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BMJ Open

Effectiveness of school-based interventions in delaying sexual debut among adolescents in sub-Saharan Africa: A protocol for a systematic review and meta-analysis

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5 6 7	2	Saharan Africa: A protocol for a systematic review and meta-analysis
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10 11	4	Short Title: School-based interventions and sexual debut
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19 Abstract

Introduction: Early sexual debut is associated with poor sexual and reproductive health outcomes across the life course. A majority of interventions aimed at delaying sexual debut among adolescents in sub-Saharan Africa (SSA) have been implemented in schools with mixed findings on the effectiveness of such interventions. This systematic review will summarize and synthesize existing evidence on the effectiveness of school-based interventions in delaying sexual debut among adolescents aged 10 - 19 years.

Methods and analysis: We will conduct a comprehensive database search of peer-reviewed studies published in PubMed, Scopus, Science Direct, Web of Science, HINARI and EBSCO (PsycINFO, Global Health, CINAHL), and in Cochrane library, National Institute of Health (NIH), and Turning Research into Practice (TRIP) databases for ongoing studies yet to be published. All studies conducted in SSA between January 2009 and December 2019, regardless of the study design, will be considered. Two authors will independently screen all retrieved records and relevant data on sexual debut extracted.

Data will be pooled using the random effects model. Dichotomous outcomes will be reported as
risk ratios and continuous data as mean difference at 95% confidence interval. Heterogeneity will
be assessed using the I² statistic. Findings will be presented in tables and charts, while providing a
description of all included studies, themes and concepts drawn from literature.

Ethics and dissemination: Ethical approval is not required. The findings will be disseminated
through peer-reviewed publications, presentations at relevant conferences, and other convening
focusing on adolescent sexual and reproductive health.

40 Strengths and limitations of this study

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- This review will synthesise evidence of school-based interventions on delaying sexual debut among adolescents in sub-Saharan Africa.
 The systematic review will adhere to the Preferred Reporting Items for Systematic Reviews
 - and Meta-Analyses (PRISMA) guidelines
 - There is a possibility only a small number of diverse studies will be eligible for inclusion in this review, and thus, limited and heterogeneous data for meta-analysis.
 - This review will be limited to peer-reviewed studies, published in English between January 2009 and December 2019

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50 Background

Adolescents aged 10-19 years in sub-Saharan Africa's (SSA) have a high prevalence of risky sexual behaviours including early sexual debut and unsafe sexual practices ($\underline{1}, \underline{2}$). Consequently, they are most-at-risk for poor sexual and reproductive health (SRH) outcomes ($\underline{3-5}$).

Early sexual debut, described as having had the first sexual intercourse at or before the age of 14 years, increases the period in which an adolescent girl is at risk of getting pregnant (6, 7) and is predominantly driven by individual, familial, contextual and socio-cultural factors (8-10). Early sexual debut is also associated with occurrence of sexual violence, unsafe abortions, unplanned pregnancies, early child marriages, sexually transmitted infections, and HIV infection (11-13), elevated risk of cervical cancer (14, 15) and poor schooling outcomes (11, 16, 17).

Implications of early sexual debut disproportionately affect women and girls, impacting on their health, socio-economic lives and overall wellbeing across the life course (18-26). For instance, young girls who get pregnant at an early age are likely to drop out of school increasing their risk of poor educational and other socio-economic outcomes (27, 28). Young girls are also at greater risk of poor maternal outcomes compared with older women. A review of maternal mortality among adolescents compared with women of other ages in 144 countries revealed a three-fold higher mortality risk among adolescent mothers compared to women above 30 years (2). Similarly, adolescents have higher risk of adverse perinatal outcomes, including low birthweight, preterm delivery, and perinatal death (29-31). The strong association between poor maternal education and poor child-health outcomes such as experiencing severe acute malnutrition, infections as well as poor cognitive growth (32-34), implies that the consequences of early sexual debut transcends generations. Delaying sexual debut is, therefore, a key strategy in averting poor SRH outcomes during and after adolescence.

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School is one institution where most adolescents spend most of their time, learning and interacting with peers and adults. Critical thinking developed in schools can be useful for questioning unhealthy behaviours. Schools thus offer a platform for socialization into healthy and unhealthy behaviours (35). As attention turns towards meeting the Sustainable Development Goals (SDGs), the global health community is increasingly committed to adolescent SRH as a prerequisite for improving lives and health of young people (36). This commitment is exemplified by the vast number of diverse school-based interventions targeted at promoting adolescent SRH across the globe, with limited but growing interest in SSA. For instance, schools are being targeted as sites for provision of age-appropriate comprehensive sexuality education that facilitates improved self-efficacy, knowledge and life skills (37-39). Other related school-based interventions such as school fees waivers, supply of menstrual products for girls, school feeding programs for vulnerable populations are also being implemented (40, 41). However, impact evaluations of school-based interventions on delaying sexual debut suggest

mixed findings (40, 42-44). Within high-income countries, the majority of school-based interventions have shown effectiveness in delaying sexual debut (42-44). Similarly, a systematic review and meta-analysis on school based sex education and HIV prevention in low-and middle-income countries globally found that students who received the interventions were less likely to initiate sexual activity (45). In a cluster randomized controlled trial assessing the effects of teacher-led school HIV prevention programs on adolescent sexual risk behaviour in Dar es Salaam, Tanzania and Cape town and Mankweng, South Africa students in Tanzania reported delay in initiating sexual activity during the study while there was no effect of the intervention among students in South Africa (46). Other studies found no significant effects of school-based interventions on delaying sexual debut (47, 48) while others found significant effects (49, 50) found

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96	significant effects. These conflicting findings suggests a need for a comprehensive review of
97	school-based interventions to assess their effectiveness on delaying sexual debut.

