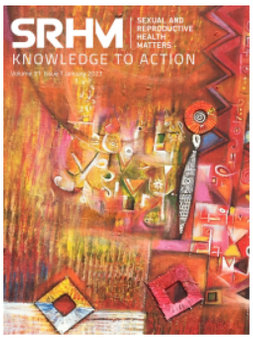

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Protocol for a multi-country implementation research study to assess the feasibility, acceptability, and effectiveness of context-specific actions to train and support facilitators to deliver sexuality education to young people in out-of-school settings

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Protocol for a multi-country implementation research study to assess the feasibility, acceptability, and effectiveness of context-specific actions to train and support facilitators to deliver sexuality education to young people in out-of-school settings

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Abstract: *Comprehensive sexuality education (CSE) is a well-established component of the package of interventions required to improve adolescent sexual and reproductive health and rights. As the international community has increased its emphasis on equity and leaving no-one behind with the Agenda for Sustainable Development, attention has been drawn to the need for complementary CSE programmes to reach young people who are not in school, or whose needs are not met by in-school CSE programmes. CSE in out-of-school contexts presents unique considerations, especially those related to facilitation. In this manuscript, we present the protocol for a multi-country implementation research study in Colombia, Ethiopia, Ghana, and Malawi to assess the feasibility, acceptability, and effectiveness of context-specific actions to prepare and support facilitators to deliver CSE in out-of-school settings to defined groups of young people with varying needs and circumstances. This study will be led by the World Health Organization and the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, in partnership with local research institutions. It will be nested within a multi-country programme led by UNFPA, in partnership with local implementing partners and with financial support from the Government of Norway. This study will shed new insight into what it takes to effectively deliver CSE in out-of-school contexts, to enhance progress towards the achievement of SDG 3 "Ensure healthy lives and promote wellbeing for all at all ages" and SDG 5 "Achieve gender equality and empower all women and girls".* DOI: 10.1080/26410397.2023.2204043

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Keywords: comprehensive sexuality education, adolescent sexual and reproductive health, people with disabilities, people living with HIV, people involved in sex work, people in detention

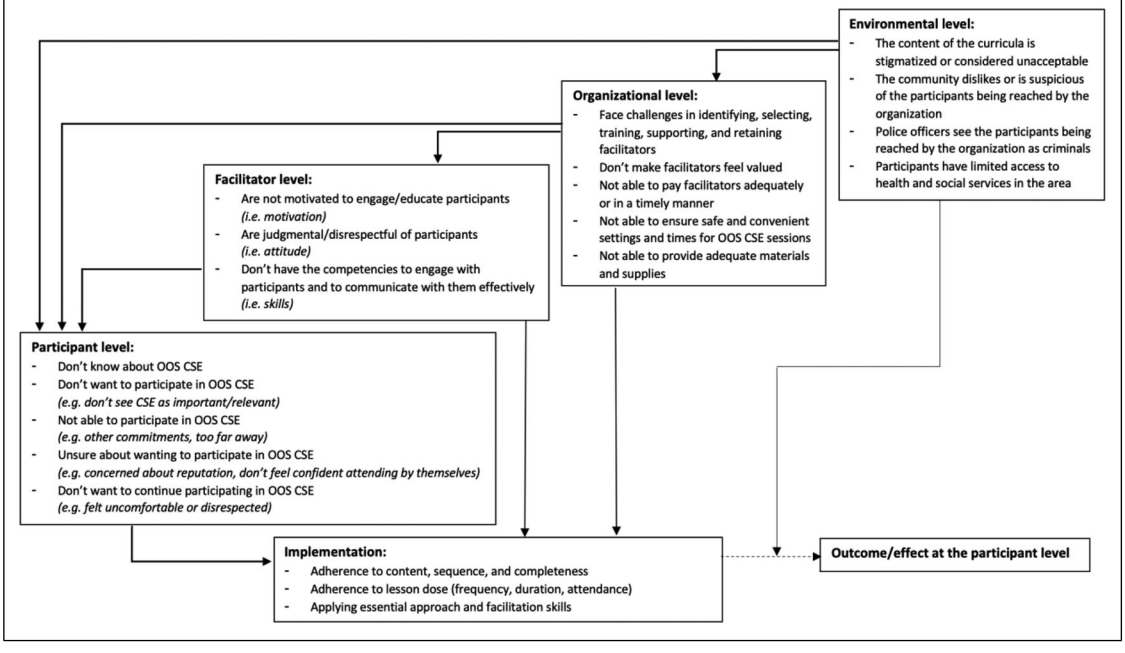
Introduction

Comprehensive sexuality education (CSE) is a well-established component of the package of interventions required to improve adolescent sexual and reproductive health and rights (ASRHR).[1–3] Over the last few decades, much of the focus with CSE has been on expanding the availability and quality of in-school CSE programmes in order to reach large numbers of young people with information they need to grow and develop in good health. As the international community has increased its emphasis on equity and leaving no-one behind with the Agenda for Sustainable Development, attention has been drawn to the need for complementary programmes to reach young people who are not in school, or whose needs are not met by in-school CSE programmes. However, several questions remain regarding how best to design and deliver CSE to young people in out-of-school contexts.[4]

CSE in out-of-school contexts presents similar challenges to CSE delivered in school settings, such as ensuring that content and methods are age-appropriate and building support for its delivery among parents and the wider community. In addition to these challenges, however, those implementing CSE in out-of-school contexts face unique considerations at the levels of the participant, the facilitator, the organisation and the wider context (Figure 1).[5] For example, while in-school CSE programmes have a ready-made setting in which sessions can be held, CSE programmes in out-of-school settings must decide on a location that is accessible and convenient for young people, while being sufficiently discreet to ensure their safety (e.g. to prevent reprisal attacks and confrontation by opposed community members) and privacy (e.g. to prevent stigmatisation of young people who face exclusion or marginalisation due to some aspect of their identity or life conditions such as being an adolescent parent or a sex worker). Taking this into account, what are ideal locations within which CSE sessions can be held? Likewise, while in-school CSE programmes benefit from a captive audience of students, CSE programmes in out-of-school settings must provide sessions when the young people are available, they need to ensure that young people see their programmes as sufficiently valuable to return session after session, and they need to reach those young people for whom the programmes are designed and who are often hard to reach. Given this, how should young people be optimally recruited and retained in their programmes? Perhaps most importantly, given its objective of reaching those who are excluded or marginalised in some way from in-school CSE, out-of-school CSE must be delivered in a way that is accessible, acceptable and attractive to these young people and that responds to their specific and heterogenous needs.

