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Addressing the social determinants and consequences of tuberculosis

Submission date	**Recruitment status**	[X] Prospectively registered
20/08/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/08/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/10/2025	Respiratory	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Tuberculosis (TB) is a bacterial infection spread through inhaling tiny droplets from the coughs or sneezes of an infected person. It mainly affects the lungs, but it can affect any part of the body, including the tummy (abdomen), glands, bones and nervous system. TB is a potentially serious condition, but it can be cured if it's treated with the right antibiotics.

Biomedical approaches do not address the main driver of TB: poverty. To do so, the World Health Organization's 'End TB Strategy' advocates social and economic (socioeconomic) support for TB-affected households. Despite preliminary evidence from middle-income Peru, there is no evidence for socioeconomic support for TB-affected households in low-income countries. To address this, we developed a locally-appropriate support intervention for TB-affected households in Nepal. The aim of the ASCOT pilot trial is to now field-test the feasibility and acceptability of the support intervention.

Who can participate?

The pilot trial will recruit 120 people with TB notified to the Nepal National TB Program (NTP) to participate. The integrated process evaluation will recruit 40 multisectoral stakeholders to participate including NTP staff, civil society members, policy makers, and ASCOT field team members.

What does the study involve?

The 120 participants will be randomised to receive i) control standard of care (30 participants), ii) social support (30 participants), iii) economic support (30 participants), and iv) socioeconomic support (30 participants). Social support will be peer-led mutual support groups in TB-affected households providing enhanced TB education and stigma reduction counselling. Economic support will be monthly cash transfers during TB treatment with expectations (not conditions) of meeting NTP goals. At 0, 2, and 6 months following TB treatment initiation, participants will be asked to complete a WHO-adapted longitudinal survey detailing the social determinants and impact of TB and also feedback their experiences of ASCOT. Process evaluation: we will complement survey data with focus group discussions (FGD), key informant interviews (KII), and a workshop with multi-sectoral stakeholders on the challenges to ASCOT’s implementation and scale-up.

What are the possible benefits and risks of participating?
Benefits to participants include:
i) One-off food basket and standard TB education package: for all participants
ii) Enhanced TB education package: for people in social support arm and socioeconomic support arm
iii) Cash transfer: for people in economic support arm or socioeconomic support arm
iv) Mutual support, stigma reduction, and empowerment through home visits and TB Clubs: for people in social support arm and socioeconomic support arm
v) Compensation for time spent participating in the study: all participants as standard at rate relevant to local context and decided by Birat Nepal Medical Trust
Risks and their mitigation include:
i) Potential for stigma relating to TB: Counselling by ASCOT field team members and informed consent of participants, which includes written and video information about the ASCOT study and focuses on the need for a randomised trial to establish the evidence for acceptability, feasibility, and impact of socioeconomic support in order that more people in Nepal might benefit if it was scaled up.
ii) Potential for ill-feeling if randomised to control arm rather than receiving the intervention or social support intervention arm rather than economic or socioeconomic intervention arm: The randomisation process will be transparent and done in real-time in front of participants.
iii) Economic support may create issues with power dynamics within households: The economic support will be accompanied by education about the expectations of how money might be used (but not conditions). In addition, the participant can nominate another member of their household to receive the economic support if they so wish as has been the case in the Chief Investigator's previous research in Peru.

Where is the study run from?
Liverpool School of Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
March 2021 to March 2025

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Protocol serial number
MR/V004832/1

Study information

Scientific Title
Addressing the Social Determinants and Consequences of Tuberculosis: a pilot randomised controlled trial with mixed-methods process evaluation in Nepal

Acronym
ASCOT

Study objectives
Social, economic, and socioeconomic support interventions for TB-affected households in Nepal are feasible and acceptable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2021, Liverpool School of Tropical Medicine’s Research Ethics Committee (Pembroke Place, Liverpool, L3 5QA, UK; +44 (0)151 7053100; no email provided), ref: 20-098

Primary study design

Interventional

Study design
A pilot randomized-controlled trial with mixed-methods process evaluation

Study type(s)
Other

Health condition(s) or problem(s) studied
Socioeconomic support for people with tuberculosis and their households

Interventions
POPULATION: the pilot trial will recruit 120 people with TB notified to the Nepal National TB Program (NTP). The integrated process evaluation will recruit 40 multisectoral stakeholders including NTP staff, civil society members, policy makers, and ASCOT field team members.