Taken together, these factors underscore the need to synthesize existing studies, and explore the linkages between school-based interventions and early sexual debut in an attempt to inform future adolescent health policies and programing. This systematic review will provide a critical synthesis of existing literature on school-based interventions aimed at delaying early sexual debut among adolescents in SSA, to inform programs, policy and research. The objective of the review is to evaluate the effects of school-based interventions on delaying sexual debut among adolescents in SSA.

105 Methods and design

This systematic review and meta-analysis will be developed in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) (51). Criteria for considering studies will include study population, type of interventions, type of outcome measures, and type of studies, and study setting, as described in the sections that follow. Important amendments made to this protocol will be documented and published alongside the results of the systematic review.

112 Study population

The study targets adolescent students aged 10 - 19 years in primary or secondary levels of education or their equivalents who participated in a school-based intervention to delay sexual debut. Studies with students younger than 10 years and/or older than 19 years, as maybe in some settings, will be included if the majority of participants (i.e. above 50%) are aged between 10 and 19 years. Studies that do not include students aged 10 - 19 years will be excluded from the review. *Types of interventions*

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All interventions with a school-based component irrespective of intervention content and instruction mode will be considered as long as they assessed sexual debut as a primary or secondary outcome. This includes interventions that are school-based only and delivered in primary and secondary schools, and those that have multiple components, one of which must be a school-based component while the other components are delivered elsewhere (e.g. health care facilities). The intervention must have reported on sexual debut as a primary or secondary outcome. Interventions that target students outside the school setting will be excluded.

Types of outcome

127 The primary outcome of interest is delayed sexual debut, defined as postponement of sexual 128 intercourse among participants who had not engaged in sexual intercourse prior to the school-129 based intervention. Secondary outcomes shown in Table 1 will be considered:

130 Table 1: Secondary outcomes

Secondary outcomes	Definitions
Intention to delay sex	Planning to wait to have sexual intercourse until older
Lifetime sexual activity	Ever engaged in sexual intercourse
Sexually active	Having engaged in sexual intercourse in the last 30 days
Current sexual activity	Having engaged in sexual intercourse in the last six months
Sexual health knowledge	Knowledge of key SRH topics and issues
Sexual attitude	Attitudes towards sexuality and sexual behaviour
Self-efficacy for safe sex	Confidence to say no to unsafe sex practices
practices	
Consistent condom use	Condom use at every sexual intercourse

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Number of sex-partners	Number of sex partners (regular and casual) in a specified
	period of time

Types of studies

The review will not be limited to studies using a specific design and meta-analytical approaches that take into consideration different study designs will be used in the analysis. We will also compare the effectiveness of the interventions by study design. Eligible studies will have been published in peer reviewed journals between January 2009 and December 2019. Only studies published in English will be considered.

138 Study setting

Only studies conducted in SSA will be considered. Given the population of interest, the review will focus on interventions implemented in primary and secondary schools or their equivalents. This review focuses on the period after the global momentum on the need for comprehensive sexuality education began. In 2008, Latin America and the Caribbean signed the Preventing through Education Declaration for the delivery of sexuality education and health services (52). In 2013, there was a Ministerial Commitment on CSE and SRH services for adolescents and young people in 20 countries across Eastern and Southern Africa (53).

146 Search strategy

- 45 147 Our search strategy will involve three methods:
 - Electronic searches four researchers will search five electronic databases including
 PubMed, Scopus, Science Direct, Web of Science and EBSCO (PsycINFO, Global Health,
 CINAHL) for published peer-reviewed journal articles. Cochrane library, National

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151	Institute of Health (NIH), and Turning Research into Practice (TRIP) databases will be				
152	searched for ongoing studies that are yet to be published.				
153	• Hand-searches – An iterative process to obtain additional studies not yet retrieved with our				
154	initial online database using the reference list of retrieved articles				
155	• Contacting authors and experts - Where published data are not sufficient, authors will be				
156	contacted for additional information				
157	While the exact search terms will vary by database, the four search components included will be				
158	(1) adolescents (2) sexual debut (3) school-based interventions (4) and sub-Saharan Africa. Search				
159	terms will be adapted for each bibliographic database in combination with database-specific filters.				
 Boolean operators 'OR', 'NOT' and 'AND' will be used to maximize or narrow the specificity in the search. Wildcards will be used to search for variations or alternate spellings of key conception As an example, we present a draft of search strategy to be used in PubMed below: 					
				163	1. (intervention[Title/Abstract]) OR (program*[Title/Abstract])
				164	2. (school[Title/Abstract]) OR (institution[Title/Abstract]) OR (academic[Title/Abstract])
165	OR (education[Title/Abstract])				
166	3. (sexual debut[Title/Abstract]) OR (sexual initiation[Title/Abstract]) OR (sexual				
167	delay[Title/Abstract]) OR (sexual activity [Title/Abstract])				
168	4. (adolesce*[Title/Abstract]) OR ("young people"[Title/Abstract]) OR				
169	(youth[Title/Abstract]) OR (teenage*[Title/Abstract]) OR (learner[Title/Abstract]) OR				
170	(children[Title/Abstract])				
171	5. (Africa south of the Sahara [MeSH Terms]) OR (Africa [MeSH Terms])				
172	6. ("2009/01/01"[Date - Publication]: "2019/12/31"[Date - Publication])				
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Data collection

Selection of studies Four reviewers, paired, will independently screen retrieved titles and abstracts of potential articles to determine their eligibility for inclusion in the review. Ravyan, a web application tool will be used to manage the screening process (54). Full article texts of included studies will then be obtained and reviewed to ascertain eligibility. Any disagreements during title and abstract review or during the full text review will be resolved by consensus. A third reviewer will be involved if a consensus is not reached by the two pairs of reviewers. Data extraction and management

