ISRCTN15908209 https://doi.org/10.1186/ISRCTN15908209

Plantar pressure measurement for footwear adjustments as a new tool to manage ulcers

Submission date
05/11/2024

Recruitment status
No longer recruiting

Registration date
08/01/2025

Overall study status
Completed

Last Edited
19/11/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Plantar ulcers are one of the common complications of leprosy leading to Grade-2 disabilities (G2D) and occur in about 10% to 20% of patients. Even at the time of diagnosis with leprosy, G2D is high in India. Ulcer prevention and appropriate treatment among people diagnosed with leprosy are necessary to achieve the World Health Organization Road map for Neglected Tropical Diseases 2021–2030 target of 75% reduction of disability-adjusted life years due to leprosy. Current practices for the prevention and management of plantar ulcers within leprosy control programs focus on self-care for ulcer prevention, wound care and MCR footwear. The customization of microcellular rubber (MCR) footwear to allow ulcers to heal is typically based on measuring the ulcer position and dimensions only. A specially trained footwear technician makes podiatric appliances to such measures. This is a widely used practice by International Federation of Anti-Leprosy Associations (ILEP) agencies, including LEPRA. Whilst new technologies are emerging including advanced computer-assisted designs and footwear-making technologies they don't account for baropodometric assessment (foot pressure analysis) to add pressure offloading properties.
High foot pressure points and offloading footwear and assistive devices are proving crucial for faster ulcer healing among diabetic patients. However, evidence for their effect on ulcer prevention is "practically non-existent". Ongoing studies on the use of baropodometric assessment to design footwear with offloading properties include a 3D-technology insole by the University of Plymouth, being tested in Nepal and a Hyderabad-based traditional Harris mat footprint with software enhancement informing footwear customization. Only the latter is field-ready because it employs a hybrid model whereby (a) in the field, a Harris mat is used to take baropodometric measurements; (b) in the clinic, footwear is designed and enhanced by software with visual tools to allow (c) customization for pressure offloading in either setting. Such a hybrid model can be implemented at the community level, allowing for extensive coverage and adequate reach in areas typically served only by self-care groups and frontline workers. Moreover, community-based follow-up using baropodometric assessment and simple clinical assessment will enable the development of a field-ready ulcer risk stratification tool. This would guide self-care practices, footwear use and identify the need for referral for wound care, and thereby creating a virtuous circle of awareness-raising and improved ulcer-related outcomes.
This study aims to compare the effectiveness of footwear made using standard MCR footwear and software-enhanced MCR footwear tailored according to baropodometric assessment taken

at the community level, in terms of change in the number of weeks per year spent ulcer-free and assess the role of standard MCR footwear and enhanced MCR footwear on awareness around the importance of and adherence to footwear use. In addition to that a risk stratification tool will be developed and evaluated for developing plantar ulcers within 6 months of assessment, using baropodometric assessment, ulcer history and lifestyle factors among participants with anesthetic feet and a history of ulcers in the past 12 months.

Who can participate?
The study will include leprosy patients aged 18 years and over with a history of ulcers in the past 12 months or a current simple ulcer from 36 SSGs across three states in India. Participants must be active SSG members, having attended at least one meeting in the past three months, and must provide consent.

What does the study involve?
The study is designed to evaluate the effectiveness of customized footwear in reducing the occurrence of foot ulcers over a 12-month period. Participants will be randomly assigned to receive either the footwear or standard footwear (control group). Participants will undergo a comprehensive baseline assessment, which includes a clinical examination, medical history review, foot examination, and baseline measurements of foot health and self-care practice, activity limitation, mental health status, and social participation. Staff from Primary Health Centers (PHC) situated in the close vicinity of the SSGs will be trained on wound management in leprosy for health system strengthening and easy access to care for the leprosy patients.
Participants in the intervention group will receive a pair of customized footwear designed specifically to reduce pressure points and provide optimal support using baropodometry.
Participants in the control group will receive standard footwear, which is commonly available MCR footwear and not customized.
Participants in both groups will be trained on self-care and a self-care kit will be provided. To be available to attend the training session, they may have to travel or take off from work, and the transportation cost and wage loss will be considered.
Participants will be followed up every month to monitor foot health, adherence to footwear use, and the occurrence of foot ulcers for a 12-month period. At the 6-month follow-up, participants in both groups will receive a new pair of footwear (customized or standard, as per their group assignment) to ensure continued efficacy and comfort. During the first 6-month follow-up, participants will receive training on using the Harris mat and taking their own foot imprints. This will empower them and promote sustainability. Focus group discussions will be conducted during the first 6-months and an ulcer risk assessment tool will be developed and validated in the next 6 months. Data will be collected through participant self-reports, and measuring the foot ulcer through standard procedure involving measuring scale. Then the endline data will be collected and compared.

