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Enhanced self-care for advanced lymphoedema

Submission date
20/02/2018

Recruitment status
No longer recruiting

Registration date
04/04/2018

Overall study status
Completed

Last Edited
07/08/2020

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Lymphatic filariasis (LF) is a parasitic disease that occurs when filarial parasites are transmitted to humans through mosquitoes. Lymphoedema (tissue swelling) from lymphatic filariasis is a major cause of disability in the world affecting over 15 million people, most of whom are living in the poorest rural areas of developing tropical countries. The global program to eliminate LF aims to interrupt disease transmission through preventive chemotherapy and provide a minimum package of care to existing patients. In Ethiopia lymphoedema is also caused by podoconiosis, a disease caused by barefoot exposure to volcanic soils. Lymphoedema from both causes can be managed through community-based home-care which is centred around a daily hygiene routine to prevent other bacterial and fungal infections (acute attacks), and also simple exercises and leg elevation. The standard self-care routine as recommended by WHO has been shown to prevent acute attacks and reduce lymphoedema in mild to moderate cases. Advanced cases, however, benefit less from this standard care. In this group the daily hygiene routine can reduce the frequency or intensity of acute attacks but there is not much reduction in the lymphoedema. This study aims to determine whether the addition of deep breathing exercises, more targeted leg exercises and lymphatic self-massage (enhanced care) can deliver increased benefits to people with moderate and severe leg lymphoedema compared to the currently recommended self-care routine (standard care).

Who can participate?
Patients aged 18 or older with moderate to severe leg lymphedema and their carers

What does the study involve?
Twenty health facilities are randomly selected in each country (Bangladesh and Ethiopia) and allocated to either the standard or enhanced care groups. Participants are asked to perform either the standard care or the enhanced care routine according to their group allocation. Standard care involves daily hygiene practices such as washing and drying the legs, applying medicated creams to any open ulcerated skin lesions, and daily elevation and simple exercises. Enhanced care involves all standard care activities and additional daily activities of deep breathing exercises, leg exercises, lymphatic massage, eating fresh fruits and vegetables, drinking adequate clean water, and walking as much as possible up to 1.5 hours daily. At the end of the study participants allocated to the standard care group receive training in the enhanced

care routine. Both groups receive all the necessary resources to carry out the daily activities (soap, towels, creams etc) and record the daily activities in a journal. Lymphoedema status is assessed at the start of the study and after 4, 12 and 24 weeks.

What are the possible benefits and risks of participating?
It is anticipated that patients with leg lymphoedema will report reduced symptoms and improved quality of life, and that both patients and carers will experience increased knowledge and awareness of lymphoedema care and reduced disruption to income-generating activities because of caring for the lymphoedema. As neither intervention involves any invasive or strenuous activities, few risks are anticipated as a result of participation in the study.

Where is the study run from?
Community health centres in Bangladesh and Ethiopia

When is the study starting and how long is it expected to run for?
As of 16/11/2018:
October 2018 to May 2019

Previously:
February 2018 to March 2019

Who is funding the study?
1. GlaxoSmithKline (UK)
2. Department for International Development (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GSK obj 5

Study information

Scientific Title
Enhanced self-care protocol for severe case management of lymphoedema

Study objectives
Standard-care protocols for self-care in the management of lymphoedema caused by filariasis and podoconiosis have been shown to benefit people with mild - moderate stages of disease but have less effect in severe cases. Enhanced self-care is expected to address this but is as yet untested in these populations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval as of 29/11/2018:
Liverpool School of Tropical Medicine Research Ethics Committee (approval number 18-012): 05 /10/2018
Bangladesh Medical Research Council (approval number 120 12 06 2018): 07/08/2018
Amhara Public Health Institute Research Ethics review Committee (approval number RTT03/15 /2018): 31/10/2018.

Previous ethics approval:
Liverpool School of Tropical Medicine Research Ethics Committee (approval number 18-012): no date provided
Ethical approval in Ethiopia and Bangladesh also obtained.

Study design
Multicentre comparative cohort six-month study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Lower limb lymphoedema caused by either; infection with lymphatic filariasis or podoconiosis

Interventions
19 districts in Bangladesh and 20 districts in Ethiopia have information on burden of disease. In each country, 20 health facility catchments are randomly selected using a random number generator. Of these 20 health facility catchments, 10 are allocated to Group A and 10 are allocated to Group B using a random number generator. However, to ensure the groups are located far enough away from each other to reduce any likelihood of discussions between groups allocated to different protocols, purposeful sampling may be used. Within each health facility catchment, community health workers (CHW) invites all known moderate and severe lymphoedema patients, over the age of 18 years to be involved in the study. participants will be allocated to group A or group B depending on their health facility allocation. CHW, patients and their carers are trained in the daily lymphoedema care protocol according to their group allocation. Upon completion of the study all participants will be trained in the enhanced care protocol.

