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Acceptability, feasibility and cost of point-of-care testing for sexually transmitted infections in adolescent health services in Cape Town, South Africa

Submission date
06/08/2023

Recruitment status
No longer recruiting

Registration date
09/01/2024

Overall study status
Completed

Last Edited
16/11/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Young people (YP) in southern Africa are at substantial risk of HIV and sexually transmitted infections (STIs). Despite the epidemiological and biological link between STIs and HIV transmission and acquisition, infections such as Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) remain widely undiagnosed. Syndromic STI management classifies STIs into easily identifiable groups of symptoms and signs and provides treatment for the most common organisms causing the syndrome and is the standard of care in low- and middle-income countries (LMICs) despite a high prevalence of asymptomatic infections. The study team conducted a prospective study to explore the acceptability, feasibility, and cost of an STI test-and-treat service for YP in Cape Town.

Who can participate?
YP aged between 15 and 23 years old who are service users at two adolescent-specific community health services

What does the study involve?
YP attending a mobile clinic (MC) and a youth centre clinic will be offered STI screening. Urine testing for CT and NG using a 90-minute molecular point-of-care (POC) test on the GeneXpert platform will be conducted and treatment provided. Data will be collated on demographics, sexual behaviour, presence of symptoms, uptake of same-day treatment, prevalence of CT/NG, and service acceptability.

What are the possible benefits and risks of participating?
STI testing services are not available in the public health sector in South Africa. As such, participants may benefit from free testing services that they would otherwise have to pay for privately to access. Participations with asymptomatic infections will benefit from access to direct testing options.

Participants are required to be sexually active to participate in the study and may be at risk of sexually transmitted infections, including HIV, and unintended pregnancy. As participants are adolescents, they may experience external or internal stigma around sexual activities and may feel distress, embarrassed, or uncomfortable while testing and waiting for the STI test results. All participants will receive risk reduction counselling to promote sexual health at every point of contact. All counselling related to sexual health or test procedures will be youth-orientated and youth-friendly. Participants are informed that their participation is voluntary and that they have the right to withdraw from the study at any time, without the risk of stigmatisation or victimisation.

Receiving a positive STI test has potential to cause distress. Participants will receive pre- and post-test counselling and are informed that they will receive access to treatment if they test positive for chlamydia or gonorrhoea.

Where is the study run from?
The Alexander Pringle Centre, North Middlesex Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2016 to March 2019

Who is funding the study?
The Desmond Tutu Health Foundation (formerly Desmond Tutu HIV Foundation) (South Africa), with GeneXpert modules and tests provided by Cepheid (USA)

Who is the main contact?
Dr Rebecca Marcus, rebeccamarcus@nhs.net (UK)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Acceptability, feasibility and cost of point-of-care testing for sexually transmitted infections in adolescent health services in Cape Town, South Africa

Acronym
STAX

Study objectives
Point of care testing for sexually transmitted infections in adolescent health services in Cape Town is acceptable, feasible and cost-effective

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/01/2017, Human Research Ethics Committee, University of Cape Town (E52-24 Old Main Building Groote Schuur Hospital Observatory, Cape Town, 7925, South Africa; +27 21 406 6338; hrec-enquiries@uct.ac.za), ref: HREC 339/2016

Study design
Prospective test-and-treat sexually transmitted infection programme study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Diagnostic, Screening, Treatment

Participant information sheet
Not available in web format, please use contact details to request a participation information sheet

Health condition(s) or problem(s) studied
Testing and treatment of chlamydia and gonorrhoea using molecular point of care testing

Interventions
Background
Young people (YP) in southern Africa are at substantial risk of HIV and sexually transmitted infections (STIs). Despite the epidemiological and biological link between STIs and HIV transmission and acquisition, infections such as Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) remain widely undiagnosed. Syndromic STI management is the standard of care in low- and middle-income settings (LMICs) despite a high prevalence of asymptomatic infections. This observational cross-sectional study will explore the acceptability, feasibility, and cost of an STI test-and-treat service for YP in Cape Town.

Participants will be offered STI screening and treatment for chlamydia (CT) and gonorrhoea (NG) using the Gene Xpert platform, molecular point-of-care technology that can detect CT/NG from a first-catch urine sample in under 90 minutes. If participants test positive for either infection, they will receive same-day treatment and contact tracing. Those who would like to participate will give informed consent. Prior to STI testing, study staff will administer a sexual risk behaviour and symptom questionnaire. Risk reduction counselling and condom provision will be performed at every visit. Participants will be offered the option to re-test after a 3-month period.

