serious where necessary. At least two reviewers will extract the data independently from the included studies and conversions or transformations will be made where necessary. Any discrepancies will be resolved through discussion or by involving a third reviewer. In studies where there is missing information, the respective authors will be contacted to get the needed information for further analysis. The extracted data will be stored in a secure and organized manner to facilitate analysis and synthesis.

Assessment of quality in the included studies

At least two reviewers will independently assess the risk of bias in the included studies using the Cochrane risk of bias tool for non-randomized studies of exposure (Robbins-E) (Version 20 June 2023) (online supplementary file 3). The risk of bias assessment will be based on a series of signalling questions across seven risk of bias domains: confounding, selection of study participants, measurement of exposure, post-exposure intervention, missing data, measurement of outcome, and selection of reported results. The signalling questions have response options ‘Yes’, ‘Probably Yes’, ‘Probably No’, 'No', and ‘No Information’. The risk of bias will be judged as ‘low’ for a domain with little or no concern about bias. Where there are some concerns about bias in a specific domain, but with no certainty of an important risk of bias, we will judge the domain as ‘Some Concerns’. For bias domains with some important bias concerns, we will judge them as ‘High risk’. Studies with suspected serious bias will be judged as having a ‘very high risk of bias’.

The results from the risk of bias assessment will be presented in a table with supporting statements from the primary studies.

For observational studies, the risk of bias in the included studies will be assessed using the quality assessment tool developed by Hoy [41] (online supplementary file 4). This tool assesses 10 domains, namely, representation, sampling, random selection, non-response bias, data collection, case definition, reliability tool, prevalence period, numerators and denominators. The first four domains assess the external validity in the included studies, whereas domains 5–10 assess internal validity. Responses to each domain will be rated as 'low', 'high' or 'unclear' risk of bias, and the overall quality will be rated as 'low' or 'high'[42]. Any discrepancies will be resolved through discussion or by involving a third reviewer.

Dealing with missing data

We will not impute data when addressing missing data but instead, we will contact primary study authors and ask for the raw data, if possible, to enable us to extract the missing information. When it is not possible to obtain missing data, only records with complete data on the outcome will be included i.e. complete case analysis.

Data synthesis

We will use Review Manager (RevMan 5.4) [43], and where necessary, STATA version 18 [44] for the analysis. Meta-analysis will be conducted for studies with comparable outcomes and study designs to estimate the association between menstrual health needs and educational outcomes. Risk ratio (RR) or odds ratio (OR) will be used to pool dichotomous outcomes data and mean differences (MD) for continuous outcomes, or standardized mean difference (SMD) for continuous outcomes that used different scales; all will be reported with their 95% confidence intervals (CIs). Heterogeneity will be assessed using I^2 statistics. Random-effects model meta-analysis will be run if heterogeneity is high, otherwise, we will use a fixed-effect model. If meta-analysis is not possible due to heterogeneity among the included studies, a narrative synthesis will be conducted to summarize the findings, identify patterns, and explore potential explanations for the observed outcomes. Heterogeneity will be assessed using I-squared statistics. If meta-analysis is not possible due to heterogeneity among the included studies, a narrative synthesis will be conducted to

summarize the findings, identify patterns, and explore potential explanations for the observed outcomes. Subgroup analyses, if applicable, will be performed based on geographical location or specific educational outcomes.

Subgroup analysis

If appreciable heterogeneity is identified between the included studies, subgroup analyses, if applicable, will be performed on the variables responsible for the variation such as geographical location or specific educational outcomes, among others.

Grading the evidence

The overall quality and strength of the evidence will be assessed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach [45,46] The GRADE approach evaluates the quality of evidence based on factors such as study design, risk of bias, inconsistency, indirectness, imprecision, and publication bias. The evidence will be graded as high, moderate, low, or very low quality. This grading will inform the confidence in the findings and the implications for policy and practice.

Ethics and dissemination

The study does not require ethical clearance as it involves the use of secondary data. The results of the systematic review and meta-analysis will be shared with stakeholders, presented at scientific conferences and published in a peer-reviewed journal. The findings will also be shared on other public platforms such as X(formerly called Twitter), LinkedIn, and WhatsApp.

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Competing interests

The authors declare no conflicts of interest.

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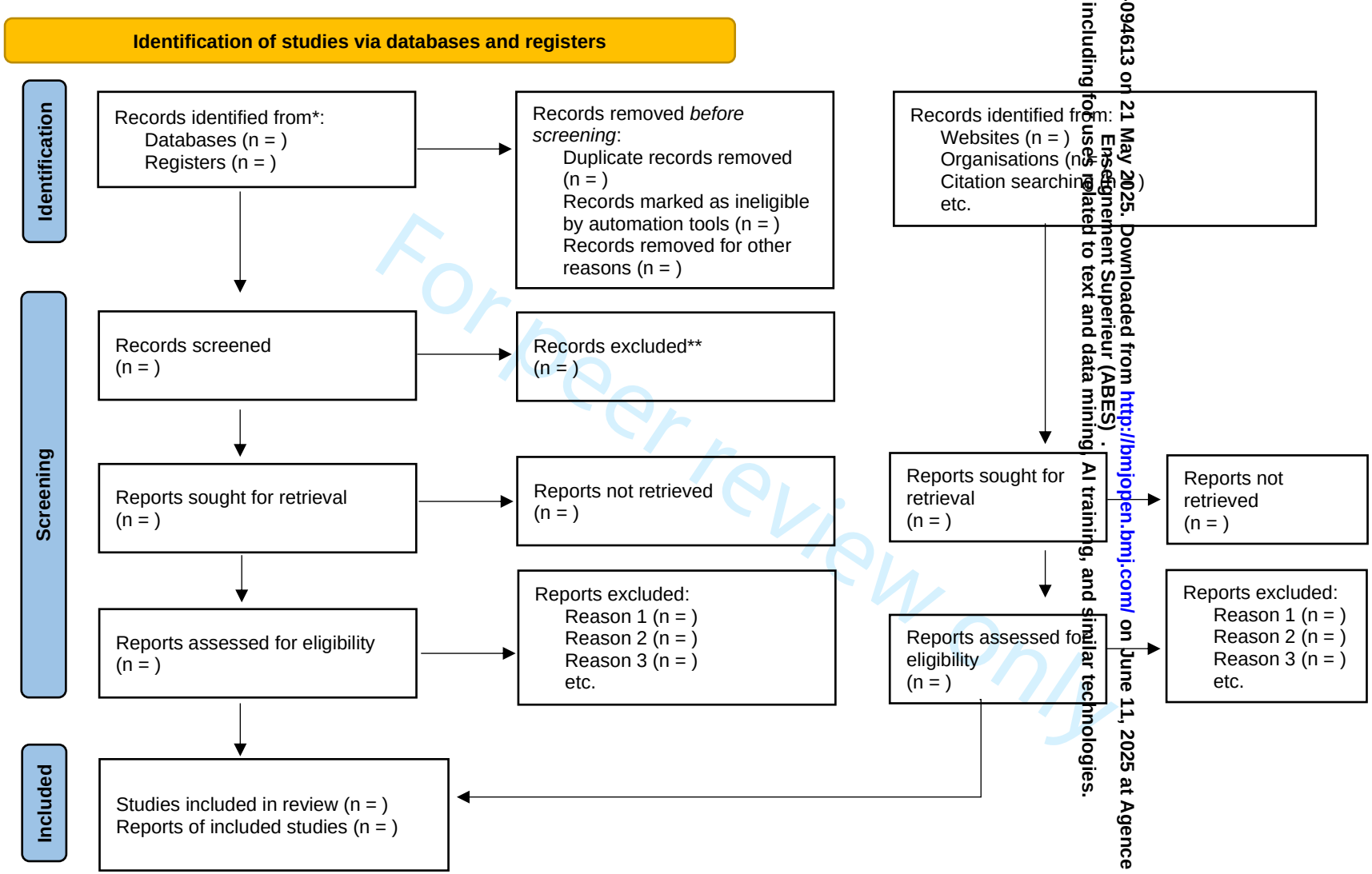
Supplemental File 1: Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) Guidelines

Section and topic	Item No	Checklist item
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 (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, 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 or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
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 (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
Information sources	9	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
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
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 (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	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
Data items	12	List and define all variables for which data will be sought (such as 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



SUPLEMENTAL FILE 2 PRISMA-P 2020 Flow Diagram to show studies retrieved from electronic databases and other sources for inclusion and flow to the final stage with studies included in the systematic review

Additional file 3: Robbins E Risk of Bias Assessment Tool

Domain 1: Risk of bias due to confounding

Domain 1, Variant (a): ***If N/PN to C5 or Y/PY to C6 or N/PN to C7*** *(only baseline confounding needs to be addressed)*

Signalling questions	Response options
1.1 Did the authors control for all the important confounding factors for which this was necessary?	Y / PY / WN (no, but uncontrolled confounding was probably not substantial) / SN (no, and uncontrolled confounding was probably substantial) / NI
1.2 **If Y/PY/WN to 1.1**: Were confounding factors that were controlled for (and for which control was necessary) measured validly and reliably by the variables available in this study?	NA / Y / PY / WN (no, but the extent of measurement error in confounding factors was probably not substantial) / SN (no, and the extent of measurement error in confounding factors was probably substantial) / NI
1.3 **If Y/PY/WN to 1.1**: Did the authors control for any variables after the start of the exposure period being studied that could have been affected by the exposure?	NA / Y / PY / PN / N / NI
1.4 Did the use of negative controls, or other considerations, suggest serious uncontrolled confounding?	Y / PY / PN / N
Risk of bias (due to confounding) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias due to confounding?	(Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Insufficient information available)
Is the risk of bias (due to confounding) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; SY = Strong yes; WY = Weak yes; SN = Strong no; WN = Weak no; NA = Not applicable; NI = No information

Domain 2: Risk of bias arising from measurement of the exposure

Domain 2, Variant (a): ***If N/PN to C5*** *(exposure was measured at a single point in time)*

Signalling questions	Response options
Mismeasurement or misclassification of the exposure.	
2.1 Does the measured exposure well-characterize the exposure metric specified to be of interest in this study? [*This was specified in the answers to D2, D3 and D4*]	Y / PY / WN (no, to a small extent) / SN (no, to a large extent) / NI
2.2 Was the exposure likely to be measured with error, or misclassified?	SY (yes, probably a substantial amount) / WY (yes, but probably not a substantial amount) / PN / N / NI
Bias in the estimated effect of exposure arising from mismeasurement or misclassification of the exposure	
2.3 If SY/WY to 2.2: Could mismeasurement or misclassification of exposure have been differential (i.e. related to the outcome or risk of the outcome)?	NA / SY (yes, to a large extent) / WY (yes, to a small extent) / PN / N / NI
2.4 If SY/WY to 2.2 and N/PN/WY to 2.3: Is non-differential measurement error likely to bias the estimated effect of exposure on outcome?	NA / SY (yes, to a large extent) / WY (yes, to a small extent) / PN / N / NI
Risk of bias (arising from measurement of exposure) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias arising from measurement of exposure?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (arising from measurement of exposure) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; SY = Strong yes; WY = Weak yes; SN = Strong no; WN = Weak no; NA = Not applicable; NI = No information

Domain 3: Risk of bias in selection of participants into the study (or into the analysis)

Signalling questions	Response options
3.1 Did follow-up begin at (or close to) the start of the exposure window for most participants? [*The exposure window is specified in D3*]	Y / PY / PN / N / NI
3.2 **If N/PN to 3.1**: Is the effect of exposure likely to be constant over the period of follow up analysed?	NA / Y / PY / PN / N / NI
3.3 Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of the exposure window being studied? [*The exposure window is specified in D3*]	Y / PY / PN / N / NI
3.4 **If Y/PY to 3.3**: Were these characteristics likely to be influenced by exposure or a cause of exposure?	NA / Y / PY / PN / N / NI
3.5 **If Y/PY to 3.4**: Were these characteristics likely to be influenced by the outcome or a cause of the outcome?	NA / Y / PY / PN / N / NI
3.6 **If N/PN to 3.2 or Y/PY to 3.5**: Is it likely that the analysis corrected for all of the potential selection biases identified in A and B above?	NA / Y / PY / PN / N / NI
3.7 **If N/PN to 3.2 or Y/PY to 3.5**: Did sensitivity analyses demonstrate that the likely impact of the potential selection biases identified in A or B above was minimal?	NA / Y / PY / WN (no, there were no sensitivity analyses or there is evidence of some impact) / SN (no, there is evidence of substantial impact)
Risk of bias (due to selection of participants into the study) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias due to selection of participants into the study?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (due to selection of participants into the study) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; SN = Strong no; WN = Weak no; NA = Not applicable; NI = No information

Domain 4: Risk of bias due to post-exposure interventions

Signalling questions	Response options
4.1 Were there post-exposure interventions that were influenced by prior exposure during the follow-up period?	Y / PY / PN / N / NI
4.2 **If Y/PY to 4.1**: Is it likely that the analysis corrected for the effect of post-exposure interventions that were influenced by prior exposure?	NA / Y / PY / PN / N / NI
Risk of bias (due post-exposure interventions) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias due to confounding?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (due post-exposure interventions) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; NA = Not applicable; NI = No information

Domain 5: Risk of bias due to missing data

Signalling questions	Response options
5.1 Were complete data on exposure status available for all, or nearly all, participants?	Y / PY / PN / N / NI
5.2 Were complete data on the outcome available for all, or nearly all, participants?	Y / PY / PN / N / NI
5.3 Were complete data on confounding variables available for all, or nearly all, participants?	Y / PY / PN / N / NI
5.4 **If N/PN/NI to 5.1, 5.2 or 5.3**: Is the result based on a complete case analysis?	NA / Y / PY / PN / N / NI

Signalling questions	Response options
5.5 **If Y/PY/NI**: Was exclusion from the analysis because of missing data (in exposure, confounders or the outcome) likely to be related to the true value of the outcome?	NA / SY (Yes, strongly related) / WY (Yes, but not strongly related) / PN / N / NI
5.6 **If N/PN to 5.5**: Were all or most predictors of missingness (in exposure, confounders or the outcome) included in the analysis model?	NA / SY (Yes, for sure) / WY (Yes, mostly or probably) / PN / N / NI
5.7 **If N/PN to 5.4**: Was the analysis based on imputing missing values?	NA / Y / PY / PN / N
5.8 **If Y/PY to 5.7**: Was imputation performed appropriately?	NA / Y / PY / WN (no, but not leading to substantial bias) / SN (no, such that bias would not be substantially reduced) / NI
5.9 **If N/PN to 5.7**: Was an appropriate alternative method used to correct for bias due to missing data?	NA / Y / PY / WN (no, but not leading to substantial bias) / SN (no, such that bias would not be substantially reduced) / NI
5.10 **If PN/N/NI to 5.1, 5.2 or 5.3**: Is there evidence that the result was not biased by missing data?	NA / Y / PY / PN / N
Risk of bias (due to missing data) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias due to missing data?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (due to missing data) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; SY = Strong yes; WY = Weak yes; NA = Not applicable; NI = No information

Domain 6: Risk of bias arising from measurement of the outcome

Signalling questions	Response options
6.1 Could measurement or ascertainment of the outcome have differed between exposure groups or levels of exposure?	Y / PY / PN / N / NI
6.2 Were outcome assessors aware of study participants' exposure history?	Y / PY / PN / N / NI
6.3 **If Y/PY/NI to 6.2**: Could assessment of the outcome have been influenced by knowledge of participants' exposure history?	NA / SY (yes, to a large extent) / WY (yes, to a small extent) / PN / N / NI
Risk of bias (arising from measurement of outcomes) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias arising from measurement of outcomes?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (arising from measurement of outcomes) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; SY = Strong yes; WY = Weak yes; NA = Not applicable; NI = No information

Domain 7: Risk of bias in selection of the reported result

Signalling questions	Response options
7.1 Was the result reported in accordance with an available, pre-determined analysis plan?	Y / PY / PN / N / NI
7.2 **If N/PN/NI to 7.1**: Is the reported effect estimate likely to be selected, based on desirability of the magnitude (or statistical significance) of the estimated effect of exposure on outcome, from multiple *exposure measurements* within the exposure domain?	NA / Y / PY / PN / N / NI

Signalling questions	Response options
7.3 Is the reported effect estimate likely to be selected, based on desirability of the magnitude (or statistical significance) of the estimated effect of exposure on outcome, from multiple *outcome measurements* within the outcome domain?	Y / PY / PN / N / NI
7.4 Is the reported effect estimate likely to be selected, based on desirability of the magnitude (or statistical significance) of the estimated effect of exposure on outcome, from multiple *analyses* of the exposure-outcome relationship?	Y / PY / PN / N / NI
7.5 Is the reported effect estimate likely to be selected, based on the basis of desirability of the results (e.g. statistical significance), from different *subgroups*?	Y / PY / PN / N / NI
Risk of bias (due to selection of the reported result) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias due to selection of the reported result?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (due to selection of the reported result) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; NA = Not applicable; NI = No information

Additional file 4: Risk of Bias Tool for Prevalence Studies

Name of author(s):_____ Year of publication:_____

Name of paper/study:-

_____

_____

This tool is designed to assess the risk of bias in population-based prevalence studies. Please read the additional notes for each item when initially using the tool. Note: If there is insufficient information in the article to permit a judgement for a particular item, please answer **No (HIGH RISK)** for that particular item.

Risk of bias item	Criteria for answers (please circle one option)	Additional notes and examples
External Validity		
1. Was the study's target population **a close representation** of the national population in relation to relevant variables, e.g. age, sex, occupation?	• **Yes (LOW RISK):** The study's target population was a close representation of the national population. • **No (HIGH RISK)**: The study's target population was clearly NOT representative of the national population.	The **target population** refers to the group of people or entities to which the results of the study will be generalised. Examples: • The study was a national health survey of people 15 years and over and the sample was drawn from a list that included all individuals in the population aged 15 years and over. The answer is: **Yes (LOW RISK).** • The study was conducted in one province only, and it is not clear if this was representative of the national population. The answer is: **No (HIGH RISK).** • The study was undertaken in one village only and it is clear this was not representative of the national population. The answer is: **No (HIGH RISK).**
2. Was the sampling frame a **true or close representation** of the target population?	• **Yes (LOW RISK):** The sampling frame was a **true or close** representation of the target population. • **No (HIGH RISK)**: The sampling frame was NOT a **true or close** representation of the target population.	The **sampling frame** is a list of the sampling units in the target population and the study sample is drawn from this list. Examples: • The sampling frame was a list of almost every individual within the target population. The answer is: **Yes (LOW RISK)**. • The cluster sampling method was used and the sample of clusters/villages was drawn from a list of all villages in the target population. The answer is: **Yes (LOW RISK)**. • The sampling frame was a list of just one particular ethnic group within the overall target population, which comprised many groups. The answer is: **No (HIGH RISK).**
3. Was some form of **random selection** used to select the sample, OR, was a census undertaken?	• **Yes (LOW RISK):** A census was undertaken, OR, some form of random selection was used to select the sample (e.g. simple random sampling, stratified random sampling, cluster sampling, systematic sampling). • **No (HIGH RISK)**: A census was NOT undertaken, AND some form of random selection was NOT used to select the sample.	A census collects information from every unit in the sampling frame. In a survey, only part of the sampling frame is sampled. In these instances, random selection of the sample helps minimise study bias. Examples: • The sample was selected using simple random sampling. The answer is: **Yes (LOW RISK)**. • The target population was the village and every person in the village was sampled. The answer is: **Yes (LOW RISK)**. • The nearest villages to the capital city were selected in order to save on the cost of fuel. The answer is: **No (HIGH RISK).**
4. Was the likelihood of **non-response bias minimal?**	• **Yes (LOW RISK):** The response rate for the study was >/=75%, OR, an analysis was performed that showed no significant difference in relevant demographic characteristics between responders and non-responders • **No (HIGH RISK)**: The response rate was <75%, and if any analysis comparing responders and non-responders was done, it showed a significant difference in relevant demographic characteristics between responders and non-responders.	Examples: • The response rate was 68%; however, the researchers did an analysis and found no significant difference between responders and non-responders in terms of age, sex, occupation and socio-economic status. The answer is: **Yes (LOW RISK)**. • The response rate was 65% and the researchers did NOT carry out an analysis to compare relevant demographic characteristics between responders and non-responders. The answer is: **No (HIGH RISK)**. • The response rate was 69% and the researchers did an analysis and found a significant difference in age, sex and socio-economic status between responders and non-responders. The answer is: **No (HIGH RISK)**.

Internal Validity		
5. Were data collected **directly from the subjects** (as opposed to a proxy)?	• **Yes (LOW RISK):** All data were collected directly from the subjects. • **No (HIGH RISK)**: In some instances, data were collected from a proxy.	A proxy is a representative of the subject. Examples: • All eligible subjects in the household were interviewed separately. The answer is: **Yes (LOW RISK)**. • A representative of the household was interviewed and questioned about the presence of low back pain in each household member. The answer is: **No (HIGH RISK)**.
6. Was an acceptable case definition used in the study?	• **Yes (LOW RISK):** An acceptable case definition was used. • **No (HIGH RISK)**: An acceptable case definition was NOT used.	• For a study on low back pain, the following case definition was used: "Low back pain is defined as activity-limiting pain lasting more than one day in the area on the posterior aspect of the body from the bottom of the 12th rib to the lower gluteal folds." The answer is: **Yes (LOW RISK)**. • For a study on back pain, there was no description of the specific anatomical location 'back' referred to. The answer is: **No (HIGH RISK)**. • For a study on osteoarthritis, the following case definition was used: "Symptomatic osteoarthritis of the hip or knee, radiologically confirmed as Kellgren-Lawrence grade 2-4". The answer is: LOW RISK.
7. Was the study instrument that measured the parameter of interest (e.g. prevalence of low back pain) shown to have **reliability and validity (if necessary)**?	• **Yes (LOW RISK):** The study instrument had been shown to have reliability and validity (if this was necessary), e.g. test-re-test, piloting, validation in a previous study, etc. • **No (HIGH RISK)**: The study instrument had NOT been shown to have reliability or validity (if this was necessary).	• The authors used the COPCORD questionnaire, which had previously been validated. They also tested the inter-rater reliability of the questionnaire. The answer is: **Yes (LOW RISK)**. • The authors developed their own questionnaire and did not test this for validity or reliability. The answer is: **No (HIGH RISK)**.
8. Was the **same mode of data collection** used for all subjects?	• **Yes (LOW RISK):** The same mode of data collection was used for all subjects. • **No (HIGH RISK)**: The same mode of data collection was NOT used for all subjects.	The mode of data collection is the method used for collecting information from the subjects. The most common modes are face-to-face interviews, telephone interviews and self-administered questionnaires. Examples: • All eligible subjects had a face-to-face interview. The answer is: **Yes (LOW RISK)**. • Some subjects were interviewed over the telephone and some filled in postal questionnaires. The answer is: **No (HIGH RISK)**.
9. Was the **length of the shortest prevalence period** for the parameter of interest appropriate?	• **Yes (LOW RISK):** The shortest prevalence period for the parameter of interest was appropriate (e.g. point prevalence, one-week prevalence, one-year prevalence). • **No (HIGH RISK)**: The shortest prevalence period for the parameter of interest was not appropriate (e.g. lifetime prevalence)	The prevalence period is the period that the subject is asked about e.g. "Have you experienced low back pain over the previous year?" In this example, the prevalence period is one year. The longer the prevalence period, the greater the likelihood of the subject forgetting if they experienced the symptom of interest (e.g. low back pain). Examples: • Subjects were asked about pain over the past week. The answer is: **Yes (LOW RISK)**. • Subjects were only asked about pain over the past three years. The answer is: **No (HIGH RISK)**.
10. Were the **numerator(s) and denominator(s)** for the parameter of interest appropriate?	• **Yes (LOW RISK):** The paper presented appropriate numerator(s) AND denominator(s) for the parameter of interest (e.g. the prevalence of low back pain). • **No (HIGH RISK)**: The paper did present numerator(s) AND denominator(s) for the parameter of interest but one or more of these were inappropriate.	There may be errors in the calculation and/or reporting of the numerator and/or denominator. Examples: • There were no errors in the reporting of the numerator(s) AND denominator(s) for the prevalence of low back pain. The answer is: **Yes (LOW RISK)**. • In reporting the overall prevalence of low back pain (in both men and women), the authors accidentally used the population of women as the denominator rather than the combined population. The answer is: **No (HIGH RISK).**
11. Summary item on the overall risk of study bias		
• **LOW RISK OF BIAS:** Further research is very unlikely to change our confidence in the estimate. • **MODERATE RISK OF BIAS:** Further research is likely to have an important impact on our confidence in the estimate and may change the estimate.		

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MENSTRUAL HEALTH NEEDS AND EDUCATIONAL OUTCOMES AMONG ADOLESCENT GIRLS LIVING IN COUNTRIES IN SUB-SAHARAN AFRICA: SYSTEMATIC REVIEW PROTOCOL

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MENSTRUAL HEALTH NEEDS AND EDUCATIONAL OUTCOMES AMONG ADOLESCENT GIRLS LIVING IN COUNTRIES IN SUB-SAHARAN AFRICA: SYSTEMATIC REVIEW PROTOCOL

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Keywords

Menstrual hygiene, menstrual health, educational performance, adolescents, teenage, girls, sub-Saharan Africa, systematic review

Abstract

Introduction

Poor menstrual health and unmet menstrual needs influence several aspects of adolescent girls' lives, including their educational outcomes. However, evidence on menstrual health needs and educational outcomes among these vulnerable girls living in countries across sub-Saharan Africa (SSA) is fragmented and inconclusive. The systematic review aims to explore the association between menstrual health needs and educational outcomes among adolescent girls (10-19 years) living in SSA.

Methods and analysis

Studies (published and unpublished) will be identified from relevant electronic databases including PubMed, CINAHL, ScienceDirect, Google Scholar and LILACS without language restriction from January 2000 to December 2024. A comprehensive set of search terms and their alternate terms together with the names of countries in sub-Saharan Africa will be used for running the searches. We will also search, Scopus, Web of Science, African Index Medicus, HINARI, African Index Medicus, African Journals Online, Academic Search Premier, MedRXIV, ProQuest, EBSCO Open Dissertations, and reference lists of relevant studies from . We will contact experts, identified through authorship of key publications in menstrual health research and recommendations from established research networks, for potentially relevant unpublished studies. All retrieved articles from the electronic databases and grey literature will be collated and deduplicated using Endnote and exported to Rayyan QCRI. The pre-defined eligibility criteria will be followed to screen papers for inclusion in the review. The flow of studies will be reported using the PRISMA Flow Diagram. Given the anticipated volume of literature to be reviewed at least two reviewers will independently select studies, extract data and assess the quality of the included studies for risk of bias using Robbins risk of bias assessment tool. Any disagreements will be resolved through discussion between the reviewers. The Joanna Briggs Institute's Sumari Software will be used for citation management. Binary outcomes will be estimated using pooled proportions (for non-comparative studies) and odds ratio (OR) or risk ratio (RR) (for comparative studies), reported with their 95% confidence intervals (CIs). The mean difference will be used for reporting continuous outcomes with their 95% (CIs). In the case where different instruments have been used to report means, we will employ standardized mean difference (SMD). Heterogeneity will be assessed graphically for

overlapping CIs and statistically using the I^2 statistic and if heterogeneity is detected to be high (>50%), subgroup analysis will be performed to assess the impact of such variation.

Ethics and dissemination

While ethical approval is not required for the systematic review methodology itself, appropriate data sharing agreements and confidentiality protocols will be followed when collecting unpublished data from experts. The findings from this review will be published in a peer-reviewed journal and presented at relevant conferences. Also, the findings will be communicated to local stakeholders (e.g. adolescent girls, parents/guardians, school authorities) in appropriate formats and languages to support translation into policy and practice to improve menstrual health and hygiene and education for adolescent girls in sub-Saharan Africa.

