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Protocol for intervention development to improve adolescent perinatal mental health in Kenya and Mozambique: The INSPIRE project

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ABSTRACT

Introduction: Mental health interventions have traditionally been developed by clinicians and researchers without the meaningful engagement and partnership with those who would receive, deliver, and fund them. Recent progress has highlighted the importance of the co-design of interventions, through stakeholder participation, as a means of increasing the integration of mental health interventions into existing health, education, and social care systems. This protocol describes the pre-implementation phase of the INSPIRE (Innovative approaches to adolescent perinatal wellbeing) project which aims to identify challenges, and design and test interventions to promote mental wellbeing and good mental health of adolescent girls during pregnancy and the year after birth with local stakeholders in Kenya and Mozambique.

Methods: A participatory approach that blends human-centred design, systems thinking, and implementation science methods will be used to engage adolescents (aged 15–19 years), their families, and other stakeholders who can influence implementation efforts, in planning and preparing interventions. First, an understanding of context, barriers, and opportunities related to adolescent perinatal mental health will be elicited through individual interviews, focus group discussions, and observations. This will be complemented by a scoping review of relevant interventions. The research team will identify contextual insights relating to adolescent and system characteristics, strengths, and challenges. These will be shared with and refined by stakeholders. Thematic analysis will be conducted to describe the experiences of adolescent girls, and barriers and enablers to maintaining good mental health. The former will be triangulated with the Context and Implementation of Complex Intervention (CICI) framework. Causal loop diagrams will be developed to illustrate the individual and system-level variables which influence adolescent perinatal mental health.

Stakeholder workshops will be used to identify priorities, brainstorm potential interventions, develop a program theory, and prototype an intervention and implementation strategies. Intervention acceptability, appropriateness, and feasibility will be assessed, and a theory of change map finalized.

Results: To date the study has recruited 169 participants to complete individual interviews, focus group discussions and observation activities.

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Conclusions: It is anticipated that the use of a participatory and systematic approach to the development of an intervention to improve mental health, will improve its perceived appropriateness, acceptability, and feasibility among key stakeholders. This may, in turn, significantly improve its availability, uptake, and sustainability.

1. Introduction

Approaches to develop interventions to improve mental health outcomes, typically have not included stakeholders vital to the delivery (e.g. health and community-based providers, policymakers) and uptake (e.g. individuals and their families), as active members of development teams (Tindana et al., 2007; Twine et al., 2016). Instead, interventions are developed largely by clinicians and researchers with limited opportunities for stakeholders to shape and drive interventions. While this approach has resulted in interventions with proven effectiveness through clinical trials, many of these interventions are never delivered outside of trial settings or fail to achieve the same levels of impact (Heneghan et al., 2017).

Reasons for the above are complex but are in part due to a failure to address the common barriers to increasing the accessibility, availability, and quality of mental health support and care. These barriers include contextual determinants such as sociocultural (e.g. high levels of stigma associated with mental health conditions) economic (e.g. lack of financial and human resources) political (low political importance), and characteristics of the service (e.g. complexity). There are also behavioural determinants such as lack of knowledge of mental health conditions, and lack of provider skills to treat patients with high quality care (Andrade et al., 2014; Rathod et al., 2017).

Participatory approaches have become more widely known and used as ways to address the chronic and complex barriers to improving mental health support and care (O'Brien et al., 2021). The recently published update of the UK Medical Research Council's complex intervention framework highlights the need for meaningful stakeholder engagement in "prioritising research questions, the co-development of programme theory, choosing the most useful research perspective, and overcoming practical obstacles to evaluation and implementation" (p. 5; Skivington et al., 2021). This is a significant step forward from inclusion through mostly tokenistic gestures (e.g. one-off interviews and focus group discussions) to genuine partnership and agency.

Successful interventions and associated delivery strategies require a deep understanding of stakeholder motivations, environments, and conceptualisations of mental wellbeing and ill health to increase their acceptability and feasibility. A key element of an intervention's success is equitable partnership with those who are essential to its provision and uptake from the start of the intervention planning process (Seward et al., 2021). Without engaging these individuals, one risks developing an intervention which, even if effective, is unsustainable. Furthermore, engagement of young people in their health has been supported by the United Nations (UN) since the UN Convention on the Rights of the Child (1989) ratified over 30 years ago. Although engagement of adults in mental health research is well established, youth engagement is less common (Wilson et al., 2020). A recent systematic review identified youth engagement in mental health research as a contributor to improved research outcomes (McCabe et al., 2023). However, none of the 14 studies included in the review took place a low- and middle-income countries (LMICs).