INTERVENTIONS WITH PEOPLE AFFECTED BY TB:
120 recruited participants will be randomly allocated (block allocation in 10 pre-sealed envelopes placed securely in each recruiting health centre in the study sites) to one of four study arms:
- Control standard of care (n=30)
- Social support (n=30)
- Economic support (n=30)
- Socioeconomic support (n=30)

Social support will be peer-led mutual support groups in TB-affected households providing enhanced TB education and stigma reduction counselling.

Economic support will be monthly cash transfers during TB treatment with expectations (not conditions) of meeting NTP goals.

At 0, 2, and 6 months following TB treatment initiation, participants will be asked to complete a WHO-adapted longitudinal survey detailing the social determinants and impact of TB and also feedback their experiences of ASCOT.
Process evaluation: we will complement survey data with focus group discussions (FGD), key informant interviews (KII), and a workshop with multi-sectoral stakeholders on the challenges to implementation and scale-up of ASCOT interventions.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome will be feasibility and acceptability of the ASCOT support intervention. Acceptability will be measured using mixed-methods including:
1. Quantitative analysis of the implementer (end of participant recruitment) and user satisfaction form (2 and 6 months following recruitment);
2. Quantitative analysis of 0, 2, and 6 month survey data and project records to establish fidelity to the intervention (e.g. adherence to and completion of socioeconomic support delivery amongst intervention arm participants); and
3. Thematic analysis of the qualitative FGD and KII data collected within Sekhon’s Framework for healthcare interventions.

Feasibility will be measured using quantitative data analysed at the end of recruitment and follow-up including:
1. Recruitment (e.g. number of people invited, recruited, and participant attrition)
2. Survey completion
3. ASCOT staff time and costs plus overall project costs recorded throughout

Key secondary outcome(s)
Health systems readiness and scalability will be assessed using mixed-methods including thematic analysis of FGD and KII data.

Completion date
01/03/2025

Eligibility

Key inclusion criteria
1. PEOPLE WITH TB
1.1. People 18 years of age or older
1.2. A person or guardian of a person notified to the Nepal National TB Program and registered in the TB register of a TB clinic within the study site district
1.3. A person or guardian of a person with TB will be eligible to be included regardless of the site of TB (e.g. intrapulmonary or extrapulmonary), HIV serostatus (e.g. HIV positive, HIV negative, or HIV status unknown), resistance profile (e.g. drug-sensitive TB [DS-TB] or drug-resistant TB [DR-TB]), or disability
1.4. A person or guardian of a person who is able to provide written, informed consent or assent (or thumb print if unable to write)

MULTISECTORAL STAKEHOLDERS TO PARTICIPATE IN PROCESS EVALUATION FGDS, KIIS, AND WORKSHOP
A scoping exercise will establish existing social and/or economic support provided to TB-affected or other households in the study site communities and identify a list of key in-country stakeholders in Nepal. The stakeholders will be from diverse groups including: civil-society organisation (CSO) representatives including from cooperatives, women's groups, grass roots organisations; community leaders (e.g. district elders); social-protection decision makers; NTP leaders and managers; and NTP multi-disciplinary staff, predominantly from the study sites. Additional stakeholders will be ASCOT field team members including community mobilisers (CMs), female community health volunteers (FCHVs), and District Program Coordinators (DPCs); and a subset of people with TB recruited to each arm of the ASCOT study will be purposively selected. Purposive selection will aim to achieve representation by gender, age, poverty level, comorbidities (e.g. HIV), and ASCOT arm.

The following stakeholders will be invited to participate in separate focus group discussions (FGDs):
CSO representatives (n=5)
Community leaders (n=5)
NTP multi-disciplinary staff (n=5)
ASCOT CMs (n=5)• ASCOT FCHVs (n=5)
People with TB (separate FGDs of n=5 with participants from each study arm)

The following stakeholders will be invited to participate in key informant interviews (KIIs):
NTP managers (n=5)

Social protection decision makers (n=5)
ASCOT DPCs (n=5)

2. STAKEHOLDER INCLUSION CRITERIA
2.1. People 18 years of age or older
2.2. Identified by desk-based scoping review or, if a person with TB or the guardian of a person with TB, participated in ASCOT pilot trial
2.3. Able to provide written, informed consent (or thumb print if unable to write)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
128

Key exclusion criteria
1. PEOPLE WITH TB
1.1. People under 18 years of age
1.2. Another member of the potential trial participant's household is already a participant in the ASCOT study
1.3. A person or guardian of a person not notified to Nepal National TB Program and not registered in the TB register of a TB clinic within the study site district
1.4. A person or guardian of a person who is unable to provide written, informed consent or thumb print

In addition to the above, pilot trial participants who receive an alternative diagnosis during their treatment (e.g. diagnosis of TB rescinded and, in some cases, alternative non-TB diagnosis made) and are removed from the NTP register will also be excluded from further follow-up.

2. MULTISECTORAL STAKEHOLDERS
2.1. People under 18 years of age
2.2. Not identified by scoping review or, if a person with TB or the guardian of a person with TB, did not participate in ASCOT pilot trial
2.3. Unable to provide written, informed consent or thumb print

Date of first enrolment
15/09/2021

Date of final enrolment

01/05/2022

Locations

Countries of recruitment
United Kingdom

England

Nepal

Study participating centre
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
United Kingdom
L3 5QA

Study participating centre
Birat Nepal Medical Trust
Lazimpat Road
Lazimpat
Kathmandu
Nepal
Ward No. 2

Study participating centre
National Tuberculosis Control Center
Araniko Highway
Madhyapur Thimi
Kathmandu
Nepal
44600

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

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 non-publically available repository.
Primary study data will be managed by the Data Manager of Birat Nepal Medical Trust. Data input, cleaning, checking and double-checking, and management will be iterative and ongoing throughout the study. Data will be checked for consistency and completeness by the Data Manager and ASCOT Project Manager and double-checked by the Chief Investigator prior to hand-off to LSTM. This data will be exported to Stata and transferred to LSTM servers for analysis. Participant information leaflets will be provided and written informed consent will be obtained from all study participants. Secondary data obtained from patient register records and other sources of the Nepal NTP will be copied and entered in an electronic database by BNMT staff.

Specifically, audio recordings from the FGDs will be stored in a password-protected digital folder on an LSTM secure server. Only the Chief Investigator, Project Manager, and transcribers will have access to the data. Audio-recording data will be stored for seven years, as per the requirement of the BNMT's data policy, after which they will be deleted.

Paper-based copies and study documents will be stored in the locked offices of BNMT. The electronic database will be stored in files within LSTM's secure server and will be password protected. Any tablet devices used for data entry will be password protected and data will be uploaded to LSTM's secure server weekly. Access to final data will be limited to the Chief Investigator, Data Manager, Project Manager, and key authorised ASCOT staff. Data will be

stored for seven years, as per the requirement of the BNMT's data policy, after which they will be deleted.

CONFIDENTIALITY AND INFORMED CONSENT

All medical records obtained from the Nepal NTP will be kept confidential. Practically, through liaison with NTP Project Staff (as per previous research in the study sites), ASCOT team members will photocopy patient records from the Nepal NTP TB register obscuring the patient's identifiable details. Photocopies will be marked with that patient's unique study number identifier. No individual patients will be identifiable from publications resulting from this study.

All paper-based copies, including medical records, informed consent forms and participant information leaflets, will contain only the registered number. These documents will be stored in a locked room in the BNMT office. All electronic data will be saved with password protection as per data management sections above. Passwords will only be given to the Chief Investigator and Project Manager.

Informed consent will be initiated prior to an individual agreeing to participate in the ASCOT pilot trial and will continue throughout that individual's participation. In obtaining and documenting informed consent, we will comply with applicable regulatory requirements and adhere to the principles of GCP.

Discussion of objectives, risks and inconveniences of this research and the conditions under which it is to be conducted will be provided to the participant, where possible, by appropriately delegated ASCOT team members with knowledge in obtaining informed consent with reference to the Participant Information Sheet (PIS). This information will emphasise that participation in the trial is voluntary and that the participant may withdraw from the trial at any time and for any reason. The participant or delegate signing consent on behalf of the participant, will be given the opportunity to ask any questions that may arise and provided the opportunity to discuss the ASCOT pilot trial with family members, friends, and/or others as required. Time will be given to consider the information prior to agreeing to participate.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol 17669.3	13/12/2023	08/03/2023	Yes	No
Participant information sheet	FGD and Workshop version 3.0	08/03/2021	20/08/2021	Yes	Yes
Participant information sheet	Survey and Pilot Trial version 3.0	08/03/2021	20/08/2021	Yes	Yes
Protocol (preprint)	Study website	26/04/2022	06/05/2022	No	No
Study website		11/11/2025	11/11/2025	No	Yes