STUDY PROTOCOL:

IMPROVING MENTAL HEALTH AND QUALITY OF LIFE OF PERSONS AFFECTED BY LEPROSY OR BURULI ULCER IN SOUTHERN NIGERIA.

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SUMMARY

Background

In Nigeria, leprosy and Buruli ulcer (BU) patients often lack access to mental health services. This gap in the National Tuberculosis and Leprosy Control Programme affirms the need to explore sustainable ways to make mental health services accessible to those in dire need.

This protocol describes a study in which we will determine the effect of using community lay counsellors, self-help groups of patients and trained frontline health workers in reducing mental disorders (especially, depression and anxiety disorders) and improving quality of life of persons affected by leprosy or BU.

Methods

A cluster randomized controlled study design will be employed. The study will involve persons affected by leprosy or Buruli ulcer. 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 by using a computer-generated list of random numbers. At baseline, data on depression will be collected using Patient Health Questionnaire-9 (PHQ-9); generalized anxiety disorders using Generalized Anxiety Disorders-7 (GAD-7), self-stigma using Stigma Assessment and Reduction of Impact (SARI) scale and quality of life using WHOQOL-BREF and Warwick-Edinburgh Mental Well-being Scale

(WEMWBS) among eligible persons affected by leprosy or BU. The intervention will last for two years and will involve the use of community lay counsellors, self-help groups and training of frontline health workers in reducing mental disorders and improve quality of life among persons affected by leprosy/BU.

Discussion

This project postulates the reduction of burden of mental health problems and improved quality of life among persons affected by leprosy or BU could be achieved through a holistic approach involving self-help groups, 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 and Control Programme and scaled up nationwide.

Trial registration

(ISRCTN) In progress

Background

Skin neglected tropical diseases including leprosy and Buruli ulcer are a group of stigmatizing and disability inducing infections. These diseases even though they may have different causes and transmission routes share the need for chemotherapy, in-patient wound care, prevention of physical disability and psychosocial support to achieve rehabilitation. [1] This necessitates for a holistic approach in the care of these patients as there is a tendency for persons affected with these diseases to develop mental health illnesses. The World Health Organization estimates that mental diseases will be the highest cause of disease burden by the year 2030. [2] In Nigeria, mental health problems especially depression were found to be high among lymphatic filariasis patients due to low self-esteem and low quality of life. [3] Another study in Lagos, Nigeria, found higher occurrence of depression among leprosy patients compared to those with other skin diseases. [4] These observations may have necessitated the quest by persons affected by Buruli Ulcer (BU) to clamour for the inclusion of psychological care in their healthcare needs. [5[

Studies have shown that self-help group(s) for patients with mental health disorder(s) have positive effects on self-esteem and quality of life, and foster greater acceptance of patients by their families and communities as well as increases the acceptability of services provided. [6,7] 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. [8-10] 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. [11]

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. [12] 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. [13] A cluster randomized trial in Nigeria demonstrated that task-shifted intervention for depression delivered by lay health workers is effective. [14] Several studies and projects have also shown that the use of lay-workers in providing counselling and psychotherapy to patients with moderate to severe depression is not just as effective as using professionals but also cost-effective. [15,16]

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. [12] To address this, our study proposes a more holistic approach which involves a network of lay community workers, self-help groups of leprosy/BU patients and general healthcare 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 cost-effective. This project postulates that reduction of burden of mental health problems (especially depression) and improved quality of life among persons affected by leprosy or BU could be achieved through a holistic approach involving self-help groups, 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 and Control Programme 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) and the quality of life among persons affected by leprosy or Buruli ulcer 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 impact of a community-oriented, holistic approach on mental health status (depression and generalized anxiety disorder (GAD)) of persons affected by leprosy or BU.
3. To determine the impact of a community-oriented, holistic approach on quality of life of persons affected by leprosy or BU.
4. To determine the impact of a community-oriented, holistic approach on social participation of persons affected by leprosy or BU.
5. To determine the effect of socio-demographic variables on mental health status (depression and GAD) status of persons affected by leprosy or BU.
6. To determine the effect of physical impairment on mental health status (depression and GAD) of persons affected by leprosy/BU.
7. To determine the impact of a community-oriented, holistic approach on access to and utilization of mental health services and number of referrals for mental health care within all the levels of care.