This protocol describes the use of a participatory approach that blends human-centred design, systems thinking, and implementation science to improve the mental health outcomes of adolescent girls during pregnancy and the year after birth in Kenya and Mozambique.

1.1. Adolescent perinatal mental health

It is estimated that in developing regions, approximately 21 million girls aged 15–19 years become pregnant and 12 million give birth (Sully et al., 2020). However, the absolute number of adolescent pregnancies has not seen a reduction during this period due to growing numbers of adolescent populations in LMICs (United Nations, 2022). Sub-Saharan Africa has the highest adolescent births with an estimated 6,114,000 births to 15–19-year-olds in 2021 (United Nations, 2022). One in four girls become pregnant before their eighteenth birthday (UNICEF, 2022).

Mozambique and Kenya are among the top ten countries in terms of the highest rates and absolute numbers of adolescent pregnancies, respectively (Loaiza and Liang, 2013). A third of deliveries in Mozambique were reported to be amongst adolescents (Jaén-Sánchez et al., 2020). A recently published survey by the Kenya National Bureau of Statistics found 15% of girls in Kenya had given birth between ages 15–19 years (KNBS and ICF, 2023).

Adolescents in LMICs regularly experience a variety of adverse events (e.g. stigma, family conflict, poor social support, poor self-esteem, gender discrimination, exclusion from education, unsafe abortions, and poverty) which increase their risk for mental health problems during the perinatal period which comprises pregnancy and the year after birth (Fisher et al., 2012; Chung et al., 2018; Kumar and Huang, 2021). In both Kenya and Mozambique, an estimated one in three adolescents who become pregnant experiences a perinatal mental health condition (Granja et al., 2002; Osok et al., 2018).

Mental wellbeing during the perinatal period is critical due to its important influence on the physical and mental health and social outcomes of mothers and their children (Laurenzi et al., 2022). Women and girls with a mental disorder are more likely to experience pre-term birth, have infants with low birth weight and poor weight gain, reduced mother-child bonding, and have negative impact on the mothers' education and employment (Bennett et al., 2016; Cook et al., 2018; Harron et al., 2021; Jarde et al., 2016; Shaw et al., 2014). Despite a clear need for support, context-specific adolescent perinatal mental health prevention interventions that meet the needs and priorities of the local population have yet to be evaluated in sub-Saharan Africa, where most the world's adolescent mothers live (Skeen et al., 2018). Such interventions are not just a health priority, but a key component in the achievement of the United Nations' Sustainable Development Goals (United Nations, 2016).

1.2. The INSPIRE project

Our previous work in Mozambique illustrated the potential for using human-centred design, to actively engage adolescents and other stakeholders in the identification of challenges to adolescent perinatal mental health and brainstorming of potential solutions (Taylor Salisbury et al., 2021). The Innovative Approaches for Adolescent Perinatal Wellbeing (INSPIRE) project builds upon this work by expanding to a second area in Mozambique and an additional country (Kenya). INSPIRE will develop and test interventions and implementation strategies to improve the mental health of adolescent mothers, which are in line with the needs, aspirations, and priorities of those directly and indirectly involved its success. This is especially important when developing interventions for adolescents, as service providers are unlikely to share the same sub-culture, desires, or experiences as their target group. By understanding the context, barriers and opportunities related to adolescent perinatal mental health, from the perspective of adolescents themselves, their families, and health and community service providers, we can identify a shared priority challenge to address. Further partnership may elicit innovative interventions and delivery strategies which are attractive, appropriate, effective, and sustainable.

The INSPIRE project consists of two phases. Phase 1 is concerned with the development of prototype interventions to improve adolescent

perinatal mental health outcomes in Kenya and Mozambique. In Phase 2, an implementation effectiveness pilot trial will evaluate the prototype on important implementation outcomes such as acceptability, appropriateness, fidelity, feasibility, and sustainability. This protocol describes the methods applied in Phase 1 of this research programme. While unusual to publish a protocol focused on formative work, the lack of deep description of the incorporation of participatory research within global health (Salisbury et al., 2021) demonstrates a need for transparency and clarity of the methods followed.

1.3. Aim and objectives

The aim of Phase 1 is to develop an intervention to promote good mental health and improve symptoms of depression and anxiety among adolescent girls during the perinatal period in Kenya and Mozambique.