What are the possible benefits and risks of participating?
To the researchers' knowledge, this is the first study assessing the effectiveness of personalised footwear based on the pressure points using baropodometry technology at the community level with a community engagement model which will serve not just the leprosy affected but also strengthen the health system by providing wound care training to the healthcare professional in the Primary Health Centers. Community-based follow-up using baropodometric assessment and simple clinical assessment will enable the development and validation of a field-ready ulcer risk stratification tool. The study includes multiple sites in three different states in India, so the findings of the study can be generalizable to all leprosy patients.
The participants will get microcellular rubber footwear (personalised and standard) and get access to advanced care. They will be provided with self-care kits which will enable better care for their foot ulcer. They will be trained on handling Harris mat to take their own foot imprints in

the intervention group which may augment satisfaction in knowing that their engagement helps advance science and may improve care for others with similar conditions. The health care providers, mainly wound dressers of the nearby Primary Health Centres, will be trained on foot ulcer care in leprosy which will ensure easy access to care and health system strengthening.
The customized footwear could cause discomfort, especially if the design is not suitable for the participant. Participants might need to adhere to wearing the footwear provided for set times or avoid other footwear, which could be inconvenient. Participants' daily routines, social activities, or personal preferences in footwear may be disrupted. Participants may struggle to correctly use the Harris mat.

Where is the study run from?
LEPRA Society - Blue Peter Public Health and Research Centre (BPHRC) (India)

When is the study starting and how long is it expected to run for?
April 2023 to September 2025

Who is funding the study?
Leprosy Research Initiative (Netherlands)

Who is the main contact?
Dr Michael Sukumar Pallapati, michael@leprahealthinaction.in

Contact information

Type(s)
Scientific

Contact name
Dr Michael Pallapati

Contact details
LEPRA Society (Opposite TVS Tread company, Cherlapally)
Hyderabad
India
501301
+91 (0)40 29551628
bphrc@leprahealthinaction.in

Type(s)
Public, Principal investigator

Contact name
Dr Michael Pallapati

Contact details
LEPRA Society (Opposite TVS Tread company, Cherlapally)
Hyderabad
India
501301
+91 (0)40 29551628
michael@leprahealthinaction.in

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
FP23\100018

Study information

Scientific Title
Personalised footwear for foot ulcers in leprosy by baropodometry through an innovative community engagement model

Study objectives
Can a low-cost technology for measuring baropodometry, undertaken at the community/primary care levels, help design personalized micro cellular rubber (MCR) footwear that reduces the risk of new ulcers among people affected by leprosy with simple ulcers or a history of plantar ulcers?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/04/2022, LEPRA Society (Opposite TVS Tyretread company, Cherlapally, Hyderabad, 501301, India; +91 (0)40-29551627; ecbphrc@leprahealthinaction.in), ref: 05/LEPRA IEC/2022

Study design
Multi-centric two-arm cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life, Efficacy

Health condition(s) or problem(s) studied
Prevention of risk of developing new ulcers among people affected by leprosy with simple ulcers or a history of plantar ulcers

Interventions
The randomized controlled trial will evaluate the effectiveness of personalized footwear using baropodometry technology. In the intervention group, participants will receive personalized footwear tailored to their identified pressure points, with foot imprints taken using a Harris mat and color imprints recorded using Podoscan software. They will also receive training on handling baropodometry equipment and self-care practices through a community engagement model.

