

## Study Protocol

# A Cluster Randomized Trial for Improving Mental Health and Well-being of Persons Affected by Leprosy or Buruli Ulcer in Nigeria: A Study Protocol

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## Abstract

This protocol describes a study in which we would assess the effect of using community lay counselors, self-help groups (SHGs), and trained frontline health workers to reduce mental disorders and improve quality of life (QOL) of persons affected by leprosy or Buruli ulcer (BU). A cluster randomized controlled study design will be employed. The study will involve persons affected by leprosy or BU. Ten local government areas (clusters) with the highest number of notified leprosy or BU cases between 2014 and 2018 in Southern Nigeria will be purposively selected. The clusters will be randomized into intervention and control groups using a computer-generated list of random numbers. At baseline, data were collected using the following validated questionnaires, Patient Health Questionnaire, Generalized Anxiety Disorder questionnaire, Stigma Assessment and Reduction of Impact Scale, World Health Organization QOL BREF and Warwick-Edinburgh Mental Well-being scale among persons affected by leprosy or BU. The intervention will last for 2 years and will involve use of community lay counselors, SHGs, and appropriately trained frontline health workers in reducing mental disorders and improving QOL of persons affected by leprosy or BU. This project postulates that the reduction of burden of mental health problems and improved QOL among persons affected by leprosy or BU could be achieved through a holistic approach involving SHGs, appropriately trained community opinion leaders, and general health-care workers as well as a functional referral system. If successful, the model will be integrated into the activities of the National Tuberculosis and Leprosy Control Programme and scaled up nationwide.

Trial registration:

ISRCTN Registry: ISRCTN 83649248.

<https://trialsearch.who.int/Trial2.aspx?TrialID=ISRCTN83649248>

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## BACKGROUND

Skin neglected tropical diseases (NTDs) including leprosy and Buruli ulcer (BU) are a group of stigmatizing and disability-inducing conditions/infections. These diseases (leprosy and BU), even though they may have different causes and transmission routes, share the need for chemotherapy, wound care, prevention of physical impairment and disability, as well as psychosocial support.<sup>[1]</sup> This necessitates a holistic approach in the care of these patients as there is a tendency

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for persons affected by these diseases to develop mental illnesses. The World Health Organization (WHO) estimates that mental diseases will be the highest contributor to disease burden by the year 2030.<sup>[2]</sup> In Nigeria, mental health problems, especially depression, were found to be frequent among lymphatic filariasis patients due to low self-esteem and low quality of life (QOL).<sup>[3]</sup> Furthermore, a study in Southeast Nigeria revealed that the risk of developing psychiatric morbidity is significantly higher among persons with leprosy than those with albinism.<sup>[4]</sup> These observations may have necessitated the quest by persons affected by BU to clamor for the inclusion of psychological care in their health-care needs.<sup>[5]</sup>

Studies have shown that self-help groups (SHGs) for patients with mental health disorder(s) have positive effects on self-esteem and QOL and foster greater acceptance of patients by their families and communities as well as increase the acceptability of services provided.<sup>[6,7]</sup> In addition, the concept of community mental health services is gradually gaining grounds in the country and has shown promise in improving access to services.<sup>[8-10]</sup> The WHO Mental Health Action Plan (2013–2020) which was endorsed in 2013 by the World Health Assembly placed emphasis on the important role of mental health in achieving health for all. One of the objectives of the plan is the provision of comprehensive integrated mental health and social care services in community-based settings.<sup>[11]</sup>

In Nigeria, shortage of mental health professionals leads to large unmet needs in mental health services, hence the need to explore efficient and effective approaches such as using lay health workers.<sup>[12]</sup> Convinced of the relevance of mental health services for persons affected by NTDs in Nigeria, a study in north-west region of the country called for holistic approach in the management of persons affected by leprosy with emphasis on the mental assessment of such individuals.<sup>[13]</sup> A cluster randomized trial in Nigeria demonstrated that task-shifted intervention for depression delivered by lay health workers is effective.<sup>[14]</sup> Several studies have also shown that the use of lay workers in providing counseling and psychotherapy to patients with moderate-to-severe depression is not just as effective as using professionals but also cost-effective.<sup>[15,16]</sup>