To achieve our research aim we will.

1. Identify the barriers and enablers to maintaining mental wellbeing during the perinatal period, and priorities in each study site;
2. Identify the essential components of adolescent perinatal mental health interventions in each study site; and
3. Formulate a programme theory demonstrating how and why the resulting interventions and associated implementation strategies will deliver expected clinical and implementation outcomes.

2. Material and methods

2.1. Setting

Research will take place in health and community settings with high rates of adolescent pregnancy in Kilifi County, Kenya and Tete Province, Mozambique (see Fig. 1). In Kenya, research will be carried out in two sub-counties of Kilifi, Mariakani and Rabai, which represent urban and peri-urban settings, respectively. Kilifi County is largely a rural area on the Kenyan Coast, 60 km north of Mombasa County with a population of 1,453,787 in 2019 (KNBS,2019). In Kilifi County, 52% of the population are female and 47% are 15 years of age and below; adolescent pregnancy rate is 12.5% (KNBS, 2019). The main economic activities are subsistence farming and fishing. Approximately 55% of the population in Kilifi County are described as having a low socioeconomic status, with 62% of the population having low literacy levels.

In Mozambique, the project will be conducted in Moatize City, the district capital, and Cateme, a rural area approximately 40 km from Moatize City. Tete province covers an area of 98,417 km^2 and has a population of approximately 2,648,941 inhabitants (Instituto Nacional de Estatistica Moçambique, 2017). It was estimated that the population would reach 450,000 inhabitants in 2020 (Ministério da Administração Estatal, 2014). An estimated one in five adolescents becomes pregnant between the ages of 15 and 19 (Ministerio da Saude, Instituto Nacional de Estatística e ICF International, 2013). Moatize district, the illiteracy rate among adolescents between 15 and 19 years is 43% and between 20 and 24 years is 59% (Ministério da Administração Estatal, 2014). While the district has seen increased developed due to the reactivation of mining activity by large multinational corporations, the workforce is mostly male.

2.2. Study design

A participatory, mixed-method study will be carried out to address the study aim and objectives, using a blended human-centred design, systems thinking, and implementation science approach over 24 months (see Fig. 2). First, individual interviews, focus group discussions, observations, service mapping, and scoping of existing literature will be carried out to elicit the motivations, behaviours, needs, and priorities of key stakeholders, in relation to adolescent mental health during the perinatal period. These insights will be used to identify priority challenges to be addressed in each country. This data will form the basis of the intervention to be developed, to ensure relevance and importance to the community including adolescent girls. Subsequent workshops will be held with stakeholders to develop potential interventions.

2.2.1. Human-centred design

Human-centred design is a participatory approach which actively engages stakeholders throughout intervention planning, preparation, delivery, and evaluation using methods to ensure interventions are optimised for both front-line use and implementation. It involves five phases of intervention development: (a) Empathize – understanding stakeholder perceptions, needs, goals and priorities; (b) Define –

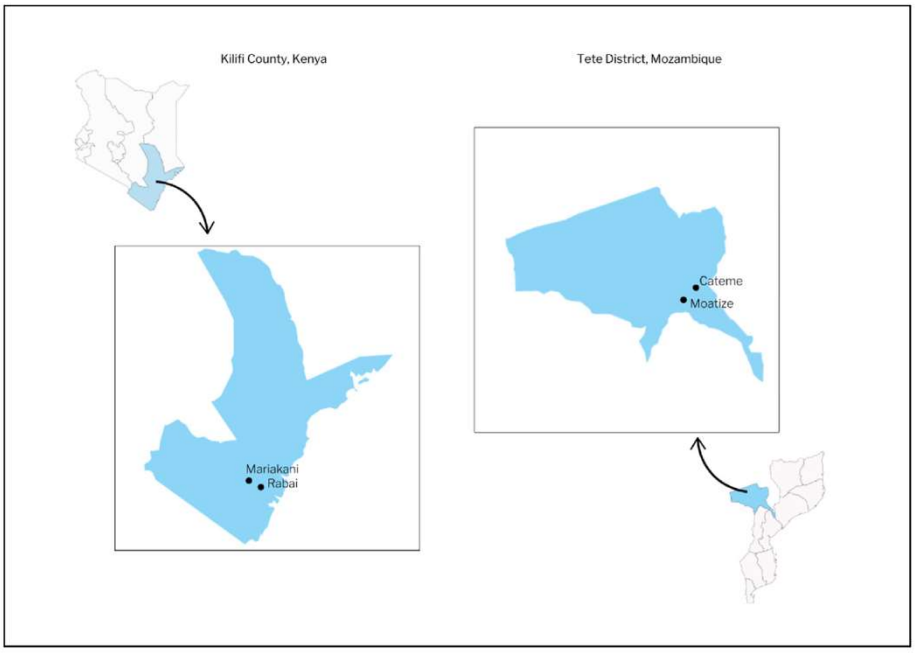


Fig. 1. INSPIRE study site locations.

