

Distributing HIV self-test kits through peer networks in Uganda

Submission date 23/08/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/11/2018	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 (human immunodeficiency virus) is a virus that damages the cells in the immune system and weakens the body's ability to fight everyday infections and disease. HIV testing rates remain low in sub-Saharan countries, particularly among men in highly mobile communities. The aim of this study is to find out whether the distribution of HIV self-testing kits through peer networks is feasible and can help address some barriers to HIV testing among fishing communities in Uganda. If so, it may help significantly increase the number of persons living with HIV who are aware of their infection and receive care.

Who can participate?

Men aged over 18 who are involved in fishing or fishing-related activities (e.g., fish trading) in Buliisa District in Uganda, an area bordering Lake Albert

What does the study involve?

First, 20 fishermen are recruited who are clients of HIV services (e.g., HIV testing clinic, antiretroviral treatment programs) supported by TASO-Uganda in Buliisa district. Each of these "seed" fishermen is given a number of HIV self-testing kits and is encouraged to distribute these kits to (some of) their peers who have not recently tested for HIV. Both the seed fishermen and the peers they recruit are then interviewed to assess if this mode of distribution of HIV self-test kit is safe and acceptable.

What are the possible benefits and risks of participating?

There are no direct benefits for participation in the study. Recruits may learn of their HIV infection during the course of the study and may then decide to access treatment services that will likely improve their health. Societal benefits may include identifying a new strategy for improving HIV testing, and the possibility of reducing further HIV transmission in affected populations. Potential risks include the risk for coercion and conflict faced by seeds and their potential recruits. For example, seed participants may occasionally face hostility from the peers they target for the distribution of HIV self-test kits. In some instances the seeds themselves may try to coerce peers and/or others into using HIV self-test kits. Other risks include risk of psychological distress following an HIV-positive test result, and the possibility of a breach in the confidentiality of study data.

Where is the study run from?

The AIDS Support Organization (TASO) – Masindi (Uganda)

When is the study starting and how long is it expected to run for?

March 2017 to June 2017

Who is funding the study?

National Institute of Allergy and Infectious Diseases (USA)

Who is the main contact?

Dr Stephane Helleringer

Contact information

Type(s)

Public

Contact name

Dr Stephane Helleringer

Contact details

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United States of America

MD 21205

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

IRB00007160

Study information

Scientific Title

Scaling-up HIV self-testing in fishing communities: a trial of distribution through peer networks in Uganda

Study objectives

The main objective is to assess the feasibility of distributing HIV self-test (HIVST) kits through the peer networks of fishermen to men who have not recently been tested for HIV. Fishermen are one of the population groups most at risk of HIV infection in Uganda and throughout Eastern Africa

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional review boards of:

1. The Johns Hopkins University Bloomberg School of Public Health in the US, 27/09/2016, ref: IRB00007160
2. The AIDS Support Organization (TASO) in Uganda, 14/10/2016, ref: TASOREC/41/16-UG-REC-009

Study design

Pilot single-arm study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Screening

Participant information sheet

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

Health condition(s) or problem(s) studied

HIV

Interventions

The study is a pilot study designed to assess the feasibility of delivering HIVST through peer networks in fishing communities of Uganda with high HIV prevalence. It is a one-arm trial of the provision of HIVST kits through peer networks. It entails recruiting 20 "seeds", i.e., fishermen who are already clients of HIV-related services. These seeds are then given up to five HIVST kits to distribute to peers (i.e., other fishermen) who have not been tested for HIV within the past year. The peers who accept these test kits then constitute "HIVST recruits" and are enrolled into the study through respondent-driven sampling (RDS), a referral procedure commonly used in studies of hard-to-reach populations. Seeds are re-interviewed one month after their initial visit to assess adverse events and uptake of HIV testing.

Intervention Type

Behavioural

Primary outcome measure

Proportion of instances of coercion among all distributed HIVST recruits, measured when recruits present for study assessment by asking recruits during an interview whether they have experienced any instance of coercion of social influence in deciding whether to use the self-test kits. Recruits are enrolled in the study through the use of a referral coupon given to them by the seeds.

Secondary outcome measures

Measured during interviews with recruits and during a follow-up interview with seeds one month after enrollment. All interviews are conducted using audio computer-assisted self-interviewing (ACASI) to reduce social desirability bias in data about sensitive behaviors (e.g., HIV testing):

1. Instances of psychological distress following an HIV-positive test result among recruits
2. Cases of inter-personal violence and harm reported by the seeds and/or the recruits
3. The proportion of HIVST recruits who are peers (i.e., fishermen)
4. Proportion of recruits tested within the last month
5. Proportion of new testers among recruits reached with HIVST
6. Proportion of recruits linked to care and treatment

7. Specificity of HIVST in measuring the HIV status of recruits

8. Sensitivity of HIVST in measuring the HIV status of recruits

Measured by comparing 1) the self-reported self-test results by the recruits, 2) reading the used HIV self-test kits returned by recruits, and 3) confirmatory HIV testing conducted by a health worker

Overall study start date

01/03/2017

Completion date

30/06/2017

Eligibility

Key inclusion criteria

The inclusion criteria for seed participants are:

1. Male
2. More than 18 years old
3. Involved in fishing or fishing-related activities (e.g., fish trading)
4. A client of the participating TASO facility HIV-related services (either ART services or HIV testing and counseling)
5. Not married or having a sexual partner at the time of enrollment

The HIVST recruits are individuals who are distributed HIVST kits by the seeds, and are referred to the health facility for assessment using a referral coupon. Seeds are instructed to recruit individuals who are:

1. Males
2. Engage in fishing activities
3. Have not been tested for HIV in more than a year
4. Aged 18 years or older

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

20 seeds and up to 100 recruits

Key exclusion criteria

1. Female
2. Younger than 18 years old
3. Not engaged in fishing activities
4. Married and/or having a sexual partner at the time of enrollment. This exclusion criterion is added because the aim is to assess the feasibility of distributing HIVST kits through peer networks, whereas married and/or partnered individuals may primarily target their spouse and/or sexual partner(s) for distribution of HIVST kits

Date of first enrolment

01/04/2017

Date of final enrolment

30/04/2017

Locations

Countries of recruitment

Uganda

Study participating centre

The AIDS Support Organization (TASO) - Masindi

Masindi

Uganda

PO Box 10443, Kampala

Sponsor information

Organisation

Johns Hopkins University

Sponsor details

615 N Wolfe Street

Baltimore

United States of America

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Sponsor type

University/education

ROR

<https://ror.org/00za53h95>

Funder(s)

Funder type

Government

Funder Name

National Institute of Allergy and Infectious Diseases

Alternative Name(s)

Instituto Nacional de Alergias y Enfermedades Infecciosas, National Institute of Allergy & Infectious Diseases, NIAID

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Publication and dissemination plan

Initial study findings have been presented at the IAS conference in Paris in July 2017. The trialists intend to publish the final results of the trial in a high-impact journal before the end of 2017. The study protocol, data analysis plan as well as the study dataset and replication files will be made available at the time of study publication.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

2017 results presented at ICASA 2017: <http://www.professionalabstracts.com/icasa2017/iplanner/#/list>

IPD sharing plan summary
Other