While challenges and questions exist at each of the levels noted above, those at the level of the facilitator are particularly pressing. For the purpose of this manuscript, we refer to a facilitator as any person who delivers CSE; this includes teachers in in-school settings and other kinds of professionals in out-of-school settings. Historically, the majority of research on CSE has focused on in-school rather than out-of-school CSE. These studies have illustrated that facilitators lie at the heart of effective CSE. Young people regularly report that facilitators are unprepared to teach CSE, and that the CSE they receive is neither comprehensive nor relevant to their lives.[6] Specifically, studies have shown that facilitators omit topics that should be included in CSE curricula; pass along their knowledge gaps, misconceptions, and personal attitudes about adolescent sexuality; feel embarrassed and uncomfortable teaching certain topics; rarely use participatory methods; and often struggle to create a safe and respectful environment.[7–11] While facilitators are often blamed for such findings, a similarly substantive body of evidence suggests that in in-school and out-of-school contexts alike, facilitators are not adequately trained and supported to develop the competencies and attitudes required to deliver CSE, or to engage effectively with parents and communities to build support for CSE and respond to resistance.[6] Many facilitators do not receive any training on CSE. For example, the majority of teachers in a review of CSE in Guatemala, Kenya, and Peru reported receiving no training before delivering CSE.[7–9] Even more facilitators lack refresher trainings and ongoing support, such as teaching and learning materials, collaborative learning, or supportive supervision.

Figure 1. Challenges to the implementation and effectiveness of CSE in out-of-school contexts. Adapted from Vanwesenbeeck et al.[5]



For example, less than 15% of teachers in Ghana reported receiving refresher trainings in the last three years, and most teachers in Ghana, Guatemala, and Peru reported a lack of lesson plans, learning activities, and other teaching materials[9–12]. In this same set of studies, these issues were noted as among the top challenges for teachers in delivering CSE in both Kenya and Peru[8,9].

Relative to research and evaluation on the delivery of CSE in schools, there is much less research on the delivery of CSE outside the school setting. The exception is small group education and skills-building of girls/young women.[13] We drew from these sources of evidence to inform aspects of the protocol, e.g. creating a supportive micro-environment for the provision of CSE, improving and sustaining improvements in the performance of facilitators, and assuring the continued participation of learners. Clearly there are both similarities and differences between in-school and out-of-school delivery of CSE; we have taken this fully on board, informed by the grey literature and discussions with key informants.

In this manuscript, we present the protocol for a multi-country implementation research study in Colombia, Ethiopia, Ghana, and Malawi that will assess the feasibility, acceptability, and effectiveness of context-specific actions to train and support facilitators to deliver CSE in out-of-school settings to defined groups of young people with varying needs and circumstances. The value of publishing research protocols is well-established and includes ensuring research is carried out to the highest standards, informing others about ongoing research activities, preventing duplication, and encouraging collaboration.[14,15] Data collection began in 2022. Future publications will describe the findings and lessons learned from the study.

Context

In January 2018, six UN agencies launched a revised edition of the *International technical guidance on sexuality education*, which provides guidance on designing and delivering CSE to support children and young people's health and well-being.[16] To complement this resource and to support the Sustainable Development Goal's agenda of leaving no one behind, UNFPA led the development of the *International technical and programmatic guidance on out of school* CSE,

which was published in 2020 and provides guidance on specific considerations in designing and delivering CSE in non-formal, out-of-school contexts and for specific groups of young people, such as young people with disabilities or young people in humanitarian settings.[17]

To support the dissemination and uptake of this Guidance, UNFPA is implementing a multi-country project titled "Reaching those most left behind through CSE for out-of-school young people" in Colombia, Ethiopia, Malawi, and Ghana, with financial support from Norway. Each of the countries in the initiative is using the Guidance to design and implement CSE that is tailored to the specific context, needs, and life experiences of the following specific groups of young people:

- In Colombia: young people in communities with a large population of Venezuelan migrants
- In Ethiopia: young people with disabilities, and young people involved in sex work
- In Ghana: young people in detention, and young people living with HIV
- In Malawi: young people with disabilities, and young people living with HIV

Alongside dissemination and implementation of the Guidance, a key objective of the initiative is to build the evidence base on designing and delivering CSE in out-of-school contexts and for specific groups of young people. This objective responds to recent reviews and evidence syntheses, which identified a relative lack of evidence on CSE in out-of-school contexts compared to in-school programmes.[17,18] To achieve this objective, the World Health Organization (WHO) and the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) are leading a multi-country implementation research study to generate evidence on what works to prepare and support facilitators to deliver CSE to young people with particular needs and circumstances in the out-of-school context. The study is being conducted in partnership with local research institutions, specifically Universidad del Norte in Colombia, Gender and Adolescence: Global Evidence (GAGE) in Ethiopia, University of Cape Coast in Ghana, and Kamuzu University of Health Sciences in Malawi.

Objectives

The overall objective of this implementation research study is to determine whether the activities used to train and support the facilitators are feasible, acceptable, and effective in enabling the facilitators to engage the defined groups of young people, deliver CSE to them in the out-of-school context, and assist them in obtaining relevant services. The study has five objectives:

1. To determine whether the plan for the project was appropriate and had the potential to achieve the project's objectives.
2. To determine whether the project's activities to identify, recruit, train, and support facilitators were feasible and whether they were implemented with fidelity.
3. To determine whether the project's activities to train and support the facilitators were effective in improving their competencies and attitudes.
4. To determine whether the facilitators:
    i perceived that the project adequately prepared and supported them to carry out their roles and responsibilities.
    ii effectively carried out their roles and responsibilities.
5. To determine whether the defined groups of young people:
    i perceived the CSE as accessible, relevant, interesting, and useful.
    ii gained in terms of knowledge, attitudes, values, and skills related to sexuality and reproduction, and in terms of the use of relevant services.

One of the study sites, Colombia, also includes objectives to evaluate additional actions to build support among parents, guardians, and other community members and engage them in the delivery of the CSE project.

Conceptual and theoretical underpinnings

There are three conceptual and theoretical perspectives that underpin this implementation research study: improving and sustaining improvements in performance, adaptive implementation and management, and fidelity of implementation. The latter relates to the nature of the intervention being studied in this research itself, while the first two relate to approaches to the implementation of a complex intervention in different contexts and for different

groups of young people and the assessment of that implementation process.

