

Economic assessment of a community-based care package for people with lower limb disorder caused by lymphatic filariasis, podoconiosis and leprosy in Ethiopia

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We conducted an implementation research study to integrate a holistic package of physical health, mental health and psychosocial care for podoconiosis, lymphatic filariasis and leprosy into routine healthcare in Gusha cluster, Guagusa Shikudad district, northwest Ethiopia. The healthcare package included training patients in lower limb hygiene and skin care and provision of shoes, hygiene supplies and medication. The implementation activities included training events, workshops, awareness raising, self-help groups, supportive supervision, staff secondments and advisory board meetings. The cost of implementing the care package in Gusha cluster, with a population of 30 558 people, was 802 655 Ethiopian birr (ETB) (£48 159) and the cost of delivering care to 235 participants was 204 388 ETB (£12 263), or 870 ETB (£52) per person. There was a 35% decrease in the mean disability scores (measured using the World Health Organization Disability Assessment Schedule 2.0) and a 45% improvement in the dermatology-specific quality of life (measured using the Dermatology Life Quality Index) at the 3-month follow-up compared with baseline. There were reductions in the number of days with symptoms, days off usual activities/work and days with reduced activity due to illness, all of which were statistically significant. Our pilot suggests that integration of the care package into routine healthcare in Ethiopia may be effective in improving health-related quality of life and disability and reducing time out of economic activity due to illness.

Keywords: care package, economic assessment, leprosy, lymphatic filariasis, podoconiosis

Introduction

Lymphatic filariasis (LF), podoconiosis and leprosy are three neglected tropical diseases (NTDs) that have a significant impact on health-related quality of life, disability and the economic activity of the rural population in Ethiopia.^{1–5} These diseases are characterised by lymphoedema (swelling due to a build-up of lymph fluid) that mainly affects the lower limbs. Lymphoedema can be further complicated by acute dermatolymphangioadenitis (ADLA) due to secondary infection of wounds, ulcers and skin breakdown between the toes. ADLA is characterised by episodes of severe pain, fever, headaches and nausea and in the long term leads to significant disfigurement and disability.⁶ LF, podoconiosis and leprosy are highly stigmatising conditions associated with significant psychological mor-

bidity, mental distress, anxiety, depression and social exclusion.^{3,7,8}

Daily home-based hygiene self-care has been shown to reduce swelling and ADLA in resource-poor settings.^{5,6,9–11} This involves daily washing and drying of affected limbs, applying ointment, bandaging, passive range of motion exercises, elevation of the affected limbs overnight and whenever possible during the day and wearing socks and shoes. In the past two decades in Ethiopia, foot hygiene treatment has been offered to people with lymphoedema mainly via non-government organisations,^{12,13} without state adoption or integration into routine primary care. The importance of these issues has been recognised by the Federal Ministry of Health of Ethiopia with podoconiosis and LF included in the national programmes for integrated control of NTDs in 2013–2020.^{14,15}

LF, podoconiosis and leprosy are common in Ethiopia, with approximately 1.53 million people affected by podoconiosis,¹⁶ 300 000 people affected by leprosy¹⁷ and 5.6 million at risk of infection with LF.¹⁸ Nationwide mapping conducted in 2013 in seven regional states in Ethiopia demonstrated that podoconiosis accounts for approximately 64.8%, LF for 13.2% and leprosy for 12.8% of the total burden of lymphoedema.¹⁹ The integrated morbidity mapping conducted in 2015 in 20 podoconiosis-LF co-endemic districts identified a prevalence of 84.9 per 10 000 population (26 123 cases in total), of whom 95.3% had leg lymphoedema only, 2.9% had hydrocele (swelling of the genitals in men), 1.5% had both leg lymphoedema and hydrocele and 0.3% had breast lymphoedema.²⁰ For the current study, the Amhara region was selected based on co-endemicity of podoconiosis, LF and leprosy.