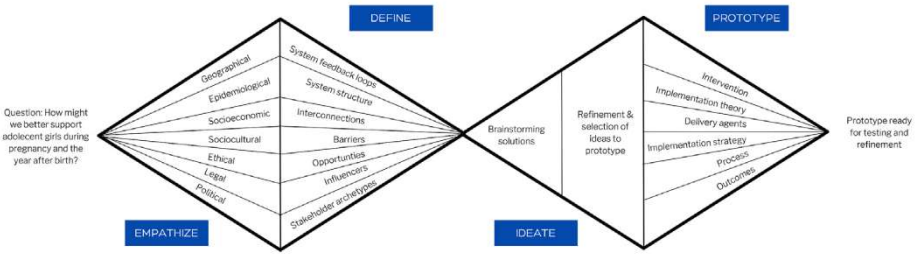


Fig. 2. Blended human-centred design, systems thinking and implementation science approach.

identifying the challenge to be addressed; (c) Ideate – developing potential interventions; (d) Prototype – refining interventions; and (e) Test – evaluating and further refinement. In the last decade, human-centred design has begun to be used within global health (including mental health) research (Bazzano et al., 2017; Chen et al., 2020; Fakoya et al., 2021; IDEO.org, 2015; Taylor Salisbury et al., 2021).

2.2.2. Systems thinking

Systems thinking aims to understand and address the interconnectedness of the micro (e.g. family, school, friends, health clinic, place of worship), meso (e.g. interaction between micro systems), and macro (e.g. culture, social values) levels of a given system (Adam and de Savigny, 2012). The goal of this approach is to identify and make explicit the models and assumptions which govern the how and why interventions work. Booth (2018) identifies the limitations of traditional human-centred design approaches when used to address complex challenges and asserts that a combination of human-centred design and systems thinking approaches may be the way forward in developing scalable and sustainable solutions. We will therefore use approaches such as causal loop diagrams, theory of change workshops, implementation science approaches alongside human-centred design to help address the complexity associated with implementing a programme within a health system and the wider community.

2.2.3. Implementation science

Implementation science offers theories, models, frameworks, and other methodologies to optimise and evaluate the implementation of evidence-informed care (Eccles and Mittman, 2006). The approaches offered through implementation science can support decisions on how best to design, deliver, adapt, and test interventions for the dynamic environments in which they are used. For example, implementation science determinant frameworks support the identification of contextual and behavioural barriers known to influence implementation outcomes and highlight key factors to consider in the evaluation of intervention implementation (Nilsen, 2015). Within INSPIRE, implementation science determinant frameworks will be used to help identify barriers and enablers to implementation and assess the intervention's acceptability, appropriateness, and feasibility. Implementation science approaches used alongside systems thinking and human-centred design can increase the alignment of a mental health intervention with a community's needs, expectations, behaviours, and existing services (Seward et al., 2021).

2.3. Sample and recruitment

Up to 85 participants will be recruited per country will include adolescent girls aged between 15 and 19 years, young women aged between 20 and 25 years, partners and family members such as parents/parents-in-law of girls and young women who became pregnant during adolescence, local service providers and government representatives working in (e.g. health, social services, education),and other influential people in the community (e.g. teachers, religious leaders, and community leaders, activists; see Table 1. A variety of stakeholder groups will be included to provide insights into the perspectives of those who are crucial to the success of the resulting intervention.

2.3.1. Adolescents and young women

Between 10 and 20 adolescents will be recruited in each country (see Table 1). Adolescents will be eligible to take part if they are between the ages of 15–19 years, pregnant or have given birth in the previous 12 months, living in the study site, and attending participating community and health-based facilities. They will be excluded from the study if they are unable to provide informed consent or unable to participate in research activities, due to existing health conditions. Consent of a legal guardian will be required before adolescents aged 15–17 years can take part in the study.

Ten young women aged between 20 and 25 years who have experienced a pregnancy between the ages of 15 and 19 years and live in the study catchment area will be recruited in each country to share their experiences of adolescent pregnancy and motherhood (see Table 1). They will be identified by the research team through participating community and health-based facilities and snowball sampling.

The sociodemographic characteristics of participants will be reviewed during recruitment to attempt to ensure a wide variety of adolescents and experiences (i.e. support from family/partner, where they live, uptake of medical services) are included in the research. Where a certain experience or characteristic is not represented, the research team will proactively recruit girls meeting these descriptions with the assistance of service providers and community influencers.

2.3.2. Partners and family members

Adolescent girls and young women will be asked by a member of the research team if they would like to invite their partners or family members to take part in the research. Up to five partners and up to 20 family members will be recruited in this way (see Table 1). Partners and family members will be eligible to participate if the adolescent or young

Table 1
Data collection activities and numbers of participants per country.

Data collection activity	Adolescent Girls	Young Women	Family Members	Partners	Community Influences	Service providers
Individual interviews	≤ 20			5		(≤ 10)
Focus group discussion participants (number of groups)	≤ 30 (up to 3)		≤20 (up to 3)		≤ 20 (2)	
Spiral Walks	4					
Photovoice	6					
Define workshops	10		6		5	5
Ideate workshops	10		6		5	5
Prototype workshops	10		6		5	5

woman agrees to their recruitment, they are at least 18 years old, and lives within the study site.

2.3.3. Service providers and government representatives

A minimum of ten local service providers and government representatives working in health, social services, education sectors in each country, will be identified per site, through their affiliation with participating health and community facilities and snowball approach (see Table 1). Participants will be eligible for the study if they are at least 18 years of age and involved in the delivery or planning of services delivered to adolescent girls.

2.3.4. Community influencers

Up to 20 individuals deemed to have influence within the community (e.g. teachers, religious leaders, community leaders, activists) will be recruited to the study (see Table 1). Influencers will be at least 18 years of age and resident in the study site to be eligible for participation. An initial set of influencers will be identified by the research teams in each country and additional influencers will be identified using a snowballing approach.

2.4. Data collection procedures

A variety of data collection methods based on human-centred design and systems thinking approaches will be used to better understand the impact of pregnancy and early motherhood on adolescent girls' lives, including interpersonal relationships, interactions with their community, social support, family life, education, employment, mental health, and physical health. Data on the micro, meso, and macro systems will be collected to better understand how system structures and interrelationships affect girls' experiences. The type and number of participants to be engaged in each data collection activity is described in Table 1. The same participants will be invited to take part in all relevant data collection activities. However, their participation is voluntary. They will be given the opportunity to opt out of later activities. Where insufficient numbers of participants from particular stakeholder groups discontinue their participation in the study, new stakeholders will be recruited to replace them.

2.4.1. Empathize

2.4.1.1. Scoping review. A scoping review will be undertaken to better understand the existing evidence for adolescent perinatal mental health interventions. Key health and social care databases (i.e. PsycINFO, MEDLINE, EMBASE, MIDRIS, CINAHL, and ERIC) will be searched to identify and collate evidence-based interventions relevant to the topic (e.g. perinatal mental health, adolescent mental health). This will be supplemented with a search of grey literature. International and local networks will be leveraged to identify existing relevant programmes and interventions being delivered within Kenya and Mozambique and information on barriers to and opportunities for implementation.

2.4.1.2. Interviews and focus groups. A mixture of individual interviews and focus group discussions will be carried out with key stakeholders in each study site (see Table 1). All interviews and FGDs will be conducted in the national or local language (Portuguese or Nyungué in Mozambique, English or Kiswahili or Kigiriama in Kenya), dependent on participant preferences, and will be audio recorded, transcribed, and translated into English where necessary. In-depth, semi-structured individual interviews will be conducted with adolescent girls to understand their experiences of the perinatal period and how they have affected their mental health and wellbeing. Interview guides will be adapted from a previous study (Taylor Salisbury et al., 2021) for use in each country site, with the local research teams. Interviews will last up to 1 h at a mutually convenient, private location. Up to three FGDs will be held with mixed groups of adolescent girls and young women to discuss the needs and priorities of adolescent girls during pregnancy and the year after birth, ways in which to address these needs and their perceptions of the views of their community.