There is evidence that health workers tend to rely more on pharmacotherapy than psychological interventions despite the fact that the latter is more culturally appropriate and equally effective.<sup>[12]</sup> To address this, our study proposes a more holistic approach which involves a network of lay community workers, SHGs of leprosy/BU patients, and general health-care workers in providing mental health services. Another reason to expand the range of options available to patients is the recurrent strike action by public sector health workers in Nigeria. During such strikes, patients would be able to access some level of care through community resources. This model can be easily replicated in communities elsewhere in Nigeria and be scaled up if found to be effective. This project postulates that reduction of burden of mental health problems (especially depression)

and improved QOL among persons affected by leprosy or BU could be achieved through a holistic approach involving SHGs, appropriately trained community leaders, and general health workers as well as a functional referral system. If successful, the model will be integrated into the National Tuberculosis and Leprosy Control Programme (NTBLCP) and scaled up nationwide.

### Primary objective

To determine the effect of a community-oriented, holistic approach on the mental health status (especially, depression and generalized anxiety disorder [GAD]) and the QOL of persons affected by leprosy or BU in Southern Nigeria.

### Secondary objectives

1. To determine the magnitude of mental disorders among persons affected by leprosy/BU in Southern Nigeria
2. To determine the effectiveness of a community-oriented, holistic approach on mental health status (depression and GAD) of persons affected by leprosy or BU
3. To determine the effectiveness of a community-oriented, holistic approach on QOL of persons affected by leprosy or BU
4. To determine the effect of sociodemographic variables on mental health status (depression and GAD) of persons affected by leprosy or BU.

## METHODS

Nigeria, a West African country of over 200 million people, is the most populous country in Africa. The country is divided into 36 states in 6 geopolitical zones and a federal capital territory. Each state is divided into local government areas (LGAs), which represent the third administrative level of governance. Altogether, there are 774 LGAs. The NTBLCP under the Federal Ministry of Health was inaugurated in 1988. The NTBLCP was initially responsible for Tuberculosis and Leprosy Control but later added BU to its mandate. At the turn of the century and up to 2007, Nigeria notified about 5000 new leprosy cases annually.<sup>[17]</sup> Case notification has since declined; however, the proportion of cases with visible deformities had remained high at 14%–15%. Despite achieving the WHO leprosy elimination target of <1 per 10,000 population in 1998, there continue to be pockets of high endemicity in some states and LGAs across the country.

In 2007, a manual for organizing and running self-care groups (SCGs) was adopted by the NTBLCP.<sup>[18]</sup> Despite the fact that an evaluation commissioned by the Netherlands Leprosy Relief found that “the SCGs have made huge impact with such outcomes as less ulcers, improved hygiene, higher self-esteem, and better contacts with the community,” SCGs were not systematically set up and followed up in Nigeria. The number of persons living with leprosy/BU-related disabilities is unknown. These data are not tracked by the national program. However, the report of a national program review conducted in 2015 put the estimated number of persons living with leprosy-related disabilities at 30,000. Levels of

awareness of leprosy and BU remain remarkably low in many parts of the country. A survey of medical students and medical doctors conducted in 2013 in Southeast Nigeria showed poor knowledge of leprosy.<sup>[19]</sup> A national NTD mapping published in 2016<sup>[20]</sup> showed that BU and leprosy are co-endemic in many states in both the north and south of Nigeria. This presents opportunities for integrated programming for the management and control of these diseases.

Mental health services in Nigeria are deficient in quantity and quality. It is estimated that there is currently one psychiatrist to one million inhabitants and 40:1,000,000 for psychiatric nurses.<sup>[21]</sup> Furthermore, distribution of the available professionals is grossly skewed in favor of urban areas.

### Study design

This is a cluster randomized trial involving 10 LGAs with the highest number of notified leprosy or BU cases between 2014 and 2018, purposively selected from 220 LGAs in southeast and south-south geopolitical zones of Nigeria.

Baseline survey will be done in the 1<sup>st</sup> year of the project in both intervention and control LGAs to determine the magnitude of depression using Patient Health Questionnaire-9 (PHQ-9), GADs using GAD-7, self-stigma using Stigma Assessment and Reduction of Impact (SARI) scale, and QOL using the WHOQOL-BREF and Warwick-Edinburgh Mental Well-being Scale (WEMWBS) among eligible persons affected by leprosy/BU.

Attitude of health workers and community leaders toward leprosy/BU patients will be assessed using focus group discussions (FGDs) and key informant interviews (KIIs). In addition, the Social Distance Scale (SDS) will also be used for community opinion leaders.

