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

Submission date
27/03/2012

Recruitment status
No longer recruiting

Registration date
19/07/2012

Overall study status
Completed

Last Edited
09/09/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
N/A

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 Reasearch Ethic Commitee, 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 paediatic 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