This article focuses on the economic assessment of introducing a community-based care package for people with lower limb disorder caused by LF, podoconiosis or leprosy in primary care in the Gusha cluster, Guagusa Shikudad district, northwest Ethiopia. The Excellence in Disability Prevention Integrated across NTDs (EnDPoINT) project is a pilot and scale-up implementation research study with a strong focus on the integration and scale-up of a holistic package of care addressing physical health, mental health and psychosocial care.¹⁶ The implementation of the care package covered three levels of the healthcare system—healthcare organisation, healthcare facility and community level—and included a wide range of activities, from training events and workshops to self-help groups and staff secondments. The pilot study, to which this article relates, also aimed to assess the care package's adoption, feasibility, acceptability, fidelity, potential effectiveness and readiness for scale-up.

The economic assessment of implementing the care package aimed to characterise the socio-economic status of the population affected by lower limb disorders caused by the three diseases, to understand the use of healthcare services by the affected population and out-of-pocket expenses related to healthcare, to cost implementation activities of the healthcare package and to assess the effectiveness outcomes, including health-related quality of life and disability, following 3 months of the intervention.

Methods

Study characteristics

The protocol for the EnDPoINT study is published elsewhere.²¹ Briefly, this was an implementation research study that included three phases: phase 1 focused on the development of a comprehensive holistic care package for people with lower limb disorder caused by the three diseases and strategies for its integration into routine healthcare. In phase 2, a pilot study was conducted to assess the feasibility, acceptability, fidelity, potential effectiveness and costs of delivering the care package. Phase 3 aimed to scale-up the care package in three districts in Ethiopia, which was postponed in April 2020 due to the coronavirus disease 2019 pandemic. This article reports the results of the economic evaluation of the care package (phase 2 pilot study). A separate article will focus on the feasibility, acceptability, fidelity and potential effectiveness of the care package.

The phase 2 study was carried out at the Gusha Health Center (Gusha cluster, Guagusa Shikudad district, Amhara region, northwest Ethiopia). The pilot district was chosen based on co-endemicity of podoconiosis, LF and leprosy. Gusha cluster includes five *kebeles* with a population of 30 558 people (14 685 males and 15 873 females) according to the District Health Office records (2019). The cluster has five health posts and one health centre. All patients with LF, podoconiosis and leprosy identified using medical records were invited to the Gusha Health Center to participate in the study. The recruitment and the baseline data collection were conducted in August–September 2019. The participants were followed up for 3 months, until the end of December 2019.

Study participants

The patients with LF, podoconiosis and leprosy were identified using medical records kept at the health posts and the Gusha Health Center. The patients were approached by health extension workers (who work in the community) and invited to participate in the study. All patients who presented at the Gusha Health Center were considered for inclusion in the study if they were residents of Guagusa Shikudad district for at least the past 6 months, ≥ 18 y of age, able to hear and communicate, understand the Amharic language and were fit to participate in the study (not terminally ill). All patients who met these criteria were asked if they were willing to participate in the study and to provide informed consent.

Intervention

The intervention was delivered between October 2019 and February 2020 by five healthcare professionals trained in morbidity management and disability prevention. The intervention included health education sessions and training in foot hygiene, skin care, bandaging, exercises and wearing of socks and shoes. The patients were provided with foot hygiene supplies, including a washing basin, soap, salt, towels and Vaseline. In total, 25 education sessions were conducted that lasted 1.5–2 h. Treatment was initiated where appropriate, including paracetamol, Whitfield ointment and antibiotics. All the patients were assessed by a mental health professional from Injibara Hospital. Counselling and antidepressants were provided where necessary. Caregivers were instructed on how to administer the antidepressants. Follow-up appointments with a mental health professional were arranged for participants with comorbid mental health issues. Prior to education sessions, foot measurements were taken to prepare custom-made shoes. The shoes were distributed at the 3-month follow-up assessment.