Methodology

Nigeria, a West African country of nearly 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 (FCT). 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 Buruli ulcer to its portfolio. At the turn of the century and up to 2007, Nigeria notified about 5,000 new leprosy cases annually. [17] Case notification declined steadily to 2687, 2447 and 2095 respectively in the last 3 years. Proportion of cases with visible deformities had remained high at 14-15%. Child and female proportion stood largely unchanged at 9% and 41% respectively. Despite achieving the WHO leprosy elimination target of less than 1 per 10,000 population in 1998, there continues 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 (SCG) was adopted by the NTBLCP. [18] Despite the fact that an evaluation commissioned by the Netherlands Leprosy Relief found that ‘the self-care groups have made huge impact with such outcomes as less ulcers, improved hygiene, higher self-esteem and better contacts with the community’, self-care groups 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 programme. However, the report of a national programme 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 Doctors conducted in 2013 in south-east Nigeria showed poor knowledge of leprosy. [19] A national NTD mapping published in 2016, [20] shows that BU and leprosy are co-endemic in many states in both Northern and Southern Nigeria. This presents opportunities for integrated programming for management and control of these diseases. While adequate chemotherapy and appropriate adjuvant surgery were provided, little or no attention was given to the mental health of the BU and leprosy patients. Persons with leprosy and BU related disabilities are faced with varying degrees of stigma and discrimination which predispose them to mental health problems especially depression and anxiety. Anecdotal evidence indicates that the level of stigma is far higher in Southern Nigeria than in the north.

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. [21] Furthermore, distribution of the available professionals is grossly skewed in favour of urban areas. The organization of mental health services is top-heavy; at the apex of the pyramid are 8 federal neuro-psychiatric hospitals and about 20 departments of Psychiatry at University Teaching Hospitals. Referral systems are cumbersome and not patient-friendly. Health workers at the secondary and primary levels including Doctors and Nurses have little practical training in or awareness of mental health issues. This leaves majority of rural dwellers who constitute majority of the population underserved. The notion of universal coverage and the Sustainable Development Goal mantra of 'leaving no one behind' will remain unattainable if these circumstances persist.

Study design

This is a cluster-randomized trial involving ten LGAs with the highest number of notified leprosy or BU cases between 2014 and 2018, purposively selected from 220 LGAs in south-east/south-south Nigeria. Five LGAs namely, Ebonyi, Ogoja, Ogbaru, Ogbia and Calabar South were randomized as intervention LGAs and five comparable LGAs – Etinan, Ethiope East, Obubra, Anambra East and Isoko South will serve as control. For allocation of clusters (LGAs) to intervention and control groups, a computer-generated list of random numbers was used.

Baseline survey will be done in the first year of the project in both intervention and control LGAs to determine the magnitude of depression using Patient Health Questionnaire-9 (PHQ-9); generalized anxiety disorders using Generalized Anxiety Disorders-7 (GAD-7), self-stigma using Stigma Assessment and Reduction of Impact (SARI) scale and quality of life using WHOQOL-BREF and Warwick-Edinburgh Mental Well-being Scale (WEMWBS) among eligible persons affected by leprosy/BU.

Attitude of health workers and community leaders towards leprosy/BU patients will be assessed using Focus Group Discussions (FGDs) and Key Informant Interviews (KII). Additionally, social distance scale (SDS) will also be used for community leaders.

Intervention

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

- Engaging selected community members as lay counselors for basic mental health management:

  Advocacy visit to community gate-keepers will provide a platform to identify suitable and willing community leaders who will be trained to serve as lay counsellors 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. Following baseline assessment of their perception by trained research assistants using the social distance scale (SDS) and FGDs, their capacity as lay counsellors for the identification and basic management of depression and general anxiety disorders will be built. The 3-day training will be facilitated by Psychiatrists/Clinical Psychologists, Leprosy/BU programme team and Person affected by NTD. Topics to be covered include: i) basic facts about leprosy and BU; ii) screening for depression and GAD using PHQ-9 and GAD-7; iii) basic skills for counselling and psychosocial support; iv) need for social inclusion for persons affected by NTDs; and v) team work/appropriate referrals. After the training, they will be supportively supervised to provide counselling services to leprosy/BU patients with mental disorders and promote their social participation in communities. Lay-counsellors represent a critical link between the formal health system and patient’s self-help groups. Supervision will be done through phone calls and online meetings reinforced by quarterly visits and yearly re-training by research team/mental health experts.

- Formation of self-help groups (SHG) among persons affected by leprosy or BU.

  Persons affected by leprosy/BU will be organized into self-help groups. 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-stigmatisation among these persons will be carried out by trained research assistants using the SARI Stigma scale. .

