

Sustainable household contact tracing and screening for tuberculosis patients and families in Blantyre, Malawi

Submission date 27/03/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/07/2012	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/09/2022	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Tuberculosis (TB) is a bacterial infection that mainly affects the lungs. It is national and international policy to reduce the spread of TB by screening all household contacts of TB patients. This active case-finding is more effective than passive case-finding, but also more expensive. Contact screening identifies candidates for both TB treatment and preventive treatment with the antibiotic isoniazid. In Malawi, household contact screening involves health workers advising index patients (the first patient in the family to be diagnosed with TB) to bring their contacts for symptom screening and clinical investigations if needed. However, this service has been poorly carried out and often not used, possibly due to transport costs and the time required to complete the screening process. The aim of this study is to test the effectiveness of a home-based TB screening intervention in the households of TB patients in urban Blantyre, Malawi.

Who can participate?

Children and adults of all ages in Blantyre, Malawi who are household contacts of pulmonary TB patients.

What does the study involve?

Participants are randomly allocated to one of two groups. One group follows the standard routine of household screening provided at the health facility. In the other group screening is carried out by either the index patient or the parent in the household. They sort household members into contacts who need TB investigation, or are eligible for isoniazid preventive treatment (IPT), and those where no further action is required. They collect sputum (a thick fluid produced in the lungs and airways) for examination from household members who have symptoms but are otherwise well. The index patient can then bring all children eligible for IPT with them to their next routine appointment (TB drugs are collected weekly from primary care clinics), where IPT can be started. If the index patient is not the parent/guardian, then the children have to be accompanied by their parent/guardian. Thereafter the index patient, or

parent of the children (if not the index patient) can collect isoniazid and carry out monthly symptom screening for isoniazid side-effects on behalf of all family members, thereby reducing the need for travel.

What are the possible benefits and risks of participating?

There are no risks associated with joining this study and treatment will be affected not in any way. If participants have any other illnesses other than TB, they will be referred for treatment.

Where is the study run from?

Queen Elizabeth Central Hospital, Blantyre, Malawi

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

June 2012 to December 2014

Who is funding the study?

Helsen Nord TB Initiative (HNTI) in collaboration with Malawi National TB Control Programme

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Study information

Scientific Title

Providing sustainable household contact tracing and screening for tuberculosis patients and families: a cluster randomised trial in Blantyre, Malawi (PACTS)

Acronym

PaCTS

Study objectives

1. Standard models of delivering contact screening, which are facility based, are ineffective because of the high burden of transport costs and time that are placed on tuberculosis (TB) patients and their families
2. That a Patient/parent-delivered contact screening model that aims to minimize the cost and inconvenience to the family will provide substantially higher uptake with TB symptom screening, higher yield of cases, and higher uptake and completion rates for IPT

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. College of Medicine Research Ethic Committee, Malawi, 01/04/2012
2. London School Of Hygiene and Tropical Medicine, UK, 25/04/2012

Study design

Cluster randomised trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Tuberculosis

Interventions

Parent/patient/household based contact based screening will be used to investigate a newly-developed approach of:

1. Initiating contact screening at home by the patient themselves, with the index patient then also responsible for:
 - 1.1. Triaging household members into contacts who need TB investigation, or are eligible for IPT, and those where no further action is indicated
 - 1.2. Collecting and bringing sputum for examination from symptomatic household members who are otherwise well
 - 1.3. Initiating other actions as indicated, aided by contact referral cards that can be used to directly access paediatric services for under 5 year old family members with symptoms of TB
2. The index patient can then bring all children eligible for IPT with them to their next routine appointment (TB drugs are collected weekly from primary care clinics), where IPT can be initiated. If the index patient is not the parent/guardian, then the child(ren) will have to be accompanied by their parent/guardian
3. Thereafter the index patient, or parent of the children (if not the index patient) can assume responsibility for collecting isoniazid and carrying out monthly symptom screening for isoniazid side-effects on behalf of all family members, thereby minimizing the need for travel

The screening tool will include questions about cough, fever, weight loss, night sweats, and (for young children) failure to thrive.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. The prevalence of bacteriologically confirmed TB in adult and child contacts diagnosed within three months of the diagnosis of the index case
2. The proportion of child contacts under 5 year who start IPT within three months of the diagnosis of the index case

Key secondary outcome(s)

The proportions of contacts under 5 years old who initiate and complete 6 months of IPT

Completion date

30/12/2014

Eligibility**Key inclusion criteria**

1. Pulmonary tuberculosis (PTB) patients registering at Queen Elizabeth Central Hospital (QECH), Malawi
2. Self-report of one or more under 5 year old household contact
3. Residence within Blantyre
4. Able and willing to provide written consent to participate in the study, including a 3 month household visit
5. If an inpatient: likely to be discharged within a two week period

Contacts will be defined as members of the same household (defined as sharing meals) or other residents of the same dwelling who share physical space such as sleeping or living rooms. Participation by contacts will be through oral consent, using a patient information leaflet.

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

1. Unable or unwilling to provide informed consent
2. Hospitalised patients who are unlikely to be discharged within a two week period (e.g due to retreatment requiring on TB treatment, and if transferred in and out of QECH)
3. Membership of a household that has already been recruited into the study

Date of first enrolment

01/06/2012

Date of final enrolment

30/12/2014

Locations

Countries of recruitment

Malawi

Study participating centre

Helse Nord Tuberculosis Initiative (HNTI)

Blantyre

Malawi

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Sponsor information

Organisation

Malawi National Tuberculosis Programme (Malawi)

Funder(s)

Funder type

Research organisation

Funder Name

Helse Nord TB Initiative Project (Malawi)

Funder Name

Malawi Liverpool Wellcome Trust (Malawi)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		08/09/2022	09/09/2022	Yes	No