Registration

This protocol has been registered in the International Prospective Register of Systematic Reviews (PROSPERO) with registration number [CRD42024565296].

Strengths and limitations of this study

- The comprehensive search strategy includes multiple databases, grey literature sources and expert consultations to minimize publication bias
- This review employs rigorous methodological quality assessment using validated tools with independent evaluation from multiple reviewers
- The broad geographical focus across sub-Saharan Africa allows for meaningful regional and country-level subgroup analyses
- Anticipated methodological heterogeneity across multiple studies may limit the ability to conduct meta-analyses for some outcomes
- Language barriers may affect comprehensiveness despite the inclusion of non-English literature

Introduction

Girls often experience a variety of emotions, such as fear, shame, embarrassment, and guilt as a result of unmet menstrual health needs, including leakage of blood and body odour during menstruation [1], resulting in frequently missing school [2][3]. When suitable and affordable menstrual care products are unavailable, some girls, even women, may struggle to meet their menstrual health needs [4] and resort to measures such as newspapers, old rags, dried leaves or socks [1], which may not provide adequate protection or maintain proper hygiene during menstruation [5].

Cultural taboos further exacerbate the challenges faced by girls, as they hinder them from seeking the necessary assistance or support to meet their menstrual health needs [6–8]. To tackle these challenges, UNICEF and various non-governmental organizations (NGOs) have devised programs aimed at addressing the issues, predominantly within the Water, Sanitation, and Hygiene (WASH) sector [9]. Access to menstrual materials such as sanitary pads as menstrual hygiene products varies across low and middle-income countries (LMICs): women and girls in Democratic Republic of the Congo (17%), Kenya (14%), Ghana (10%) and Indonesia (9%) reported not using commercial sanitary pads for menstrual health and hygiene respectively. Additionally, non-use of sanitary pads was even higher in India (54%), Ethiopia (41%), Nigeria (37%) and Uganda (36%) due to inequalities within countries according to demographics [10].

The lack of comprehensive policy direction to address menstrual health needs is concerning, although some countries like India, the Philippines, Kenya, South Africa, and Zambia have initiated efforts to address this issue [11,12]. Government-led initiatives have the potential to challenge societal taboos by encouraging open discussions about menstruation and addressing the specific menstrual health needs of schoolgirls who face socioeconomic disadvantages, live in rural areas with limited infrastructure, or belong to marginalized communities where cultural taboos are strongest. Evidence suggests that inadequate menstrual hygiene management is associated with decreased concentration in class, school absenteeism, and poor educational performance, particularly among these groups [13–15]. Some governments have collaborated with key stakeholders to establish national guidelines on menstrual health and hygiene [16]. At the grassroots level, numerous international and local non-governmental organizations (NGOs) have focused on improving school toilets, providing sanitary

products (such as pads or menstrual cups), and offering puberty education including menstrual health and hygiene-related content. School-based interventions may improve attendance rates by 5-10% among adolescent girls during their menstrual periods [17,18]. While these efforts are promising, further peer-reviewed evidence is needed to assess their effectiveness [19,20]. This systematic review aims to strengthen the evidence base on the association between menstrual health needs and educational outcomes among adolescent girls, potentially informing future policy decisions and interventions.

Rationale for this systematic review

The main purpose of the present review is to explore the association between menstrual health needs and educational outcomes (academic performance, absenteeism, and school dropouts) among adolescent girls aged 10-19 years in SSA. Educational outcomes are crucial to the overall development and future opportunities of adolescents [21,22]. Understanding the association between menstrual health needs and educational outcomes is essential for addressing significant challenges such as high taxes on menstrual hygiene products, which affect affordability, and limited access to WASH facilities in schools.

Unmet menstrual health needs can lead to physical discomfort, infections, and psychosocial stress, causing adolescent girls to miss school, perform poorly academically, or drop out altogether. Cultural taboos and stigma surrounding menstruation further exacerbate these issues by making it difficult for girls to seek help or access necessary resources to meet their menstrual health needs [23,24]. Therefore, examining how menstrual health needs impact educational outcomes can provide important information on the barriers that adolescent girls face in SSA.

The evidence generated from this review will be crucial for informing the planning of context-specific, culturally acceptable, and locally sustainable programs and policies. These interventions can mitigate the negative educational outcomes associated with unmet menstrual health needs among adolescent girls in SSA. By synthesizing existing quantitative evidence, this review aims to provide a comprehensive understanding of how menstrual health needs influence educational outcomes, thereby supporting efforts to improve both menstrual health and educational attainment for girls in this region.

Moreover, the findings from this review will contribute to achieving several Sustainable Development Goals (SDGs), including SDG 3 (Good Health and Well-being), SDG 4 (Quality Education), SDG 5 (Gender Equality), and SDG 6 (Clean Water and Sanitation). Highlighting the association between menstrual health needs and educational outcomes will advocate for integrated approaches that ensure girls have access to affordable menstrual hygiene products and adequate WASH facilities in schools. This, in turn, will help reduce absenteeism, improve academic performance, and decrease school dropout rates, thereby promoting gender equality and enhancing the overall well-being of adolescent girls in SSA. [25]. By focusing on the intersection of menstrual health needs and education, the study aims to support efforts towards achieving these interconnected SDGs and their specific targets.

A preliminary literature search has identified several existing systematic reviews relating to menstruation, for example, menstrual cup usage [23], menstrual hygiene management [3,26] and menstrual experiences of adolescent girls [27] and the effectiveness of menstrual health interventions in low-and-middle-income countries in East Asia and the Pacific region [28] but none assessed the outcomes of interest in our review. Systematic reviews on this topic in the African context have focussed mostly on other issues such as knowledge, attitudes, and practices of menstrual health and hygiene across English-speaking West African countries [29], and the prevalence of good menstrual hygiene practices and associated factors among adolescent girls in sub-Saharan Africa [30] or focused on a specific country's context [5]. A closely related systematic review addressed menstrual hygiene management interventions' ability to improve education and psychosocial outcomes for women and girls in low and middle-income countries (not SSA context). The review found insufficient evidence to establish the effectiveness of menstruation management interventions due to the high risk of bias and clinical heterogeneity in the included studies [20]. The review authors recommended further studies to establish the role of menstrual health and hygiene in educational performance, psychosocial outcomes and employment. Given the significant time elapsed since this review and the potential emergence of new evidence, there is a need to revisit this topic with a specific focus on adolescent girls in the sub-Saharan African region.

Aim and research questions

The aim of this systematic review is to explore the association between menstrual health needs and educational outcomes among adolescent girls aged 10-19 years in sub-Saharan Africa. By narrowing the scope to this population and geographical area, and considering only the most recent and relevant literature, this systematic review aims to provide a comprehensive and updated synthesis of the evidence to inform effective policies and interventions. The findings from this review will help address the gap identified in the previous review and contribute to informing effective policies and interventions to support menstrual health and education for adolescent girls in sub-Saharan Africa. This review will address the question, is there an association between menstrual health needs and academic performance among adolescent girls in SSA? A secondary research question is what is the relationship between menstrual health needs and school abstenteeism among adolescent girls in SSA? By comprehensively reviewing and synthesizing the available evidence, this review will contribute to the existing knowledge base, identify gaps in the literature, and provide insights for future research and interventions.

Methods and Analysis

This systematic review will be prepared following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Protocols (PRISMA-P) guidelines (online supplementary file 1) [31]. We have followed the Cochrane guidelines specified in the Cochrane Handbook for preparing systematic reviews [32] and methods used in published works [33–44]. The full systematic review will be reported following the checklist specified in PRISMA [45] and the study flow encompassing the searches and selection will be reported using the PRISMA flow diagram (online supplementary file 2). The full review is expected to start on 1st November, 2024 and be completed by 31st May 2025.

Patient and public Involvement

This review recognizes the importance of involving the public, including stakeholders and relevant communities, in the research process particularly to ensure evidence is co-produced. The insights and perspectives of relevant stakeholders in menstrual health research have informed the research question, preliminary search strategies and protocol development.. To ensure relevance and applicability, we have involved teenage and adolescent girls to understand outcomes that are

important to them, the general public, and key stakeholders such as educators, health professionals and community leaders through stakeholder consultations.

Criteria for Considering Studies for this review

Eligibility Criteria

The following criteria will be used to determine study eligibility for inclusion in this systematic review:

Publication Types

Peer-reviewed literature: Original research articles published in peer-reviewed journals that report primary data on the association between menstrual health needs and educational outcomes.

Grey literature: Technical reports, dissertations, theses, conference proceedings, policy documents, and working papers from recognized institutions, organizations, or academic repositories that contain primary research data on our topic of interest. Grey literature must have a clear methodology section and report primary empirical findings.

Inclusion Criteria

Studies published between January 1, 2012 (when WHO/UNICEF Joint Monitoring Programme provided a formal definition for menstrual hygiene management) and October 31, 2024 will be eligible for inclusion. Only studies conducted in sub-Saharan African countries and focusing on adolescent girls aged 10-19 years will be considered. We will include quantitative observational studies (cohort, case-control, and cross-sectional studies) that assess the association between menstrual health needs and educational outcomes. Studies published in any language will be eligible, with translation services to be used when necessary. For inclusion, studies must report at least one of our predefined primary or secondary outcomes.

Exclusion Criteria

We will exclude opinion pieces, commentaries, letters to editors, and narrative reviews. Case reports or case series and theoretical or conceptual papers without empirical data will not be considered. Multi-country studies that do not disaggregate data for sub-Saharan African countries will be excluded, as will studies that combine data from adolescents and adults without separate analysis for our target age group. Studies focusing exclusively on clinical aspects of menstruation

without educational outcomes will be ineligible. We will exclude intervention studies that do not report baseline observational data on the association between menstrual health needs and educational outcomes. Additionally, studies with substantial methodological limitations or inadequate reporting of methods that prevent quality assessment will not be included in the review.

Participants

This review will include studies that involve adolescent girls (aged 10-19 years) residing in sub-Saharan Africa. In this systematic review, we define an adolescent girl as a girl aged 10 to 19 years. Eligible participants will include in-school or out-of-school girls, or both, as well as those from urban and rural areas. We will consider studies involving participants from various settings such as schools, communities, and healthcare facilities. If adolescent and adult data have been lumped there is no way we could disaggregate the data, such datasets will also be excluded.

Interventions

This systematic review is not an intervention review.

Comparison:

While this is primarily a non-comparative review, we will extract data on the following comparison groups where available: girls with adequate access to menstrual products versus those without; girls with access to private, clean sanitation facilities versus those without; girls with adequate menstrual health knowledge versus those without; pre-intervention versus post-intervention measures for studies evaluating menstrual health programs; girls experiencing menstrual-related pain or symptoms versus those who do not; and school attendance during menstruation versus non-menstruation periods. These comparisons will allow us to analyze how different menstrual health factors are associated with educational outcomes

Outcomes

Primary outcomes

- Academic performance: measured by grades, standardized test scores and overall GPA
- School enrolment: measured by the number of girls enrolled during the study period

Secondary outcomes

- School attendance: measured by the number of school days attended versus days missed due to menstrual issues
- School engagement: measured by the extent to which students are involved, attached, and committed to the academic and social activities provided in school.

Search strategy.

A comprehensive search terms were identified from the PICOS-formulated review title and used to develop the search strategy (Table 1). The search will involve electronic databases and other sources. Studies will be identified from relevant electronic databases including PubMed, CINAHL, ScienceDirect, Google Scholar and LILACS from 1st January 2012 (when WHO/UNICEF Joint Monitoring Programme provided a formal definition for menstrual hygiene management) to 31st October 2024, without language restriction. The search will use a combination of keywords and controlled vocabulary terms (e.g., MeSH terms) related to menstrual hygiene, educational achievement, adolescent girls, and sub-Saharan Africa (see Table 1 for further details). We will also search, Scopus, Web of Science, African Index Medicus, HINARI, African Index Medicus and African Journals Online. Grey literature sources, such as conference proceedings, Academic Search Premier, MedRXIV, ProQuest, EBSCO Open Dissertations and institutional repositories will also be searched. The reference lists of relevant articles will be screened to identify additional studies and experts in the field will be contacted for additional studies published but missed by our searches and unpublished studies they may know the subject of discussion. Experts will be defined as researchers who have published at least two peer-reviewed articles on menstrual health and education in sub-Saharan Africa within the past ten years, or who hold leadership positions in relevant research networks or organizations focused on adolescent health in the region. These experts will be identified through bibliometric analysis of key publications and through established professional networks. When contacting experts for unpublished data, we will follow data sharing best practices by using formal data request procedures, ensuring confidentiality of shared information, and obtaining written confirmation that any shared unpublished data has received appropriate ethical clearance from the original institutions where the research was conducted. No personally identifiable information from study participants will be requested.

Table 1: PubMed Search Strategy (to be adapted for the other databases)

Search	Query
#1	Search: (((((((((("menstrual cycle") OR (menstruation[MeSH Terms])) OR (menses)) OR (period)) OR (menstrual)) OR ("menstrual products")) OR ("menstrual hygiene")) OR ("menstrual hygiene products")) OR ("menstrual hygiene management")) OR ("period products")
#2	Search: ((((((adolescent) OR (adolescence)) OR (teens)) OR (teenager)) OR ("young adults")) OR (youth)) OR (girls)
#3	(#1 AND #2)
#4	Search: (((((((((((((((("Educational status"[MeSH Terms]) OR (education)) OR (school)) OR (schooling)) OR (learning)) OR ("school attendance")) OR ("academic performance")) OR ("academic achievement")) OR ("academic engagement")) OR ("school dropout")) OR ("school disengagement")) OR ("school drop out")) OR ("school absenteeism")) OR ("school absence")) OR ("school avoidance")) OR ("school refusal behavior")) OR ("academic failure")) OR ("academic underachievement")) OR ("subpar performance")
#5	(#3 AND #4)
#6	Search: ((Africa) OR ("sub-Saharan Africa")) OR (Algeria)) OR (Angola)) OR (Benin)) OR (Bostwana)) OR ("Burkina Faso")) OR (Burundi)) OR ("Cabo Verde")) OR ("Cape Verde")) OR (Cameroon)) OR ("Central African Republic")) OR (Chad)) OR (Comoros)) OR ("Democratic Republic of Congo")) OR ("DR Congo")) OR (Congo)) OR (Djibouti)) OR (Egypt)) OR ("Equatorial Guinea")) OR (Eritrea)) OR (Eswatini)) OR (Ethiopia)) OR (Gabon)) OR (Gambia)) OR (Ghana)) OR (Guinea)) OR ("Guniea-Bissau")) OR ("Ivory Coast")) OR ("Cote d'Ivoire")) OR (Niger)) OR (Nigeria)) OR ("Sao Tome and Principe")) OR (Senegal)) OR (Seychelles)) OR ("Sierra Leone")) OR (Somalia)) OR (Kenya)) OR (Lesotho)) OR (Liberia)) OR (Libya)) OR (Madagascar)) OR (Malawi)) OR (Mali)) OR (Mauritania)) OR (Mauritius)) OR (Morocco)) OR (Mozambique)) OR (Namibia)) OR ("South Africa")) OR ("South Sudan")) OR (Tanzania)) OR (Togo)) OR (Tunisia)) OR (Uganda)) OR (Zambia)) OR (Zimbabwe)
#7	(#5 AND #6)

Managing the search results and study selection

Studies retrieved from the electronic databases, grey literature and other sources will be uploaded into Endnote where duplicates will be removed. The deduplicated studies will then be exported into Rayyan where study screening and selection will be performed. The study selection process will involve two stages: title and abstract screening, followed by full-text review. Depending on the search output, at least two reviewers will independently screen the identified articles against the predetermined inclusion and exclusion criteria using a pre-tested study selection flow chart

(Fig. 1). Any disagreements will be resolved through discussion between the independent reviewers or by involving a third reviewer.

Data extraction and management

A standardized data extraction form will be developed to elicit relevant information from the included studies. The data extraction form will capture details such as study characteristics (e.g., author, year and country the study was conducted), study design (RCTs, quasi-RCTs and cluster RCTs, etc.), participant demographics (age, rural or urban setting, in-school or out of school including school dropouts), menstrual information, intervention details including type (provision of menstrual hygiene products such as sanitary pads, menstrual cups etc., menstrual hygiene education and awareness programs, access to appropriate facilities for example, clean and private toilets, and other supportive measures. The characteristics of the comparison group will also be extracted, as well as data on outcome measures (academic performance, school attendance and enrolment), school drop-out, menstrual hygiene practices and menstrual hygiene knowledge. We will extract adverse events data and classify them as serious and non-serious where necessary. At least two reviewers will extract the data independently from the included studies and conversions or transformations will be made where necessary. Any discrepancies will be resolved through discussion or by involving a third reviewer. In studies where there is missing information, the respective authors will be contacted to get the needed information for further analysis. The extracted data will be stored in a secure and organized manner to facilitate analysis and synthesis.

Assessment of quality in the included studies

At least two reviewers will independently assess the risk of bias in the included studies using the Cochrane risk of bias tool for non-randomized studies of exposure (Robbins-E) (Version 20 June 2023) (online supplementary file 3). The risk of bias assessment will be based on a series of signalling questions across seven risk of bias domains: confounding, selection of study participants, measurement of exposure, post-exposure intervention, missing data, measurement of outcome, and selection of reported results. The signalling questions have response options ‘Yes’, ‘Probably Yes’, ‘Probably No’, 'No', and ‘No Information’. The risk of bias will be judged as ‘low’ for a domain with little or no concern about bias. Where there are some concerns about bias in a specific domain, but with no certainty of an important risk of bias, we will judge the domain as

'Some Concerns'. For bias domains with some important bias concerns, we will judge them as 'High risk'. Studies with suspected serious bias will be judged as having a 'very high risk of bias'. The results from the risk of bias assessment will be presented in a table with supporting statements from the primary studies.

For observational studies, the risk of bias in the included studies will be assessed using the quality assessment tool developed by Hoy [46] (online supplementary file 4). This tool assesses 10 domains, namely, representation, sampling, random selection, non-response bias, data collection, case definition, reliability tool, prevalence period, numerators and denominators. The first four domains assess the external validity in the included studies, whereas domains 5–10 assess internal validity. Responses to each domain will be rated as 'low', 'high' or 'unclear' risk of bias, and the overall quality will be rated as 'low' or 'high'[47]. Any discrepancies will be resolved through discussion or by involving a third reviewer.

Dealing with missing data

We will not impute data when addressing missing data but instead, we will contact primary study authors and ask for the raw data, if possible, to enable us to extract the missing information. When it is not possible to obtain missing data, only records with complete data on the outcome will be included i.e. complete case analysis.

