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Improving the mental health and wellbeing of people affected by leprosy or Buruli ulcer in Nigeria

Submission date	Recruitment status	☒ Prospectively registered
02/03/2021	No longer recruiting	☒ Protocol
Registration date	**Overall study status**	☐ Statistical analysis plan
18/03/2021	Completed	☒ Results
Last Edited	**Condition category**	☐ Individual participant data
31/10/2025	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

Leprosy and Buruli ulcer (BU) are infectious diseases that co-exist in many states across Nigeria. Both are diseases of public health importance and are often associated with high levels of stigma and discrimination owing to their tendency to cause visible deformities.

Mental health services in Nigeria suffer from multiple gaps. It is estimated that there is only one mental health expert for hundreds of thousands of inhabitants. In view of the dearth of mental health professionals coupled with a skewed distribution of professionals in favour of the cities as well as poor budgetary allocation by the government, there is a need to explore sustainable ways to make mental health services accessible to those in dire need, especially persons affected by leprosy and BU.

Some studies and projects have been undertaken to assess the burden of mental health problems especially depression among persons with various NTDs as well as appropriate ways to address them. Some of the findings are quite promising. They show that a community-oriented approach run by trained laypersons (without specialist mental health background) with appropriate supervision, can improve access to effective, acceptable and cost-effective mental health services. The study aims to determine the impact of a community-oriented, holistic approach on the mental health status (especially, depression and generalized anxiety disorder) and the quality of life among persons affected by leprosy or Buruli ulcer in Southern Nigeria.

Who can participate?

People affected by leprosy or BU in southern Nigeria, especially those registered for treatment from 2014 up to 1 year before the end of the intervention. It essentially includes those aged between 15 to 65 years who agree to participate. Moreover, participants will be selected from the 10 LGAs with the highest number of leprosy/BU patients in southern Nigeria. The states and local government areas (LGAs) are Anambra State (Anambra East and Ogbaru LGAs), Akwa Ibom State (Etinan LGA), Bayelsa State (Ogbia LGA), Cross River State (Ogoja, Obubra and Calabar South LGAs), Delta State (Ethiope East and Isoko South LGAs) and Ebonyi State (Ebonyi LGA).

What does the study involve?

This study has a dual objective: to determine the burden/extent of mental illness (especially depression) among persons affected by leprosy or BU and ascertain whether a holistic (multi-layered) community-oriented approach involving patient self-help groups, lay community counsellors and non-specialist health workers improves the mental health and well-being of leprosy/BU patients in southern Nigeria. It is believed that the use of self-help groups (SHG), lay community counsellors and trained health workers will reinforce and complement each other in a synergistic manner, resulting in better outcomes to approaches based on health workers alone. Advocacy visits to relevant groups will follow the ethical approval of the project from appropriate authorities. A baseline survey will be conducted to ascertain the burden of mental health problems among leprosy or Buruli ulcer patients using appropriate research tools. Social discrimination against persons affected by leprosy or Buruli ulcer by community members will also be measured at the preliminary stage of the project. Self-help groups will be established to provide an enabling platform for peer-support through regular interactions/meetings, reduce self-stigma and promote self-esteem among patients. Selected community opinion leaders will be trained as lay-counsellors to provide counselling for patients identified to have depression or anxiety and promote social participation. Trained health workers will ensure effective treatment and/or adequate referral services for patients. At the end of the project, patients will be re-assessed to determine any difference in their mental health status and quality of life.

What are the possible benefits and risks of participating?
Participants will be actively involved in self-help groups with others who may have suffered similar psychological and emotional trauma due to stigma and social discrimination. Peer-interaction and experience sharing by other patients might remarkably give hope to people who are depressed and restore self-esteem and mental well-being. Community leaders who serve as counsellors might go further to defend the human rights of persons affected by leprosy and BU through the platform of self-help groups. Similarly, healthcare workers involved alongside community leaders in some of the self-help group meetings will provide mental health services where necessary to participants. However, participants may suffer the risk of having their disease status disclosed to other participants and facilitators in order to receive the necessary help.