A mixture of interviews and FGDs will be conducted with other stakeholders to gain deeper insight into their own experiences with adolescents' girls during the pregnancy and the year after birth, their perceptions of the experience of the adolescents, and their perceptions of needs and priorities in relation to adolescent girls' mental wellbeing. Semi-structured interview and FGD topic guides will be tailored to each stakeholder group, to capture information and experiences unanticipated by the team. The guides will be agreed by the research team prior to the commencement of data collection. Individual interviews will be conducted by a single member of the research team and last up to 1 h. Focus group discussions will be conducted by two members of the research team and last up to 2 h.

Up to three FGDs will be held with family members. Single gender groups will be held in line with cultural expectations, guided by members of the Kenyan and Mozambican team, to encourage participants to freely express their thoughts. Up to two FGDs will also be conducted with community influencers. Where it is not possible to arrange FGDs, individual interviews will be offered. Due to anticipated constraints on the availability of local service providers and health systems, semi-structured individual interviews will be conducted in lieu of FGDs.

2.4.1.3. Observation (PhotoVoice). An unobtrusive method of observation, which uses the PhotoVoice method (Wang, 2006) will be used to gain a deeper understanding of the home environments and their daily routines of adolescent girls, without intrusive and unnecessary shadowing. Adolescent girls recruited to take part in individual interviews will be invited to take part and included until six in each country site agree to participate. Consenting adolescents will be given a camera, shown how to use it, and prompted to take pictures of situations which support or challenge their wellbeing over a one-week period. The adolescents will then meet in a FGD to review their photographs and identify those they would like to share. They will then share their photographs using the SHOWeD technique, which uses a series of questions to allow for a critical description of challenges or support, and how it relates to ways to resolve a problem (Wang, 2006). PhotoVoice FGDs will be recorded, last up to 2 h, and be facilitated by two researchers in a local language.

2.4.1.4. Service mapping. A subsample of adolescent girls (n = 4) will be purposively selected per country (to ensure adequate representation) from those taking part in interviews, to identify places girls can find formal and informal support during the perinatal period. This will be done using a technique called a spiral walk (Davis et al., 2019). A spiral walk is a mapping technique in which a participant walks with a researcher in expanding circles (or a spiral) from a central point to the margins of a given area while identifying locations of interest which are marked on a map and then discussed. The purpose of the circular motions is to reach every part of the community, including those that might typically be overlooked. By doing so, the researcher aims to observe the community's intricate social structures and systems. This method allows for gathering of valuable contextual and location-based information quickly, as well as more nuanced information about each location and people's emotional and historical connections to space and place. A researcher will meet the girl at her home or another agreed location in the community (i.e. the central point). They will then begin the spiral walk and the girl will be asked to identify existing health and community-based services that are attended by adolescents who are pregnant or new mothers. They will also be asked about other places where they spend their time throughout the day, which they view positively or negatively (e.g. market, playground, park, church, mosque) (Davis et al., 2019). Informal conversations will take place during the walks and following the exercise, the researcher will also provide an

opportunity for the participant to verbally identify any other relevant services that lie outside of the geographical scope of the spiral walk. This allows for mapping places and people of potential significance to the intervention and identifying places/settings in which an intervention might be provided. Following the walk, the researcher will record their walking route and document their experience in field notes. Additional information will be collected through individual interviews and FGDs with stakeholders to complement the spiral walk data.

2.4.2. Developing an intervention

Following the completion of the Empathize stage a series of workshops will be conducted to define a priority challenge to address, brainstorm potential solutions, and, finally, develop an intervention. Each workshop will be audio recorded and facilitated by at least two members of the research team. Workshops will be conducted in mixed stakeholder groups or with groups separately depending on stakeholder preferences and availability. Within multi-stakeholder workshops, small groups will be formed which comprise of participants from different stakeholder groups. For example, a small group may contain a partner, mother-in law, midwife, and teacher. Adolescent girls will form their own small group, supported by a member of the research team, to ensure that their experiences, thoughts, and preferences do not get lost and remain central to all decisions.

2.4.2.1. Define. Adolescent girls will meet to discuss the findings presented by the research team on the experiences of and challenges faced by girls during the perinatal period. Through a series of activities, they will agree on three biggest challenges to their wellbeing during this time and discuss potential ways to address them. A second, multi-stakeholder workshop will be held to agree a priority challenge the intervention will focus on. Participants will work in small groups to discuss the three biggest challenges identified by the adolescent girls and their potential to be successfully addressed by a feasible, acceptable, and sustainable intervention. The group will then agree on a single challenge to develop an intervention for during the remaining workshops.

2.4.2.2. Ideate. A series of individual activities and creative techniques will be carried out to generate interventions for the identified challenge in each country. These may include activities such as group discussion of themes that were identified in the empathize stage, voting activities to determine key priorities, storyboards depicting adolescent girls' journeys, and creating personas (e.g. fictional characters based on the research to help build empathy and support) (IDEO.org. 2015).

Up to three multi-stakeholder workshops will take place where they will discuss their ideas and vote for those, they like the most. During mixed workshops, adolescents will complete activities separately in their own tables, which will then be shared in larger group and discussed together. Facilitators will take care to ensure that adolescents can share their thoughts and opinions and participate in the discussions. Based on these findings and further discussion about how potential interventions might work, up to three interventions will be agreed upon by stakeholders and the research team for further development through prototyping.

2.4.2.3. Prototype. The research team will develop initial prototypes of interventions selected in the Ideate stage to be presented to multi-stakeholder groups in each country over two workshops. Prototypes will be further informed by the findings of the mapping activity and scoping review to improve their ability to embed into existing services, structures, and systems. Prototypes will provide a visual description of how each intervention would work. They may include but, are not limited to, storyboards illustrating a new service design, role-plays of the intervention, diagrams, and videos. Stakeholders will provide feedback on each prototype which will be documented through field notes and actively used shape the refinement of each intervention. At the end of the first prototyping workshop, a single intervention, which is considered to have the best potential for success, will be selected (and agreed by participants and the research team) through a voting process. During the second workshop, the prototype will be further refined and assessed on its acceptability, appropriateness, and feasibility using the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM) and Feasibility of Intervention Measure (FIM), respectively (Weiner et al.., 2017). These brief, four-item instruments have been developed by implementation scientists and mental health professionals and display good psychometric properties (Weiner et al.., 2017). Cultural and linguistic adaptation of the measures will be undertaken in Kenya and Mozambique prior to their use.

2.4.3. Developing a theory of change

A program theory for the resulting intervention will be developed with stakeholders throughout the Define, Ideate, and Prototype stages. Theory of change (ToC) activities will be included within each workshop to describe how the intervention will address the identified challenge, be delivered, and assessed (Breuer et al., 2015). The programme theory will define who the intervention is for, provide vital contextual information, describe assumptions, and identify constraints and criteria that the intervention must fulfil ('success criteria').

2.5. Data analysis

2.5.1. Analysis of adolescent characteristics, needs and strengths during the perinatal period

Local researchers in each country will undertake thematic analysis of local language transcripts from Empathize stage interviews and FGDs to understand and describe the experiences of adolescent girls during the perinatal period. Intersectoral differences will be examined among stakeholder groups as well as their characteristics across both countries. Two members of the research team will read through the first transcripts for each stakeholder group to immerse themselves in the data; they will then independently separate the data into meaningful fragments and identify and label emerging themes. Instances of disagreement will be discussed until a consensus is reached. Constant comparison of data will be used to delineate similarities and differences between the codes to form higher-level conceptual categories. A coding framework will then be developed, which will be discussed and refined at a meeting with local teams. A qualitative data analysis software (NVivo (QSR International, 2002) or similar, license-free software) will be used to process the transcripts and enable us to systematically manage the data, to identify, code and retrieve concepts. Ideas about categories, subcategories and their relationships will be recorded in theoretical memos and discussed in regular team meetings. The findings will be reported as a narrative.

Data from interviews, FGDs, researcher field notes, PhotoVoice photographs, and service maps will be used by the research team to identify initial contextual insights relating to the characteristics, needs, and strengths of adolescent girls and local systems. During the Define, Ideate, and Prototype stages these insights and scenarios will be presented to participants for individual and group analysis, prompting dialogue to explore contexts, confirm (or contest) insights and add detail. Stakeholders will be invited to contribute their own insights and vote or rank them by influence/importance. Common themes will be drawn out in small groups, with these findings presented to the larger group, and a consensus sought.

Causal loop diagrams are a system thinking method which helps to visualise and unpack complex health system behaviours, by considering the links between variables, how they are interconnected and what types of behaviours they will produce (BeLue et al., 2012). These will be developed with stakeholders to create a visualisation of the key variables (individual-, family- and system-level) which positively and negatively influence adolescent perinatal mental health and their inter-relationships. These diagrams will be used to support stakeholder identification of potentially useful interventions and places within a system to intervene.