Control Group A: Participants in this group receive the standard lymphoedema self-care (WHO guidelines) including;
1. Daily washing and drying of the limbs
2. Attending to entry lesions to prevent secondary bacterial infections
3. Daily elevation and simple exercises

Intervention Group B: Participants in this group receive the enhanced lymphoedema self-care including
1. All standard-care activities as described above
2. Daily deep breathing exercises
3. Additional exercises and walking
4. Daily lymphatic massage
5. Daily consumption of fresh fruits and vegetable
6. Daily consumption of adequate clean water

Lymphoedema status will be assessed at baseline prior to participants receiving the training in lymphoedema-care, and after 4, 12 and 24 weeks of performing the daily protocol.

Intervention Type
Behavioural

Primary outcome measure
Lymphoedema status is measured at baseline prior to participants receiving the training in lymphoedema care, and after 4, 12 and 24 weeks of performing the daily protocol using:
1. Lymphoedema stage according to the Dreyer 7 stage system
2. Limb circumference at mid-calf using a tape measure
3. Subcutaneous tissue compressibility at mid-calf using an indurometer (the Indurometer is a small hand held device which non-invasively measures the degree of tissue compressibility in the

skin and subcutaneous compartment. This device is previously validated in women with breast cancer-related arm lymphoedema and young, asymptomatic people residing in an LF endemic region in Myanmar)

Secondary outcome measures
1. Adherence to the self-care protocol measured at baseline prior to participants receiving the training in lymphoedema care, and after 4, 12 and 24 weeks of performing the daily protocol using:
1.1. Daily journal kept by the participant and collected at each follow-up measure
1.2. Knowledge, attitudes and practices (KAP) questionnaire administered at baseline and after 24 weeks
2. Self-reported symptoms measured at baseline prior to participants receiving the training in lymphoedema care, and after 4, 12 and 24 weeks of performing the daily protocol using:
2.1. Pain
2.2. Perceived level of functional disability
2.3. Frequency and duration of acute attacks (secondary bacterial infections)
2.4. Days of work lost due to the disease
3. Quality of life measured using visual analogue scale at baseline prior to participants receiving the training in lymphoedema care, and after 4, 12 and 24 weeks of performing the daily protocol

Overall study start date
01/02/2018

Completion date
10/05/2019

Eligibility

Key inclusion criteria
Patients lymphoedema, their carers and community health workers who:
1. Reside within a 10 km radius of the selected health facilities
2. Are 18 years of age or older
3. Patients must have moderate to severe leg lymphoedema as defined as stage 3 or above according to the Dreyer staging system for filarial lymphoedema
4. Patients must be able to perform the daily self-care protocol either independently or with the aid of a carer.
5. Carers must be available on a daily basis to assist the patient with lymphoedema-care activities as needed
6. All participants must be able to provide informed consent

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
280 patients, 280 carers, 80 community health workers 18 years or older, able to give informed consent, able and willing to perform daily lymphoedema-care activities

Total final enrolment
618

Key exclusion criteria
Patients lymphoedema, their carers and community health workers who:
1. Are under 18 years of age
2. Decline to be involved in the study
3. Are unable to give informed consent
4. Are too unwell to participate
5. Lymphoedema patients who have mild leg lymphoedema as defined as stage 2 or below according to the Dreyer staging system for filarial lymphoedema
6. Patients with any medical condition eg heart, kidney, lung disease
7. Patients with severe arthritis
8. Patients with traumatic injury or surgery on the lymphoedema limb
9. Patients or carers who are unable or unwilling to perform daily lymphoedema-care activities

Date of first enrolment
08/10/2018

Date of final enrolment
21/11/2018

Locations

Countries of recruitment
Bangladesh

Ethiopia

Study participating centre
Community Health Centre
Ethiopia
-

Study participating centre
Community Health Centre
Bangladesh
-

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Preliminary results will be provided to the Ethiopian Federal Ministry of Health and the Bangladesh Ministry of Health and Family Welfare after data is collected at baseline and final follow-up. Results of statistical analysis and case-study reports will be prepared for publication in peer reviewed journals.

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Indurometer reliability and agreement evaluation	01/08/2020	08/05/2020	Yes	No
Protocol article	protocol	04/09/2019	08/05/2020	Yes	No
Results article	results	30/07/2020	07/08/2020	Yes	No