Project for Reproductive Equity through Volunteers and Entrepreneurship, Networks and Technology
The PREVENT Project Protocol

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Background

Tanzania has one of the highest rates of adolescent fertility globally with 27% of girls in-between the ages of 15 and 19 being currently pregnant or having a previous pregnancy. Furthermore, the unmet need for contraceptive services is 42% for adolescent girls in Kilimanjaro Region.[1] As a result, many adolescent pregnancies are unplanned and unintended.[2]

Access to nearly all forms of contraceptive services in Tanzania are free of charge. However, adolescent girls often do not seek contraception through community clinics due to a plethora of factors. This includes the stigma and presumed promiscuity that is associated with accessing contraceptive services. The current method of accessing free contraceptive services lacks both privacy and confidentiality for girls in this age group.[3-5] Furthermore, a lack of exposure to education on adolescent friendly sexual and reproductive health (AFSRH) contributes to uptake of contraceptives among adolescent girls.[6] Barriers to access and uptake of contraceptive services are multifaceted and complex. While some barriers exist on an individual level, a country's approach to appreciating the importance of sexual and reproductive health services and rights are impacted by social, religious, and cultural norms, as well as political, economic, and legal contexts.[7-8]

The PREVENT Project is a multifaceted, adolescent friendly, culturally competent program addressing the issues surrounding unplanned pregnancies and lack of access and uptake of contraceptive services among adolescent girls. The intervention uses a mobile platform that provides educational SMS messaging, interactive voice response (IVR), and connects adolescent girls to community based AFSRH counselling services, as well as discreet contraceptive access points headed by female entrepreneurs (Figure 1). The program will be piloted for 12 months in various wards and villages in rural and urban Kilimanjaro, Tanzania.

Figure 1: The PREVENT Project Mobile Platform

Figure 1: The PREVENT mobile platform combines continuous educational SMS messaging on AFSRH topics, access to IVR counselling services, and details on contraceptive access points.

Objectives

The primary objectives of the outcome evaluation are to evaluate the effectiveness of the PREVENT program in reducing the unmet need for contraceptive access, reducing the number of unwanted/unplanned pregnancies, and improving SRH knowledge among participants. They will be measured using the following outcomes:

Primary Outcome:
- % Reduction in unmet need for contraceptives among study participants

Secondary Outcomes:
- Improved health knowledge among participants regarding sexual and reproductive health through engagement with the program
- Reduction in unwanted/unplanned pregnancies among participants in the program

Tertiary Outcomes:
- Number of beneficiaries who utilize the interactive voice response system and access AFSRH counseling
- Improved knowledge on non-judgmental, confidential and empowering care delivery practices for female clients aged 15-19 years among health workers, and SRH counselors

The acceptability and practicality of the intervention will be assessed using mixed methods. This includes questionnaires and focus groups that will be conducted with the study participants, as well as the medical and non-medical volunteers at the start and end of the pilot.

Methods

Study Participants
PREVENT will target adolescent girls from Newlands, Mabogini, Chekerini, and Pasua in rural and urban Kilimanjaro.

Inclusion Criteria
- Women 15-19 years of age
- Reside within the study area for the duration of the study
- Have a personal mobile phone and be willing to provide the phone number to the researchers to receive the intervention messages
- Report being SMS literate (ie. able to read text messages in English or Swahili)
- Be able and willing to return for follow-up after 12 months
- Be able and willing to give written informed consent for enrolment in the study

Exclusion Criteria
- Be pregnant or planning pregnancy within 12 months (assessed when obtaining consent using HCG urine dipstick).
- Participation in another study or intervention that may affect the outcome of this study.
- Having a medical or non-medical condition detected through screening that hinders study participation, as confirmed by the local principal investigator

Interventions Under Study
Adolescent girls who enroll into the PREVENT project will be individually randomized into one of two intervention groups (Table 1). Interventions under the PREVENT project were designed in accordance with the Tanzanian Ministry of Health and Social Welfare National Family Planning Guidelines and Standards, as well as the mobile health (mHealth) evidence reporting and assessment (mERA) checklist.[9, 10]

Table 1: Case and Control Interventions Under the PREVENT program

Intervention Group	Interventions
Control	**Education** . Receive educational SMS (text) messages on AFSRH . Access individually tailored educational resources through IVR services via PREVENT mobile platform **Personal Support** . Contact with a SRH community peer mentor in the community for AFSRH counselling and support
Case	**Education** . Receive educational SMS (text) messages on AFSRH . Access to individually tailored educational resources through IVR services via PREVENT mobile platform **Personal Support** . Contact with a SRH community peer mentor in the community for AFSRH counselling and support **Access to Contraception** . Provided with information on accessing PREVENT all contraceptive access points used in the study.

Table 1: While only the case groups receive the access to contraceptive access points, both case and control groups receive the education and personal support components of the intervention.

Sample Size Calculations and Considerations
Based on the 2015-2016 Demographic and Health Survey and Malaria Indicator Survey of Tanzania, we believe that 42% of the young women in the control arm will report having inadequate access to birth control at the end of the trial.[1] We believe that the intervention could reduce unmet need for contraception by over 10%, and we consider 10% a large enough improvement to support widespread implementation of the program. To achieve 90% power to detect a 10% difference (from 42% to 32%) between arms at a two-sided alpha=0.05, we would require approximately 477 participants per arm. However, we will double the sample size so that 90% power is maintained by an intent-to-treat analysis if up to 25% of the participants randomized to the control arm received the intervention and an additional 10% were lost to follow-up (inflation factor=1/[(1-crossover rate)2X(1-loss to follow-up rate)]=1/[(1-.25)2*(1-.1)]=1.975). Thus, we will enroll a total of 1908 participants.

Methods

Study Volunteer Team
The study will be heavily supported by a female-only team of medical and non-medical volunteers (Figure 1). While each group of volunteers will receive training tailored to their roles and responsibilities, all volunteers will receive basic training on how to use the mobile platform.

Figure 2: PREVENT Study Volunteer Team

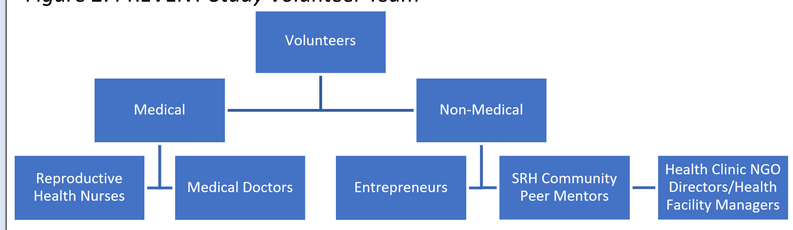

Figure 2: The interdisciplinary volunteer involves non-medical staff the manage enrollment and AFSRH counselling, while the medical volunteers provide medical care and family planning services.

Ethics and Dissemination

Participants will give written and oral consent after a counseling session. Consent will be confirmed by personally dated signature of both the participant and the person conducting the informed consent session. Consent forms will be kept and participants will be informed that they can withdraw participation and unenroll at any time. At the time of enrollment participants will be offered a pregnancy test that is voluntary; a pregnancy test is only required before receiving oral contraception and would be done at the time of obtainment. As this is a study on improving access, knowledge, and obtainment of contraception, and not a study on a new contraception medication or device or medical procedure, parental consent is not considered a necessary requirement for this age group and as per the Age of Consent: Legal Review Tanzania Country Report.[11]

Our findings will be disseminated through peer-reviewed journal publications and shared with local Tanzanian health officials and primary stakeholders.

Conclusion

The design aims to assess a mobile platform enabled method to improving access to contraceptive services among adolescent girls in Kilimanjaro, Tanzania. In doing so, adolescent girls and health workers will be provided with AFSRH education that in turn may reduce the number of unwanted pregnancies among adolescent girls in the region. If the results of the pilot demonstrate feasibility and preliminary effectiveness in reducing unmet need for contraceptive services, a larger scale randomized controlled trial will be conducted.

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