Improving and sustaining improvements in performance

The first concept underpinning this research study is focused on how improvements in performance are achieved and maintained. Teaching any subject requires knowledge about the subject and skills to teach it. Beyond this, teaching about sexuality, reproduction, and sexual and reproductive health also requires comfort to teach what is in the curriculum, willingness to do so even if some of the content is inconsistent with one's views and values, and commitment to doing the best that one can.[3] As described in the introduction, CSE in out-of-school settings presents unique challenges and opportunities; thus, delivering CSE in out-of-school settings takes these prerequisites one step further. It requires that a facilitator be fully knowledgeable about the subject, be able to engage participants who may have come in for their one and only session, be able to "sell" the session to them, and be responsive to their particular needs so that they come back for more. In addition, they must be able to engage young people who may be dealing with difficult situations in their lives, face exclusion or marginalisation due to some aspect of their identity, and/or be reluctant to share much about themselves because they are wary of others, especially authority figures.

There is growing recognition that teachers who have the capacity to deliver CSE and are committed to delivering it to the best of their ability are crucial ingredients of a CSE programme. For example, Haberland and Rogow call for the "scale up of school-based programmes with serious investments to strengthening teachers' capacity to deliver CSE that is participatory, and generates critical reflection and dialogue about gender, power, sexuality and rights".[18] Vanwesenbeeck et al echo these comments; they stress that programmes need teachers: "who are capable of empowering their students rather than simply improving their knowledge or regulating their behaviour".[5]

Based on research evidence and programmatic experience, there are growing calls for a package of actions to achieve this. Based on a rigorous study in the Bahamas, Wang et al note that "pre-implementation teacher training was essential to equip teachers with necessary skills for implementation, but it is not enough. Biweekly implementation monitoring, personal assistance, and mentoring during programme delivery were important to ensure teachers' quality of implementation".[19]

This is consistent with findings outside the school context. A review of 44 girls' and youth development clubs and life skills programmes by Marcus et al. found that "the most effective programmes typically provided regular in-service training to mentors, and monitored their activity to ensure they were providing good-quality programmes and support. They also made sure mentors were adequately paid and provided refresher courses to help them improve the quality of their facilitation".[13]

Adaptive implementation and management

The second theoretical perspectives guiding this study are *adaptive implementation* and *adaptive management*. *Adaptive implementation* is conceptualised as the degree to which an innovation or intervention is modified (via additions, alterations, and/or deletions) in the process of adoption and implementation.[20] *Adaptive management* is defined as intentional adoption of strategies and actions to facilitate critical reflection and analysis of data, information, and knowledge – on a continuous basis and from a wide range of sources – to inform decisions that optimise programme implementation and effectiveness in expected, unexpected, and changing circumstances.[21] These perspectives – which to some extent appear to be in conflict with the concept of *fidelity of implementation*, discussed below – assert that the intention is not to change the goal of implementation, but rather the path being used to achieve the goal in order to respond to local realities and cultural considerations.[22] For example, young people living in the selected rural communities in Colombia might need a different approach than young people who migrated from marginal urban settings in Venezuela to the selected communities. These perspectives emphasise the importance of constant learning and reflection through cycles of planning, monitoring, and evaluation to allow for iterative course corrections to interventions.[23–25] Importantly, they warn that such adaptations require an enabling organisational culture and leadership that acknowledges and accepts a degree of risk and uncertainty and utilises correspondingly flexible and conducive funding practices.[23] In recent

years, a growing number of funding agencies including the World Bank and DFID have recognised this and called for organisations to move away from "best practice" towards "good fit" solutions and promote "a culture of learning and adaptive programming".[24]

Fidelity of implementation

The third conceptual perspective that underpins this research is *fidelity of implementation*. This refers to the degree to which an intervention is delivered as intended.[26,27] A practical framework to understand this perspective, developed by Carroll et al., includes four aspects to consider in the measurement of implementation fidelity: content, coverage, frequency, and duration.[26] The degree to which the intended content or frequency of an intervention is implemented is the degree of implementation fidelity achieved for that intervention.[26] It is important to note that the level of fidelity achieved may be affected by other variables, such as quality of delivery and participant responsiveness. For example, the less interested young people are in CSE, the less likely the CSE programme will be implemented properly and completely.

Evaluation of implementation fidelity is important to prevent false conclusions about intervention effectiveness. Unless such an evaluation is made, it cannot be determined whether a lack of impact is due to poor implementation or inadequacies inherent in the intervention itself.[26] Evaluating a programme that has not actually been fully implemented may lead to the erroneous conclusion that the programme itself is not effective.[28] The opposite is also true if impact was achieved; was that impact due to the intervention as originally envisioned, or due to changes made during its implementation? To avoid such erroneous conclusions, clear and feasible strategies for continuous monitoring and measuring implementation fidelity should be defined prior to the study of an intervention.[27,29–32]

These conceptual and theoretical perspectives offer important considerations for implementing interventions in different countries with diverse actors. In the pursuit of improving and maintaining the performance of facilitators to deliver CSE in out-of-school settings, we seek to promote fidelity to the broad principles and strategies guiding the facilitation of CSE, on the one hand. This is largely because commonalities do exist regarding the sexual and reproductive health needs of young people in various countries, as well as the barriers young people face in accessing quality CSE. On the other hand, we also recognise the particularities of the contexts in which such programmes will be implemented – with regard to social and cultural aspects of a context, as well as the geographic scope and entry points/venues used – coupled with facilitator and learner level characteristics. The implication of this is that some level of adaptation is likely to be required for successful implementation. We propose that fidelity to the broad tenets of the intervention combined with adaptive management will be key to providing cross-cultural and multi-site learning.

The International Technical and Programmatic Guidance on out-of-school CSE contains four components: (i) identify the group(s) of young people to be reached, understand their needs and preferences, and engage them as partners, (ii) create a supportive – micro/meso – environment for delivering CSE, (iii) deliver CSE that is appropriate to their needs and preferences, and (iv) forge links to health and social services.

The first theoretical underpinning (i.e. improving and sustaining improvements in performance) relates to the third component of the Guidance. In each site, this will lead to a package of interventions to improve facilitator performance, including training based on a needs assessment, ongoing monitoring and support following the training, and refresher trainings as needed. The second underpinning (i.e. adaptive implementation) is meant to guide implementers in making the modifications needed to their respective work plans and to carefully document both why they were done and what actually was done. The third underpinning (i.e. fidelity of implementation) is meant to press for the delivery of CSE to be as standardised as possible to ensure both compliance with evidence-based recommendations and to assist in post-intervention evaluation.

The context-specific actions to train and support facilitators

In the spirit of true implementation research, this implementation research study will be nested within the ongoing initiative described above. Thus, the research team has no control over the design or implementation of the initiative, including the context-specific actions used to train and support the facilitators. In each of the four countries, the UNFPA country office and local

implementation partners have designed a multi-component and context-specific package of actions to train and support the CSE facilitators, in line with the recommendations set forth in the recently published Guidance on out-of-school CSE (Table 1).