To monitor the quality of care, the project established a community advisory board group that consisted of 16 stakeholders, including health professionals from relevant offices. During the 3 months of the intervention, participants met with the frontline health workers in their area to discuss how the intervention was going and what difficulties they faced.

Data collection

Data collection was conducted at baseline and at the 3-month follow-up by trained data collectors from the Center for

Innovative Drug Development and Therapeutic Trials for Africa, Addis Ababa University (CDT-Africa). The data were collected in face-to-face interviews with study participants at the Gusha Health Center. The average time of interviews was 45 min. The data were collected using the Open Data Kit (ODK) software.²² ODK is open-source software for off-line data collection on mobile devices in resource-constrained environments. Submission of the data to a server can be performed whenever Internet connectivity is available. The collected data included personal participant information; socio-economic characteristics; measurement of leg swelling; lymphoedema management and questionnaires on general health, social support and discrimination, stigma related to lymphoedema, suicidal behaviour, alcohol consumption, disability and health-related quality of life. A range of measures used in the health economics analysis are outlined below. A separate article will focus on the effectiveness outcomes of the healthcare package.

Costing care package integration

The implementation of the healthcare package included a range of activities delivered at three levels: the healthcare organisation level (training healthcare specialists in morbidity management and disability prevention and training on integrated supportive supervision); the healthcare facility (training health workers in morbidity management and disability prevention, supply chain management training, training for health extension workers, facility-level supportive supervision and outpatient department secondments) and the community level (community awareness raising and a stigma reduction workshop, community conversation facilitators training, self-help group training, training for health extension workers and community-level supportive supervision).

The training in morbidity management and disability prevention covered both the healthcare organisation and healthcare facility levels. Cross-cutting issues between the three levels were addressed by the advisory board meetings. A detailed description on implementation activities is provided in the Results section.

The cost of the intervention was estimated using monthly and quarterly financial project reports based on the project agreement protocol, project activity reports and purchase requisition documents. The costing categories included trainer travel and subsistence, participant travel and subsistence, training materials, hall hire and refreshments. We did not account for salaries since the intervention was delivered by the existing staff. We excluded research costs associated with intervention design and data collection (e.g. training data collectors and the care package validation workshop). The cost of the care package implementation components was based on the number of participants attending. Costs were converted to British pounds (£) using the average exchange rate for 2019²³ and purchasing power parity²⁴ (PPP; a comparison of the purchasing power in different countries).

Costing healthcare supplies

Costs of healthcare supplies covered foot care supplies, medication and transportation of supplies to the Gusha Health Center. The foot care supplies included shoes, washing basins, soap, salt,

towels and Vaseline. The medication included Whitfield ointment, paracetamol, antibiotics (amoxicillin, doxycycline and ceftriaxone) and antidepressants (amitriptyline and fluoxetine). Costs of healthcare supplies were obtained from the financial project reports.

Health-related quality of life

The health-related quality of life was assessed using the Dermatology Life Quality Index (DLQI)²⁵, a dermatology-specific quality of life instrument, that had previously been translated into Amharic and validated among patients with pododermatitis in southern Ethiopia.²⁶ It consists of 10 questions concerning patient perception of the impact of skin diseases on different aspects of their life, including symptoms and feelings, daily activities, leisure, work or school and personal relationships. Each question is scored on a 4-point Likert scale (0–3). The scores of individual items are added together to yield a total score ranging from 0 to 30, where higher scores imply lower quality of life. The DLQI questionnaires were administered in face-to-face interviews at baseline and at the 3-month follow-up.

Disability

The World Health Organization Disability Assessment Schedule (WHODAS) 2.0 is a generic instrument for assessing health and disability.²⁷ It includes 12 items covering cognition, mobility, self-care, interaction with people, life and community activities. The Amharic version of WHODAS 2.0 was previously validated in people with severe mental disorders in rural Ethiopia.²⁸ The items are rated using a 5-point Likert scale (1–5), where higher scores mean greater disability. The DLQI and WHODAS 2.0 total scores were calculated by adding the scores for each item.

Economic measures

Economic data were collected using a purpose designed questionnaire focused on socio-economic characteristics of study participants, demographics, housing, economic activities, use of healthcare services and out-of-pocket expenses related to the lower limb disorder. The questionnaire also included questions on the number of days with symptoms, days totally unable to do work/usual activities and days with reduced activity due to lymphoedema.

Out-of-pocket expenses covered the hospital stay; travel to the hospital; overnight stay for accompanying person; food for accompanying person; medication and care products (e.g. soap, bandages, disinfectant); traditional remedies and money borrowed from family, relatives or the community.

Statistical analysis

Data analysis was conducted in Excel 2010 (Microsoft, Redmond, WA, USA). Resource use, costs and health outcomes are presented as means and standard deviations. The 95% confidence intervals for the differences in health outcomes were derived using a non-parametric bootstrap²⁹ in Stata 12.1 (StataCorp, College Station, TX, USA). Results of the health economics analyses are presented in disaggregated format to inform the future

scale-up study. We did not attempt to assess the cost-effectiveness of the intervention since this study was not powered to detect statistically significant differences in health outcomes.

Results

Resource use and costs of implementation activities

The costs of implementation of the healthcare package are summarised in Table 1. These include costs of training events, workshops, awareness raising, self-help groups, supportive supervision, staff secondments and advisory board meetings. A brief description of the implementation activities is provided below.

Training health workers in morbidity management and disability prevention

This was a 5-d training course for healthcare professionals to ensure inclusion of care for lower limb disorder caused by the three diseases into primary healthcare, availability of trained health workers at the health centres and the District Health Office and to enhance the access to lower limb care and comorbid mental healthcare. The training was conducted 8–12 April 2019 in Bahir Dar town and was attended by 25 healthcare professionals, including officials from the District Health Office. The training consisted of lectures, practical exercises, experience sharing by champion patients and a group presentation. The training was delivered by four trainers and three facilitators. Trainees were provided with compact discs and printouts of training materials.

Community awareness-raising and stigma reduction workshop

The workshop was conducted on 27 July 2019 in Injibara town for 60 community members, including *kebele* (lowest-level administration unit) and district administrators, community leaders, religious leaders and representatives from the patient association. The aims of the training were to increase awareness of the disease and the practice of wearing shoes, to reduce stigma and discrimination and to facilitate social reintegration. The workshop was delivered by one trainer and two facilitators and included a lecture followed by group discussion.

Integrated supportive supervision training

The training took place from 21 to 23 July 2019 in Injibara town. The aim of the training was to ensure that practice was in line with evidence-based guidelines and that there was a constant supply of medication. The training was attended by 15 participants from the Gusha Health Center and Guagusa Shikudad District Health Office. The training was delivered by two facilitators and included lectures, practical exercises and a group presentation. Printed materials were provided to the participants.

Training for health extension workers

This was a 2-d training for 15 health extension workers and their supervisors. The aim of the training was to enable the identifica-

tion of patients with lower limb disorder and comorbid mental health issues, conduct community awareness-raising activities and to ensure monitoring of adherence and support. The training was conducted on 25–26 July 2019 in Injibara town and included lectures, practical exercises and a group presentation. The training was delivered by two trainers and two facilitators. The participants were provided with printed materials.

Self-help group

This training was conducted on 4–5 October 2019 in Dangla town. The aims of the self-group training were to empower people with disability through social integration and equalization of opportunities and to engage the family, community and relevant organizations in providing opportunities and support for the disabled. The training was attended by 25 participants from five *kebeles* in the Gusha cluster. The participants were selected from associations established at the *kebele* level. Each *kebele* association was represented by its chairperson, vice chair, secretary, finance head and auditor. The training included lectures, practical exercises and a group presentation. The training was delivered by two trainers and three facilitators. Participants were provided with printed materials.