### Intervention

The intervention will be at three different levels expected to work synergistically with the intention to reduce mental disorders and improve QOL among persons affected by leprosy/BU. The intervention will include the following:

- Engaging selected community members as lay counselors for basic mental health services: Advocacy visit to community gatekeepers will provide a platform to identify suitable and willing community leaders who will be trained to serve as lay counselors for persons affected by leprosy/BU. Depending on the size of each LGA, at least 5 persons will be selected per LGA so that leprosy/BU patients will not need to travel long distances to access care or social support. Baseline assessment will be carried out to ascertain the perception of leprosy/BU among community opinion leaders. This will be carried out by the research team using SDS and FGDs. Thereafter, selected community opinion leaders will be trained as lay counselors to provide psychosocial support for persons affected by leprosy or BU with depression or general anxiety disorders. This training will be facilitated by a team of mental health service providers who will

undergo special mental health training by a psychiatrist and clinical psychologist to enable them train community lay counselors and frontline health-care workers. The mental health team will comprise technical staff of German Leprosy and TB Relief Association (GLRA) Enugu Nigeria, selected leprosy/BU program managers, and persons affected by NTD.

- Formation of SHGs among persons affected by leprosy or BU: Persons affected by leprosy/BU will be organized into SHGs. The SHGs will be for all patients whether they have mental health problems or not. At the outset, a baseline assessment of level of self-stigmatization among these persons will be carried out by research team using the SARI Stigma scale. Level of depression of each person affected by leprosy/BU will be assessed routinely during each SHG meeting, using PHQ-9. The purpose of SHGs is to reduce self-stigma and improve QOL through peer support. During the formation of SHGs, orientation will be provided to group members and their leaders by the research team.
- Training of health-care workers: Health workers from primary health-care units will be trained on screening persons affected by leprosy/BU for mental health problems using PHQ-9, GAD-7 for depression/GAD, and WEMWBS for QOL. They will also be trained to provide pharmacological and psychosocial treatment and/or effective referrals to psychiatrists/clinical psychologists for cases they may not be able to handle. Topics covered in the training include those of community lay counselors in addition to basic treatment for common mental disorders, especially depression and GAD, and supportive referrals to appropriate levels of care.
- Interlinkage of services and collaboration among the three pillars of care: Health-care workers and community lay counselors will hold joint review meetings with SHGs at agreed locations once every 3 months. During interactive sessions, project progress will be reappraised and challenges to optimal mental health care, social participation, and well-being of leprosy/BU patients in the community will be addressed.

The intervention phase will take 2 years with quarterly joint meetings of patient SHGs, health-care workers, and community lay counselors during supervisory visits by research team. It is believed that this will promote social inclusion, raise awareness on mental health problems, and availability of services to create demand and enhance utilization. Retraining of service providers and SHGs will be done twice throughout the project period.

All assessments done at baseline will be repeated postintervention in both intervention and control groups, to capture any changes. If successful, the project will provide evidence for a holistic, community-oriented approach for improving access and utilization of mental health services which can be scaled up nationwide.

## Study population

The study involves three key populations: community opinion leaders, health-care workers, and SHGs of persons affected by leprosy or BU.

Community opinion leaders will serve as lay counselors for patients with mental health disorders. These may include religious leaders, school teachers, retired civil servants, youth and women leaders, and other respected members of the community. At least five lay counselors will be selected per LGA.

The primary health-care workers include nurses, community health extension workers, and community health officers. They will work with community leaders to provide mental health care in the form of pharmacotherapy and psychotherapy to diagnosed patients as well as ensure referral to a psychiatrist/clinical psychologist whenever necessary. At least five health-care workers will be recruited per LGA.

## Inclusion criteria

- Any person affected by leprosy/BU
- All persons affected by leprosy/BU registered for treatment up to 1 year before end of intervention
- Participants aged between 18 years and above registered for leprosy treatment or participants registered for BU including children.

## Exclusion criteria

- Refusal to give consent
- Patients who need urgent medical attention
- Patients unable to communicate clearly.

## Sample size calculation

A study in Nigeria revealed that 58% of leprosy patients have mental disorders.<sup>[4]</sup> This study anticipates that 50% of respondents will have mental disorders and 35% reduction is desired after intervention. A study demonstrated that training of community lay workers could reduce prevalence of depression by more than 20%.<sup>[15]</sup> A World Bank study revealed that 22% of Nigerians are depressed.<sup>[22]</sup> Therefore, sample size calculation for matched pairing at power = 80%,  $P = 0.05$ , and anticipated 30% loss to follow-up is 400 leprosy patients (200 each group: intervention/control). Calculation was powered by leprosy alone, because data on mental disorders among BU patients are unavailable. However, it is known that many features (disfigurements and stigma) known to result in mental health disorders are similar in both diseases. All eligible BU patients will be included.