Where is the study run from?
German Leprosy and TB Relief Association (Nigeria)

When is the study starting and how long is it expected to run for?
July 2020 to December 2023

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
708.20.15/LRI

Study information

Scientific Title
Improving the mental health and quality of life of people affected by leprosy or Buruli ulcer in Southern Nigeria

Study objectives
A community-oriented, holistic approach improves the mental health (depression and generalized anxiety disorder) status and the quality of life of people affected by leprosy or Buruli ulcer in Southern Nigeria.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 27/08/2020, Health Research and Ethics Committee, University of Nigeria Teaching Hospital (Ituku-Ozalla, Enugu, P.M.B. 01129, Enugu, Nigeria; +234 (0)42-252022, 252573, 252172, 252134; cmdunth2019@gmail.com), ref: NHREC/05/01/2008B-FWA00002458-1RB00002323

Study design
Cluster-randomized trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Mental health and quality of life of persons affected by leprosy or Buruli ulcer

Interventions
The study proposes a holistic, community-oriented approach for improving access and utilization of mental health services through interventions using holistic approach work synergistically to reduce mental disorders and improve quality of life among persons affected by leprosy or Buruli ulcer, viz:
1. Engaging selected community members as lay counsellors to provide psychotherapy and counselling services for persons affected by leprosy or Buruli ulcer
2. Formation of self-help groups (SHG) among persons affected by leprosy or Buruli ulcer for peer support and improving self-esteem
3. Training of healthcare workers to provide pharmacological treatment or referral services to experts where necessary

The intervention phase will take about 1 - 2 years with quarterly community sensitization during supervisory visits by the research team to promote social inclusion, raise awareness on mental health problems and availability of services to create demand and enhance utilization. Re-training of service providers and self-help groups will be done twice throughout the project period.

The control arm will not receive any form of intervention.

Intervention Type
Behavioural

Primary outcome(s)
Mental health status (especially, depression and generalized anxiety disorder) and the quality of life measured using PHQ-9, GAD-7 and WHOQOL-BREF at baseline (before intervention) and repeated after 2 years of intervention

Key secondary outcome(s))
1. Mental well-being of patients measured using the Warwick Edinburgh Mental Well-being Scale (WEMWBS) at baseline (before intervention) and repeated after 2 years of intervention
2. Self-stigma of leprosy patients measured with SARI Stigma Scale at baseline (before intervention) and repeated after 2 years of intervention
3. Social inclusion of leprosy patients by community members measured using the Social Distance Scale (SDS) at baseline (before intervention) and repeated after 2 years of intervention

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Any person affected by leprosy or Buruli ulcer
2. All people affected by leprosy or Buruli ulcer registered for treatment from 2014 up to 1 year before the end of the intervention
3. Participants aged between 15 to 65 years registered for treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
280

Key exclusion criteria
1. Refusal to give consent
2. Pregnant women
3. Patients who need urgent medical attention
4. Patients unable to communicate clearly

Date of first enrolment
01/06/2021

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
Nigeria

Study participating centre
German Leprosy and TB Relief Association
56 Nza Street
Independence Layout
Enugu

Nigeria
400241

Sponsor information

Organisation
Deutsche Lepra- und Tuberkulosehilfe

ROR
https://ror.org/04jntfm70

Funder(s)

Funder type
Research organisation

Funder Name
Leprosy Research Initiative (LRI)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from GLRA Secretariat (glra.nigeria@dahw.org). The primary data of patients will be available after the study completion on 30/06/2024 and will be available for about 5 years. Only the soft copy will be provided upon request for research purposes only. These will be released following data anonymization in accordance with best practices.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/10/2025	31/10/2025	Yes	No
Protocol article		14/06/2022	04/07/2022	Yes	No
Participant information sheet			18/03/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			18/03/2021	No	No