Community conversation facilitators training

The training was conducted on 1–3 October 2019 in Dangla town. It aimed to generate individual and collective responses through behavioural change in order to facilitate preventive measures and improve self-care for people with lower limb disorder. The training was attended by 30 community conversation facilitators from the Women's Development Army (unpaid community health workers from five *kebeles* in Gusha cluster). The training was delivered by two trainers and included a lecture, a practical exercise and a group presentation. The participants were provided with printed materials.

Facility-level supportive supervision

On-site supportive supervision for facility-based health workers at the Gusha Health Center was conducted by four CDT-Africa staff members on 27 January 2020. The supervision aimed to identify any shortcomings in care delivery, to support staff with overcoming these shortcomings and to communicate findings to relevant stakeholders.

Community-level supportive supervision

The community-level supportive supervision for health extension workers from the Absla and Gusha Health Centers was conducted on 26 January 2020 by four CDT-Africa staff members. The aim of the supervision was to follow the delivery of the intervention in the community and to fill gaps in the provision of care to people with lower limb disorder.

Outpatient department secondments

Six health professionals from the Gusha Health Center participated in a 1-week secondment in Felegehiwot Hospital

Table 1. Summary of intervention activities and costs

Care package elements	Units	Duration	Unit cost, ETB	Total cost, ETB	Total cost, £ (PPP-based)	Total cost, £ (exchange rate)
Training health workers in morbidity management and disability prevention						
Trainer costs						
Travel	7	Lump sum	4000	28 000	1680	750
Accommodation and food (trainers)	4	3 d	3500	42 000	2520	1126
Accommodation and food (facilitators)	3	5 d	700	10 500	630	281
Participants' costs						
Travel	25	Lump sum	800	20 000	1200	536
Accommodation and food	25	7 d	400	70 000	4200	1876
Training materials						
CD	25	Lump sum	15	375	23	10
Printed materials	25	Lump sum	150	3750	225	101
Hall rent	1	5 d	1500	7500	450	201
Stationery materials	32	Lump sum	30	960	58	26
Refreshments	32	5 d	240	38 400	2304	1029
Total cost (training health workers)				221 485	13 289	5936
Cost per worker trained				8859	532	237
Community awareness-raising and stigma reduction workshop						
Staff costs						
Travel	3	Lump sum	4000	12 000	720	322
Accommodation and food (trainers)	1	1 d	4500	4500	270	121
Accommodation and food (facilitators)	2	1 d	700	1400	84	38
Participants' costs						
Travel	60	1 d	400	24 000	1440	643
Accommodation and food	60	1 d	800	48 000	2880	1286
Hall rent	1	1 d	1500	1500	90	40
Stationery materials	63	Lump sum	35	2205	132	59
Refreshments	63	1 d	120	7560	454	203
Total cost (workshop)				101 165	6070	2711
Cost per workshop attendant				1686	101	45
Training on integrated supportive supervision						
Trainer costs						
Travel	2	Lump sum	4000	8000	480	214
Accommodation and food	2	3 d	700	4200	252	113
Participants' costs						
Travel	15	Lump sum	800	12 000	720	322
Accommodation and food	15	3 d	400	18 000	1080	482
Training materials	15	Lump sum	150	2250	135	60
Hall rent	1	3 d	1000	3000	180	80
Stationery materials	17	Lump sum	30	510	31	14
Refreshments	17	3 d	120	6120	367	164
Total cost (training)				54 080	3245	1449
Cost per trainee				3605	216	97
Training of health extension workers						
Trainer costs						
Travel	4	Lump sum	4000	16 000	960	429
Accommodation and food (trainers)	2	2 d	3000	12 000	720	322
Accommodation and food (facilitators)	2	2 d	700	2800	168	75

