

Reduction of disability in leprosy through enhanced self-care

Submission date 17/08/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/08/2022	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/03/2025	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 Chhattisgarh 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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Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 disability 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.

Study design

Prospective interventional cohort study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

See study outputs table

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 Mitans (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 Mitans (health care workers) facilitated by community development officers (CDO) of the Replicability Model (implementer of the intervention) team.

In India, Mitans 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 Mitans supervised by one Mitan 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 Mitans, in a phased manner.

The Mitans 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 Mitans 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 measure

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 Mitan trainers' training measured using pre and post test questionnaire at on off training program for trainers

- 1.2. Evaluation of cascaded training of Mitans by Mitans 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 Mitans
 - 2.4. Interview with mitans documented using interview guide at least 12 weeks after cascaded training of Mitans
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 Mitans.
 - 3.2. Interview with community representatives using interview guide at least 12 weeks after cascaded training of Mitans.

Secondary outcome measures

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.

Overall study start date

07/01/2022

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

Age group

Adult

Sex

Both

Target number of participants

16 clusters each with 5 to 10 people affected by leprosy who are at risk of an ulcer and another 5 to 8 patients with impairments in eye, hands with or without impairment in the foot who will require self-care.

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

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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

Publication and dissemination plan

We plan to publish results in a high-impact peer-reviewed journal.

The results of the study will be reported to collaborators of this study. Equal credit will be given to those who have collaborated in the trial.

The findings will be shared with the patients and communities through the networks of The Leprosy Mission Trust India, who have extensive experience in working with the patient communities.

Findings will be presented at conferences of Indian Association of Leprologists (IAL), Indian Association of Dermatologists, Venereologists and Leprologists (IADVL), the Annual Neglected Tropical Disease NGO (NNN) conference, International Leprosy Congress in 2022 and Diabetes disease related conferences.

Tools used to disseminate the research output will include: bite-sized research reports in lay format; publication in peer reviewed international journals; public announcements in LMICs; policy briefings; print and online media; the director's news blog (680+ subscribers); institutional and social media accounts and websites.

The context (Chhattisgarh) specific principles and guidelines to promote self-care practice in the community with an emphasis on prevention of recurrent leprosy ulcers will be disseminated across different networks of The Leprosy Mission Trust India.

Intention to publish date

31/05/2025

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?
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Participant information sheet	version 1.1		18/08/2022	No	Yes
Protocol file	version 1.1	21/03/2022	18/08/2022	No	No
Statistical Analysis Plan			22/08/2024	No	No