Two reviewers will use a standardized data extraction form to independently extract data on background or process-oriented information from each included study to provide a basis for data charting, themes and variables for use in answering the research question. Reviewers will pilot the data extraction form with a sample of included papers and amendments will be made as necessary. All information will be drawn from the studies highly scored based on the quality of their methodology, robustness of results and level of evidence. From each relevant study, data will be extracted on the following domains:

- General information on the study: authors, date of publication, publication type, country, and funding source
- Study characteristics: study setting, location, study design, sampling frame and sampling
 methods, and year(s) of study implementation
 - Participant characteristics: age, gender, number of participants, participants lost to followup, length of follow-up

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 Intervention: detailed description of the intervention, composition of intervention and control groups
 Outcomes: for primary outcome (delay in sexual debut), data on the number of participants experiencing delayed sexual debut on both intervention versus control arms will be extracted. If a

summary estimate (e.g., risk ration) is reported instead of raw numbers, these will be extracted. A
similar approach will be used for secondary outcomes. Where more than one article described the
same intervention, data will be extracted from all papers. The eligible studies will be exported into
the comprehensive meta-analysis (CMA) software.

204 Risk of bias assessment

Two independent reviewers will assess the methodological quality of studies depending on study design. For RCTs, the reviewers will judge each quality domain based on the following three-point scale as suggested in Cochrane Handbook for Systematic Reviews of Interventions (55): Yes (low risk of bias: plausible bias unlikely to seriously alter the results if all criteria were met); No (high risk of bias: plausible bias that seriously weakens confidence in the results if one or more criteria were not met); and Unclear (plausible bias that raises some doubt about the results if one or more criteria were assessed as unclear. The following items in the risk of bias assessment for RCTs will be included:

• Sequence generation (whether allocation sequence was adequately generated)

• Allocation concealment (whether allocation was adequately concealed)

• Masking/ blinding (whether knowledge of the allocated intervention was adequately prevented during the study, i.e., whether participants, personnel, outcome assessors and/or data analysts are blinded)

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3 4	218	• Incomplete outcome reporting (whether incomplete outcome data was adequately
5 6 7	219	addressed)
7 8 9	220	• Selective reporting (whether reports of the study were free of selective outcome reporting)
10 11	221	• Other sources of data (e.g., whether reports of the study included sample size computation,
12 13 14	222	alpha error, etc.)
14 15 16	223	For non-RCT studies, the following items will be included in the risk of bias assessment as
17 18	224	suggested by Viswanathan, Berkman, Dryden et al. (56):
19 20 21	225	• Selection bias – do the inclusion/exclusion criteria vary across the comparison groups (for
22 23	226	multiple-arm studies) or within groups (for single arm/cross-sectional studies)?
24 25	227	Performance bias – does the study fail to account for important variations in the execution
26 27 28	228	of the study from the proposed protocol?
20 29 30	229	• Detection bias - was the assessor not blinded to the outcome, exposure, or intervention
31 32	230	status of the participants? Were valid and reliable measures not used or not implemented
33 34 25	231	consistently across all study participants to assess inclusion/exclusion criteria,
35 36 37	232	intervention/exposure outcomes, participant benefits and harms?
38 39	233	• Attrition bias – was the length of follow-up different across study groups? In cases of
40 41	234	missing data was the impact not assessed (e.g., through sensitivity analysis or other
42 43 44	235	adjustment method)?
45 46	236	• Selective outcome reporting - Are any important primary outcomes missing from the
47 48	237	results?
49 50 51 52 53	238	• Overall assessment: Are the results believable taking study limitations into consideration?
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Discussions and consensus will be used to crosscheck the extracted information and to resolve disagreements. The level of risk of bias in each of these domains will be presented separately for each study in tables in the final review publication.

Risk of bias in individual studies

Methodological quality of each individual article will be appraised using a checklist adapted from
Critical Appraisals Skills Programme (CASP). Two authors will independently appraise each
article.

Measures of intervention effect

Dichotomous outcomes such as sexual debut (initiated versus not initiated sexual activity during the study period) will be summarized as risk ratios or odds ratio with 95% confidence intervals for each study. Continuous outcomes such as number of sex partners will be summarized as (unstandardized) mean differences and standard errors. In cases where sexual debut may be reported as a median age at sexual debut, published procedures for transforming median to mean and standard deviation to facilitate computation of relevant statistics will be used. If enough information is not provided to calculate an effect size, study authors will be contacted for clarification or to provide additional statistics. If the authors do not provide this information after one month, this study will be removed from the analysis but this effort will be reported.

If results of a repeated measure analysis are reported, authors will need to provide the correlation between pre-post measurements or provide enough information to calculate the correlation between measurements. If these statistics are not available, either in publication or after request, and the study was a controlled design, an effect size will be generated using postintervention statistics provided groups are similar at baseline with respect to the outcome of interest and other relevant covariates.

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Unit of analysis

Data will be extracted from each included study (unit of analysis) as follows. For dichotomous variables, number of participants in the intervention group and the number of participants in the standard/control group will be used. For continuous variables, the mean, standard deviation, and the number of participants in the intervention and control groups will be used. For studies with multiple intervention groups, each pair-wise comparison will be included separately. Moreover, for dichotomous outcomes, we will divide both the number of events and the total number of participants. For continuous outcomes, means and standard deviations will not be changed but will be divided by the total number of participants. Assessment of heterogeneity

Heterogeneity among studies and between subgroups will be assessed using a Chi² test with a significance level at p < 0.10. The degree of heterogeneity among studies and between subgroups will be assessed using the I² statistic using the following guide: I² = 0% to 40% as heterogeneity that might not be important, I² = 30% to 60% as moderate heterogeneity, I² = 50% to 90% as substantial heterogeneity, and I² = 75% to 100% as considerable heterogeneity (57)

3 277 Assessment of reporting bias

Publication bias will be assessed if at least 10 studies are included in the review. A funnel plot will
be used to assess the magnitude of reporting bias as per Cochrane guidelines.

5 280 Data synthesis

Data will be pooled using the random effects model according to Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (57). Dichotomous outcomes' data (e.g.,
number of participants who experience sexual debut) will be reported as risk ratios and continuous
data (e.g., number of sexual partners) as mean differences. All analyses will be done at 95%

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confidence intervals. Data will be analysed using the statistical software Comprehensive MetaAnalysis (CMA). In studies where the effects of clustering have not been taken into account,
standard deviations will be adjusted for the design effect, using intra-class coefficients, if they are
provided in the study reports, or alternatively using external estimates obtained from similar
studies. Stratifications will be done by school level (primary or secondary (or age, if applicable),
grade level, instructor (e.g., teacher or peer), intervention type (e.g. behaviour change
communication, study setting)

Findings will be organised in tables and charts, while presenting a description of the themes and concepts found in literature reflecting the review objectives. A summary narrative that synthesizes the information across tables and charts will be developed, critically highlighting the advances and gaps in research, with a focus to draw implications for future research.

Patient and public involvement

297 Patients and public will not be involved in the design and conduct of this review

298 Ethics and dissemination
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Ethics approval is not required. The findings of this systematic review will be disseminated through peer-reviewed publications as well as in relevant stakeholders' fora. In case of any amendments to the protocol following its publication, the date of each amendment will be provided, change(s) described, and report the rationale for the change(s) in future publications arising from this protocol.

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PRISMA-P 2015 Checklist

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

Section/tonio	#	Checklist item	Information reported		Line
Section/topic	#	Checklist item		No	number(s)
ADMINISTRATIVE INFO	RMAT	ON			
Title					
Identification	1a	Identify the report as a protocol of a systematic review	\square		1 - 2
Update	1b	If the protocol is for an update of a previous systematic review, identify as such		\boxtimes	Not applicable
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract		\square	Not registered
Authors					
Contact	3а	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	\square		6 - 15
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	\square		447 - 450
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	\square		98 - 100
Support	Support				
Sources	5a	Indicate sources of financial or other support for the review	\square		451 - 452
Sponsor	5b	Provide name for the review funder and/or sponsor	\boxtimes		451 - 452
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol			451 - 452
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	\square		74 - 91
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)			91 - 93



			Informatio	n reported	Line
Section/topic	#	Checklist item	Yes	No	number(s)
METHODS					•
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	\boxtimes		95 - 134
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	\boxtimes		135 - 151
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	\boxtimes		152 - 161
STUDY RECORDS					-
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	\boxtimes		164 - 192
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	\boxtimes		164 - 170
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	\boxtimes		172 - 177
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	\boxtimes		177 - 192
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	\boxtimes		115 - 119
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	\boxtimes		193- 230
DATA					•
	15a	Describe criteria under which study data will be quantitatively synthesized	\square		270 - 285
Synthesis	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., <i>I</i> ² , Kendall's tau)	\boxtimes		235 - 265
-	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta- regression)	\square		275 – 277
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned			282 - 285
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	\boxtimes		276 - 281
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	\boxtimes		231 - 234





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Effectiveness of school-based interventions in delaying sexual debut among adolescents in sub-Saharan Africa: A protocol for a systematic review and meta-analysis

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Keywords:	PUBLIC HEALTH, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Community child health < PAEDIATRICS

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1 Effectiveness of school-based interventions in delaying sexual debut among adoles	scents in sub-
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- Saharan Africa: A protocol for a systematic review and meta-analysis 2
 - Short Title: School-based interventions and sexual debut

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19 Abstract

Introduction: Early sexual debut is associated with poor sexual and reproductive health outcomes across the life course. A majority of interventions aimed at delaying sexual debut among adolescents in sub-Saharan Africa (SSA) have been implemented in schools with mixed findings on the effectiveness of such interventions. This systematic review will summarize and synthesize existing evidence on the effectiveness of school-based interventions in delaying sexual debut among adolescents aged 10 - 19 years.

Methods and analysis: We will conduct a comprehensive database search of peer-reviewed studies published in PubMed, Scopus, Science Direct, Web of Science, HINARI and EBSCO (PsycINFO, Global Health, CINAHL), and in Cochrane library, National Institute of Health (NIH), and Turning Research into Practice (TRIP) databases for ongoing studies yet to be published. All studies conducted in SSA between January 2009 and December 2020, regardless of the study design, will be included. Two authors will independently screen all retrieved records and relevant data on sexual debut extracted.

Data will be pooled using the random effects model. Dichotomous outcomes will be reported as
risk ratios and continuous data as mean difference at 95% confidence interval. Heterogeneity will
be assessed using the I² statistic. Findings will be presented in tables and charts, while providing a
description of all included studies, themes and concepts drawn from literature.

Ethics and dissemination: Ethical approval is not required. The findings will be disseminated
through peer-reviewed publications, presentations at relevant conferences, and other convening
focusing on adolescent sexual and reproductive health.

40 Strengths and limitations of this study

2		
3 4	41	• To the best of our knowledge, this is the first systematic review and meta-analysis to focus
5 6 7	42	on the effectiveness of school-based interventions on delaying sexual debut among
7 8 9	43	adolescents in sub-Saharan Africa.
10 11	44	• The systematic review and meta-analysis includes all interventions with a school-based
12 13	45	component regardless of the study design used in the study.
14 15 16	46	• The systematic review and meta-analysis will adhere to the Preferred Reporting Items for
17 18	47	Systematic Reviews and Meta Analyses (PRISMA) guidelines.
19 20	48	• To minimise the likelihood of reviewer bias, two reviewers will screen for study eligibility
21 22 22	49	and perform the quality assessment.
23 24 25	50	• This review will be limited to peer-reviewed studies, published in English between January
26 27	51	2009 and December 2020
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53 Background

Adolescents aged 10-19 years in sub-Saharan Africa's (SSA) have a high prevalence of risky sexual behaviours including early sexual debut and unsafe sexual practices (, 2). Consequently, they are most-at-risk for poor sexual and reproductive health (SRH) outcomes (3-5).

Early sexual debut, described as having had the first sexual intercourse at or before the age of 14
years, increases the period in which an adolescent girl is at risk of getting pregnant (<u>6</u>, <u>7</u>) and is
predominantly driven by individual, familial, contextual and socio-cultural factors (<u>8-10</u>). Early
sexual debut is also associated with occurrence of sexual violence, unsafe abortions, unplanned
pregnancies, early child marriages, sexually transmitted infections, and HIV infection (<u>11-13</u>),
elevated risk of cervical cancer (<u>14</u>, <u>15</u>) and poor schooling outcomes (<u>11</u>, <u>16</u>, <u>17</u>).

Implications of early sexual debut disproportionately affect women and girls, impacting on their health, socio-economic lives and overall wellbeing across the life course (18-26). For instance, young girls who get pregnant at an early age are likely to drop out of school increasing their risk of poor educational and other socio-economic outcomes (27, 28). Young girls are also at greater risk of poor maternal outcomes compared with older women. A review of maternal mortality among adolescents compared with women of other ages in 144 countries revealed a three-fold higher mortality risk among adolescent mothers compared to women above 30 years (2). Similarly, adolescents have higher risk of adverse perinatal outcomes, including low birthweight, preterm delivery, and perinatal death (29-31). The strong association between poor maternal education and poor child-health outcomes such as experiencing severe acute malnutrition, infections as well as poor cognitive growth (32-34), implies that the consequences of early sexual debut transcends generations. Delaying sexual debut is, therefore, a key strategy in averting poor SRH outcomes during and after adolescence.

School is one institution where most adolescents spend most of their time, learning and interacting with peers and adults. Critical thinking developed in schools can be useful for questioning unhealthy behaviours. Schools thus offer a platform for socialization into healthy and unhealthy behaviours (35). As attention turns towards meeting the Sustainable Development Goals (SDGs), the global health community is increasingly committed to adolescent SRH as a prerequisite for improving lives and health of young people (36). This commitment is exemplified by the vast number of diverse school-based interventions targeted at promoting adolescent SRH across the globe, with limited but growing interest in SSA. For instance, schools are being targeted as sites for provision of age-appropriate comprehensive sexuality education that facilitates improved self-efficacy, knowledge and life skills (37-39). Other related school-based interventions such as school fees waivers, supply of menstrual products for girls, school feeding programs for vulnerable populations are also being implemented (40, 41).

However, impact evaluations of school-based interventions on delaying sexual debut suggest mixed findings (40, 42-44). Within high-income countries, the majority of school-based interventions have shown effectiveness in delaying sexual debut (42-44). Similarly, a systematic review and meta-analysis on school based sex education and HIV prevention in low-and middle-income countries globally found that students who received the interventions were less likely to initiate sexual activity (45). In a cluster randomized controlled trial assessing the effects of teacher-led school HIV prevention programs on adolescent sexual risk behaviour in Dar es Salaam, Tanzania and Cape town and Mankweng, South Africa students in Tanzania reported delay in initiating sexual activity during the study while there was no effect of the intervention among students in South Africa (46). Other studies found no significant effects of school-based interventions on delaying sexual debut (47, 48) while others found significant effects (49, 50) found

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99 significant effects. These conflicting findings suggests a need for a comprehensive review of100 school-based interventions to assess their effectiveness on delaying sexual debut.

Taken together, these factors underscore the need to synthesize existing studies, and explore the linkages between school-based interventions and early sexual debut in an attempt to inform future adolescent health policies and programing. This systematic review will provide a critical synthesis of existing literature on school-based interventions aimed at delaying early sexual debut among adolescents in SSA, to inform programs, policy and research. The objective of the review is to evaluate the effects of school-based interventions on delaying sexual debut among adolescents in SSA.

108 Methods and design

109 This systematic review and meta-analysis will be developed in accordance with the Preferred 110 Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) (51). Criteria 111 for considering studies will include study population, type of interventions, type of outcome 112 measures, and type of studies, and study setting, as described in the sections that follow. Important 113 amendments made to this protocol will be documented and published alongside the results of the 114 systematic review.

115 *Study population*

The study targets adolescent students aged 10 - 19 years in primary or secondary levels of education or their equivalents who participated in a school-based intervention to delay sexual debut. Studies with students younger than 10 years and/or older than 19 years, as maybe in some settings, will be included if the majority of participants (i.e. above 50%) are aged between 10 and 19 years. Studies that do not include students aged 10 - 19 years will be excluded from the review. *Types of interventions*

All interventions with a school-based component irrespective of intervention content and instruction mode will be included as long as they assessed sexual debut as a primary or secondary outcome. This includes interventions that are school-based only and delivered in primary and secondary schools, and those that have multiple components, one of which must be a school-based component while the other components are delivered elsewhere (e.g. health care facilities). The intervention must have reported on sexual debut as a primary or secondary outcome. Interventions that target students outside the school setting will be excluded.