Table 1. continued

Care package elements	Units	Duration	Unit cost, ETB	Total cost, ETB	Total cost, £ (PPP-based)	Total cost, £ (exchange rate)
Participants' costs						
Travel	15		800	12 000	720	322
Accommodation and food	15	2 d	400	12 000	720	
Printed materials	15	Lump sum	50	750	45	20
Hall rent	1	2 d	1500	3000	180	80
Stationery materials	19	Lump sum	30	570	34	15
Refreshment	19	2 d	120	4560	274	122
Total cost (training)				63 680	3821	1707
Cost per trainee				4245	255	114
Supply chain management training						
Trainer costs						
Travel	3	Lump sum	4000	12 000	720	322
Accommodation and food (trainers)	1	1 d	4500	4500	270	121
Accommodation and food (facilitators)	2	1 d	700	1400	84	38
Participants' costs						
Travel	15	Lump sum	400	6000	360	161
Accommodation and food	15	1 d	800	12 000	720	322
Hall rent	1	1 d	1500	1500	90	40
Stationery materials	18	Lump sum	30	540	32	14
Refreshments	18	1 d	120	2160	130	58
Total cost (training)				40 100	2406	1075
Cost per trainee				2673	160	72
Community conversation facilitators training						
Staff costs						
Travel	3	Lump sum	4000	12 000	720	322
Accommodation and food (trainers)	1	3 d	5000	15 000	900	402
Accommodation and food (facilitators)	2	3 d	700	4200	252	113
Participants' costs						
Travel	30	Lump sum	800	24 000	1440	643
Accommodation and food	30	3 d	400	36 000	2160	965
Training materials	30	Lump sum	35	1050	63	28
Hall rent	1	3 d	1500	4500	270	121
Stationery materials	33	Lump sum	30	990	59	27
Refreshments	33	3 d	120	11 880	713	318
Total cost (training)				109 620	6577	2938
Cost per trainee				3654	219	98
Self-help group training						
Staff costs						
Travel	5	Lump sum	4000	20 000	1200	536
Accommodation and food (trainers)	2	2 d	2250	9000	540	241
Accommodation and food (facilitators)	3	2 d	700	4200	252	113
Participants' costs						
Travel	25	Lump sum	800	20 000	1200	536
Accommodation and food	25	2 d	400	20 000	1200	536
Training materials	25	Lump sum	35	875	53	23
Hall rent	1	2 d	1500	3000	180	80
Stationery materials	30	Lump sum	30	900	54	24
Refreshments	30	2 d	120	7200	432	193
Total cost (training)				85 175	5111	2283
Cost per trainee				3407	204	91

Table 1. continued

Care package elements	Units	Duration	Unit cost, ETB	Total cost, ETB	Total cost, £ (PPP-based)	Total cost, £ (exchange rate)
Community-level supportive supervision						
Staff costs						
Travel	3	Lump sum	4000	12 000	720	322
Accommodation and food (facilitators)	3	4 d	700	8400	504	225
Total cost (supervision)				20 400	1224	547
Cost per supervisor				6800	408	182
Facility-level supportive supervision						
Staff costs						
Travel	3	Lump sum	4000	12 000	720	322
Accommodation and food (facilitators)	3	4 d	700	8400	504	225
Total cost (supervision)				20 400	1224	547
Cost per supervisor				6800	408	182
Outpatient Department secondments						
Participants' costs						
Travel	6	Lump sum	400	4800	288	129
Accommodation and food	6	5 d	400	12 000	720	322
Total cost (secondments)				16 800	1008	450
Cost per trainee				2800	168	75
Advisory board meeting 1						
Staff costs						
Travel	2	Lump sum	4000	8000	480	214
Accommodation and food	2	1 d	700	1400	84	38
Participants' costs						
Travel	15	Lump sum	400	6000	360	161
Accommodation and food	15	1 d	800	12 000	720	322
Hall rent	1	1 d	1500	1500	90	40
Stationery materials	17	Lump sum	30	510	31	14
Refreshments	17	1 d	120	2040	122	55
Total cost (meeting)				31 450	1887	843
Cost per participant				2097	126	56
Advisory board meeting 2						
Staff costs						
Travel	4	Lump sum	4000	12 000	720	322
Accommodation and food	4	1 d	700	2600	156	70
Participants' costs						
Travel	16	Lump sum	400	6400	384	172
Accommodation and food	16	1 d	800	12 800	768	343
Hall rent	1	1 d	1500	1500	90	40
Stationery materials	20	Lump sum	30	600	36	16
Refreshments	20	1 d	120	2400	144	64
Total cost (meeting)				38 300	2298	1026
Cost per participant				2394	144	64
Total cost of implementation activities				802 655	48 159	21 511

