ISRCTN12572449 https://doi.org/10.1186/ISRCTN12572449

Improving the management of leprosy ulcers through a community self-care (EARLY) intervention

Submission date
09/08/2022

Recruitment status
No longer recruiting

Registration date
18/08/2022

Overall study status
Completed

Last Edited
14/09/2022

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
In low- and middle-income countries (LMICs), there are diseases that tend to affect the poorest of poor people. Leprosy is one such disease. Antibiotics can kill the bacteria that cause disease in the first place, but that is not the end of the story. In the case of leprosy, local nerve damage leads to repeated injury and hence recurring and disfiguring ulcers. Patients (and their families) face stigma, social isolation and catastrophic costs. This study aims to improve self-care in the community for patients who are at risk of recurring leprosy ulcers. This project will be based in South Eastern Nigeria and will be managed by the German Leprosy and Tuberculosis Relief Association in Enugu.

Who can participate?
The study will be conducted in clusters made up of villages local to either Mile Four or St. Benedict's hospital. Leprosy-affected individuals living in the clusters can participate if they have an existing ulcer, they had an ulcer, or if they suffer from loss of sensation in their limbs.

What does the study involve?
The study involves the creation of self-care groups which will provide education to group members on conducting self-care activities.

What are the possible benefits and risks of participating?
There are no known side effects to the practice of self-care. All previous research points to self-care having a beneficial effect. Participants will benefit from the tailored education on performing self-care and from the social support available through the newly formed groups.

Where is the study run from?
The study is conducted by the German Leprosy and TB Relief Association in Enugu, Nigeria with support and supervision from the University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
July 2020 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?
1. Prof. Richard Lilford, R.J.LILFORD@bham.ac.uk
2. Dr Anthony Meka, anthony.meka@dahw.org

Contact information

Type(s)
Principal Investigator

Contact name
Prof Richard Lilford

Contact details
Room 108, First Floor
Murray Learning Centre
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 6772
R.J.LILFORD@bham.ac.uk

Type(s)
Scientific

Contact name
Dr Onaedo Ilozumba

Contact details
Room 117, Murray Learning Centre
Birmingham
United Kingdom
B13 9WZ
+44 (0)7404187819
u.ilozumba@bham.ac.uk

Type(s)
Public

Contact name
Dr Anthony Meka

Contact details
56 Nza St, Independence Layout
Enugu

Nigeria
400001
+234 (0)803 702 8796
anthony.meka@dahw.org

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR200132

Study information

Scientific Title
ImplementatioN Science sTudy In Leprosy: Improving the management of leprosy ulcers through a community self-care intervention using a stepped wedge cluster randomised trial

Acronym
INSTIL Nigeria

Study objectives
It is hypothesised that following the intervention, ulcers will form less often and that, when they do form, they will be smaller and less likely to progress to the point where hospital treatment is required. It is hypothesised that the intervention will be associated with improved quality of life and welfare among all people in the self-care groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/08/2020, University of Nigeria Teaching Hospital (Ituku Ozalla P.M.B 01129, Enugu, Nigeria; +234 (0)42 252 022; cmduth2019@gmail.com), ref: UNTH/CSA/329/VOL5/08

Study design
Incomplete stepped-wedge cluster randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)

Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Recurring leprosy ulcers

Interventions
Clusters will be constituted by villages local to either Mile Four or St Benedict's Hospital. All of the clusters will receive the intervention by the end of the study, as a complete rollout is required so that the central hospital can provide a consistent level of care. Furthermore, as the interventions cannot be delivered in parallel their implementation will be staggered over time. The researchers will include all ten clusters in Abakaliki (Mile Four Hospital) and all five in Ogoja (St. Benedict's Hospital).

The order of implementation and observation will be randomised with the hospital catchment area. A random number will be generated for each cluster and the order determined by the ascending value of the random numbers.

People will be recruited at baseline before their group is allocated to the intervention phase, to avoid any interaction between intervention status and participation. The researchers will follow all patients in each cluster as a cohort (to capture individual-level effects and provide more statistical power).

The 'active' phase of intervention will involve 10 days of on-site outreach activity from the 'intervention team' over a one-month period. In the 'sustainability' phase, outreach will be reduced to about 1 day per 6 weeks.

The self-care intervention will be delivered face-to-face in a group setting. Self-care training is based on the ISSOD-F, a routine series of steps namely Inspection, Soaking, Scraping, Oiling, Dressing and Footwear. The training will be delivered by group facilitators to group members.

Intervention Type
Behavioural

Primary outcome measure
The two-primary ulcer-related outcomes are:
1. The number of ulcers
2. The area of the largest ulcer on the hands/feet (cm^2)

The limbs will be inspected and their condition described using a standard form with information on anaesthesia, ulcers and any deformities using the World Health Organisation (WHO) disability grading system. Any ulcers will be noted and described on a form, resident on the electronic tablet. The clinical appearance of the wound (e.g. any residual exudate) will be recorded. The largest ulcer will be photographed in a standard manner for independent analysis blind to 'treatment' status. In addition, photographs of the plantar surfaces of the two feet together will

also be taken from all participants. Ulcer metrics will be based on photographs taken during dressing changes in a standardised manner, as recommended in the literature. The photographs will be obtained by the research fellow using the camera in the data collection tablet and metrics obtained using the Electronic Pressure Ulcer Scale for Healing (PUSH) tool version 3.0. The PUSH tool enables measurement of the surface area (cm^2) of the lesion calibrated from a plastic ruler, cleaned in spirit, placed in the photograph frame at the level of the ulcer.

Measured at:
Baseline Collection 1: Timepoint 1
Baseline Collection 2: 3 months after baseline 1
Post-Intervention 1: 3 months after 6-week intervention completion
Post-Intervention 2: 3 months after the post-intervention 1

Secondary outcome measures
Quality of life measured using EQ-5D-3L at Baseline Collection 1: Timepoint 1, Baseline Collection 2: 3 months after baseline 1, Post-Intervention 1: 3 months after 6-week intervention completion, and Post-Intervention 2: 3 months after the post-intervention 1

Overall study start date
06/07/2020

Completion date
01/11/2024

Eligibility

Key inclusion criteria
People with a high risk of leprosy ulcer will be invited to enter the study and those who consent will contribute baseline data as stated above. People will be eligible if they have a risk of limb ulceration based on one or more of the following:
1. Current ulcer
2. Previous ulcer
3. Sensory loss in one or more extremities
People will be recruited at baseline before their group is allocated to the intervention phase, to avoid any interaction between intervention status and participation. The researchers will follow all patients in each cluster as a cohort (to capture individual-level effects and provide more statistical power).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
15 clusters with 6-12 individuals per cluster

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/04/2021

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
Nigeria

Study participating centre
German Leprosy and Tuberculosis Relief Association
56 Nza St, Independence Layout
Enugu
Nigeria
400001

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
+44 (0)7814 650 003
researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
Non-identifiable cluster and individual level data will be available on request after trial completion. All anonymized data demographic data and completed surveys (EQ-5D-3L and A life satisfaction) would be available for use. Data will be made available 6 months after the completion of the trial (June 2025) and will be available for 5 years. Data will be shared after the assessment of a detailed proposal by the Chief Investigator Prof. Richard Lilford (R.J. LILFORD@bham.ac.uk). Data will be shared with researchers affiliated with academic institutions, non-governmental agencies and governmental agencies. The analyses will be proposed by the researcher requesting the data, it cannot have require identifying information of study participants. Data will be shared via an agreed-upon secure channel that is accessible to both the trial research team and the researcher requesting the data.

IPD sharing plan summary
Available on request