The purpose of forming SHGs is to reduce self-stigma and improve quality of life among them through peer support. During the formation of SHGs, orientation provided by the research team will include objectives and procedures for establishment of self-help groups. Through an interactive discussion, feedback from persons affected by leprosy/BU will inform essential revisions on the protocol and expected deliverables of the SHGs in line with project objectives. Roles of each member as well as strategies for collaboration with identified community leaders and healthcare givers serving each group will be clearly outlined. Thereafter, the standard operating procedures (SOP) for the SHGs finalized. Members of the SHGs will be guided to elect/appoint their group leaders for effective coordination of the SHGs.

Members of SHGs will be trained to provide psychosocial support to each other through: (i) early and prompt identification of group members with features suggestive of depression or GAD, for example those who suddenly withdraw from social gatherings, meeting absentees or share experiences in group meetings related to mental illness; (ii) each member contacting community opinion leaders directly or through SHG leaders for action (iii)participation in bimonthly meetings to share personal experiences and how to overcome them; (iv) regular communication of SHG leaders/members with the healthcare workers or/ and community leaders regarding physical, mental or social needs members of the group; (v) secured interest of members through regular feedbacks/report from SHG leaders to research team regarding patient satisfaction with mental healthcare received from community leaders and health workers, etc.. Home visits to members who are inconsistent in meetings will also be part of their activities. The opportunity of meetings could be used for skill acquisition and they can form cooperative thrift to support each other financially.

Depending on the number of patients in each LGA, there could be more than one self-help group with an average of 15 persons which will be based on proximity of participants to each other.

- Training of healthcare workers:

  Health workers from primary healthcare 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 quality of life; providing pharmacological and psychosocial treatment and/or effective referrals to psychiatrists/clinical psychologists for severe cases. Topics covered in the training include those of community lay-counsellors in addition to basic treatment for common mental disorders especially depression and GAD and supportive referrals to appropriate levels of care.

- Inter-linkage of services and collaboration among the three pillars of care:

  Healthcare workers and community lay-counsellors will hold joint review meetings with SHGs at agreed locations once every two months. During interactive sessions, project progress will be re-appraised and challenges to optimal mental healthcare, social participation and well-being of leprosy/BU patients in the community addressed. In-between meetings, members/leaders of SHGs who observe features suggestive of mental illness in any member will report same to community lay-counsellor who evaluates and provides basic counselling after documentation. Whenever necessary, the community lay-counsellor contacts the healthcare worker on behalf of the patient and supports patient to receive required attention including chemotherapy or referral to psychiatrist/clinical psychologist through the health worker after documentation. New cases of leprosy/BU who report to facilities will also be referred by healthcare workers to the nearest SHG while providing routine services.

The intervention phase will take 1 to 2 years with quarterly community sensitization during supervisory visits by 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.

All assessments done at baseline will be repeated post-intervention 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, healthcare workers and self-help groups of persons affected by leprosy/BU.

Community opinion leaders will serve as lay-counsellors 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-counsellors will be selected per LGA.

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

Inclusion criteria

- Any person affected by leprosy/BU
- All persons affected by leprosy/BU registered for treatment from 2014 up to one year before end of intervention.
- Participants aged between 15 to 65 years.

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. [4] 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%. [15] A World Bank study revealed 22% of Nigerians are depressed.[22] 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.

2.5.6 Data collection methods:

Data will be collected from persons affected by leprosy/BU at baseline and post intervention and from community leaders and healthcare workers in intervention and control LGAs. Data collection tools include: PHQ-9, GAD-7, WEMWBS, SARI stigma scale, WHOQOL-BREF, SDS, FGD/KII guides, Log-books kept by community leaders and SHGs and registers for routine leprosy/BU data collection. Data will include:

- Bio-demographic information
- Prevalence of mental disorders among persons affected by Leprosy/BU using PHQ-9 as screening tool for depression and GAD-7 (see annex for tools) to screen for GAD.
- Attitude of community leaders towards leprosy/BU patients using SDS and FGD/KII.
- Stigma perception among persons affected by leprosy/BU using SARI Stigma scale
- Quality of life and mental well-being of persons affected by leprosy/ BU using WHOQOL-BREF and WEMWBS.
- Perception of healthcare 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, quality of life 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 field work, a short validation will be done to validate the WEMWBS 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 field work.

Recruitment

To recruit study participants, first, names and contact details of leprosy or BU patients will be obtained from LGA Leprosy and Buruli ulcer 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. Newly detected, eligible leprosy or BU patients registered for treatment at the health facilities during intervention will also be evaluated for depression and GAD by healthcare workers using the research tools and thereafter introduced to nearby SHGs. All leprosy/BU patients who are eligible regardless of mental health status will be enrolled into SHGs up to one year before end of intervention. However, patients who come after the deadline will join the SHGs and receive appropriate services, but not included in final research analysis. All suspected cases of BU or leprosy found by community leaders or members of SHGs will be referred to health workers for diagnosis.