Data synthesis

We will use Review Manager (RevMan 5.4) [48], and where necessary, STATA version 18 [49] for the analysis. Meta-analysis will be conducted for studies with comparable outcomes and study designs to estimate the association between menstrual health needs and educational outcomes. Risk ratio (RR) or odds ratio (OR) will be used to pool dichotomous outcomes data and mean differences (MD) for continuous outcomes, or standardized mean difference (SMD) for continuous outcomes that used different scales; all will be reported with their 95% confidence intervals (CIs). Heterogeneity will be assessed using I^2 statistics. Random-effects model meta-analysis will be run if heterogeneity is high, otherwise, we will use a fixed-effect model. If meta-analysis is not possible due to heterogeneity among the included studies, a narrative synthesis will be conducted to summarize the findings, identify patterns, and explore potential explanations for the observed

outcomes. Heterogeneity will be assessed using I-squared statistics. If meta-analysis is not possible due to heterogeneity among the included studies, a narrative synthesis will be conducted to summarize the findings, identify patterns, and explore potential explanations for the observed outcomes. Subgroup analyses, if applicable, will be performed based on geographical location or specific educational outcomes.

Subgroup analysis

If appreciable heterogeneity is identified between the included studies, subgroup analyses, if applicable, will be performed on the variables responsible for the variation such as geographical location or specific educational outcomes, among others.

Grading the evidence

The overall quality and strength of the evidence will be assessed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach [50,51] The GRADE approach evaluates the quality of evidence based on factors such as study design, risk of bias, inconsistency, indirectness, imprecision, and publication bias. The evidence will be graded as high, moderate, low, or very low quality. The GRADE assessment will be conducted independently by two reviewers with experience in evidence synthesis methodologies. Any discrepancies in grading will be resolved through discussion or by consulting a third reviewer with expertise in GRADE methodology. The reviewers will document their justifications for each judgment to ensure transparency in the assessment process. This grading will inform the confidence in the findings and the implications for policy and practice.

Ethics and dissemination

This systematic review primarily involves the synthesis of previously published data and therefore does not require formal ethical approval. For the Patient and Public Involvement (PPI) activities that informed our research question and protocol development, we followed good practice principles for public involvement including providing clear information about consultation purposes, obtaining verbal consent for participation, and ensuring confidentiality. These consultative PPI activities were confirmed by our institution's research governance team to fall outside the scope of formal ethical review requirements. When contacting experts for unpublished

data, we will request confirmation that the original studies received appropriate ethical approval and that data sharing complies with the original consent agreements. No personally identifiable data will be requested or used. We will establish data sharing agreements where necessary to ensure appropriate use of unpublished data.

The results of the systematic review and meta-analysis will be shared with stakeholders, presented at scientific conferences and published in a peer-reviewed journal. The findings will also be shared on other public platforms such as X (formerly called Twitter), LinkedIn, and WhatsApp. We will additionally develop tailored dissemination materials appropriate for adolescent girls, educators, and health practitioners in sub-Saharan Africa.

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Competing interests

The authors declare no conflicts of interest.

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Figure Legend

Figure 1: Study selection flow chart

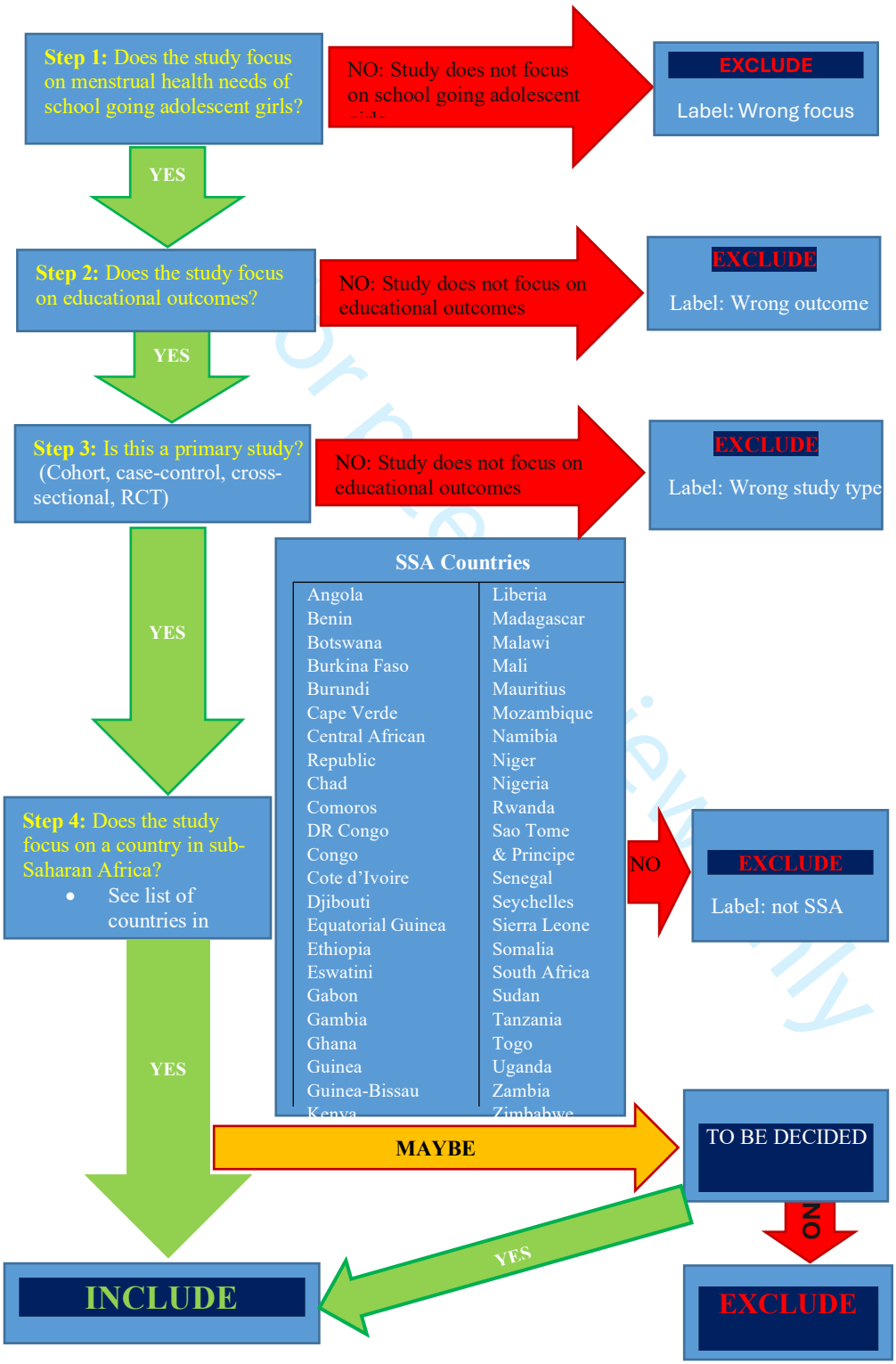
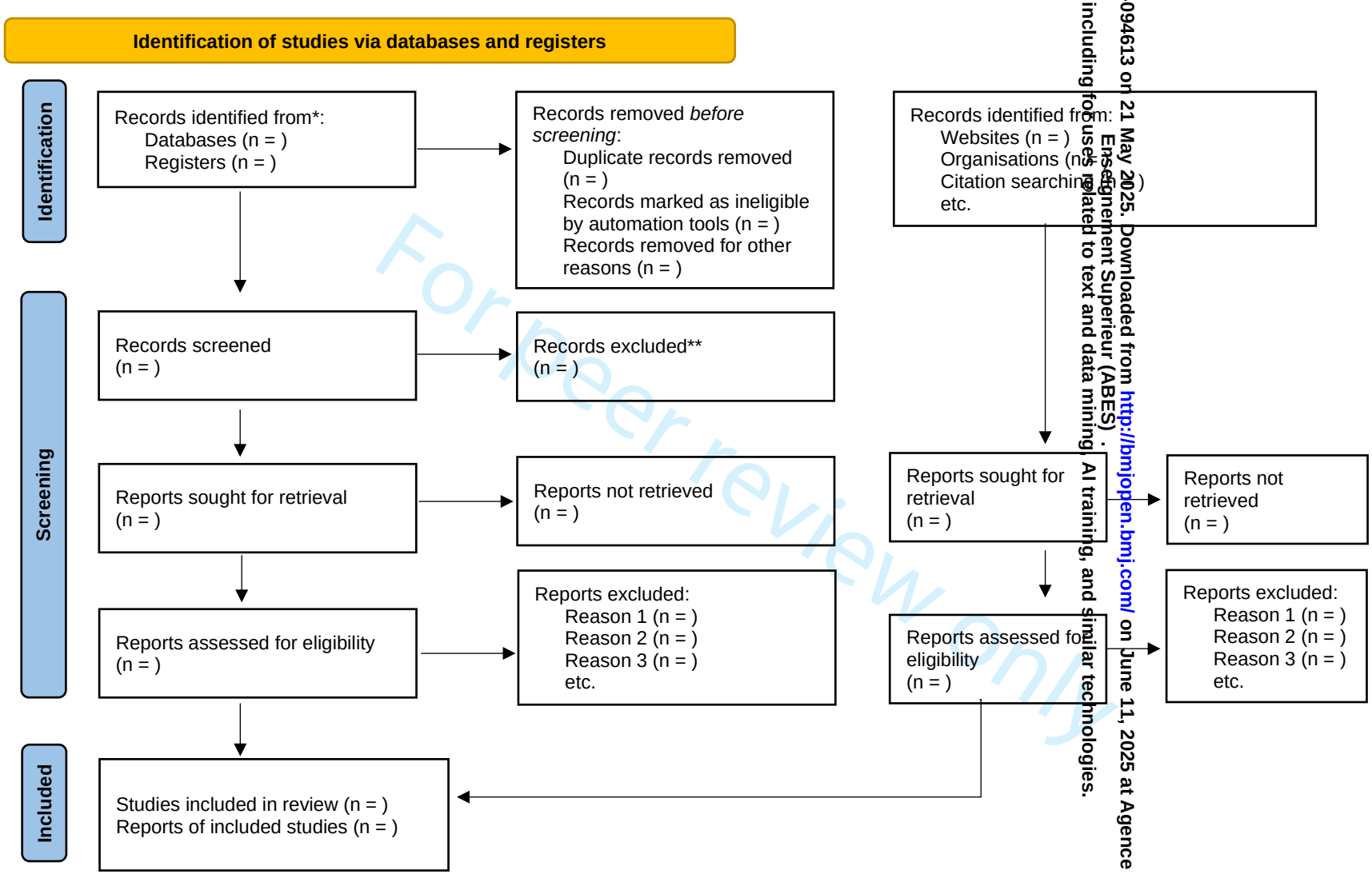


Fig. 1: Study selection flow chart

Supplemental File 1: Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) Guidelines

Section and topic	Item No	Checklist item
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 (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, 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 or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
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 (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
Information sources	9	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
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
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 (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	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
Data items	12	List and define all variables for which data will be sought (such as 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



SUPLEMENTAL FILE 2 PRISMA-P 2020 Flow Diagram to show studies retrieved from electronic databases and other sources for inclusion and flow to the final stage with studies included in the systematic review

Additional file 3: Robbins E Risk of Bias Assessment Tool

Domain 1: Risk of bias due to confounding

Domain 1, Variant (a): ***If N/PN to C5 or Y/PY to C6 or N/PN to C7*** *(only baseline confounding needs to be addressed)*

Signalling questions	Response options
1.1 Did the authors control for all the important confounding factors for which this was necessary?	Y / PY / WN (no, but uncontrolled confounding was probably not substantial) / SN (no, and uncontrolled confounding was probably substantial) / NI
1.2 **If Y/PY/WN to 1.1**: Were confounding factors that were controlled for (and for which control was necessary) measured validly and reliably by the variables available in this study?	NA / Y / PY / WN (no, but the extent of measurement error in confounding factors was probably not substantial) / SN (no, and the extent of measurement error in confounding factors was probably substantial) / NI
1.3 **If Y/PY/WN to 1.1**: Did the authors control for any variables after the start of the exposure period being studied that could have been affected by the exposure?	NA / Y / PY / PN / N / NI
1.4 Did the use of negative controls, or other considerations, suggest serious uncontrolled confounding?	Y / PY / PN / N
Risk of bias (due to confounding) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias due to confounding?	(Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Insufficient information available)
Is the risk of bias (due to confounding) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; SY = Strong yes; WY = Weak yes; SN = Strong no; WN = Weak no; NA = Not applicable; NI = No information

Domain 2: Risk of bias arising from measurement of the exposure

Domain 2, Variant (a): ***If N/PN to C5*** *(exposure was measured at a single point in time)*

Signalling questions	Response options
Mismeasurement or misclassification of the exposure.	
2.1 Does the measured exposure well-characterize the exposure metric specified to be of interest in this study? [*This was specified in the answers to D2, D3 and D4*]	Y / PY / WN (no, to a small extent) / SN (no, to a large extent) / NI
2.2 Was the exposure likely to be measured with error, or misclassified?	SY (yes, probably a substantial amount) / WY (yes, but probably not a substantial amount) / PN / N / NI
Bias in the estimated effect of exposure arising from mismeasurement or misclassification of the exposure	
2.3 If SY/WY to 2.2: Could mismeasurement or misclassification of exposure have been differential (i.e. related to the outcome or risk of the outcome)?	NA / SY (yes, to a large extent) / WY (yes, to a small extent) / PN / N / NI
2.4 If SY/WY to 2.2 and N/PN/WY to 2.3: Is non-differential measurement error likely to bias the estimated effect of exposure on outcome?	NA / SY (yes, to a large extent) / WY (yes, to a small extent) / PN / N / NI
Risk of bias (arising from measurement of exposure) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias arising from measurement of exposure?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (arising from measurement of exposure) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; SY = Strong yes; WY = Weak yes; SN = Strong no; WN = Weak no; NA = Not applicable; NI = No information

Domain 3: Risk of bias in selection of participants into the study (or into the analysis)

Signalling questions	Response options
3.1 Did follow-up begin at (or close to) the start of the exposure window for most participants? [*The exposure window is specified in D3*]	Y / PY / PN / N / NI
3.2 **If N/PN to 3.1**: Is the effect of exposure likely to be constant over the period of follow up analysed?	NA / Y / PY / PN / N / NI
3.3 Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of the exposure window being studied? [*The exposure window is specified in D3*]	Y / PY / PN / N / NI
3.4 **If Y/PY to 3.3**: Were these characteristics likely to be influenced by exposure or a cause of exposure?	NA / Y / PY / PN / N / NI
3.5 **If Y/PY to 3.4**: Were these characteristics likely to be influenced by the outcome or a cause of the outcome?	NA / Y / PY / PN / N / NI
3.6 **If N/PN to 3.2 or Y/PY to 3.5**: Is it likely that the analysis corrected for all of the potential selection biases identified in A and B above?	NA / Y / PY / PN / N / NI
3.7 **If N/PN to 3.2 or Y/PY to 3.5**: Did sensitivity analyses demonstrate that the likely impact of the potential selection biases identified in A or B above was minimal?	NA / Y / PY / WN (no, there were no sensitivity analyses or there is evidence of some impact) / SN (no, there is evidence of substantial impact)
Risk of bias (due to selection of participants into the study) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias due to selection of participants into the study?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (due to selection of participants into the study) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; SN = Strong no; WN = Weak no; NA = Not applicable; NI = No information

Domain 4: Risk of bias due to post-exposure interventions

Signalling questions	Response options
4.1 Were there post-exposure interventions that were influenced by prior exposure during the follow-up period?	Y / PY / PN / N / NI
4.2 **If Y/PY to 4.1**: Is it likely that the analysis corrected for the effect of post-exposure interventions that were influenced by prior exposure?	NA / Y / PY / PN / N / NI
Risk of bias (due post-exposure interventions) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias due to confounding?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (due post-exposure interventions) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; NA = Not applicable; NI = No information

Domain 5: Risk of bias due to missing data

Signalling questions	Response options
5.1 Were complete data on exposure status available for all, or nearly all, participants?	Y / PY / PN / N / NI
5.2 Were complete data on the outcome available for all, or nearly all, participants?	Y / PY / PN / N / NI
5.3 Were complete data on confounding variables available for all, or nearly all, participants?	Y / PY / PN / N / NI
5.4 **If N/PN/NI to 5.1, 5.2 or 5.3**: Is the result based on a complete case analysis?	NA / Y / PY / PN / N / NI

Signalling questions	Response options
5.5 **If Y/PY/NI**: Was exclusion from the analysis because of missing data (in exposure, confounders or the outcome) likely to be related to the true value of the outcome?	NA / SY (Yes, strongly related) / WY (Yes, but not strongly related) / PN / N / NI
5.6 **If N/PN to 5.5**: Were all or most predictors of missingness (in exposure, confounders or the outcome) included in the analysis model?	NA / SY (Yes, for sure) / WY (Yes, mostly or probably) / PN / N / NI
5.7 **If N/PN to 5.4**: Was the analysis based on imputing missing values?	NA / Y / PY / PN / N
5.8 **If Y/PY to 5.7**: Was imputation performed appropriately?	NA / Y / PY / WN (no, but not leading to substantial bias) / SN (no, such that bias would not be substantially reduced) / NI
5.9 **If N/PN to 5.7**: Was an appropriate alternative method used to correct for bias due to missing data?	NA / Y / PY / WN (no, but not leading to substantial bias) / SN (no, such that bias would not be substantially reduced) / NI
5.10 **If PN/N/NI to 5.1, 5.2 or 5.3**: Is there evidence that the result was not biased by missing data?	NA / Y / PY / PN / N
Risk of bias (due to missing data) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias due to missing data?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (due to missing data) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; SY = Strong yes; WY = Weak yes; NA = Not applicable; NI = No information

Domain 6: Risk of bias arising from measurement of the outcome

Signalling questions	Response options
6.1 Could measurement or ascertainment of the outcome have differed between exposure groups or levels of exposure?	Y / PY / PN / N / NI
6.2 Were outcome assessors aware of study participants' exposure history?	Y / PY / PN / N / NI
6.3 **If Y/PY/NI to 6.2**: Could assessment of the outcome have been influenced by knowledge of participants' exposure history?	NA / SY (yes, to a large extent) / WY (yes, to a small extent) / PN / N / NI
Risk of bias (arising from measurement of outcomes) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias arising from measurement of outcomes?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (arising from measurement of outcomes) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; SY = Strong yes; WY = Weak yes; NA = Not applicable; NI = No information