The control group will receive standard MCR footwear, with foot measurements taken using the standard procedure. They will be trained only in self-care practices and will not receive training on handling the Harris mat for baropodometry. Participants in both arms will receive two pairs of footwear. The follow-up duration is 12 months. The first pair of footwear is provided at the start of the study, and the second pair is given at the 6-month mark. Regular follow-up assessments are conducted every month.

Three states (Andhra Pradesh, Bihar, Odisha) are participating in the study, with one Lepra Society Referral Centre established in each state. Each referral centre will include 12 Self-Supported Groups (SSGs), divided into two arms with six SSGs in each arm. Some of their leprosy patients are organised into SSGs. These SSGs are the Primary Sampling Units. It is planned to have a fixed number of 36 SSGs overall. Participants are randomly assigned to either the intervention group or the control group using a computer-generated randomization sequence.

For the purpose of this intervention, each Referral Centre will dedicate one Footwear Technician and one field coordinator who will receive standardised training for all components of the study apart from Harrismat and enhanced footwear making, which will be offered to the intervention arm only. Staff at Primary Health Centres located nearby will be trained in foot ulcer care to enhance their skills. This training will contribute to strengthening the health system and improving access to ulcer care for leprosy patients.
Field coordinators will be trained on the baseline data collection procedure and guidelines and standard operating procedures will be crafted for adherence. In the intervention arm, Harris mat imprints will be sent to the referral centres for color imprint analysis. In the control arm, foot size will be marked on white paper using a pen or pencil. The measurements will be shared with the shoe technician where there will be two boxes dedicated to both the arms to store the footwear and within the 10 days of foot measurement, footwear will be delivered to the participants.

Each month, study participants with a simple ulcer or a history of ulcers in the past 12 months - evidenced by clinical records, scars, or self-report - who are active members of their local Self-Support Groups (having attended at least one meeting in the past 3 months) and who have consented (≥18 years) to participate in the study, will be followed up. If patients will miss their follow-up visit, local staff will reach out to them. Foot measurements will be taken again in the 5th month, and footwear will be provided in the 6th month. Follow-up will continue until the 12th month, culminating in an endline evaluation. Additionally, a risk assessment tool will be developed during the 6-month follow-up and validated in the subsequent project period.

Intervention Type
Mixed

Primary outcome(s)
Cumulative ulcer (wound)-free time will be measured over 12 months = 52 weeks – number of weeks with ulcers, as determined by the date of the start and date of healing of each ulcer and followed up monthly for a 12-month follow-up

Key secondary outcome(s))
1. Size of the ulcer: the length and width of the foot ulcer of the participants will be measured using a measuring scale at baseline and every month for 12 months
2. Physical, mental and general well-being measured using the Screening of Activity limitation and Safety Awareness scale, Warwick-Edinburgh Mental Well-Being Scale (WEMWBS), and Participation Scale Short Simplified questionnaire at baseline and every month for 12 months

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Leprosy-affected individuals with a past history of ulcers in the last 12 months, either evident from clinical records, scars or self-reported or having simple plantar ulcer
2. Active members of their local self-support groups, operationalized as having attended at least one meeting in the past 3 months
3. Consented to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
288

Key exclusion criteria
1. Complicated plantar ulcers
2. Due for reconstructive surgery
3. Found severely diabetic after random blood sugar test
4. Foot drop
5. Lost more than one digit

Date of first enrolment
27/12/2023

Date of final enrolment
04/06/2024

Locations

Countries of recruitment

India

Study participating centre
Vijayawada Referral Centre, LEPRA Society
Room No. 5D, New Govt., General Hospital
Vijayawada
India
520 008

Study participating centre
Little flower Hospital
Sunderpur , Raxaul
East Champaran District
India
845305

Study participating centre
Koraput Referral Centre
Hati Line, Behind collectorate
Koraput
India
764020

Sponsor information

Organisation
Lepra Society

ROR
https://ror.org/04141fq07

Funder(s)

Funder type
Charity

Funder Name
Leprosy Research Initiative

Alternative Name(s)
The Leprosy Research Initiative, Lepra Research Initiative, Iniciativa de investigación de la lepra, Iniciativa de Pesquisa em Hanseníase, Inisiatif Penelitian Kusta, , , LRI

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes