

Improving access to health services for populations at higher risk for HIV infection in Tanzania

Submission date 27/08/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/11/2019	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

HIV/AIDS has rolled back decades of socio-economic development in Sub Saharan Africa. While there are indications of declining HIV infection rates in the general population, men who have sex with men (MSM), female sex workers (FSW) and people who inject drugs (PWIDS), now called Key Populations (KP) for HIV epidemic have 2-20 times higher infections rates and contributes up to 30% of new HIV infection. Despite such high infection rates, only a third has access to health services due to stigma and discriminations. The overall objective of this study is to increase access to health services among key populations through studying factors which influence the use of health services among them and test the effectiveness of healthcare worker and peer to peer engagement in improving access to comprehensive HIV intervention package among HIV at-risk population in Tanzania.

Who can participate?

Adults who inject drugs, men who regularly or occasionally engage in sexual relationships with other men, women who exchange sex for goods or money and healthcare workers.

What does the study involve?

The study involves the promotion of key population friendly facilities through training of healthcare workers on the comprehensive HIV intervention package and developing a cadre of peers to support health access. This will be done in Dar es salaam as an intervention region and Tanga region will be used as a control region.

What are the possible benefits and risks of participating?

Enrolling in the study will improve access to health services among study participants hence better health.

Where is the study run from?

The study will take place at the Muhimbili University of health and Allied Sciences Dar es salaam, Tanzania.

When is the study starting and how long is it expected to run for?
The study is planned to take place from May, 2017 to April, 2021.

Who is funding the study?
The Danida Fellowship Centre (DFC) through grant No 16-P03-TAN.

Who is the main contact?
Prof. Elia John Mmbaga (elijajelia@yahoo.co.uk).

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
16-P03-TAN

Study information

Scientific Title
Access to health services for key populations in Tanzania: a quasi-experimental design

Acronym

Study objectives

1. An interplay between individual, interpersonal, contextual, structural, and sociocultural and health system factors influence health service access among KP.
2. Integration of CHPs in the existing health system is feasible, sustainable and cost-effective.
3. Intervention delivery modalities developed by and for KP sustainably improve access to CHIPs for KP.
4. Building KP research capacity through masters and PhD training will increase the generation of new evidence and intervention evaluation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 15/03/2016, Muhimbili University of Health and Allied Sciences Ethics Committee (P.O. Box 65001; 022 2152489; drp@muhas.ac.tz), ref: 2016-03/AEC/Vol. IX/197.

Study design

Quasi Experimental Design

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

HIV infection

Interventions

Healthcare workers Training

Selected health care workers will be trained on the delivery of the comprehensive Intervention package for HIV which will include modules on prevention, HIV and STI testing, HIV treatment with ART, psychosocial counselling and violence mitigation.

Peer-to peer mentoring

Selected members of the key population will be trained and peer mentors on how to navigate their fellows to health facilities, linkage to KP friendly facilities and violence prevention.

Training timing

Training will be done during the second year and booster training is done after 12 months of follow up.

Participants follow up

Participants will be followed up after 12 months and 24 months following the intervention.

Intervention Type

Behavioural

Primary outcome measure

The proportion of the population at risk accessing HIV services is determined using questionnaire (if one has ever gone to a health facility during the past 12 months when one had STI or general conditions) at baseline, month 12 and 24 following the intervention.

Secondary outcome measures

1. Safer sexual behaviors are measured using Questionnaire (condom use at last sexual act, number of sexual partners past 12 months at baseline, months 12 and 24 following the intervention.
2. Number of PhD trained is measured using project records on the number of project affiliated PhD graduates at the end of the project (months 60).
3. Integration of high-risk group services into the existing health system is measured using health facility records of the number of health care workers and the number of the key population seeking services in the 4 selected health facilities involved in the project at baseline, month 12 and month 24.

Overall study start date

01/05/2017

Completion date

30/04/2021

Eligibility

Key inclusion criteria

1. Aged 18 or above and injects drugs.
2. Men who regularly or occasionally engage in sexual relationships with other men aged 18 and above.
3. Women who exchange sex for goods or money.
4. Health care workers aged 18 or above.

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

900 in intervention region and 900 from the control region (Total 1800)

Key exclusion criteria

1. Refuse to provide informed consent.
2. Not a resident of a participating region.
 - 2.1. Do not have an address and have not lived there for the past six months.
3. Have mental illness or are too sick to participate.

Date of first enrolment

01/11/2017

Date of final enrolment

31/03/2021

Locations**Countries of recruitment**

Tanzania

Study participating centre

Muhimbili University of Health and Allied Sciences

P.o.Box 65016

9 United Nation Road

Dar es Salaam

Tanzania

+255

Sponsor information**Organisation**

Danida Fellowship Centre DFC

Sponsor details

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research@dfcentre.dk

Sponsor type

Research council

Website

<https://dfcentre.com/about-us/contact/>

ROR

<https://ror.org/05qvpbw57>

Funder(s)

Funder type

Research council

Funder Name

Danida Fellowship Centre

Alternative Name(s)

DFC

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Denmark

Results and Publications

Publication and dissemination plan

1. Key population Community Advisory Board
2. Local and International Conferences
3. Local International seminars and symposium
4. Peer reviewed Journal Publication

Intention to publish date

01/04/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Elia John Mmbaga (elijahelia@yahoo.co.uk). Quantitative and qualitative data anonymized and will be available after publications or end of project on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/11/2019	08/11/2019	Yes	No