Study settings

As with the packages of actions, the study settings in each of the four countries are dictated by the implementation areas selected by the UNFPA country office and local implementation partners. The rationale for the selection of these implementation areas by the UNFPA country office and local implementation partners in each country is described in Table 2.

Study participants

In each of the four sites, the study participants include programme managers, facilitators, and the defined group of young people; in Colombia, the study participants also include parents/guardians, community leaders, and health, education, and protection officials. The rationale for the selection of the defined group of young people by the UNFPA country office and local implementation partners in each country is described in Table 3. The project managers and facilitators will be professionally involved in the initiative and therefore will be easy to reach and engage in the research. This could be different for the young participants who are voluntarily involved in the programme. The recently published Guidance states that particular considerations are necessary when designing and delivering CSE in out-of-school contexts and for specific groups of young people.[17] The same is true for involving these young people in research. To be able to involve people with certain vulnerabilities, research methods need to be modified to their specific needs. Researchers will need to respect the unique life situations of the respondents and make sure that the questions are understood and asked in places and time slots that suit the young respondents. For example, logistical impediments such as work schedules or transport issues can influence continued engagement of young people in research.[33] For this study, advice on how to implement this in each specific context will be provided by the facilitators of the CSE program, the young participants themselves, and other experts involved in the study and experienced in working with these groups of young people. In the case of young people with disabilities, adapted research interview formats will be used, drawing on experience that research team members have in carrying out qualitative research with young people with diverse disabilities.

Study design and methods

A mixed-methods time-series quasi-experimental research design is proposed for a 9-month period. Table 4 provides a detailed overview of the study objectives and their corresponding research questions, data collection methods, sampling and timeline, study instrument, and data analysis method. The study will use a total of nine tools:

1. Checklist for workplan and curricula review
2. Interview guide with project managers
3. Checklist of project report review
4. Interview guide with facilitators
5. Pre/post training assessment
6. Focus group discussion guide with facilitators
7. Checklist to observe facilitators during sessions
8. Interview guide with young people, including pre/post training assessment
9. Focus group discussion guide with young people

The use of different methods permits for data triangulation and increases the credibility and validity of the findings. In this study, five different methods will be utilised. The first method that will be used is record review using checklists for the workplan and curricula (tool 1) and for project reports (tool 3). The second method that will be used is in-depth interviews with the project managers (tool 2), the facilitators (tool 4), and the young people (tool 8) to collect information about the design of the project and the activities for the facilitators, as well as their implementation and effectiveness. The third method that will be used is assessments for facilitators (tool 5) and young people (tool 8) to evaluate their competencies and attitudes. The fourth method that will be used is focus group discussions with facilitators (tool 6) and young people (tool 9). Finally, the fifth method that will be used is observation, using a checklist developed to evaluate the performance of the facilitators while conducting a CSE session (tool 7).

Data collection, management, and analysis

To improve the consistency and coherence of the results obtained in the four countries where this study will be conducted, three manuals were

Table 1. Packages of actions to train and support facilitators implemented in the four countries

	Package of actions to train and support facilitators				
	Training				
	Length/ duration	Profile of trainer(s)	Content/curriculum	Group size	Ongoing support
Colombia	Three days (each for seven hours).	CSE specialist with a Master's degree in education from the UNFPA country office. CSE specialist with training in social work from the implementing partner.	• Basic concepts of sexuality (sex, gender). • Dignity, freedom, equality and non-discrimination • Social and gender norms regarding gender roles and stereotypes, the beginning of sexual relations, and motherhood/ fatherhood. • Gender inequality and its consequences • Romantic love • Attention and oversight routes • Sexual diversity • Sexual and reproductive health and rights, and how to access services such as contraceptive methods, including emergency contraception • STI/HIV prevention.	Six facilitators in total, plus a pedagogical coordinator and an administrative assistant.	Monthly two-hour virtual meetings to discuss challenges and share lessons learned. Periodic follow-up visits to programme sites to provide on-site mentorship and support.
Ethiopia	Five days (first round). 10 days (second round).	Programme staff of the implementing partners.	• SRHR topics (including HIV/AIDS, STIs, gender-based violence and how to access health services) • Alcohol and addiction • Life skills training • Income generating activities and savings.	20 facilitators in total (12 for AYWDs, and 8 for young people involved in sex work).	Mentorship by professional experts from relevant government sectors, e.g. the Bureau of Women and Social Affairs and the Bureau of Health twice per month.
Ghana	Five days.	Programme staff of the implementing partner and the National AIDS Control Programme. Independent	The UNFPA ESARO Regional Comprehensive Education Resource Package for Out-of-School Young People, titled the iCAN manual.	26 facilitators in total per region (10 for young people living with HIV, and 16 for AYWD).	Daily post-session meetings with facilitators to discuss learnings on what went well, missed opportunities, and quality

		training consultant with experience working with UN agencies.			improvement. Online support group on WhatsApp where facilitators can share and solicit suggestions/ guidance on difficult matters. Consultations with ART doctors or nurses to clarify medical/clinical questions.
Malawi	Five days.	CSE specialist from the UNFPA ESARO Office. Programme staff of the implementing partner.	The UNFPA ESARO Regional Comprehensive Education Resource Package for Out-of-School Young People, titled the iCAN manual. The UNFPA ESARO Regional Comprehensive Education Resource Package for working with young people with disabilities.	107 youth facilitators in total, including young people living with HIV.	Annual refresher trainings. Quarterly supervision and mentorship sessions with District Officers.

Abbreviations: ESARO – UNFPA Eastern and Southern Africa Regional Office.

developed: (1) a data collection manual, (2) a data management manual, and (3) a data analysis manual.

The data collection manual provides for each data collection tool: the corresponding research objectives and research questions, the sampling method (who is expected to participate and when), the timeline (the number and frequency of data collection rounds), the necessary preparation for data collection (e.g. preparation of audio recorders, pencils and paper, reading results from former rounds of data collection), a detailed description and explanation of the questions asked in the tools (e.g. detailed description of options in Likert scales), and the steps to be taken to follow-up the data collection (e.g. which documents to upload). Exceptions to the standard guidelines for a specific country (e.g. deviation of timeslots) are also indicated in the manual.

The data management manual provides templates for the transcriptions of the different tools, guidelines for safe storage and sharing of data (e.g. pseudonymisation of the data, data storage, labelling of the documents, and data sharing), technical details about data collection (e.g. which tool needs to be collected on paper vs. audio), and agreements about transcription and translations. The data management manual also includes three Excel files. The first of these Excel files contains variables and labels for all the closed questions in the tools and can be uploaded in a statistical data analysis programme such as SPSS or STATA. The second Excel file provides an overview of the codes of the participants and their individual names, which will allow the researchers to link longitudinal data. The third Excel file presents an overview of the collected data. Additionally, a data sharing agreement was developed and agreed upon with the research teams.