## Sampling

Ten LGAs with the highest number of notified leprosy or BU cases between 2014 and 2018 were purposively selected from 220 LGAs in southeast and south-south geopolitical zones of Nigeria. The LGAs served as clusters which were then randomized into study group (5 LGAs) and control group (5 LGAs). All persons diagnosed with leprosy and BU in the selected LGAs within the period indicated above and who are willing to participate in the study will be included.

## Data collection methods

Data will be collected from persons affected by leprosy/BU at baseline and postintervention and from community leaders and health-care workers in intervention and control LGAs. Data collection tools include PHQ-9, GAD-7, WEMWBS, SARI Stigma scale, WHOQOL-BREF, SDS, FGD/KII guides, logbooks kept by community leaders and SHGs, and registers for routine leprosy/BU data collection. Data will include the following:

- Biodemographic information
- Prevalence of mental disorders among persons affected by leprosy/BU using PHQ-9 as screening tool for depression and GAD-7 to screen for GAD
- Attitude of community leaders toward leprosy/BU patients using SDS and FGD/KII.
- Stigma perception among persons affected by leprosy/BU using the SARI Stigma scale
- QOL and mental well-being of persons affected by leprosy/BU using WHOQOL-BREF and WEMWBS
- Perception of health-care workers on mental well-being of leprosy/BU patients using FGD/KII.

The study and control groups will be compared after intervention to determine change in mental health status, QOL, and social participation of study participants.

Data quality will be guaranteed by:

- Training and supervision of research assistants
- Double transcription of voice recordings of KIIs and FGDs.

## Validation of study tools

Prior to fieldwork, a short validation will be done to validate the tool in all relevant study sites in Nigeria.

This involves:

- Translation/back translation of tool in Pidgin English, Igbo, and Efik languages
- Conduct interviews to ascertain how well tool is understood (interpretability)
- Several rounds of translation/back translation with 5–10 persons
- Further validation will be done during fieldwork.

## Recruitment

To recruit study participants, first, names and contact details of leprosy or BU patients will be obtained from LGA Leprosy and BU Treatment Registers, respectively. Eligible persons will be contacted by phone calls through the LGA Tuberculosis and Leprosy Supervisors (LGTBLS) and invited for orientation meeting on a scheduled date. All leprosy/BU patients who are eligible regardless of mental health status will be enrolled into SHGs up to 1 year before end of intervention. However, patients who come after the deadline may join the SHGs and receive appropriate services, but not included in the final research analysis.

For recruitment of community opinion leaders, advocacy visit to community gatekeepers to introduce the project will precede

identification of suitable persons in the community. Criteria for selection include residence in community, age above 18 years, completion of basic education, and willingness to provide psychosocial support to persons affected by leprosy/BU. Selected community members have no prior professional training in mental health and should win the acceptance of persons affected by leprosy/BU.

To recruit study health-care workers, LGTBLS of each LGA will be requested to provide basic information on primary health-care facilities and health-care workers in the LGA during the advocacy visits. The health workers shall be contacted through phone calls and invited to participate in FGDs on a scheduled date to ascertain their perception on mental health services for persons affected by leprosy or BU.

### Data management

Data entry and analysis for (quantitative data collection method) will be done using IBM Statistical Package for Social Sciences (SPSS) statistical software version 25 (IBM Corp. Armonk, NY, United States). Categorical variables will be summarized using frequencies and proportions while that for continuous variables will be done using mean and standard deviation. Comparison of categorical variables between the study and control groups will be done using Chi-square test of statistical significance while continuous variables will be compared using Student's *t*-test. Between-group comparisons (like study group before and after intervention) will be done using McNemar's Chi-square test for categorical variables and the dependent Student's *t*-test for continuous variables. In determining predictors of the outcome variables, independent variables that have  $P < 0.2$  on bivariate analysis will be entered into the logistic regression model. The result of the logistic regression analysis will be reported using adjusted odds ratio and 95% confidence interval, and the level of statistical significance will be determined by  $P < 0.05$ . Analysis of qualitative data will be done using QDA Miner Lite v2.0.6.

