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Are self-care interventions effective for the management of skin neglected tropical diseases in Anambra State, Nigeria?

Submission date 13/08/2021	**Recruitment status** No longer recruiting
Registration date 27/08/2021	**Overall study status** Completed
Last Edited 27/09/2021	**Condition category** Skin and Connective Tissue Diseases

☐ Prospectively registered
☒ Protocol
☐ Statistical analysis plan
☒ Results
☐ Individual participant data

Plain English summary of protocol

Background and study aims

Lymphatic filariasis (LF), Buruli ulcer (BU), and leprosy are neglected tropical diseases (NTDs) of the skin. These diseases often occur together in the same communities. The cutaneous manifestations of these diseases may include physical changes and losses to body structures causing permanent impairments and disability. Due to the frequent co-existence of these NTDs and the similarity in their management and control the World Health Organization (WHO) has called for their integrated management and care. However, not enough is known about the impact of integrated morbidity management and disability prevention in people with these conditions. The authors assessed the effectiveness of an integrated self-care intervention for people with these skin NTDs in two communities in terms of the effectiveness of self-care interventions on participants' costs of care for the impairment, disability status, and health-related quality of life.

Who can participate?

Individuals diagnosed with LF, BU, or leprosy who had completed specific treatment for their condition but who still had morbidities (like impairments, ulcers, etc) requiring additional care.

What does the study involve?

Individuals diagnosed with LF, BU, or leprosy who had completed specific treatment for their condition but who still had morbidities (like impairments, ulcers, etc) requiring additional care were trained to offer themselves self-care for their impairment and lesion. For each patient, the self-care skills and training were tailored to their need. Participants were instructed to visit a selected nearby health facility where a healthcare worker reinforces the taught self-care skills and interact with other patients.

Of the 48 participants recruited from December 2017 to March 2018, 30 of them reached the the last follow-up by June 2018

What are the possible benefits and risks of participating?
Improvement in the well-being, quality of life and reduction in the disability status of participants including their costs of managing the impairment

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

When is the study starting and how long is it expected to run for?
September 2017 to June 2018

Who is funding the study?
The study was funded by the American Leprosy Mission, USA. The funders provided technical assistance in the training of field healthcare workers as well as technical support during the project. The funders had no role in study design, data collection and analysis, preparation of the manuscript or the decision to publish the manuscript.

Who is the main contact?
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Additional identifiers

Protocol serial number
GLRA001

Study information

Scientific Title
Effectiveness of self-care interventions for integrated morbidity management of skin neglected tropical diseases in Anambra State, Nigeria

Study objectives
The objective of the study was to assess the effectiveness of self-care interventions on participants costs of care, disability status and health-related quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/09/2017, Health Research Ethics Committee of the Anambra State Ministry of Health (Okechukwu Chidi, Jerome Udoji Secretariat Complex, Ministry of Health, PMB 6002, Awka, Anambra State, Nigeria; no telephone number provided; no email provided), ref: MH/AWK/M:321/383

Study design
Quasi-experimental pre-test/post-test design

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Skin neglected tropical diseases: Leprosy, Buruli Ulcer (BU), or Lymphatic Filariasis (LF) and non-neglected tropical diseases skin lesions (such as diabetic ulcers, sickle cell disease and trauma)

Interventions
In the study setting, the cadre of healthcare workers involved in the project are community health extension workers and community health officers. The self-care intervention for integrated morbidity management of skin NTDs had the following components:

a) Improvement of healthcare workers' (HCWs) knowledge and skills to identify and manage NTD impairments and complications locally or refer participants to other individuals or organizations that could help. This involved a 5-day non-residential training of HCWs in integrated management of NTD impairments using the American Leprosy Mission's monograph, "Ten steps: A guide for health promotion and empowerment of people affected by NTDs" . The training involved the identification and management of common impairments and teaching self-care to affected participants. In addition, HCWs received guidance on measuring and recording impairments (for example, ulcer size, size of swelling, and limitations of movement) during participants' baseline and follow-up visits at the health service. Six HCWs (who were community health extension workers and community health officers) from four primary health centres in the study sites were trained in integrated morbidity management and disability prevention for skin NTDs.

b) HCWs' provision of health education about NTDs and teaching participants with NTD self-care skills on how to manage their own impairments at home. This involved HCWs working with each participant to identify and care for his/her impairments so that they could manage their own care. The skills taught to participants during monthly visits with HCWs included skin and scar care, wound dressing, guidance on sterilisation of bandages, management of swelling and prevention and management of movement limitations. Monthly visits were not feasible for participants who lived too far away, but every participant had at least two visits. During these visits, the HCWs evaluated the participants' impairments, addressed concerns or challenges faced by the participant when implementing self-care at home, and recorded changes in participants' impairments.

c) Improvement in self-care practices among participants with skin NTDs. All participants in the study had BU, leprosy or LF with impairments and movement limitations or had similar impairments not related to NTDs (such as diabetic ulcers, sickle cell disease and trauma). Welcoming participants without NTDs was important to increase uptake and reduce resentment among those who otherwise would have been turned away. All of those who wanted to participate were trained at the health facility on self-care specific to their needs using the "10-steps" monograph. Enrolled patients were expected to report to participating health facilities at least once every month for reassessment of impairment, reinforcement of self-care teaching and refill of self-care materials where necessary. In order to evaluate the success of the project, participants were asked to report monthly costs of their impairment care, disability status and Quality of Life (QoL) at baseline and follow-up after the intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. Self-reported economic costs of managing the impairment or lesion before (December 2017) and after (May/June 2018) the intervention period assessed with a costing tool
2. Disability status due to the impairment or lesion before (December 2017) and after (May/June 2018) the intervention period assessed using the World Health Organization Disability Scale-2 (WHODAS-2.0)
3. Quality of life due to the impairment or lesion before (December 2017) and after (May/June 2018) the intervention period assessed using the World Health Organization Quality of Life-BREF (WHOQOL-BREF) tool

Key secondary outcome(s))

1. Self-reported economic costs of managing the impairment or lesion assessed with a costing tool by patients who provided baseline data but did not complete follow-up compared to those who completed follow-up.
2. Disability status due to the impairment or lesion assessed using the World Health Organization Disability Scale-2 (WHODAS-2.0) by patients who provided baseline data but did not complete follow-up compared to those who completed follow-up.
3. Quality of life due to the impairment or lesion assessed using the World Health Organization Quality of Life-BREF (WHOQOL-BREF) tool by patients who provided baseline data but did not complete follow-up compared to those who completed follow-up.

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Diagnosed with LF, BU or leprosy
2. Completed specific treatment for their condition but still had morbidities requiring additional care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
48

Key exclusion criteria
Participants who had no impairment due to neglected tropical diseases or related conditions with similar impairment

Date of first enrolment
01/12/2017

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
Nigeria

Study participating centre
Primary Health Centres
Okpoko and Ogbakuba in Ogbaru Local Government Area
Anambra
Nigeria
431108

Sponsor information

Organisation
DAHW German Leprosy and TB Relief Association (GLRA) Nigeria

Funder(s)

Funder type
Charity

Funder Name
American Leprosy Missions

Alternative Name(s)
ALM

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. The Medical Department of German Leprosy and TB Relief Association, contact Ms Chinwe Eze, chinwe.eze@dahw.org, deanonymized data will be

made available upon reasonable request for research and educational purposes. Access to the data will be given by email and any further research based on the dataset must be by collaboration with the study authors

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/09/2021	27/09/2021	Yes	No
Protocol file			25/08/2021	No	No