Finally, the data analysis manual begins with a description of the data analysis framework that links the overall research questions to the questions in the data collection tools. This framework will be helpful also for describing the answers to the research questions. Next, the manual includes detailed guidance for the analysis of the data for both open and closed questions. For open questions, a core set of codes and labels is provided.

Table 2. Study sites in the four countries

Country	Study setting	Rationale
Colombia	Three municipalities in the Department of Atlántico (Sabanalarga, Santa Lucía, and Campo de la Cruz)	This department was selected based on three considerations. Firstly, it has a higher percentage of girls aged 15–19 who report already being mothers or pregnant, as compared to the country as a whole. Secondly, it has a lower coverage rate of secondary education, as compared to the country as a whole. Finally, it hosts a large proportion of the Venezuelan migrants currently living in Colombia. More than half of these migrants are estimated to have an irregular status and thus face additional barriers to accessing health and education services.
Ethiopia	Selected kebeles (sub-administration) of Addis Ababa city administration and Hawassa City administration of Sidama Region	These kebeles were selected because they are known to be areas with large numbers of young women involved in sex work, and comparatively large numbers of young people with visual and hearing impairments and physical disabilities. Regarding the latter group, this is in part because there are more services available for persons with disabilities in larger urban centres.
Ghana	Accra Correctional Centre and three other study centres in Accra (Greater Accra), Kumasi (Ashanti), and Tamale (Northern) regions	Accra Correctional Centre is currently the only facility in the country that serves young people in conflict with law. It is operated/managed by the Prison Service of Ghana and Department of Social Welfare of the Ministry of Gender, Children and Social Protection. The other regions were selected to reflect the different HIV prevalence levels nationally and in the three ecological zones (Savannah, Middle, and Coastal). In absolute numbers, the selected regions have the highest numbers of PLHIV in each ecological zone.
Malawi	Selected traditional authorities (local administrative domains) in six districts (Nkhatabay, Mchinji, Dedza, Mangochi, Chiradzulu, and Chikwawa)	The districts were selected due to comparatively worse sexual and reproductive health indicators, as compared to the country as a whole. The districts were also selected to ensure representation of three geographic areas of the country, with Nkhatabay in the Northern Region, Mchinji and Dedza in the Central Region, and Mangochi, Chiradzulo and Chikwawa in the Southern Region.

For closed questions, an overview of the different response options and the different types of analyses that can be conducted on the data are provided. Guidance on how to prepare the data to be able to conduct the analyses is also described.

Ethical considerations

Research on vulnerable populations has always generated concern, mainly because vulnerable individuals are assumed to have restricted autonomy. In other words, such individuals might not be able to assess the risks of participating in research or provide informed consent under the same considerations as persons not regarded as vulnerable.[33]

In designing the protocol for this study, the research team sought to align the processes with the general *International Ethical Guidelines for Health-related Research* developed by the Council for International Organizations of Medical Sciences and WHO. Given the focus of the research, the research team also took into account the *WHO's Ethical Considerations for Research on Adolescent Sexual and Reproductive Health*, published in 2018.[48] Below are described the ethical considerations relevant to working with adolescents and illustrations of how they will be applied in the study.

First, the WHO guidelines describe the importance of properly defining the study population. This definition is crucial as it also impacts study

Table 3. Profile and rationale for the defined groups of young people and facilitators in the four countries

Country	Defined groups of young people	Rationale	Facilitators	Rationale
Colombia	Young people in communities with a large population of Venezuelan migrants.	The Department of Atlántico is one of the largest recipients of migrants from Venezuela, including those of Venezuelan nationality and those of Colombian nationality who have returned to the country. A large part of this population is young and faces barriers to accessing education and health services, including CSE. Further, the Atlántico Department has worse sexual and reproductive health (SRH) indicators, as compared to the country as a whole.	Facilitators are professionals in health sciences, social sciences or human sciences with at least three years of experience in workshops on sexuality with adolescents. Required attitudes: • Understanding adolescence from a positive perspective with the capacity for participation and change. • Respect for others without imposing personal beliefs and behaviours. • Positive recognition of sexuality, sexual pleasure, and autonomy. • Commitment to comprehensive sexuality education. Required competencies: • Ability to create a safe environment that protects the privacy of participants. • Ability to communicate effectively. • Ability to react appropriately to sensitive questions and statements. • Ability to plan and prepare for CSE sessions. • Ability to work collaboratively to respond to the diverse needs and questions young people may have.	This profile was defined based on the assertion that in order to effectively provide CSE, knowledge of adolescent development, sexuality, and SRH is required, as well as experience delivering such information using a human-rights based approach.
Ethiopia	Young people with disabilities. Young people involved in sex work.	Young people with disabilities are more likely to be out of school due to stigma, discrimination, and structural and attitudinal barriers to inclusive education.[34–37] They face heightened vulnerability to sexual violence, while also having a high unmet need for	*Young people with disabilities* Facilitators are graduates with basic degrees in a range of disciplines (from social work to accounting) between the ages of 24–36 years. All but one are persons with disabilities (visual impairment $N = 2$; physical impairment $N = 7$ and hearing	*Young people with disabilities* The facilitators were selected by organisations for people with disabilities, and youth-led organisations working on SRH as peer educators in their respective towns. The rationale for this was

		SRH information and services.[38–41] Young people involved in sex work are vulnerable to economic precarity, sexual violence and transmission of HIV/AIDS and STIs.[42,43] They face challenges accessing SRH services and information due to stigma, lack of connection to the local community due to many being migrants from other areas, and available services focusing primarily on HIV/AIDS prevention.[44–46]	impairment $N = 1$). The facilitator without a disability has a BA in Special Needs Education. The gender breakdown is 4 men and 7 women. Required competencies: • communication ability, • role model for young people with disabilities whose life experiences have been validated by locals; • active participation in Organisations of Persons with Disabilities (OPD). *Young people involved in sex work* Facilitators are graduates with basic degrees from a range of disciplines (predominantly nursing or public health) between the ages of 23–36 years. The gender breakdown was 1 man and 9 women. Required competencies: • educational background in field of health • experience working with out-of-school young people • communication ability • role model for out-of-school young people whose life experiences have been validated by locals • active participation in Wise Up programme on SRH rights.	that YPWD would be more likely to develop rapport with peer educators and to engage with them around topics related to SRH, which are often stigmatised and sensitive. *Young people involved in sex work* The rationale for selecting these facilitators was to ensure that they had experience working as facilitators on SRH issues and in working with young people. Women were prioritised so that they could serve as peer educators and facilitate rapport and trust with the young women involved in sex work.
Ghana	Young people in detention. Young people living with HIV.	YPiD and YPLHIV were selected on account of their particular vulnerabilities related to SRH, as well as the fact that they are largely excluded from existing interventions and programmes for young people.[47]	Facilitators are staff members of the implementing partners, specifically Hope for Future Generation, Alliance for Reproductive Health and Rights, the Network of Persons Living with HIV and ART Clinic nurses and midwives from Ghana Health Service.	The motivation for working with personnel of diverse backgrounds and expertise was to capitalise on the unique contribution each could bring to facilitation – in respect of theoretical/conceptual knowledge as well as real life experiences. By blending subject experts and non-technical facilitators, we aim to