Domain 7: Risk of bias in selection of the reported result

Signalling questions	Response options
7.1 Was the result reported in accordance with an available, pre-determined analysis plan?	Y / PY / PN / N / NI
7.2 **If N/PN/NI to 7.1**: Is the reported effect estimate likely to be selected, based on desirability of the magnitude (or statistical significance) of the estimated effect of exposure on outcome, from multiple *exposure measurements* within the exposure domain?	NA / Y / PY / PN / N / NI

Signalling questions	Response options
7.3 Is the reported effect estimate likely to be selected, based on desirability of the magnitude (or statistical significance) of the estimated effect of exposure on outcome, from multiple *outcome measurements* within the outcome domain?	Y / PY / PN / N / NI
7.4 Is the reported effect estimate likely to be selected, based on desirability of the magnitude (or statistical significance) of the estimated effect of exposure on outcome, from multiple *analyses* of the exposure-outcome relationship?	Y / PY / PN / N / NI
7.5 Is the reported effect estimate likely to be selected, based on the basis of desirability of the results (e.g. statistical significance), from different *subgroups*?	Y / PY / PN / N / NI
Risk of bias (due to selection of the reported result) in the estimated effect of exposure on the outcome	Low risk / Some concerns / High risk / Very high risk
What is the predicted direction of bias due to selection of the reported result?	Towards benefit of (higher) exposure / Towards harm of (higher) exposure / Towards null / Away from null / Insufficient information available
Is the risk of bias (due to selection of the reported result) sufficiently high, in the context of its likely direction and the magnitude of the estimated exposure effect, to threaten conclusions about whether the exposure has an important effect on the outcome?	Yes / No / Cannot tell

Y = Yes; PY = Probably yes; PN = Probably no; N = No; NA = Not applicable; NI = No information

Additional file 4: Risk of Bias Tool for Prevalence Studies

Name of author(s):_____ Year of publication:_____

Name of paper/study:-

_____

_____

This tool is designed to assess the risk of bias in population-based prevalence studies. Please read the additional notes for each item when initially using the tool. Note: If there is insufficient information in the article to permit a judgement for a particular item, please answer **No (HIGH RISK)** for that particular item.

Risk of bias item	Criteria for answers (please circle one option)	Additional notes and examples
External Validity		
1. Was the study's target population **a close representation** of the national population in relation to relevant variables, e.g. age, sex, occupation?	• **Yes (LOW RISK):** The study's target population was a close representation of the national population. • **No (HIGH RISK)**: The study's target population was clearly NOT representative of the national population.	The **target population** refers to the group of people or entities to which the results of the study will be generalised. Examples: • The study was a national health survey of people 15 years and over and the sample was drawn from a list that included all individuals in the population aged 15 years and over. The answer is: **Yes (LOW RISK).** • The study was conducted in one province only, and it is not clear if this was representative of the national population. The answer is: **No (HIGH RISK).** • The study was undertaken in one village only and it is clear this was not representative of the national population. The answer is: **No (HIGH RISK).**
2. Was the sampling frame a **true or close representation** of the target population?	• **Yes (LOW RISK):** The sampling frame was a **true or close** representation of the target population. • **No (HIGH RISK)**: The sampling frame was NOT a **true or close** representation of the target population.	The **sampling frame** is a list of the sampling units in the target population and the study sample is drawn from this list. Examples: • The sampling frame was a list of almost every individual within the target population. The answer is: **Yes (LOW RISK)**. • The cluster sampling method was used and the sample of clusters/villages was drawn from a list of all villages in the target population. The answer is: **Yes (LOW RISK)**. • The sampling frame was a list of just one particular ethnic group within the overall target population, which comprised many groups. The answer is: **No (HIGH RISK).**
3. Was some form of **random selection** used to select the sample, OR, was a census undertaken?	• **Yes (LOW RISK):** A census was undertaken, OR, some form of random selection was used to select the sample (e.g. simple random sampling, stratified random sampling, cluster sampling, systematic sampling). • **No (HIGH RISK)**: A census was NOT undertaken, AND some form of random selection was NOT used to select the sample.	A census collects information from every unit in the sampling frame. In a survey, only part of the sampling frame is sampled. In these instances, random selection of the sample helps minimise study bias. Examples: • The sample was selected using simple random sampling. The answer is: **Yes (LOW RISK)**. • The target population was the village and every person in the village was sampled. The answer is: **Yes (LOW RISK)**. • The nearest villages to the capital city were selected in order to save on the cost of fuel. The answer is: **No (HIGH RISK).**
4. Was the likelihood of **non-response bias minimal?**	• **Yes (LOW RISK):** The response rate for the study was >/=75%, OR, an analysis was performed that showed no significant difference in relevant demographic characteristics between responders and non-responders • **No (HIGH RISK)**: The response rate was <75%, and if any analysis comparing responders and non-responders was done, it showed a significant difference in relevant demographic characteristics between responders and non-responders.	Examples: • The response rate was 68%; however, the researchers did an analysis and found no significant difference between responders and non-responders in terms of age, sex, occupation and socio-economic status. The answer is: **Yes (LOW RISK)**. • The response rate was 65% and the researchers did NOT carry out an analysis to compare relevant demographic characteristics between responders and non-responders. The answer is: **No (HIGH RISK)**. • The response rate was 69% and the researchers did an analysis and found a significant difference in age, sex and socio-economic status between responders and non-responders. The answer is: **No (HIGH RISK)**.

Internal Validity		
5. Were data collected **directly from the subjects** (as opposed to a proxy)?	• **Yes (LOW RISK):** All data were collected directly from the subjects. • **No (HIGH RISK)**: In some instances, data were collected from a proxy.	A proxy is a representative of the subject. Examples: • All eligible subjects in the household were interviewed separately. The answer is: **Yes (LOW RISK)**. • A representative of the household was interviewed and questioned about the presence of low back pain in each household member. The answer is: **No (HIGH RISK)**.
6. Was an acceptable case definition used in the study?	• **Yes (LOW RISK):** An acceptable case definition was used. • **No (HIGH RISK)**: An acceptable case definition was NOT used.	• For a study on low back pain, the following case definition was used: "Low back pain is defined as activity-limiting pain lasting more than one day in the area on the posterior aspect of the body from the bottom of the 12th rib to the lower gluteal folds." The answer is: **Yes (LOW RISK)**. • For a study on back pain, there was no description of the specific anatomical location 'back' referred to. The answer is: **No (HIGH RISK)**. • For a study on osteoarthritis, the following case definition was used: "Symptomatic osteoarthritis of the hip or knee, radiologically confirmed as Kellgren-Lawrence grade 2-4". The answer is: LOW RISK.
7. Was the study instrument that measured the parameter of interest (e.g. prevalence of low back pain) shown to have **reliability and validity (if necessary)**?	• **Yes (LOW RISK):** The study instrument had been shown to have reliability and validity (if this was necessary), e.g. test-re-test, piloting, validation in a previous study, etc. • **No (HIGH RISK)**: The study instrument had NOT been shown to have reliability or validity (if this was necessary).	• The authors used the COPCORD questionnaire, which had previously been validated. They also tested the inter-rater reliability of the questionnaire. The answer is: **Yes (LOW RISK)**. • The authors developed their own questionnaire and did not test this for validity or reliability. The answer is: **No (HIGH RISK)**.
8. Was the **same mode of data collection** used for all subjects?	• **Yes (LOW RISK):** The same mode of data collection was used for all subjects. • **No (HIGH RISK)**: The same mode of data collection was NOT used for all subjects.	The mode of data collection is the method used for collecting information from the subjects. The most common modes are face-to-face interviews, telephone interviews and self-administered questionnaires. Examples: • All eligible subjects had a face-to-face interview. The answer is: **Yes (LOW RISK)**. • Some subjects were interviewed over the telephone and some filled in postal questionnaires. The answer is: **No (HIGH RISK)**.
9. Was the **length of the shortest prevalence period** for the parameter of interest appropriate?	• **Yes (LOW RISK):** The shortest prevalence period for the parameter of interest was appropriate (e.g. point prevalence, one-week prevalence, one-year prevalence). • **No (HIGH RISK)**: The shortest prevalence period for the parameter of interest was not appropriate (e.g. lifetime prevalence)	The prevalence period is the period that the subject is asked about e.g. "Have you experienced low back pain over the previous year?" In this example, the prevalence period is one year. The longer the prevalence period, the greater the likelihood of the subject forgetting if they experienced the symptom of interest (e.g. low back pain). Examples: • Subjects were asked about pain over the past week. The answer is: **Yes (LOW RISK)**. • Subjects were only asked about pain over the past three years. The answer is: **No (HIGH RISK)**.
10. Were the **numerator(s) and denominator(s)** for the parameter of interest appropriate?	• **Yes (LOW RISK):** The paper presented appropriate numerator(s) AND denominator(s) for the parameter of interest (e.g. the prevalence of low back pain). • **No (HIGH RISK)**: The paper did present numerator(s) AND denominator(s) for the parameter of interest but one or more of these were inappropriate.	There may be errors in the calculation and/or reporting of the numerator and/or denominator. Examples: • There were no errors in the reporting of the numerator(s) AND denominator(s) for the prevalence of low back pain. The answer is: **Yes (LOW RISK)**. • In reporting the overall prevalence of low back pain (in both men and women), the authors accidentally used the population of women as the denominator rather than the combined population. The answer is: **No (HIGH RISK).**
11. Summary item on the overall risk of study bias		
• **LOW RISK OF BIAS:** Further research is very unlikely to change our confidence in the estimate. • **MODERATE RISK OF BIAS:** Further research is likely to have an important impact on our confidence in the estimate and may change the estimate.		