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Reduction of disability in leprosy through enhanced self-care

Submission date	Recruitment status	[X] Prospectively registered
17/08/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
25/08/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/07/2026	Infections and Infestations	[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Leprosy, also known as Hansen's disease (HD), is a long-term infection by the bacteria Mycobacterium leprae or Mycobacterium lepromatosis. Infection can lead to damage of the nerves, respiratory tract, skin, and eyes. This nerve damage may result in a lack of ability to feel pain, which can lead to the loss of parts of a person's extremities from repeated injuries or infection through unnoticed wounds. An infected person may also experience muscle weakness and poor eyesight.
Nerve damage in leprosy increases the risk of repeated injuries and ulcers in the feet and hands, leading to the disfigurement of limbs which in turn may result in stigma, restriction in social participation and loss of work.
We aim to evaluate an enhanced self-care program in collaboration with stakeholders, which will be embedded within a larger care and prevention program called the Replicable Model (system - National leprosy eradication program: strengthening project in Chhattisgargh district , India).

Who can participate?
Patients with neuropathy in their eyes, hands and feet from the three blocks (sub-unit of district) of Janjgir-Champa district.

What does the study involve?
This is a prospective interventional cohort study where the intervention (enhanced self-care program) will be delivered by the Replicability Model project team through the National Leprosy Program. The research (RIGHT research project) team will evaluate the program using a mixed methods approach. The enhanced self-care program will be implemented through front-line health workers (Mitanin) of the public health system in Janjgir-Champa district, Chhattisgarh state, India. Patients will be followed up twelve months after the implementation of the enhanced self-care program. The main outcomes will be the prevalence of ulcers among those at risk of an ulcer; the total surface area of ulcers (cm2) among those with ulcers and disability severity level as measured using the Eye, Hand and Foot score (EHF score). Qualitative observations of the implementation of the progress will be made.

What are the possible benefits and risks of participating?
Benefits: Training and uptake of enhanced self-care that will reduce and prevent disability due

to leprosy.
Risks: No risks identified

Where is the study run from?
TLM Bethesda Leprosy Home and Hospital (India)

When is the study starting and how long is it expected to run for?
January 2022 to July 2024

Who is funding the study?
UK National Institute for Health Research (NIHR) Research and Innovation for Global Health Transformation (RIGHT) Programme

Who is the main contact?
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Additional identifiers

Protocol serial number
TLMTI C-62

Study information

Scientific Title
REductioN of disABility in Leprosy through Enhanced self care in Janjgir-Champa district, Chhattisgarh, India

Acronym
ENABLE India

Study objectives
Does enhanced self care practices delivered by frontline workers enhance uptake and adherence to self care to prevent and reduce disabiltiy due to leprosy ?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/03/2022, TLMTI Research Ethics Committee (16, Pandit Pant Marg, CNI Bhavan, New Delhi, 110001, India; +91 9811912026; monicathomaschandy@gmail.com), ref: TLMTI C62.

Primary study design
Interventional

Study design
Prospective interventional cohort study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of disability in leprosy (Hansen's disease)

Interventions
Prevention and reduction of disability by self-care in the community is facilitated using existing public health systems and Mitanins (front-line health worker) .The self-care intervention will be staggered across the districts and their constituent Primary Health Centres (PHCs). The NIHR RIGHT team have developed international guidelines documents for self-care. These will be contextualized and will be called 'Enhanced self-care intervention', for implementation and dissemination in Chhattisgarh, in collaboration with colleagues responsible for implementing and supporting self-care in the community. The delivery of the self-care intervention to the

patients will be through Mitanins (health care workers) facilitated by community development officers (CDO) of the Replicability Model (implementer of the intervention) team.
In India, Mitanins are the pillars of the National Health Mission in implementation activities of various health programs and are familiar with, and accepted in their own communities, as the first person to be called for health-related problems. There are about 20 Mitanins supervised by one Mitanin trainer (MTs) in each block of a district. All MTs from the blocks the ENABLE study is recruiting from will receive training on the enhanced self-care intervention by CDOs of the Replicability Model team in a one-off training session. The MTs in turn will train their respective existing Mitanins, in a phased manner.
The Mitanins will deliver the self-care intervention in the form of training and demonstration to the patients from their respective villages and follow them up. The follow-up will be done monthly, documenting the conditions of the limbs in a register. The CDO's of the Replicability Model team will support Mitanins in provision of footwear, self-care kits and assistive devices. If there is deterioration in the impairments / ulcers, they will refer to the primary health centre.
The evaluation of enhanced self-care intervention will happen in three blocks of the Champa-Janjgir district. All patients with neuropathy due to leprosy, at risk for developing ulcers (had an ulcer in the past) and currently having an ulcer will be included in the self-care program.

Intervention Type
Behavioural

Primary outcome(s)
Quantitative outcome
1. The prevalence of ulcers among those at risk of an ulcer is measured using case record form for clinical assessment at baseline , 3 months , 6 months and 12 months.
2. The total surface area of ulcers (cm2) among those with ulcers is measured using photographs at baseline, 3 months, 6 months and 12 months.
3. Disability severity level: Eye, Hand and Foot score (EHF score) is measured using case record form for clinical assessment at baseline, 3 months, 6 months and 12 months.

Qualitative outcome
1. Fidelity:
1.1. Evaluation of Mitanin trainers' training measured using pre and post test questionnaire at on off training program for trainers
1.2. Evaluation of cascaded training of Mitanins by Mitanin trainers to measure delivery of training using observation checklist and knowledge gain using pre and post questionnaires.
2. Delivery of intervention
2.2. Home visit records (of over 4 week period prior to data extraction) measured at 4 weeks after Post intervention assessment at 3 months, 4 weeks after Post intervention assessment 2 at 6 months and 4 weeks before final intervention assessment at 12 months
2.3. Observation of home visits documented using checklist at least 12 weeks after cascaded training of Mitanins
2.4. Interview with mitanins documented using interview guide at least 12 weeks after cascaded training of Mitanins
3. Community member experience of intervention and impact
3.1. Interview with patients and family members using interview guide at least 12 weeks after cascaded training of Mitanins.
3.2. Interview with community representatives using interview guide at least 12 weeks after cascaded training of Mitanins.

Key secondary outcome(s)

1. Psychological Outcome
1.1. Quality of life is measured using EQ 5D 3L and EQ VAS (visual analogue scale) at Baseline, 6 months and 12 months
1.2. Subjective well being is measured using life satisfaction questionnaire at Baseline, 6 months and 12 months
2. Social outcomes using Participation scale at Baseline, 6 months and 12 months.

Completion date
01/07/2024

Eligibility

Key inclusion criteria
All patients with neuropathy due to leprosy, at risk for developing ulcers (had an ulcer in the past) or currently have an ulcer will be included in the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
261

Key exclusion criteria
Children less than 18 years old

Date of first enrolment
25/08/2022

Date of final enrolment
28/01/2023

Locations

Countries of recruitment
India

Study participating centre
TLM Bethesda Leprosy Home and Hospital
P. O. Champa

Janjgir-Champa district
Champa
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495671

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
UK National Institute for Health Research (NIHR) Research and Innovation for Global Health Transformation (RIGHT) Programme

Results and Publications

Individual participant data (IPD) sharing plan
Data will be shared on request.
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IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			08/07/2026	No	No
Participant information sheet	version 1.1		18/08/2022	No	Yes
Plain English results			08/07/2026	No	Yes
Protocol file	version 1.1	21/03/2022	18/08/2022	No	No
Statistical Analysis Plan			22/08/2024	No	No