				enrich the experiential and intellectual capacity of learners. Also, facilitators are able to learn and improve their own competencies through collaborative learning.
Malawi	Young people with visual impairment, hearing impairment, and/or a physical disability. Young people living with HIV.	Young people with disabilities in Malawi represent a vulnerable group that faces discrimination and isolation and are at high risk of experiencing gender-based violence. Most YPWD never have the opportunity to participate in any formal education, because there is a limited number of schools that provide services catered to their needs. Because CSE in Malawi is delivered in schools through the life skills curriculum, most YPWD thus miss out on the opportunity to receive any CSE despite having a particularly strong need for it. Malawi has one of the highest prevalence rates of HIV, and adolescents and young people face the highest risk of new infections. Despite various HIV campaigns, PLHIV, especially those who are young, still face stigma and discrimination. Thus YPLHIV were selected due to their increased vulnerability as well as the isolation that they face.	Trainers-of-trainers are staff/members of the implementing partners including Ministry of Youth District Officers, Malawi Girl Guides Association Officers, UNFPA officers and teachers. Peer facilitators are young people from the communities, including YPLHIV themselves.	The rationale for including trainers-of-trainers within the implementing districts was to train as many facilitators as possible. The peer facilitators were selected based on their ability to engage and relate with their fellow youth.
Abbreviations: YPiD – Young people in detention; YPLHIV – Young people living with HIV; YPWD – Young people with disabilities.				

design, including inclusion and exclusion criteria. The study protocol – which was developed in a collaborative manner with all involved researchers – stipulates that the research will focus on young people between the ages of 10 and 24 years, thus including adolescents (10–19 years of age) and youth (15–24 years of age). In addition, the specific populations with unique circumstances and vulnerabilities are described for each country.

Second, the WHO guidelines emphasise the need to seek informed consent and assent appropriately. All project managers and facilitators involved in the project are legal adults. The project managers are already aware of the proposed research and have been in contact with the research team to keep them updated on the plans and status of the initiative. At the start of the study, the research team will inform them in greater detail about the research and seek their informed consent. The facilitators are not yet aware of the research; thus, when the study is ready to begin, the research team and the project managers will jointly inform them about it, invite them to participate in the study, and seek their informed consent. Regarding the young participants, informed consent will be sought directly from those older than 18 years. For those younger than 18 years, assent will first be sought from the minor followed by consent from their parent or legal guardian. For young people with disabilities, special consideration will be given to determining their capacity to provide consent/assent, where relevant, and to ensuring that the consent/assent process is conducted in a way that is appropriate and accessible to them (e.g. using sign language for those with hearing impairments). Emancipated minors – in this case those who have assumed adult responsibilities on account of being pregnant, mothers, fathers, or married – will provide their own consent.

One issue related to consent/assent that was considered to be particularly relevant to this study is voluntariness, given the relatively small populations from which participants will be sampled and the power dynamics at play. This has been addressed by establishing clear protocols for providing proper explanations about the purpose of the research study, the risk mitigation measures involved, and the fact that individuals will face no penalties if they refuse to participate in the research study now or agree to participate but decide to withdraw from the study in the future. In some cases, additional measures will be taken. For example, to mitigate the potential for peer pressure regarding participation in the study among young people in detention in Ghana, a participatory activity will be conducted at the start of the research study to codesign the participant recruitment process with the young people in the detention centre. This will ensure that those who are not sampled will not feel sidelined.

The WHO guidelines also recommend that researchers centre decision-making around the principle of the "best interests of the child", including not asking questions that reference unlawful practices and ensuring that all people involved in the research act in the best interest of the young participants. In this research, the former has been and will continue to be ensured through the involvement of local researchers. Additionally, given that the study focuses on evaluating the performance of the facilitators and relating their performance to the training and support they received, there is a risk that facilitators could be penalised for poor performance or that young participants could be penalised for negative assessments of their facilitators. This risk is heightened by the relatively small numbers of young people, facilitators, and project management personnel, in each study site. This concern is addressed in the protocol in two primary ways. First, understanding and agreement will be secured – through formal Memorandums of Understanding – with the implementing partners that the information collected is to be used to inform improvements to the design and delivery of training and support for facilitators and the delivery of the intervention by facilitators, not for penalising facilitators for sub-optimal performance or penalising young people for sharing perceptions of facilitators' sub-optimal performance. Second, proper procedures have been outlined for de-identification of data, proper data collection, data management and data analysis, and establishment of formal confidentiality agreements among research team members.

In addition, given that the study involves various groups of young participants with specific vulnerabilities, the research study will be diligent to ensure that additional child safeguarding and child protection measures are followed.[49] First, referral pathways were identified and/or created to assist young people in accessing relevant health, social, and legal services, when needed.

Table 4. Study design details

Objective	Research question	Data collection methods	Sampling and timeline	Tools	Data analysis methods
1. To determine whether the plan for the project was appropriate and had the potential to achieve the project's objectives	Was the plan for the project appropriate for the context and the needs of the defined group of young people, and did it include evidence-based interventions and evidence-based delivery approaches?	Workplan and curricula review	All workplans and curricula. One time: Month 3	Check list for workplan and curricula review – tool 1	Triangulation of findings from individual interviews with project management and from the findings of the workplan and curricula review
		Semi-structured individual interviews with project managers	All project managers staff. One time: Month 3 (part 1)	Interview guide with project managers – tool 2	
2. To determine whether the project's activities were feasible and whether they were implemented with fidelity.	Did the project effectively carry out its planned activities to identify and recruit facilitators, build their competencies and attitudes, and support them to engage the defined group of young people, deliver CSE to them in the out-of-school context, and assist them in obtaining relevant services?	Report review	All project reports Two times: Months 3 and 7	Check list for project report review – tool 3	Triangulation of findings from individual interviews with project management, from individual interviews with facilitators, and from the findings of the report review.
		Semi-structured individual interviews with project managers	All project managers staff One time: Month 7 (part 2)	Interview guide with project management – tool 2	
		Semi-structured individual interviews with facilitators	All facilitators. Two times: Months 3 and 7	Interview guide with facilitators – tool 4	
3. To determine whether the project's activities were effective in improving the competencies and attitudes of the facilitators	Did the facilitators acquire relevant competencies and attitudes to engage the defined group of young people, deliver CSE to them in the out-of-school context, and assist them in obtaining relevant services?	Pre/post training assessment	All facilitators. Two times: Months 3 and 7	Pre/post training assessment – tool 5	Trend analysis of triangulated findings of pre/post training assessments and individual interviews with facilitators.
		Semi-structured individual interviews with facilitators, including vignettes	All facilitators Two times: Months 3 and 7	Interview guide with facilitators – tool 4	
4. To determine whether the facilitators:	Did the facilitators perceive that the project's activities			Focus group discussion guide	

a. perceived that the project's activities adequately prepared and supported them to carry out their roles and responsibilities b. effectively carried out their roles and responsibilities.	prepared and supported them to effectively engage the defined group of young people, deliver CSE to them in the out-of-school context, and assist them in obtaining relevant services?	Focus group discussions with facilitators	All facilitators. Two times: Months 3 and 7	with facilitators – tool 6	Trend analysis of the findings of focus group discussions with facilitators.
	Did the facilitators effectively engage the defined group of young people, deliver CSE to them in the out-of-school context, and assist them in obtaining relevant services?	Semi-structured individual interviews with facilitators	All facilitators Two times: Months 3 and 7	Interview guide with facilitators – tool 4	Trend analysis of triangulated findings of individual interviews with facilitators and findings from the observation of facilitators engaging with and teaching young people
		Observation of facilitators engaging with and teaching young people	Two sessions with each facilitator. Two times: Months 3 and 7	Observation check list – tool 7	
5. To determine whether the defined group of young people: a. perceived the CSE as accessible, relevant, interesting, and useful. b. gained in terms of knowledge, attitudes, values, and skills related to sexuality and reproduction, and in terms of the use of relevant services	Did the defined group of young people perceive the CSE as accessible, feel a sense of connection with the facilitators, perceive the CSE as helping to improve their knowledge, attitudes, values, and skills related to sexuality, and perceive that the facilitators assisted them in accessing relevant services?	Semi-structured individual interviews with the young people	5% of the young people reached, Two times: Months 3 and 7	Interview guide with young people – tool 8	Trend analysis of triangulated findings of individual interviews and focus group discussions with the young people
		Focus group discussions with the young people	5% of the young people reached, Two times: Months 3 and 7	Focus group discussion guide with young people – tool 9	
	Were there changes in the defined group of young people's knowledge, attitudes, values, and skills related to sexuality and reproduction, and in terms of the use of relevant services?	Semi-structured individual interviews with the young people	5% of the young people reached Two times: Months 3 and 7	Interview guide with young people – tool 8	Trend analysis of individual interviews with the young people.

Second, local research partners with experience working with the groups of young people in question were selected. Third, robust interviews and employee screening procedures by the research partners will be utilised to ensure that their staff are suitable to interact with vulnerable young people and are well-informed on appropriate referral to health and protection services.

Finally, findings from this implementation research study will be disseminated in an appropriate manner with all stakeholders, including young participants, to ensure that they are properly interpreted and used to advance policy and intervention development. The findings from this study will primarily be utilised to inform future potential adaptations and/or scale-up of the project. The research team and the project implementers will collaborate from the outset with local stakeholders at all levels to ensure that analysis and interpretation is grounded in the context and that the findings are used to improve provision of CSE. The findings will be disseminated to the academic community through journal articles and conferences. Further, they will feed into advocacy efforts to strengthen policies and programmes at international, national, and sub-national levels to improve the design and delivery of CSE for adolescents and youth with particular needs and circumstances.

Ethical approval for this implementation research study was secured by each research partner at the appropriate national or local ethical committee and at the ethics review committee of the WHO. In Colombia, the study was approved by Research Ethics Committee of the Health Area of the Universidad del Norte (protocol # 213, 30 July 2020). In Ethiopia, the study was approved by the Ethiopian Society of Sociologists, Social Workers and Anthropologists (protocol # 015/2021, reference # ESSSWA/L/AA/076/2022, 17 March 2021). In Ghana, the study was approved by the Ghana Health Service Ethics Review Committee (protocol # GHS-ERC 007/08/20, 9 October 2020). In Malawi, the study was approved by the College of Medicine Research Ethics Committee (protocol # P.11/20/3194, 4 March 2021).

Discussion

This multi-country implementation research study will provide insight into whether the activities used to train and support facilitators within the context of a multi-country programme are feasible, acceptable, and effective in enabling the facilitators to engage a defined group of young people, deliver CSE to them in the out-of-school context, and assist them in obtaining relevant services. As such it will help to fill important evidence gaps in several key areas: (1) on different approaches to strengthening the performance of CSE facilitators, particularly in out-of-school settings, (2) on involving different types of facilitators in the delivery of CSE, (3) on meeting the specific needs of different groups of young people who are excluded and/or marginalised (in general and also specifically regarding CSE) due to some aspect of their identity, and (4) on conducting research (and implementation research, in particular) in this area. In each of these areas, this research will help us to learn more about what works for whom and why. In all of these areas, it will seek to illuminate the value of innovation and adaptation in the design and delivery of out-of-school CSE, as also emphasised in the recently published *International Technical and Programmatic Guidance on Out-Of-School CSE*, and elucidate key considerations for implementing this in practice.[17] For example, the facilitators delivering CSE to young people with disabilities in Ethiopia will themselves have disabilities. What is the value of this, and what needs to be done differently to train and support these facilitators?

Importantly, this study will be conducted in four different countries to allow for cross-cultural comparisons about which elements are key – across different countries, settings, and groups – to provide effective out-of-school CSE, considering the differences in the intervention design and defined groups of young people in each context. It will also do so using a variety of methods, which will allow for various perspectives and data types to contribute to responding to the study objectives through data triangulation.

This study will build upon other evidence regarding the delivery of out-of-school CSE. Most importantly, it builds on the knowledge consolidated in the recently published *International Technical and Programmatic Guidance on Out-Of-School CSE*. However, while the guidance is based on available evidence and the experiences of those who have worked on out-of-school CSE, it notes that there is a "lack of peer-reviewed literature on out-of-school CSE in general, as well as for the specific groups of young people addressed in the guidance".[17] Within the evidence gaps, it specifically draws attention to the limited amount

of evidence from low- and middle-income countries, insufficient analysis or understanding of why programmes that are deemed effective work, and the key factors that make them effective, [and] insufficient studies of programme quality, integrity or fidelity, and of the impact of facilitators on the outcomes.[17]

This research study aims to generate evidence that will help to fill each of those gaps. Additionally, it will build on learnings from efforts to build the competencies of other professionals, such as health workers and teachers, broadly and specifically in relation to ASRHR.[50,51]

This study has several limitations. First, as a multi-country research study, harmonising survey questions and responses is not simple. The research team attempted to address this challenge by involving experienced researchers from each of the study sites, as well as researchers with experience in conducting multi-country studies – such as the Global Early Adolescent Study (GAGE), and the Community-Embedded Reproductive Health Care for Adolescents (CERCA) study – in the design and development of the study protocol and instruments and the data collection, management, and analysis manuals. Second, there are also limitations related to the research methods, including that outcomes of the research can be caused by confounding variables and that participants for obvious reasons are not randomly assigned, nor are control groups included. However, by using a mixed-method time-series quasi-experimental research approach which allows triangulation of findings through several research questions at different points in time, the researchers aim to capture the complex picture. Third, questions and answer options in the study instruments can be interpreted differently in different contexts and cultures. This risk will be minimised through use of the data collection manual. Fourth, cross-country analyses of research data can be challenging due to the fact that we included different groups of vulnerable young people and facilitators with diverse training and support trajectories. In addition, various methods of processing the data were applied. By providing a data management and data analysis manual and a "data sharing agreement", the research team has attempted to reduce the impact of these challenges before initiating the study. Despite this, there are likely to be important differences between study sites and groups of participants that cannot be fully mitigated through the approaches put in place. These differences will thus be considered when analysing the data and interpreting the results. Nevertheless, former cross-country studies – such as the Global Early Adolescent Study – have indicated that it is feasible and important to compare research data on vulnerable youth from diverse contexts.

Conclusion

CSE has been recognised as an important entry point for promoting adolescent health, both as an end in itself and as a means to achieve overall health and wellbeing of populations.[52] To enhance progress related to SDG 3 "Ensure healthy lives and promote wellbeing for all at all ages" and SDG 5 "Achieve gender equality and empower all women and girls", however, efforts must expand beyond those used to reach young people within formal education systems and ensure that those with specific needs and circumstances also have access to quality CSE in settings and formats that are accessible and acceptable to them. This multi-country implementation research study will shed new insight into what it takes to prepare and support facilitators to deliver effective out-of-school CSE in real-world settings in diverse country contexts and with different groups of vulnerable young people.

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Authors' contributions

All authors participated in the protocol development process. MP and VC developed the core

protocol. MP, SDM, and VC prepared a draft of the paper. The other authors reviewed and revised the paper. MP and SDM finalised the paper.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Résumé

L'éducation complète à la sexualité (ECS) est un élément bien établi du panier d'interventions requis pour améliorer la santé et les droits sexuels et reproductifs des adolescents. Alors que la communauté internationale met davantage l'accent sur l'équité et la volonté de ne laisser personne de côté avec le programme de développement durable, l'attention a été attirée sur le besoin de programmes complémentaires d'ECS pour atteindre les jeunes qui ne sont pas scolarisés ou dont les besoins ne sont pas satisfaits par les programmes d'ECS à l'école. L'ECS dans les contextes non scolaires présente des considérations singulières, spécialement celles qui se rapportent à la facilitation. Dans ce manuscrit, nous présentons le protocole pour une étude multipays de mise en œuvre en Colombie, en Éthiopie, au Ghana et au Malawi, pour évaluer la faisabilité, l'acceptabilité et l'efficacité de mesures spécifiques au contexte en vue de préparer et soutenir les animateurs à dispenser une ECS dans des environnements extrascolaires à des groupes définis de jeunes présentant divers besoins et placés dans des circonstances différentes. Cette étude sera dirigée par l'Organisation mondiale de la santé et le Programme spécial PNUD/FNUAP/OMS/Banque mondiale de recherche, de développement et de formation à la recherche en reproduction humaine, en partenariat avec des institutions de recherche locales. Il s'inscrira dans le cadre d'un programme multipays géré par le FNUAP, en collaboration avec des partenaires d'exécution locaux et avec le soutien financier du Gouvernement norvégien. L'étude apportera un éclairage nouveau sur les conditions requises pour assurer

Resumen

La educación integral en sexualidad (EIS) es un componente bien establecido del paquete de intervenciones necesarias para mejorar la salud y los derechos sexuales y reproductivos de adolescentes (SDSRA). Dado que la comunidad internacional ha aumentado su énfasis en la equidad y en no dejar a nadie atrás con la Agenda de Desarrollo Sostenible, se ha dirigido la atención a la necesidad de programas suplementarios de EIS para llegar a las personas jóvenes que no están en la escuela, o cuyas necesidades no son satisfechas por los programas escolares de EIS. En contextos fuera de la escuela, la EIS presenta consideraciones únicas, especialmente aquellas relacionadas con la facilitación. En este manuscrito, presentamos el protocolo para la ejecución de un estudio de investigación multinacional, en Colombia, Etiopía, Ghana y Malaui, para evaluar la viabilidad, aceptabilidad y eficacia de acciones adaptadas a cada contexto específico para preparar y apoyar a los facilitadores para impartir EIS en entornos fuera de la escuela a grupos definidos de jóvenes con diversas necesidades y circunstancias. Este estudio será liderado por la Organización Mundial de la Salud y el Programa Especial de Investigaciones y Desarrollo y de Formación de Investigadores sobre Reproducción Humana de UNDP/UNFPA/OMS/Banco Mundial, en alianza con instituciones de investigaciones locales. Será alojado por un programa multinacional liderado por UNFPA, en alianza con socios ejecutores locales y con apoyo financiero del Gobierno de Noruega. Este estudio arrojará una nueva perspectiva de lo que se necesita para impartir EIS de manera eficaz en contextos fuera

efficacement l'ECS dans des environnements extrascolaires, accroître les progrès vers la réalisation de l'ODD 3, « permettre à tous de vivre en bonne santé et promouvoir le bien-être de tous à tout âge », et de l'ODD 5, « parvenir à l'égalité des sexes et autonomiser toutes les femmes et les filles ».

de la escuela, con el fin de acelerar la consecución del ODS 3 "Garantizar una vida sana y promover el bienestar de todos a todas las edades" y del ODS 5 "Lograr la igualdad entre los géneros y empoderar a todas las mujeres y las niñas".