For recruitment of community opinion leaders, advocacy visit to community gate-keepers to introduce the project will precede identification of suitable persons in the community. Criteria for selection should 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 on mental health and should win the acceptance of persons affected by leprosy/BU. Both healthcare workers in the area and persons affected by leprosy/BU including leaders of their SHGs will be involved in the search or nomination of suitable community opinion leaders who will be trained as lay-counsellors and social advocates for patients in the community. This will be done during advocacy meeting with persons affected by leprosy/BU and healthcare workers. This process will ensure the recruitment of suitable persons for the project.

To recruit study healthcare workers, LGTBLS of each LGA will be requested to provide basic information on primary healthcare facilities and healthcare workers in the LGA during the advocacy visits. The health workers shall be contacted through phone calls and invited to participate in focus group discussions (FGDs) on a scheduled date to ascertain their perception on mental health services for persons affected by leprosy or BU. At least two FGD sessions will be conducted with PHC healthcare workers purposively selected in each LGA. LGTBLS will serve as key informants for the key informant interviews (KII). During the intervention, at least 5 healthcare workers from different PHC centres in each LGA will be selected for training on provision of mental health services. Priority will be given to health workers already involved in case management of leprosy/BU patients. The LGTBLS and heads of PHCs will be requested to identify willing and committed health workers who will be trained to provide mental health services to leprosy/BU patients. Consideration for recruitment will include those who work in areas close to SHGs and also indicate interest in collaborating with SHGs and community leaders in providing services to patients.

Data management

Two research assistants per LGA comprising members of the selected communities will be trained for one day for data collection using the interviewer administered questionnaire. The research assistants must have attained at least secondary education. They will be trained on privacy and confidentiality before the study begins. The researchers will conduct the FGDs and KIIs. Interviewers will be trained on confidentiality procedures and undertake to ensure confidentiality as part of their engagement agreement.

A secured box will be made available in German Leprosy and TB Relief Association head office for the safe storage of the questionnaires and other materials related to the research. The recordings used for FGDs and KIIs will be transcribed immediately after the interview. English, Pidgin English, Efik or Igbo languages will be used to conduct FGDs and the discussions will take place in secluded areas of the selected communities like public primary schools and town halls.

Data entry and analysis for (quantitative data collection method) will be done using IBM Statistical Package for Social Sciences (SPSS) statistical software version 25. Categorical variables among the study and control groups will be compared using Chi square test of statistical significance while continuous variables will be compared using Student t test. In between group comparisons (like study group before and after intervention) will be done using Mcnemar Chi square test for categorical variables and the dependent Student t test for continuous variables. In determining predictors of the outcome variables, independent variables that have a p value of less than 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 a p value of <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. Then each script will be checked against the audiotape by an independent reviewer. As a way of verifying the quality of translations, tapes will be doubly transcribed after which both scripts will be checked for similarity and where differences exist; these will be reconciled by the transcribers. Coding of the transcript will be based on themes as they emerge during the coding process. Soft copies of relevant data will be safely stored away in password-protected, 1terabyte (1TG) capacity external (computer) storage device.

Ethical considerations

A number of steps will be taken to address the ethical issues essential for this study. These include the following:

Ethical approval: Ethical approval for the study will be obtained from the Health Research and Ethics Committee of University of Nigeria Teaching Hospital, Ituku Ozalla, Enugu. Also, consent of key community leaders will be obtained accordingly during community entry.

Participant Information Sheet: Participants will be provided with sufficient information about the project to enable them freely make informed consent regarding their participation.

Informed consent: The respondents will be required to sign or thumb print to a written informed consent before the interview and the nature of the study, its relevance and the level of their participation will be made known to them.

Voluntary participation: Participation in the study will be voluntary. Also, respondents will be assured that, there would be no victimization of respondents who will refuse to participate or who will decide to withdraw from the study after giving consent.

Assurance of confidentiality: Respondents will be assured that all information provided through the questionnaire will be kept confidential. Also, the names of the respondents will not be written on the questionnaire.

Beneficence to participants: Respondents will be informed that the outcome of this research will be useful in improving the mental health and quality of life of people affected with Leprosy and Buruli Ulcer.

Non-maleficence to participants: There will be no risk to the clients with regards to their participation in this survey and this will be made known to them.

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