2.5.2. Implementation science determinant frameworks to address barriers and enablers to maintaining mental wellbeing

Thematic analysis of Empathize stage interviews and FGDs will be carried out to identify barriers and enablers to maintaining good adolescent perinatal mental health. Intersectoral differences will be examined among stakeholder groups as well as their characteristics across both countries. Identified themes, categories and subcategories will be triangulated with the Context and Implementation of Complex Intervention (CICI) framework and reported as a narrative synthesis. The CICI framework offers a detailed approach to identifying determinants from the external context (e.g. sociocultural, socioeconomic, political, epidemiological, ethical, and legal) that are known to influence implementation effectiveness that are particularly relevant to LMICs (Pfadenhauer et al., 2017).

2.5.3. Evaluating the acceptability, appropriateness and feasibility of essential intervention components and implementation strategies

Interventions will be assessed at the micro, meso, and macro levels for triangulation with insights from interviews and FGDs, and causal loop diagrams. Implementation barriers and enablers at the individual- and systems-levels will be identified, and strategies developed using the CICI framework. Means and standard deviations for acceptability (AIM), appropriateness (IAM), and feasibility (FIM) measures will be calculated for potential interventions and delivery strategies.

Scores from these measures will be combined with the results of stakeholder voting on preferred interventions and strategies to select the solution to pilot in each country. This approach will help to ensure interventions and implementation strategies align with stakeholder priorities, goals, and resources. A ToC map developed by the research team and stakeholders will illustrate the connections between the intervention and implementation strategies, assumptions, impact (positive and negative), and evaluation methods at the individual and system levels.

3. Results

The INSPIRE project was funded by UK Research and Innovation in September 2020. Ethical approval for this protocol was obtained from Psychiatry, Nursing and Midwifery Research Ethics Committee, King's College London, UK (ref: HR/DP-20/21–21956); Institutional Scientific and Ethics Review Committee, Aga Khan University, Kenya (ref: 2021/IERC-/31 (V2)); and National Bioethics Committee, Ministry of Health, Mozambique (ref: 691CNBS/21). Data collection began in November 2021. As of May 2022, 169 (Kenya = 89; Mozambique = 80) participants have been recruited.

4. Discussion

This pre-implementation phase work combines human-centred design, systems thinking, and implementation science methods. The sustainability of evidence-based mental health interventions in real-world settings has been hampered, in part, by a lack of engagement of those whom the interventions target and those who would fund and deliver them. The INSPIRE project attempts to engage stakeholders including recipients of the interventions, health and social care practitioners, community champions, local and central government officials, and policy makers, who can actively support in the delivery and have the power to allocate funds and resources to support the sustainability of interventions. While the main aim of Phase 1 of INSPIRE is to develop an intervention, adolescent girls and their families may benefit from meeting others with similar experiences, providing an opportunity to learn from each other and share information about services and support. Being involved in this process may have a positive impact on the self-confidence of adolescent girls and young women. Other stakeholders may benefit from participating in workshops alongside local adolescent girls, gaining valuable insight into their challenges and needs.

By identifying individual and systems-level barriers and facilitators to good mental health, the intervention developed, and implementation strategies used will leverage enablers for sustainability. Stakeholders can play an important part in identification of existing services in the community/health system in which the intervention might easily be embedded; integration of the intervention into existing or future policy or programme planning by local and/or national government and alignment of the intervention to the needs and goals of adolescent and their communities to support uptake and delivery of the intervention.

Potential limitations of the proposed program may include difficulties relating to recruitment of stakeholders. However, the local partners are experienced in conducting research and have established relationships with the local governing bodies and authorities which can be leveraged. The HCD method requires engagement of adolescent girls and young women and relies greatly on their engagement including during workshops. Researchers/facilitators will be trained to support and encourage their participation and to ensure that girls voices are heard during mixed stakeholder workshops.

Authors' contribution

TS, MT, SG, JW, and ND conceptualized the project. All authors contributed to the development of the protocol. KL and TS drafted the manuscript. All authors have contributed to and approved the manuscript.

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5. Declaration of completing interests

The authors declare no competing interests.

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List of abbreviations

AIM	Acceptability of Intervention Measure
CICI	Context and Implementation of Complex Intervention
FGD	Focus-group discussion
FIM	Feasibility of Intervention Measure
IAM	Intervention Appropriateness Measure
LMIC	Low- and middle-income country

ToC	Theory of change
UK	United Kingdom

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