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Investigating ways of encouraging fishermen in Malawi to access schistosomiasis and HIV testing and treatment

Submission date
28/09/2020

Recruitment status
No longer recruiting

Registration date
05/10/2020

Overall study status
Completed

Last Edited
17/12/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Both HIV infection and schistosomiasis (infection with a parasitic flatworm caught by contact with fresh water) are major public health problems worldwide, with 1.8 million new HIV infections each year and up to 110 million untreated schistosomiasis (bilharzia) cases globally. The Rift Valley in Africa suffers a high rate of both HIV infection and schistosomiasis, but both are treatable if the infection is diagnosed. Lake fishermen are more at risk of HIV and schistosomiasis than the general population. Recent studies have suggested that female genital schistosomiasis increases the risk of HIV infection 3 to 4 times in women. The link between HIV and genital schistosomiasis is not yet established in men, but it is biologically plausible. There are local initiatives to control HIV in fishing communities, but these might not reach everyone and it is not known whether HIV and schistosomiasis can be tackled together effectively.
The aim of this trial is to identify the best methods of delivering integrated HIV and schistosomiasis services for fishermen, particularly investigating the effect of using social networks, HIV self-test kits and beach clinic services.

Who can participate?
Male adult (aged 18 years or older) fishermen resident in the Mangochi lake district of Malawi

What does the study involve?
Boat teams of fishermen will be randomly allocated to one of three arms. The first group will be given a leaflet explaining the importance of receiving treatment for schistosomiasis (a drug called praziquantel) and HIV services for fishermen. The second group will receive the leaflet and will have it explained to them by a fellow fisherman who has been trained as a peer educator. The third group will receive the leaflet and will have it explained to them by a fellow fisherman who has been trained as a peer educator and will also provide HIV self-test kits to the group.
A beach clinic will be set up as part of the trial. The clinic will provide HIV services including HIV testing and referral for treatment at the nearest HIV treatment clinic, and treatment for schistosomiasis without a diagnosis (presumptive treatment) for all trial arms. 9 months following delivery of the trial services, fishermen will provide a urine sample to assess the

percentage of fishermen cured from genital schistosomiasis as well as answering questions on whether they started HIV treatment for those with a positive HIV test result.

What are the possible benefits and risks of participating?
Potential risks include discomfort with some questions on the questionnaire. Treatment for schistosomiasis may lead to headache, nausea, abdominal pain, dizziness, drowsiness, fatigue, weakness, joint/muscle pains, loss of appetite, vomiting, sweating, itching. These are usually mild and transient, lasting from 30 minutes to up to 4 hours. Serious side effects that are very rare include bloody diarrhoea, fever, irregular or slow heartbeat or seizures/convulsions.
There are no side effects to using oral HIV self-test kits. However, misunderstandings between the wider fishermen group and the peer educator may occur and could lead to physical violence or abuse.
There are no direct benefits for participating in the trial.

Where is the study run from?
Malawi Liverpool Wellcome Trust Clinical Research Programme (Malawi)

When is the study starting and how long is it expected to run for?
August 2019 to December 2024

Who is funding the study?
Wellcome Trust (UK) and the National Institute for Health Research (UK)

Who is the main contact?
Dr Augustine Choko, achoko@mlw.mw

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

WT 216458/Z/19/Z

Study information

Scientific Title
Creating demand for fishermen’s schistosomiasis and HIV services (FISH): piloting and delivery of a 3-arm cluster randomized control trial (cRCT) in Malawi

Acronym
FISH

Study objectives
HIV self-testing (HIVST) promoted by peer educators (PE) or provided by peer-distributor-educators (PDE) will achieve higher coverage of health interventions (recent HIV testing, linkage to voluntary male medical circumcision [VMMC] and antiretroviral therapy [ART] as indicated, and praziquantel) than beach-side services alone, and will leave men with increased understanding of the benefits of early treatment and prevention for both diseases.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 16/09/2020, University of Malawi College of Medicine Research and Ethics Committee, (Mahatma Gandhi Road, Chimutu Building Room # 822, P/Bag 360 Chichiri, Blantyre 3, Malawi; +265 01 871 911/01 874 377; comrec@medcol.mw), ref: P.03/20/2975
2. Approved 14/04/2020, Liverpool School of Tropical Medicine Research Ethics Committee (Pembroke Place, Liverpool, L3 5QA, UK; +44 (0)151 705 3100; lstmrec@lstmed.ac.uk), ref: 20-027

Study design
3-arm open-label cluster randomized trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
HIV infection and/or schistosomiasis (Schistosoma haematobium) infection

Interventions
'Boat teams' will be randomised 1:1:1 using computerized restricted randomization (geographical spread, cluster size, traditional authority, and HIV and schistosomiasis estimates) at a public randomisation ceremony.

Arms:
1. Standard of care (SOC) arm with leaflets available at the shore explaining the importance of receiving presumptive treatment for schistosomiasis (praziquantel) and HIV services for fishermen
2. SOC plus a peer (peer-educator [PE]) explaining the leaflet to his fellow fishermen in a boat

team
3. Peer-distributor-educator (PDE) arm with HIV self-test kits delivered to the boat team fishermen by the PDE in addition to the PDE explaining the leaflet

Intervention Type
Mixed

Primary outcome(s)
All primary outcome measures will be assessed at 9 months of trial delivery
1. Number of boat-team fishermen who self-report starting ART
2. Number of boat-team fishermen who self-report undergoing VMMC
3. Number of boat-team fishermen who have at least one S. haematobium egg seen on light microscopy of the filtrate from 10 ml urine ('egg-positive').

Key secondary outcome(s)
All secondary outcome measures will be assessed at 9 months of trial delivery
1. Number of boat-team fishermen who self-report recent (last 9 months) HIV testing
2. HIV prevention knowledge score assessed using a questionnaire at endline (9 months after enrollment)
3. Schistosomiasis knowledge score assessed using a questionnaire at endline (9 months after enrollment)
4. Number of boat-team fishermen who self-report high-risk sex in the previous month
5. S. haematobium intensity assessed using urine sample at endline (9 months after enrollment)

Completion date
30/12/2024

Eligibility

Key inclusion criteria
1. Fisherman resident in a fishing community in Mangochi, Malawi
2. Aged 18 years or older

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria

1. Already on HIV treatment
2. Already taken praziquantel in the last 3 months

Date of first enrolment
01/01/2021

Date of final enrolment
30/10/2021

Locations

Countries of recruitment
Malawi

Study participating centre
Mangochi District Health Office
Ministry of Health
Mangochi District Hospital
PO Box 42
Mangochi
Mangochi
Malawi
265

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (https://datacompass.lshtm.ac.uk/)

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Baseline survey findings	04/05/2023	09/05/2023	Yes	No
Protocol article		07/01/2022	10/01/2022	Yes	No
Participant information sheet	version v1.3	26/08/2020	05/10/2020	No	Yes
Participant information sheet	version v1.3	26/08/2020	05/10/2020	No	Yes
Protocol file	version 1.4	11/01/2021	20/07/2022	No	Yes

Statistical Analysis Plan	version 0.1	20/07/2022	20/07/2022	No	Yes