Types of outcome

The primary outcome of interest is delayed sexual debut, defined as postponement of sexual intercourse among participants who had not engaged in sexual intercourse prior to the school-based intervention. While secondary outcomes shown in Table 1 will be considered as a first step, other SRH outcomes reported by at least two studies will also be considered. Such may include contraceptive use, pregnancy and history of STIs:

Table 1: Secondary outcomes

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Table 1: Secondary outcomes				
Secondary outcomes	Definitions			
Intention to delay sex	Planning to wait to have sexual intercourse until older			
Lifetime sexual activity	Ever engaged in sexual intercourse			
Sexually active	Having engaged in sexual intercourse in the last 30 days			
Current sexual activity	Having engaged in sexual intercourse in the last six months			
Sexual health knowledge	Knowledge of key SRH topics and issues			
Sexual attitude	Attitudes towards sexuality and sexual behaviour			
Self-efficacy for safe sex	Confidence to say no to unsafe sex practices			
practices				

Consistent condom use	Condom use at every sexual intercourse
Number of sex-partners	Number of sex partners (regular and casual) in a specified
	period of time

Types of studies

The review will include all studies focused on delaying sexual debut, regardless of the study design employed. Meta-analytical approaches that take into consideration different study designs will be used in the analysis, and where meta-analysis is not possible, other methods of analysing the effect measures outlined by McKenzie and Brennan (52) will be employed . We will also compare the effectiveness of the interventions by study design. Eligible studies will have been published in peer reviewed journals between January 2009 and December 2020. Only studies published in English will be included.

145 Study setting

Only studies conducted in SSA will be included. Given the population of interest, the review will focus on interventions implemented in primary and secondary schools or their equivalents. The review focuses on studies published since 2009, the period after the global momentum on the need for comprehensive sexuality education began. In 2008, Latin America and the Caribbean signed the Preventing through Education Declaration for the delivery of sexuality education and health services (53). In 2013, there was a Ministerial Commitment on CSE and SRH services for adolescents and young people in 20 countries across Eastern and Southern Africa (54).

153 Search strategy

154 Our search strategy will involve three methods:

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2 3 4	155	• Electronic searches - four researchers will search five electronic databases including
5 6	156	PubMed, Scopus, Science Direct, Web of Science and EBSCO (PsycINFO, Global Health,
7 8	157	CINAHL) for published peer-reviewed journal articles. Cochrane library, National
9 10	158	Institute of Health (NIH), and Turning Research into Practice (TRIP) databases will be
11 12 13	159	searched for ongoing studies that are yet to be published.
14 15	160	• Hand-searches – An iterative process to obtain additional studies not yet retrieved with our
16 17	161	initial online database using the reference list of retrieved articles
18 19	162	• Contacting authors and experts - Where published data are not sufficient, authors will be
20	102	• Contacting autions and experts - where published data are not sufficient, autions will be
21 22 23	163	contacted for additional information
23 24 25	164	While the exact search terms will vary by database, the four search components included will be
26 27	165	(1) adolescents (2) sexual debut (3) school-based interventions (4) and sub-Saharan Africa. Search
28 29	166	terms will be adapted for each bibliographic database in combination with database-specific filters.
30 31 32	167	Boolean operators 'OR', 'NOT' and 'AND' will be used to maximize or narrow the specificity for
33 34	168	the search. Wildcards will be used to search for variations or alternate spellings of key concepts.
35 36	169	Below, and in the supplementary document, we present a search strategy to be used in PubMed
37 38 20	170	below:
39 40 41	171	1. (intervention[Title/Abstract]) OR (program*[Title/Abstract])
42 43	172	2. (school[Title/Abstract]) OR (institution[Title/Abstract]) OR (academic[Title/Abstract])
44 45	173	OR (education[Title/Abstract])
46 47 48	174	3. (sexual debut[Title/Abstract]) OR (sexual initiation[Title/Abstract]) OR (sexual
49 50	175	delay[Title/Abstract]) OR (sexual activity [Title/Abstract])
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3 4	176	4. (adolesce*[Title/Abstract]) OR ("young people"[Title/Abstract]) OR
5 6	177	(youth[Title/Abstract]) OR (teenage*[Title/Abstract]) OR (learner[Title/Abstract]) OR
7 8 0	178	(children[Title/Abstract])
9 10 11	179	5. (Africa south of the Sahara [MeSH Terms]) OR (Africa [MeSH Terms])
12 13	180	6. ("2009/01/01"[Date - Publication]: "2020/12/31"[Date - Publication])
14 15	181	7. #1 AND #2 AND #3 AND #4 AND #5 AND #6
16 17 18	182	("intervention"[Title/Abstract] OR "program*"[Title/Abstract]) AND
19 20	183	("school"[Title/Abstract] OR "institution"[Title/Abstract] OR "academic"[Title/Abstract]
21 22	184	OR "education"[Title/Abstract]) AND ("sexual debut"[Title/Abstract] OR "sexual
23 24 25	185	initiation"[Title/Abstract] OR "sexual delay"[Title/Abstract] OR "sexual
25 26 27	186	activity"[Title/Abstract]) AND ("adolesce*"[Title/Abstract] OR "young
28 29	187	people"[Title/Abstract] OR "youth"[Title/Abstract] OR "teenage*"[Title/Abstract] OR
30 31	188	"learner"[Title/Abstract] OR "children"[Title/Abstract]) AND ("africa south of the
32 33 34	189	sahara"[MeSH Terms] OR "africa"[MeSH Terms]) AND 2009/01/01:2020/12/31[Date -
35 36	190	Publication]
37 38	191	
39 40	192	Data collection
41 42 43	193	Selection of studies
44 45	194	Four reviewers, paired, will independently screen retrieved titles and abstracts of potential articles
46 47	195	to determine their eligibility for inclusion in the review. Rayyan, a web application tool will be
48 49 50	196	used to manage the screening process (55) . Full article texts of included studies will then be
50 51 52 53	197	obtained and reviewed to ascertain eligibility. Any disagreements during title and abstract review
54 55 56		

