Participant Information Sheet

1. Research Project Title

Improving mental health and wellbeing of persons affected by leprosy or Buruli ulcer in southern Nigeria.

2. Invitation

You are being invited to take part in this research project. Before you decide to do so, it is important you understand why the research is being done and what it will involve. Please take time to read (or listen to) the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading (or listening to) this.

3. What is the project's purpose?

The primary purpose of the project is to determine the impact of a community-oriented, holistic approach on improving mental health and wellbeing of persons affected by leprosy or Buruli ulcer. This will entail the use of patient self-help groups, training selected community leaders as lay-counsellors and training health workers to appropriately treat/refer any person with mental disorders. We hope that the combined approach will reinforce and complement each other in a synergistic manner to improve mental wellbeing of persons affected by leprosy or Buruli ulcer.

4. Why have I been selected?

You have been selected as a person who was once diagnosed or treated for leprosy or Buruli ulcer.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be able to keep a copy of this information sheet and you should indicate your agreement by signing the consent form. Whatever decision you make will not affect your care. You can still withdraw at any time. You do not have to give a reason.

6. What will happen to me if I take part?

You will simply be asked a set of questions by our trained research assistants. The interview will last about 45 minutes. You may also wish to agree to join a self-help group nearest to you in order to participate in their monthly meetings. You may wish to participate in a follow-up interview to find out more about your wellbeing.

7. What do I have to do?

You will be asked to respond to the questions from an interviewer. There are no other commitments or lifestyle restrictions associated with your participation.

8. What are the possible disadvantages and risks of taking part?

Participating in the research is not anticipated to cause you any disadvantages or discomfort. The potential physical and/or psychological harm or distress will be the same as any experienced in everyday life.

9. What are the possible benefits of taking part?

Whilst there are no immediate benefits for those participating in the project, it is hoped that this work will have a beneficial impact on how best to provide mental health services to marginalized groups such as persons affected by leprosy or Buruli ulcer. Your participation may contribute to wellbeing of many patients who suffer similar health challenges, since the results will be shared with participants and policy makers. Any participant eventually found to have depression and anxiety disorders will be treated at no cost.

10. What happens if the research study stops earlier than expected?

Should the research stop earlier than planned and you are affected in any way we will tell you and explain why.

11. What if something goes wrong?

If you have any complaints about the project in the first instance you can contact any member of the research team. If you feel your complaint has not been handled to your satisfaction you can contact the German Leprosy and Tuberculosis Relief Association to take your complaint further (see below).

12. Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be able to be identified or identifiable in any reports or publications. Your community will also not be identified or identifiable. Any data collected about you by our research assistants will be safely and securely stored in official digital storage devices in a form protected by relevant security processes and technologies.

Data collected may be shared in an anonymized form to allow reuse by the research team and other third parties. These anonymized data will not allow any individuals or their communities to be identified or identifiable.

13. Will I be recorded, and how will the recorded media be used?

You will not be recorded in any way other than your input to the questionnaire without separate permission being gained from you.

14. What type of information will be sought from me and why is the collection of this information relevant for achieving the research project's objectives?

You will be asked questions about your general wellbeing, thoughts and feelings within the past two weeks. Your views and experience are just what the project is interested in finding out.

15. What will happen to the results of the research project?

Results of the research will be published. You will not be identified in any report or publication. Your home or community will not be identified in any report or publication. If you wish to be given a copy of any reports resulting from the research, please ask us to provide it for you.

16. Who is organizing and funding the research?

The project is organized by German Leprosy and Tuberculosis Relief Association. It is funded by Leprosy Research Initiative

17. Who has ethically reviewed the project?

This project has been ethically approved by the Research Ethics Committee of University of Nigeria Teaching Hospital, Ituku Ozalla, Enugu, Nigeria.

18. Contacts for further information

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The Secretariat of German Leprosy and Tuberculosis Relief Association can be reached through the following contacts:
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Thank you for taking part in this research.