ISRCTN15013425 https://doi.org/10.1186/ISRCTN15013425

Sexually transmitted infections in CHIEDZA (STICH): Impact of testing for Chlamydia trachomatis, Neisseria gonorrhoeae and Trichomonas vaginalis and comprehensive STI management among youth aged 16-24 years in Zimbabwe

Submission date
01/06/2022

Recruitment status
No longer recruiting

Registration date
20/06/2022

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
CHIEDZA (Community based interventions to improve HIV outcomes in youth: a cluster randomised trial in Zimbabwe) is a cluster-randomised trial of a youth-friendly service (registered with the ClinicalTrials.gov number: NCT03719521). Its aim is to determine the impact of an integrated community-based package of HIV services incorporating HIV testing, linkage to care and ongoing adherence support, combined with sexual and reproductive health (SRH) services and general health counselling for 16- to 24-year-olds on population level HIV viral load in a high HIV prevalence setting.

The CHIEDZA intervention is a community-based package of services that includes: HIV testing and counselling, delivery of antiretroviral therapy, adherence support groups, mHealth, condoms, menstrual hygiene management, contraception and treatment of sexually transmitted infections, referral for voluntary medical male circumcision, risk reduction counselling and general health information and counselling. The intervention will be implemented over a 30 month period in each cluster. The intervention will be implemented in 3 provinces, and 4 clusters in each province, each with a population of approximately 2500 16–24-year-olds. These will be compared to 4 control clusters in each province.

STICH (Sexually Transmitted Infections in CHIEDZA) is an intervention consisting of outreach, promotion and mobilisation strategies applied to STI services, with unselected testing for chlamydia, gonorrhoea, and trichomonas, using urine tests, and treatment offered for those positive and their partners.

The aim of this study is to measure the impact of unselected STI testing and treatment of young people on population-level STI prevalence. The study will also:
1. Measure the impact of STI testing and treatment of young people on population-level prevalence of Chlamydia trachomatis, Neisseria gonorrhea, and Trichomonas vaginalis.
2. Determine uptake, prevalence, and yield of STI testing
3. Determine the uptake of partner notification
4. Describe acceptability of self-collected vaginal swabs
5. Determine factors predicting acceptance of STI testing
6. Assess knowledge, attitudes, and practices towards STIs, STI testing, and partner notification

Who can participate?
Screening will be offered to young people aged 16-24 years who live in Harare City and Bulawayo City in Zimbabwe during the time the study is running. Young people aged 18-24 years who live in randomly selected households on a STICH Day will be invited to participate in the prevalence survey .

What does the study involve?
A survey on STI prevalence will be conducted among young people aged 18-24 years living in randomly selected households on a day allocated to STICH sampling. The study involves provision of a urine sample from all participants to test for chlamydia, gonorrhoea, and trichomonas. Any participants who test positive for any STI will be followed up by telephone and offered free treatment and partner treatment.

What are the possible benefits and risks of participating?
The possible benefits of participating are receiving free testing and treatment for STIs and counselling. The possible risk of participating is that some of the topics discussed during counselling may be personal.

Where is the study run from?
Biomedical Research and Training Institute, Harare (Zimbabwe)

When is the study starting and how long is it expected to run for?
From April 2018 to December 2022

Who is funding the study?
London School of Hygiene and Tropical Medicine (UK)

Who is the main contact?
Dr Chido Dziva Chikwari
chido.dzivachikwari@lshtm.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Chido Dziva Chikwari

ORCID ID
https://orcid.org/0000-0003-1617-3603

Contact details
10 Seagrave Road
Avondale
Harare
Zimbabwe
00263
+263 772773879
chido.dzivachikwari@lshtm.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Grant codes: MR/T040327/1

Study information

Scientific Title
Impact of STI screening and comprehensive management among youth: a cluster randomised trial in Zimbabwe

Acronym
STICH

Study objectives
Community-based screening for and comprehensive management of curable STIs among adolescents and young people can reduce the population level prevalence of STIs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 12/02/2019 Medical Research Council of Zimbabwe (Josiah Tongogara/Mazoe Street, P.O. Box CY 573, Causeway, Harare, Zimbabwe; +263 791792; mrcz@mrcz.org.zw), ref: MRCZ/A/2387
2. Approved 25/04/2019 London School of Hygiene and Tropical Medicine Research Ethics Committee, (Keppel Street, London, UK, WC1E 7HT; +44 (0)2076368636; ethics@lshtm.ac.uk), ref: 16124 - 1

Study design
Multi-centre interventional cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis

Interventions
The study will be conducted in two provinces of Zimbabwe (Harare and Bulawayo). A total of 16 study clusters, stratified by province, will be randomised in a 1:1 allocation ratio to one of the following arms:
1. Control Arm - Existing SRH services
2. Intervention Arm - Community-based intervention including STICH

STICH (Sexually Transmitted Infections in CHIEDZA) is an intervention consisting of outreach, promotion, and mobilisation strategies applied to STI services for youth aged 16-24 years in community settings, with unselected testing, using urine tests, and treatment offered for those positive and their partners. The intervention will be implemented in 2 provinces (Harare and Bulawayo) and 4 clusters in each province, for a 12-month period, staggered by 3 months. These intervention clusters were randomly allocated and will be compared to 4 control clusters in each of the 2 provinces using a population-based prevalence survey of STIs.

Outcomes will be measured at the population level with a community cross-sectional survey, which will recruit 300 participants aged 18-24 years in each of the 16 clusters and will take place between October 2021 and March 2022.

Intervention Type
Other

Primary outcome(s)
The proportion of participants reporting a positive test result for any of Chlamydia trachomatis, Neisseria gonorrhea, and/or Trichomonas vaginalis measured using a community cross-sectional survey where urine samples for STI testing will be collected at a single time point for each participant. Indeterminate test results will be excluded.

Key secondary outcome(s))
1. The proportion of participants with each of the following STIs:
1.1. Chlamydia trachomatis measured using urine samples for STI testing collected at a single time point for each participant
1.2. Neisseria gonorrhea measured using urine samples for STI testing collected at a single time point for each participant
1.3. Trichomonas vaginalis measured using testing urine samples for STI testing collected at a single time point for each participant
2. The impact of STI testing and treatment of young people on population-level prevalence of Chlamydia trachomatis, Neisseria gonorrhea, and Trichomonas vaginalis measured by counting the numbers of participants who attend, who are tested, and who take up treatment, recorded on service uptake forms for the intervention, at a single time point for each participant
3. Uptake, prevalence, and yield of STI testing and treatment measured by counting the numbers of participants who attend, who are tested, and who take up treatment, recorded on service uptake forms for the intervention, at a single time point for each participant
4. Uptake of partner notification measured by counting the number of participants who take up partner notification, recorded on service uptake forms for the intervention, at a single time

point for each participant
5. Acceptability of self-collected vaginal swabs measured using structured questionnaires administered by research assistants to the study participants during the survey as well as service uptake data in the intervention collected at a single time point for each participant
6. Factors predicting acceptance of STI testing measured using structured questionnaires administered by research assistants to the study participants during the survey as well as service uptake data in the intervention collected at a single time point for each participant
7. Knowledge, attitudes, and practices towards STIs, STI testing, and partner notification measured using structured questionnaires administered by research assistants to the study participants during the survey as well as service uptake data in the intervention collected at a single time point for each participant

Completion date
31/12/2022

Eligibility

Key inclusion criteria
STICH intervention:
1. Lives within one of the STICH intervention clusters
2. Aged 16-24 years
3. Attends CHIEDZA service between 21 September 2020 and 30 September 2021 (Harare) or 1 January 2021 and 31 December 2021 (Bulawayo), the times when the STICH intervention is operational

Prevalence survey:
1. Aged 18-24 years
2. Consent from the household to participate
3. Surveyed on a day allocated to STICH sampling

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
24 years

Sex
All

Total final enrolment
15000

Key exclusion criteria
STICH intervention:
1. Has had an STI test within the previous 3 months

Prevalence survey:
1. Unable or willing to provide informed consent
2. Unable or unwilling to provide a urine sample

Date of first enrolment
21/09/2020

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
Zimbabwe

Study participating centre
Biomedical Research and Training Institute, Harare
10 Seagrave Raod
Car S Nujoma and Seagrave Road
Harare
Zimbabwe
00263

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
An anonymised dataset generated from the study will be stored in the publically available repository LSHTM Data Compass (https://datacompass.lshtm.ac.uk). Specific data-sharing plans will be made available at a later date.

Added 29/03/2023:
1. Name of the repository: LSHTM Data Compass (https://datacompass.lshtm.ac.uk/)
2. The data will be stored in two formats, as a Stata file and a csv file
3. Data will be publicly available. If for some reason it is not, there will be a button to request access at the weblink. All requests will be responded to within 30 days
4. Consent was obtained from participants
5. Data will be fully anonymised, including the removal of information such as date of birth

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/06/2024	25/06/2024	Yes	No
Results article	Primary outcome	14/11/2024	21/01/2025	Yes	No
Protocol article		14/02/2022	08/02/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	version 1.0	28/04/2022	16/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes