

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/06/2022	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2025	Condition category Infections and Infestations	<input type="checkbox"/> 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
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Study website

<https://www.chiedza.co.zw>

Contact information

Type(s)

Principal Investigator

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Screening

Participant information sheet

No participant information sheet available

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/04/2018

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

Age group

Mixed

Lower age limit

16 Years

Upper age limit

24 Years

Sex

Both

Target number of participants

The STICH intervention will be delivered to ~10000 youth and the endline survey will recruit 300 participants in each of the 16 clusters (4800 total)

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 Road

Car S Nujoma and Seagrave Road

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Sponsor information

Organisation

London School of Hygiene & Tropical Medicine

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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

Publication and dissemination plan

The protocol for the CHIEDZA study can be found at <https://wellcomeopenresearch.org/articles/7-54>. Findings will be presented locally to policy makers and other relevant stakeholders at provincial and national level meetings, and at local academic meetings. Results will also be shared with participating communities and collaborators. International dissemination will be through academic peer-reviewed publications in open-access journals and presentations at international meetings. A study report will be sent to regulatory authorities and a policy brief will be developed to facilitate translation of findings into health policy where appropriate.

Intention to publish date

01/07/2023

Individual participant data (IPD) sharing plan

An anonymised dataset generated from the study will be stored in the publicly 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?
Protocol article	version 1.0	14/02/2022	08/02/2023	Yes	No
Statistical Analysis Plan		28/04/2022	16/03/2023	No	No
Results article	Primary outcome	13/06/2024	25/06/2024	Yes	No
Results article		14/11/2024	21/01/2025	Yes	No