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Intensified HIV/TB prevention linking home-based HIV testing, including the option of self-testing, with HIV care

Submission date
26/02/2012

Recruitment status
No longer recruiting

Registration date
29/02/2012

Overall study status
Completed

Last Edited
17/07/2020

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
All countries in Southern Africa, including Malawi, have been affected by greatly increasing rates of tuberculosis (TB) because of the Human immunodeficiency virus (HIV) epidemic. People with HIV infection have a high risk of getting sick with TB if they become infected. In countries where both TB and HIV infection are common, such as Malawi, about one third of adults have TB infection in the body (latent TB infection) and most TB patients are HIV positive. People with HIV can be protected from TB using drugs to treat their HIV (antiretroviral treatment), or drugs to treat latent TB infection. However, uptake and frequency of HIV testing through routine services remains too low to identify HIV before the onset of TB in many patients, and when HIV is diagnosed many patients delay seeking care for many months or even years. The aim of this study is to investigate whether or not local HIV testing and counselling services will increase knowledge of HIV status and encourage early entry into HIV care leading to fewer new episodes of TB among the entire community. HIV testing will include the option of self-testing for HIV at home and in private. HIV care will be provided through the routine public health services, but with the addition of a drug (isoniazid) provided by the study team to prevent TB.

Who can participate?
All adults living in the 14 neighbourhoods that receive the self-testing intervention.

What does the study involve?
28 neighbourhoods of about 1,200 adult residents are randomly allocated to one of two groups: one group of 14 neighbourhoods receiving the self-testing intervention; one group of 14 neighbourhoods receive standard care. Each neighbourhood is followed up for two and half years, with recording of all TB cases and adult deaths. A survey at the end of two and half years investigates the amount of undiagnosed HIV left after the study. Adults from the intervention neighbourhoods are offered local HIV test services from the house of one of their neighbours who is trained as a resident community counsellor. Residents are able to bring their partners so that they can test together. Each resident is able to receive two HIV tests in the first year of study, and can choose to self-test in private without having to disclose their results. TB symptom screening is carried out with HIV counselling before the test. After the test, community

counsellors provide information that can be given without knowing the result. All participants are advised to go to their local primary care clinic for confirmatory testing for HIV and HIV care if their self-test was positive. All participants are provided with information and a self-referral slip to encourage them to access local HIV care services. Antiretroviral treatment is provided through national HIV care services. HIV-positive adults for the intervention neighbourhoods are offered isoniazid preventive therapy (which is national policy, but not yet implemented in Malawi) as part of their routine HIV care. Addresses from TB patients registering for treatment with the routine health services are used to identify whether or not they live in a study cluster. Four volunteers are recruited from each of the study neighbourhoods to meet regularly with study staff. Volunteers report any deaths occurring in their neighbourhood. Households are visited when a death occurs in order to interview the main carer about the circumstances leading up to the person's death.

What are the possible benefits and risks for participating?
Having an HIV test is stressful, and some people find it difficult to cope after a positive result. Some studies have shown that relationships can suffer, including a risk of violence, if one partner is found to be HIV-positive. There is very little known about self-testing for HIV, but there may be an increased risk of not coping when people decide to self-test and then find themselves to be HIV positive without a counsellor there to help them. People who are HIV infected are less likely to die or suffer serious illnesses if they find out and start taking treatment before their HIV infection is very advanced. Isoniazid preventive therapy is international standard of care for people living with HIV, and reduces the risk of getting sick with TB. There is a small risk of side effects, including inflammation of the liver.

Where is the study run from?
The study neighbourhoods are all in poor suburbs in the City of Blantyre, Malawi. The study is run from the Malawi-Liverpool-Wellcome Trust Clinical Research Programme and the College of Medicine, both of which are in Blantyre, Malawi, and is supported from the London School of Hygiene and Tropical Medicine and Liverpool School of Tropical Medicine, in the UK.

When is the study starting and how long is it expected to run for?
March 2012 to September 2015

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
Dr Liz Corbett
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1.1

Study information

Scientific Title
Intensified HIV/TB prevention linking home-based HIV testing, including the option of self-testing, with HIV care: a cluster-randomised trial in Blantyre, Malawi

Study objectives
A package of care including:
1. Convenient local access to home-based human immunodeficiency virus (HIV) self-testing, provided with generic (not results based) counselling and
2. Facilitated access to HIV care including isoniazid preventive therapy and routine antiretroviral therapy (ART), will have sufficient impact on the uptake and timeliness of HIV diagnosis and care to result in population-level reduction in TB incidence and untreated HIV infections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. College of Medicine Research Ethics (COMREC), 01/04/2011, ref: P02/11/1037
2. London School of Hygiene and Tropical Medicine (LSHTM), 06/09/2011, ref: 6021

Study design
Cluster randomised trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)/Tuberculosis (TB)

Interventions
Intervention versus Standard of Care (SOC)

Intervention:
1. Provision of access to home-based HIV testing and counselling and tuberculosis (TB) symptom

screening, including the option of self-testing (without need to disclose results), through resident community counsellors
2. Faciliated access into routine facility-based HIV and TB care services through use of a "self-referral" card and post-test information provided at the time of community-based HIV testing and counselling
3. Delivery of isoniazid preventive therapy (300mg once daily for 6 months) and pyridoxine (25mg once daily while taking IPT) through the existing facility-based routine HIV care services for all intervention-arm adult cluster residents accessing local HIV care services.

SOC: Routine facility-based access to HIV testing and care services

All clusters - adult residents will be followed for TB over 2.5 years, ending with an HIV/TB survey in month 31.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The case-notification rate of bacteriologically-confirmed TB in adult (16 yrs or older) cluster residents, in months 7 to 31 of intervention

Key secondary outcome(s))
1. The case-notification rate of bacteriologically-confirmed TB in HIV-positive adult residents in months 7 to 31 of intervention. This analysis will use cluster-specific HIV prevalence estimate from a post-intervention HIV/TB prevalence survey as the denominator
2. The prevalence of HIV infection that, by self-report, is either undiagnosed (no previous positive HIV test) or not being treated [neither antiretroviral therapy (ART), nor cotrimoxazole nor isoniazid preventive therapy (IPT)] at the time of the post-intervention prevalence survey (month 31 after the start of intervention)

Completion date
30/09/2015

Eligibility

Key inclusion criteria
Home-based HIV testing and counselling:
1. Age 16 years or above
2. Usual residence within a study cluster
3. Able and willing to provide written or witnessed informed consent to HTC, either as standard counsellor-provided or as supervised self-testing

Supervised self-testing only:
1. Attends in person to collect kit
2. Passes a test of understanding
3. Agrees to return test kit packaging and the used kit in a sealed envelope
4. Agrees to receive post-test health information

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age 15 years or below
2. Usual residence outside of the intervention cluster
3. Has tested previously on 2 occasions under the community counsellor system

Date of first enrolment
01/03/2012

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
United Kingdom

England

Malawi

Study participating centre
London School of Hygiene and Tropical Medicine
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust - Senior Fellowship Renewal (GR014469)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/02/2016		Yes	No
Results article	results	01/07/2017		Yes	No
Results article	results	01/07/2017		Yes	No
Results article	cost-effectiveness results	03/04/2018		Yes	No
Results article	qualitative results	01/03/2019	17/07/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes