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Comparison of a removable offloading device and routine care to heal plantar ulcers due to leprosy and diabetes in the community

Submission date	**Recruitment status**	[_] Prospectively registered
18/04/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/08/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/08/2023	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Plantar ulcers are a serious complication in leprosy and diabetes globally resulting in hospitalization, disability, and amputation. Continued pressure over the vulnerable site leads to ulcers and then impedes ulcer healing. Therefore, in addition to the removal of infection off-loading the ulcer area is essential to heal the ulcer. The current proposed feasibility plus study is based on using a removable off-loading walker boot fitted with a soft insole which can be easily applied with limited training and may allow the patient to continue their essential daily routine activities. The study aims to test the feasibility and acceptability of using this device and set the scene for a further trial to test the effectiveness of this device type in reducing ulcer development and ulcer complications in a community setting.

Who can participate?

Patients aged 18 years and above with loss of sensation (inability to feel monofilament of 10 grams) and plantar ulcer in the foot due to leprosy or diabetes. Patients with multiple or bilateral ulcers will be included alongside those with just one ulcer.

What does the study involve?

Intervention group

A removable walker boot will be applied to offload the ulcer area(s). The removable nature facilitates daily dressing of the ulcer and monitoring its progress. This also allows patient mobility to carry out essential activities of daily living. The details of the intervention are described below.

Control group

The current standard of care provided in the community, Micro-cellular rubber footwear.

Follow-up

The patient will be followed up for 8 weeks and photographs of ulcers will be taken at baseline and after every until the ulcer heals or at 8 weeks, whichever is earlier, to measure the ulcer area and to record the pedometer values.

Outcomes
Adherence to the removable walker boot will be measured using a pedometer; one placed inside the walker boot and a second on the patient's wrists as a watch/in the pocket. User satisfaction will be measured using a standard questionnaire. Ulcer healing will be measured and all observations will be based on 'blind' assessment.

Qualitative interview
User experience on the removable walker boot will be explored through semi-structured interviews. Ten patients in each site, sampled purposively, will be asked about their experiences of using the device. In the interviews, the study team will seek to elicit reasons for adherence and non-adherence to the removable walker.

What are the possible benefits and risks of participating?
The research team anticipate that the application of a removable cast in the community will help ulcers heal faster without requiring hospital admission. Patients may develop skin abrasions due to ill-fitting walker boots. However, the removable walkers used in this study come with a soft inner lining to prevent skin abrasions. Frequent monitoring will be done to diagnose and manage abrasions if any.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
January 2023 to November 2024

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

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparison of a removable offloading device and routine care to heal plantar ulcers due to leprosy and diabetes in the community: A feasibility plus trial

Acronym
Mobility Trial

Study objectives
In this study, we will generate pilot data to inform a larger clinical trial to evaluate the impact of a removable offloading device on adherence and ulcer healing. The current proposed feasibility plus study is based on a removable off-loading walker boot fitted with a soft insole. This device can be easily applied with limited training and may allow the patient to continue their essential daily routine activities. We will test the feasibility and acceptability of using this device and set the scene for a potential trial to test the effectiveness of this device type in reducing ulcer development and ulcer complications in a community setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/03/2023, The Leprosy Mission Trust India ethics committee (16, Pandit Pant Marg, New Delhi, 110001 India; +919899969713; monicathomaschandy@gmail.com), ref: C-68/ TLMTI EC

Study design
Community-based randomized feasibility plus trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Leprosy and diabetes mellitus

Interventions
The problem of plantar ulcers in leprosy and diabetes
Plantar ulcers are a serious complication in leprosy and diabetes globally resulting in hospitalization, disability, and amputation. About 26 million people worldwide annually have a diabetic foot ulcer with another 130 million at risk of diabetic neuropathy. Though the actual burden of ulcers in leprosy is unknown, it is estimated that over 3 million people are living with disability due to leprosy and that 20-50% of patients with peripheral neuropathy due to leprosy will experience ulcers.

The prevalence of diabetes is 8.4% in India and 8.5% in Nepal. These figures are higher than the global prevalence of 6.3%. About one-third of diabetic patients develop foot ulcers in their lifetime. While the lifetime incidence of foot ulcers in leprosy is not known, an ongoing cross-sectional study on the prevalence of disabilities due to leprosy has shown that over 30% of patients with an anesthetic foot presented with a plantar ulcer. Foot ulcers reduce patient

mobility, social interaction, and health-related quality of life. The treatment of foot ulcers increases the substantial burden on healthcare. Therefore, proper management and expedited healing of foot ulcers are important to limit the burden of ulcer care.

Challenges in the management of plantar ulcers in leprosy and diabetes
The role of pressure on the sole of the foot in the pathogenesis of neuropathic plantar ulcers is well established. Continued pressure over the vulnerable site leads to ulcers and then impedes ulcer healing. Therefore, in addition to removing any infection, an effective way to promote the healing of ulcers is rest - either complete bed rest, which is rarely possible or, commonly, rest to the affected part using an off-loading method. The gold standard alternative to rest is the use of a total contact cast with Bohler irons. The total contact cast method is considered superior as there is forced compliance since patients cannot remove the cast, but is not favored by the patients and clinicians alike. Clinicians find total contact cast unfavorable because of the associated skin abrasions and iatrogenic ulcers. Prolonged use of total contact casts has been associated with muscle atrophy and reduced bone density. A practical problem with the total contact case is that it requires a skilled technician to apply and requires constant monitoring. The expertise is fast disappearing and poorly applied plaster casts will cause more ulcers than they heal. Ulcer specialists and their patients are therefore seeking a more flexible, less cumbersome method than a total contact cast. These alternatives include:
1. Knee-high removable off- V0.3 Ethics approved version 271-032-2023 11 loading walker boot
2. Ankle-high removable off-loading walker boot
3. Footwear with a soft insole (micro-cellular rubber) with off-loading provision using orthosis

The advantage of all these removable off-loading methods is that they can be used with minimal training and in community settings. They are less bulky and cause fewer problems in carrying out daily routine activities. The main difference between removable and total contact casts is that with the latter, adherence to treatment is the patients' choice as they can remove the device, and thus, patient adherence to using these devices has a large impact on healing. Therefore, understanding the factors that influence patients’ adherence to using removable off-loading devices is vital to improving the use and effectiveness of off-loading treatments and the healing outcomes for people with plantar ulcers.

Intervention group: Removable walker boot(s) with a customized insole will be applied to offload the ulcer area(s). The removable nature facilitates daily dressing of the ulcer and monitoring its progress. This also allows patient mobility to carry out essential activities of daily living. The details of the intervention are described below.
Control group: The current standard of care provided in the community is Micro-cellular rubber footwear.
Other than the difference in the offloading methods, the dressings and self-care education provided will be the same between the groups. The dressings will be done by the patients themselves or by caregivers who will be provided with the required materials for dressing. Study participants will receive information on the importance of offloading pressure to aid ulcer healing, with an emphasis on the need for adherence to the off-loading methods. On completion of the trial, patients in the intervention and control group will be provided with appropriate MCR footwear to prevent the recurrence of ulcers.

Description of intervention and control intervention
The Intervention – Removable walker boot: The removable walker is a brace which offers stabilization and immobilization to the foot, ankle and lower leg with comfort which can help in off-loading the ulcer area through the pre-cut insole. The removable walker boot works on the same principle as a total contact cast in offloading pressure from the ulcer area except that it is removable. The material that covers the leg is soft and facilitates proper fitting with the

removable property allowing wound inspection, dressing and hygiene. It has a sufficient broad bottom sole that promotes natural gait, reduces plantar pressure and at the same time provides stability. The rigid stirrup on both sides provides stability and immobilization to the ankle joint while walking.

We will be inserting the insole with a 'precut' (excavated under the wound area) for off-loading the ulcer area which will be determined by the health professional based at the healthcare facility. The insole will be made of Ethyl Vinyl Acetate (EVA) polyurethane rubber which is lightweight and has mechanical properties comparable with Microcellular rubber on the distribution of weight across the plantar surface of the foot except over the ulcer area. The insole will be custom-made according to the size and shape of the patient's foot and the location of the ulcer, thereby facilitating the distribution of weight over the entire foot, except over the ulcer area. The custom-made insole will be fitted inside the removable walker to offload the ulcer area. We will cut and remove the part of the insole which is directly below the ulcer area to offload the pressure. For example, if the ulcer is in the first metatarsal head (MTH), the insole which is directly below the first and part of the second MTH will be removed to off-load the ulcer. If the ulcer is in the third MTH, the insole which comes directly in contact with the third MTH and part of second MTH and part of fourth MTH will be removed to off-load the ulcer. If the ulcer is in the heel, the complete heel part of the insole will be removed to offload the ulcer. The removable walker is readymade and available in different sizes, which can be fitted for varying lengths and circumferences of the leg. The Velcro straps in the removable walker allow for accommodating varying circumferences of the leg. Special attention will be paid to ensure adherence to the wearing of the walker. During the self-care training, we will educate the patients on the importance of adherence to wearing the walker and opening the walker only for dressing changes. On exiting the trial, patients will be provided with appropriate protective (MCR) footwear to prevent the recurrence of ulcers.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
Removable walker boot

Primary outcome(s)
Adherence to the removable walker boot measured using pedometers, one is placed inside the walker boot and a second is placed on the patient's wrist as a watch or in a pocket, to provide data on the number of steps taken by the patient during the assessment period which will be recorded weekly

Key secondary outcome(s))
1. User satisfaction with the off-loading devices measured using the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) 2.0 at complete healing of ulcer or at 8 weeks from recruitment, whichever is earlier
2. Ulcer healing (complete epithelisation of ulcer) and the rate of healing measured by masked observers in another site using the Pressure Ulcer Scale for Healing (PUSH) tool. All observations will be based on a 'blind' assessment. The patient will be followed up for 8 weeks and

photographs of ulcers will be taken at baseline and after every 2 weeks until the ulcer heals or at 8 weeks, whichever is earlier, to measure the ulcer area. The ulcer will be measured from the photographs taken using the data collection tablets.

Completion date
30/11/2024

Eligibility

Key inclusion criteria
1. Aged 18 years old and above
2. With loss of sensation (inability to feel monofilament of 10 grams) and plantar ulcer in the foot due to leprosy or diabetes
3. Patients with multiple or bilateral ulcers will be included alongside those with just one ulcer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Multiple plantar ulcers where the largest ulcers cannot be offloaded effectively due to the presence of other ulcers
2. Sign of infection or infected ulcer or with the signs of sinus tracks
3. Insensitive feet along with orthopaedic conditions in the ankle, knee and hip or limb length discrepancy
4. Amputation; forefoot and above on the contralateral leg
5. Patients who are wheelchair dependent

Date of first enrolment
01/06/2023

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
India

Nepal

Study participating centre
The Bethesda Leprosy Hospital
Janjgir-Champa
Chhattisgarh
Champa
India
495671

Study participating centre
Anandban Hospital
Lalitpur State - 3
Lalitpur
Nepal
44600

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Confidentiality
The raw data collected will be locked and protected. The electronic data will be password protected. The raw data collected during the research will be stored and maintained by the local PIs in TLMTI and TLM Nepal. The other principal investigators will have a copy of the electronic data.
All the principal investigators will be responsible for the safety of the data. The data will be the intellectual property of TLMTI and TLM Nepal and it will be submitted to TLMTI after the submission of the thesis/publications.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

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
Protocol file	version 0.3	27/03/2023	28/04/2023	No	No
Protocol file	version 0.7	08/06/2023	07/08/2023	No	No