South Africa - Isisekelo Sempilo:Endline recruitment of participants

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Identification

SURVEY ID NUMBER
AHRI.IsisekeloSempilo.Endline.Recruitment.Datasets

TITLE
Isisekelo Sempilo:Endline recruitment of participants

COUNTRY

Name	Country code
South Africa	ZA

ABSTRACT
Background
Antiretroviral therapy (ART) through universal test and treat (UTT) and HIV pre-exposure prophylaxis (PrEP) substantially reduces HIV-related mortality, morbidity and incidence. Effective individual-level prevention modalities have not translated into population-level impact in southern Africa due to sub-optimal coverage among adolescents and youth who are hard to engage. We aim to investigate the feasibility, acceptability, and preliminary population level effectiveness of HIV prevention services with or without peer support to reduce prevalence of transmissible HIV amongst adolescents and young adults in KwaZulu-Natal.

Methods
A 2x2 factorial randomised controlled trial among young men and women aged 16-29 years, randomly selected from the Africa Health Research Institute demographic surveillance area. Participants are randomly allocated to one of four intervention combinations: 1) Standard of Care (SOC): nurse-led services for HIV testing plus ART if positive or PrEP for those eligible and negative; 2) Sexual and Reproductive Health (SRH): Baseline self-collected vaginal and urine samples with study-organized clinic appointments for results, treatment and delivery of HIV testing, ART and PrEP integrated with SRH services; 3) Peer-support: Study referral of participants to a peer navigator to assess their health, social and educational needs and provide risk-informed HIV prevention, including facilitating clinic attendance; or 4) SRH + peer-support.

The primary outcomes for effectiveness are: (1) the proportion of individuals with infectious HIV at 12 months and (2) uptake of risk-informed comprehensive HIV prevention services within 60 days of enrolment. At 12 months, all participants were contacted at home and the study team will collect a dried blood spot for HIV ELISA and HIV viral load testing.

Discussion
This trial will enable us to understand the relative importance of SRH and peer support in creating demand for effective and risk informed biomedical HIV prevention and preliminary data on their effectiveness on reducing the prevalence of transmissible HIV amongst all adolescents and youth.

Trial Registry: clincialtrials.gov
Trial registration: NCT04532307
<https://clinicaltrials.gov/ct2/show/NCT04532307>
Registered: March 2020

KIND OF DATA
Survey data, census/enumeration data, agreegate data, event/transaction data, program source code, machine-readable text, administrative records data, experimental data, psychological test, textual data, coded textual, coded documents, budget diaries, observation data/ratings, process-produced data, etc. No description just a single phrase, e.g., Genetic sequences

UNIT OF ANALYSIS
Basic unit(s) of analysis or observation that the study describes: For PANGEA is each record a sequence from a specimen, or are there multiple records for a single specimen or study participant

Version

VERSION DESCRIPTION
V1.0.0

Scope

KEYWORDS

Keyword	Vocabulary	URI
HIV prevention, sexual reproductive health, peer navigators, adaptive trial, homebased STI testing Coverage	Africa Health Research Institute	www.ahri.org

Coverage

GEOGRAPHIC COVERAGE

Demographic surveillance area of the Africa Health Research Institute; KwaZulu-Natal, uMkhanyakude district

UNIVERSE

We conducted a 2x2 factorial design intervention pilot trial including 1700500 men and women aged 16-29-years old and living in the AHRI surveillance area. The study duration was 18 28 months. Participants are randomly allocated to one of four intervention combinations: 1) Standard of Care (SOC): nurse-led services for HIV testing plus ART if positive or PrEP for those eligible and negative; 2) Sexual and Reproductive Health (SRH): Baseline self-collected vaginal and urine samples with study-organized clinic appointments for results, treatment and delivery of HIV testing, ART and PrEP integrated with SRH services; 3) Peer-support: Study referral of participants to a peer navigator to assess their health, social and educational needs and provide risk-informed HIV prevention, including facilitating clinic attendance; or 4) SRH + peer-support.

For our primary outcomes of interest, 1) the proportion of individuals with infectious HIV at 12 months and (2) uptake of risk-informed comprehensive HIV prevention services within 60 days of enrolment. we assessed uptake of comprehensive HIV prevention services, including Pre-Exposure Prophylaxis (PrEP) and Universal Test and Treat (UTT) and the reduction of the proportion of individuals at a population level with infectious HIV (population viral load).

Over a period of 12 months after enrolment and randomisation we collected routine data on uptake of Thetha Nami and Clinical Services as well as adverse events. At 12 months following enrolment we approached all those who were enrolled consented at endline by phone, in their homes or wherever they preferred to be seen. Following Informed Consent, we conducted a brief redcap survey to collect information on uptake and experience of HIV prevention and care services, uptake of contraception and incidence of pregnancy, mental health (using PHQ9), and quality of life. We also offered point of care HIV testing and linkage to care, collect dry blood spot for HIV ELISA and HIV viral load, and offered STI testing and treatment to all.

Throughout the study In addition, we conducted a mixed-method process evaluation to collect data on uptake and retention and fidelity of each component of the intervention; assess service users and providers and the community experience, i.e. which facets of the package are valued; and any social harms. A costing analysis will be undertaken to establish the cost of delivering the intervention through the different models of care.

Producers and sponsors

PRIMARY INVESTIGATORS

Name	Affiliation
Prof Maryam Shahmanesh	Africa Health Research Institute (AHRI)

PRODUCERS

Name
Africa Health Research Institute

FUNDING AGENCY/SPONSOR

Name	Abbreviation	Role

3ie	3ie	Funder
Nationational Institute of Health	NIH	Funder

OTHER IDENTIFICATIONS/ACKNOWLEDGMENTS

Name	Affiliation	Role
Jaco Dreyer	Africa Health Research Institute	Data management, cleaning and analysis

Sampling

SAMPLING PROCEDURE

We use the AHRI demographic surveillance as a sampling frame to select a random sample of 3000 men and women aged 16-29 years old, stratified by sex, and invite them to participate in the study. Individuals are eligible to enrol in the study if they are between 16-29 years old, resident in the surveillance area, willing and able to provide informed consent, willing to be followed up at 12 months, and willing to provide a dried blood spot (DBS) for anonymous HIV testing and HIV viral load measurement at 12 months. Based on previous studies in this setting, we expected that 2000 will be contactable and eligible, and 1500 (75%) will enrol. In fact we enrolled 1743.

Data collection

DATES OF DATA COLLECTION

Start	End
2021-09-16	2022-06-05

Access policy

ACCESS CONDITIONS

The representative of the Receiving Organization agrees to comply with the following conditions:

1. Access to the restricted data will be limited to the Lead Researcher and other members of the research team listed in this request.
2. Copies of the restricted data or any data created on the basis of the original data will not be copied or made available to anyone other than those mentioned in this Data Access Agreement, unless formally authorized by the Data Archive.
3. The data will only be processed for the stated statistical and research purpose. They will be used for solely for reporting of aggregated information, and not for investigation of specific individuals or organizations. Data will not in any way be used for any administrative, proprietary or law enforcement purposes.
4. The Lead Researcher must state if it is their intention to match the restricted microdata with any other micro-dataset. If any matching is to take place, details must be provided of the datasets to be matched and of the reasons for the matching. Any datasets created as a result of matching will be considered to be restricted and must comply with the terms of this Data Access Agreement.
5. The Lead Researcher undertakes that no attempt will be made to identify any individual person, family, business, enterprise or organization. If such a unique disclosure is made inadvertently, no use will be made of the identity of any person or establishment discovered and full details will be reported to the Data Archive. The identification will not be revealed to any other person not included in the Data Access Agreement.
6. The Lead Researcher will implement security measures to prevent unauthorized access to licensed microdata acquired from the Data Archive. The microdata must be destroyed upon the completion of this research, unless the Data Archive obtains satisfactory guarantee that the data can be secured and provides written authorization to the Receiving Organization to retain them. Destruction of the microdata will be confirmed in writing by the Lead Researcher to the Data Archive.
7. Any books, articles, conference papers, theses, dissertations, reports, or other publications that employ data obtained from the Data Archive will cite the source of data in accordance with the citation requirement provided with the dataset.
8. An electronic copy of all reports and publications based on the requested data will be sent to the Data Archive.
9. The original collector of the data, the Data Archive, and the relevant funding agencies bear no responsibility for use of the data or for interpretations or inferences based upon such uses.

10. This agreement will come into force on the date that approval is given for access to the restricted dataset and remain in force until the completion date of the project or an earlier date if the project is completed ahead of time.
11. If there are any changes to the project specification, security arrangements, personnel or organization detailed in this application form, it is the responsibility of the Lead Researcher to seek the agreement of the Data Archive to these changes. Where there is a change to the employer organization of the Lead Researcher this will involve a new application being made and termination of the original project.
12. Breaches of the agreement will be taken seriously and the Data Archive will take action against those responsible for the lapse if willful or accidental. Failure to comply with the directions of the Data Archive will be deemed to be a major breach of the agreement and may involve recourse to legal proceedings. The Data Archive will maintain and share with partner data archives a register of those individuals and organizations which are responsible for breaching the terms of the Data Access Agreement and will impose sanctions on release of future data to these parties.

Metadata production

DDI DOCUMENT ID
DDI.AHRI.IsisekeloSempilo.Endline.Recruitment.Datasets

PRODUCERS

Name	Abbreviation
Africa Health Research Institute	AHRI

Data Dictionary

Data file	Cases	Variables
AHRI.IsisekeloSempilo.AirtimeIncentive.2022.v1	1702	7
AHRI.IsisekeloSempilo.AssessmentOfCapacity.2022.v1	1702	8
AHRI.IsisekeloSempilo.CombinedDataset.2022.v1	1702	700
AHRI.IsisekeloSempilo.CompletionPage.2022.v1	1702	6
AHRI.IsisekeloSempilo.ContactAttempts.2022.v1	1702	79
AHRI.IsisekeloSempilo.DBSSpecimenCollection.2022.v1	1702	10
AHRI.IsisekeloSempilo.ExposureToIntervention.2022.v1	1702	35
AHRI.IsisekeloSempilo.IndivEduEcoNutritionSituation.2022.v1	1702	85
AHRI.IsisekeloSempilo.IndivGeneralHealth.2022.v1	1702	98
AHRI.IsisekeloSempilo.IndividualConsent_Age13-17.2022.v1	1702	14
AHRI.IsisekeloSempilo.IndividualConsent_Age18-30.2022.v1	1702	18
AHRI.IsisekeloSempilo.ManageHIVRapidTestAndResults.2022.v1	1702	22
AHRI.IsisekeloSempilo.MeasureMediateVars.2022.v1	1702	49
AHRI.IsisekeloSempilo.OtherRiskBehaviour.2022.v1	1702	6
AHRI.IsisekeloSempilo.ParentGuardianConsent.2022.v1	1702	11
AHRI.IsisekeloSempilo.PersonalInformation.2022.v1	1702	12
AHRI.IsisekeloSempilo.QualityOfLive.2022.v1	1702	9
AHRI.IsisekeloSempilo.SatisfyWithInterv.2022.v1	1702	20
AHRI.IsisekeloSempilo.SexualRelatInterviewer.2022.v1	1702	67
AHRI.IsisekeloSempilo.SexualRelatSelFilled.2022.v1	1702	187
AHRI.IsisekeloSempilo.STISampleCollection.2022.v1	1702	15