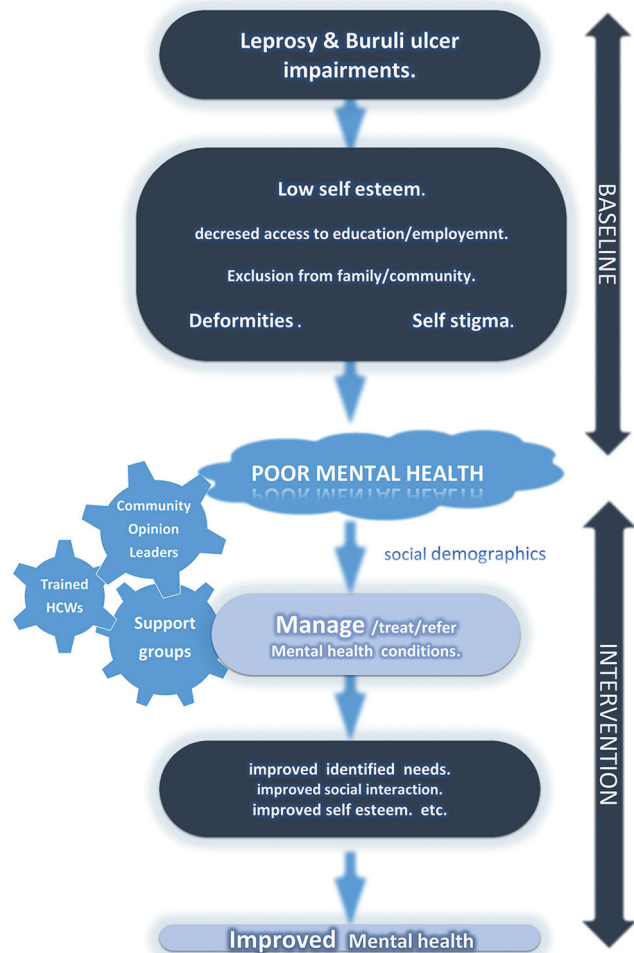
The recorded discussions of FGD and KII will be transcribed verbatim following each session by transcribers and then translated to English by two individuals with good command of both languages. For quality assurance purposes, the scripts will be compared with the written notes for completeness and accuracy. Coding of the transcript will be based on themes as they emerge during the coding process.

### Conceptual framework

Leprosy and BU are diseases associated with impairments. This could lead to low self-esteem which when combined with decreased access to education and employment opportunities coupled with exclusion from family and community could lead to poor mental health.

The intervention which includes use of SHGs, trained community lay counselors, and general health workers is expected to work synergistically with the intention to reduce mental disorders and improve QOL among persons affected by leprosy/BU [Figure 1].

### Intervention pathway towards improving mental health of persons affected by leprosy or Buruli ulcer



**Figure 1:** Intervention pathway towards improving mental health of persons affected by Leprosy or Buruli Ulcer (Developed by the Researchers)

### Ethical considerations

The research will be performed in accordance with the Helsinki Declaration of 1975 as revised in the year 2000 for Human Research of the World Medical Association. Approval has been granted by the Health Research and Ethics Committee of University of Nigeria Teaching Hospital, Ituku Ozalla, Enugu, Nigeria (NHREC/05/01-2008B-EWA0000 2458-IRB00002323), reference number UNTH/CSA/329/vol. 5/08 and dated March 13, 2020. Again, the consent of key community leaders will be obtained during community entry.

### Consent form

Participants in the study will be required to sign or thumb print a written informed consent form before the interview, and the nature of the study, its relevance, and the level of their participation will be made known to them. Participation in the study will be voluntary and respondents will be assured that there would be no victimization of persons who refused to participate or who decided to withdraw from the study

after giving consent. Respondents will be assured that all information provided through the questionnaire will be kept confidential. Furthermore, there will be nowhere the names of the respondents will be written on the questionnaire. Respondents will be informed that the outcome of the research will be useful in understanding the mental health and well-being of persons affected by leprosy or BU. There will be no risk to the participants with regard to their participation in this survey, and this will be made known to them.

### Limitations of the study

There is the possibility of attrition among the respondents that will be included in the study bearing in mind the duration of the intervention period. Some respondents may also change their area of residence. There could also be social desirability bias on the part of the respondents in response to the variables in the study tools. Efforts will be made to explain the objectives of the study to the respondents and that no identifiers will be included during the process of data collection.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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