Study groups
15-23 year old adolescents living in Cape Town, South Africa. Two study cohorts were considered: adolescents receiving care from a clinic situated within a peri-urban youth centre (YC) in the southern peninsula of Cape Town and adolescents receiving care from a mobile clinic (MC) on rotation at different low-income, high-density locations in the Cape Town area.

Intervention provider
• Healthcare providers at the clinic and mobile service were registered nurses trained in adolescent-friendly healthcare delivery and HIV counselling.
• Medical doctors, which comprised a team of medical officers and infectious disease specialists, provided clinical oversight at both sites.

Modes of delivery
Services were provided face-to-face on an individual basis.

Locations
• Youth clinic: the youth clinic is a free-standing building located within a Youth Centre. It is situated in a peri-urban township area in the Southern peninsula of Cape Town.
• Mobile clinic: the mobile clinic is an established service provider run by the Desmond Tutu Health Foundation. The mobile clinic is equipped to conduct screening and testing related to sexual reproductive health as well as a range of HIV prevention and treatment options. The mobile operates on a schedule whereby it rotates across different low-income, high-density locations in the Cape Town area.

There is no overlap between the areas served by the youth clinic and the mobile clinic. All staff at each site are trained healthcare providers with experience in conducting clinical and socio-behavioural research studies. Infrastructure for the collection and safe storage of research data are available at each site.

Intervention Type
Mixed

Primary outcome measure
1. To evaluate the uptake of an STI test and treat programme for adolescents (aged 15-23 years) at a stand-alone youth clinic compared to a mobile clinic serving two peri-urban areas in Cape Town, South Africa. Participants will be offered free STI testing for chlamydia (CT) and gonorrhoea (NG) using a GeneXpert, a molecular point-of-care test that can detect CT/NG within 90 minutes.
2. To assess the acceptability of an STI test and treat programme amongst adolescents (aged 15-23 years) using a self-administrated paper-based questionnaire where participants rate the STI test and treat services by answering Likert-type scale questions (including how helpful the service was, whether they would use this service if it were more widely available and if participants experienced any negative consequences as a result of using the service).
3. To establish participant characteristics and site of testing associated with uptake of STI testing and treatment though a descriptive analysis of participant demographic details, disaggregated by site.

Secondary outcome measures
Establish the proportion of participants testing positive for chlamydia and/or gonorrhoea and the participant and site characteristics associated with positivity measured using the recorded results after the intervention

Overall study start date
05/10/2016

Completion date
08/03/2019

Eligibility

Key inclusion criteria
1. Aged between 15 and 23 years old
2. Willing and able to provide signed informed consent/assent for the study

3. Sexual activity within the past two years
4. Willing to wait for results, receive results by text/phone call, or return the following day for results

Participant type(s)
Service user

Age group
Mixed

Lower age limit
15 Years

Upper age limit
23 Years

Sex
Both

Target number of participants
400

Total final enrolment
366

Key exclusion criteria
1. Treatment for STI or presumed STI in the past 21 days
2. Has any condition that, in the opinion of the investigator, would preclude informed consent or make study participation unsafe
3. Appears psychologically unstable, intoxicated or under the influence of alcohol or other drugs at the time of informed consent

Date of first enrolment
23/02/2017

Date of final enrolment
28/08/2018

Locations

Countries of recruitment
South Africa

Study participating centre
Desmond Tutu Health Foundation (formerly Desmond Tutu HIV Foundation)
P.O. Box 13801
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Sponsor information

Organisation
Desmond Tutu HIV Foundation

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Sponsor type
Research organisation

Website
https://desmondtutuhealthfoundation.org.za/

ROR
https://ror.org/02asra118

Funder(s)

Funder type
Research organisation

Funder Name
Desmond Tutu Health Foundation (formerly Desmond Tutu HIV Foundation)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal, such as BMC Health Services Research

Intention to publish date
14/08/2023

Individual participant data (IPD) sharing plan
The datasets generated during and analysed from this study will be available on request from Carey Pike, carey.pike@hiv-research.org.za

Anonymised, de-linked databases have been shared on the University of Cape Town ZivaHub: https://zivahub.uct.ac.za/projects/The_STAX_Study/151755. These are available for review by interested parties. Consent from participants for participation in the study and the use of the data collected for research purposes was obtained.

IPD sharing plan summary
Available on request