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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34	198	or during the full text review will be resolved by consensus. A third reviewer will be involved if a
	199	consensus is not reached by the two pairs of reviewers.
	200	Data extraction and management
	201	Two reviewers will use a standardized data extraction form to independently extract data on
	202	background or process-oriented information from each included study to provide a basis for data
	203	charting, themes and variables for use in answering the research question. Reviewers will pilot the
	204	data extraction form with a sample of included papers and amendments will be made as necessary.
	205	From each relevant study, data will be extracted on the following domains:
	206	• General information on the study: authors, date of publication, publication type, country,
	207	and funding source
	208	• Study characteristics: study setting, location, study design, sampling frame and sampling
	209	methods, and year(s) of study implementation
	210	• Participant characteristics: age, gender, number of participants, participants lost to follow-
	211	up, length of follow-up
35 36	212	• Intervention: detailed description of the intervention, composition of intervention and
37 38 39 40	213	control groups
	214	Outcomes: for primary outcome (delay in sexual debut), data on the number of participants
42 43	215	experiencing delayed sexual debut on both intervention versus control arms will be extracted. If a
44 45	216	summary estimate (e.g., risk ration) is reported instead of raw numbers, these will be extracted. A
46 47 48	217	similar approach will be used for secondary outcomes. Where more than one article described the
48 49 50	218	same intervention, data will be extracted from all papers. The eligible studies will be exported into
51 52	219	the Comprehensive Meta-Analysis (56)software.
53 54 55	220	Risk of bias assessment
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3 4	221	Two independent reviewers will assess the methodological quality of studies depending on study
5 6	222	design. For RCTs, the reviewers will judge each quality domain based on the following three-point
7 8 9	223	scale as suggested in Cochrane Handbook for Systematic Reviews of Interventions (57): Yes (low
10 11	224	risk of bias: plausible bias unlikely to seriously alter the results if all criteria were met); No (high
12 13 14 15	225	risk of bias: plausible bias that seriously weakens confidence in the results if one or more criteria
	226	were not met); and Unclear (plausible bias that raises some doubt about the results if one or more
17 18	227	criteria were assessed as unclear. The following items in the risk of bias assessment for RCTs will
19 20	228	be included:
21 22 23	229	• Sequence generation (whether allocation sequence was adequately generated)
23 24 25	230	• Allocation concealment (whether allocation was adequately concealed)
26 27	231	• Masking/ blinding (whether knowledge of the allocated intervention was adequately
28 29 30	232	prevented during the study, i.e., whether participants, personnel, outcome assessors and/or
30 31 32	233	data analysts are blinded)
33 34	234	• Incomplete outcome reporting (whether incomplete outcome data was adequately
35 36	235	addressed)
37 38 39	236	• Selective reporting (whether reports of the study were free of selective outcome reporting)
40 41	237	• Other sources of data (e.g., whether reports of the study included sample size computation,
42 43	238	alpha error, etc.)
44 45 46	239	For non-RCT studies, the following items will be included in the risk of bias assessment as
47 48	240	suggested by Viswanathan, Berkman, Dryden et al. (58):
49 50	241	• Selection bias – do the inclusion/exclusion criteria vary across the comparison groups (for
51 52 53	242	multiple-arm studies) or within groups (for single arm/cross-sectional studies)?
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3 4	243	Performance bias – does the study fail to account for important variations in the execution
5 6	244	of the study from the proposed protocol?
7 8 9	245	• Detection bias - was the assessor not blinded to the outcome, exposure, or intervention
9 10 11	246	status of the participants? Were valid and reliable measures not used or not implemented
12 13	247	consistently across all study participants to assess inclusion/exclusion criteria,
14 15 16	248	intervention/exposure outcomes, participant benefits and harms?
10 17 18 19 20 21	249	• Attrition bias - was the length of follow-up different across study groups? In cases of
	250	missing data was the impact not assessed (e.g., through sensitivity analysis or other
21 22	251	adjustment method)?
23 24 25 26 27 28 29 30 31 32 33 34 35 36	252	• Selective outcome reporting - Are any important primary outcomes missing from the
	253	results?
	254	• Overall assessment: Are the results believable taking study limitations into consideration?
	255	Discussions and consensus will be used to crosscheck the extracted information and to
	256	resolve disagreements. The level of risk of bias in each of these domains will be presented
	257	separately for each study in tables in the final review publication.
37 38 39	258	Risk of bias in individual studies
40 41	259	Methodological quality of each individual article will be appraised using a checklist adapted from
42 43	260	Critical Appraisals Skills Programme (CASP). Two authors will independently appraise each
44 45 46	261	article.
40 47 48	262	Measures of intervention effect
49 50	263	Dichotomous outcomes such as sexual debut (initiated versus not initiated sexual activity during
51 52	264	the study period) will be summarized as risk ratios or odds ratio with 95% confidence intervals for
53 54 55	265	each study. Continuous outcomes such as number of sex partners will be summarized as
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(unstandardized) mean differences and standard errors. In cases where sexual debut may be reported as a median age at sexual debut, published procedures for transforming median to mean and standard deviation to facilitate computation of relevant statistics will be used (59). If enough information is not provided to calculate an effect size, study authors will be contacted for clarification or to provide additional statistics. If the authors do not provide this information after one month, this study will be removed from the analysis but this effort will be reported.

If results of a repeated measure analysis are reported, authors will need to provide the correlation between pre-post measurements or provide enough information to calculate the correlation between measurements. If these statistics are not available, either in publication or after request, and the study was a controlled design, an effect size will be generated using postintervention statistics provided groups are similar at baseline with respect to the outcome of interest and other relevant covariates.

278 Unit of analysis

Data will be extracted from each included study (unit of analysis) as follows. For dichotomous variables, number of participants in the intervention group and the number of participants in the standard/control group will be used. For continuous variables, the mean, standard deviation, and the number of participants in the intervention and control groups will be used. For studies with multiple intervention groups, each pair-wise comparison will be included separately. Moreover, for dichotomous outcomes, we will divide both the number of events and the total number of participants. For continuous outcomes, means and standard deviations will not be changed but will be divided by the total number of participants.

287 Assessment of heterogeneity

Heterogeneity among studies and between subgroups will be assessed using a Chi² test with a significance level at p < 0.10. The degree of heterogeneity among studies and between subgroups will be assessed using the I² statistic using the following guide: $I^2 = 0\%$ to 40% as heterogeneity that might not be important, $I^2 = 30\%$ to 60% as moderate heterogeneity, $I^2 = 50\%$ to 90% as substantial heterogeneity, and $I^2 = 75\%$ to 100% as considerable heterogeneity (<u>60</u>)

293 Assessment of reporting bias

Publication bias will be assessed if at least 10 studies are included in the review. A funnel plot will
be used to assess the magnitude of reporting bias as per Cochrane guidelines.

296 Data synthesis

Data will be pooled using the random effects model according to Chapter 9 of the Cochrane Handbook for Systematic Reviews of Interventions (60). Dichotomous outcomes' data (e.g., number of participants who experience sexual debut) will be reported as risk ratios and continuous data (e.g., number of sexual partners) as mean differences. Depending on the different types of interventions identified, such as sexuality education, economic interventions or a combination of different approaches, we will conduct pooled effects for each type of interventions to examine which are more effective in delaying sexual debut. Additionally, and where possible, we will identify and consider conceptual groupings such RCTs and non-RCT studies while conducting the analysis. All analyses will be done at 95% confidence intervals. Data will be analysed using the statistical software Comprehensive Meta-Analysis(56). In studies where the effects of clustering have not been taken into account, standard deviations will be adjusted for the design effect, using intra-class coefficients, if they are provided in the study reports, or alternatively using external estimates obtained from similar studies. Stratifications will be done by school level (primary or

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secondary (or age, if applicable), grade level, instructor (e.g., teacher or peer), intervention type
(e.g. behaviour change communication, study setting).

Other acceptable data synthesis methods such as those descried by McKenzie and Brennan 312 (52) will be considered where meta-analysis is not possible. Such methods include summarizing 313 effect estimates in case estimates of intervention effects are available but the variances of the 314 315 effects are not reported or are not correct (52). Another method described by McKenzie and Brennan (52) is combining P values if no other information is available; differing statistical tests 316 and outcomes across studies; or non-parametric test results reported. Lastly, vote counting based 317 on the direction of the effect can be used when only the direction of effect is reported or there is 318 no consistent effect measure or data reported across studies (52). 319

Findings will be organised in tables and charts, while presenting a description of the themes and concepts found in literature reflecting the review objectives. A summary narrative that synthesizes the information across tables and charts will be developed, critically highlighting the advances and gaps in research, with a focus to draw implications for future research.

324 Patient and public involvement

325 Patients and public will not be involved in the design and conduct of this review

326 Ethics and dissemination

Ethics approval is not required. The findings of this systematic review will be disseminated through peer-reviewed publications as well as in relevant stakeholders' fora. In case of any amendments to the protocol following its publication, the date of each amendment will be provided, change(s) described, and report the rationale for the change(s) in future publications arising from this protocol.

1 2		
2 3 4	332	Author contribution: BWM, KJ, EKI and JO contributed to the conceptualization, and
5 6	333	development of the protocol. BWM and KJ provided the initial draft of the protocol. HW and
7 8 9 10 11	334	CWK provided a critical review of the protocol. All authors read and approved the final draft of
	335	the protocol.
12 13	336	Funding statement: Authors' time to develop this protocol was supported by the International
14 15	337	Development Research Centre (Grant number 108676-002) and the Swedish International
16 17 18	338	Development Cooperation Agency (Grant number 12103)
19 20	339	Competing interests: None declared
21 22	340	Patients consent for publication: Not required
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Search strategy

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- 1. (intervention[Title/Abstract]) OR (program*[Title/Abstract])
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 OR (education[Title/Abstract])
- (sexual debut[Title/Abstract]) OR (sexual initiation[Title/Abstract]) OR (sexual delay[Title/Abstract]) OR (sexual activity [Title/Abstract])
- 4. (adolesce*[Title/Abstract]) OR ("young people"[Title/Abstract]) OR (youth[Title/Abstract]) OR (teenage*[Title/Abstract]) OR (learner[Title/Abstract]) OR (children[Title/Abstract])
- 5. (Africa south of the Sahara [MeSH Terms]) OR (Africa [MeSH Terms])
- 6. ("2009/01/01"[Date Publication]: "2020/12/31"[Date Publication])
- 7. #1 AND #2 AND #3 AND #4 AND #5 AND #6

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PRISMA-P 2015 Checklist

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

Section/tonio	#	Checklist item	Informatio	Line	
Section/topic	#		Yes	No	number(s)
ADMINISTRATIVE INFO	RMAT	ION			
Title					_
Identification	1a	Identify the report as a protocol of a systematic review	\square		1 - 2
Update	1b	If the protocol is for an update of a previous systematic review, identify as such		\boxtimes	Not applicable
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract		\square	Not registered
Authors					
Contact	3а	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	\boxtimes		6 - 15
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	\square		447 - 450
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			98 - 100
Support					
Sources	5a	Indicate sources of financial or other support for the review	\square		451 - 452
Sponsor	5b	Provide name for the review funder and/or sponsor	\square		451 - 452
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol			451 - 452
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	\square		74 - 91
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)			91 - 93



Pastion/tonio			Informatio	d Line	
Section/topic	#	Checklist item	Yes	No	number(s)
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review			95 - 134
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage			135 - 151
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	\square		152 - 161
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review			164 - 192
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)			164 - 170
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	\square		172 - 177
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications			177 - 192
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale			115 - 119
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis			193- 230
DATA					•
	15a	Describe criteria under which study data will be quantitatively synthesized	\square		270 - 285
Synthesis	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., <i>I</i> ² , Kendall's tau)			235 - 265
-	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta- regression)			275 – 277
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned			282 - 285
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)			276 - 281
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	\square		231 - 234



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