Numbers are rounded to nearest ETB/£.

Table 2. Summary of healthcare supplies and costs

Care package elements	Units	Quantity	Unit cost, ETB	Total cost, ETB	Total cost, £ (PPP)	Total cost, £ (exchange rate)
Hygiene and treatment supplies						
Washing basin	Item	250	50.00	12 500	750	335
Soap	Pack	250	12.00	3000	180	80
Salt	Pack	250	25.00	6250	375	168
Towel	Item	250	50.00	12 500	750	335
Vaseline	Tube	250	15.00	3750	225	101
Shoes	Pair	250	570.00	142 500	8550	3819
Subtotal (hygiene supplies)				180 500	10 830	4837
Medication						
Paracetamol	Tab	2500	0.20	500	30	13
Amoxicillin	Tab	4500	1.00	4500	270	121
Doxycycline	Tab	2500	0.60	1500	90	40
Ceftriaxone	Tab	250	20.30	5075	305	136
Amitriptyline	Tab	250	0.65	162.5	10	4
Fluoxetine	Pack	150	36.00	5400	324	145
Whitfield ointment	Tube	250	15.00	3750	225	101
Subtotal (medication)				20 888	1253	560
Transportation	Lump sum	1	N/A	3000	180	80
Total healthcare supplies				204 388	12 263	5478

Numbers are rounded to nearest ETB/£.

(Bahir Dar town) from 19 to 23 August 2019. The aims of the secondment were to train health professionals in diagnostics and treatment of lower limb disorder and comorbid mental health issues and to enhance referral capacity for cases above current levels. The focus was on practical examination of patients. The training was assisted by a senior psychiatrist in the hospital.

Supply chain management training

The training was conducted on 24 July 2019 in Injibara town for 15 professionals from the pilot health facility stores and dispensaries and district store managers. The aim of the training was to improve the understanding of the basic supply system of the Ethiopian Pharmaceutical Fund and the Supply Agency, stock acquisition and managing supplies. The training included a lecture and a group discussion. The training was delivered by one trainer and two facilitators.

First advisory board meeting

The first advisory board meeting took place on 6 October 2019 in Dangla town. The meeting was attended by 15 stakeholders from the District Administration Office; District Health Office; District Education Office; District Labour and Social Affairs Office; Women, Youth and Children's Affairs Office; a religious leader representative; a community representative; a patient association representative; a representative from Amhara Credit and Saving Institution and four staff members from CDT-Africa. The District Advisory Board was established to advise public health services

on communication with communities and to discuss the performance of the project. The meeting included a presentation and a discussion.

Second advisory board meeting

The second District Advisory Board meeting was conducted on 13 March 2020 in Dangla town. The meeting was attended by 16 stakeholders (see above) and four staff members from CDT-Africa. The aim of the meeting was to discuss the performance of the project in the last 6 months. The activity report and the research findings were presented and discussed.

Intervention costs

The educational sessions were delivered to 235 participants by five healthcare professionals trained in morbidity management and disability prevention. In total, 25 education sessions were conducted that lasted 1.5–2 h. A list of healthcare supplies and their costs is provided in Table 2. Medication treatment was initiated where appropriate and included paracetamol, Whitfield ointment, antibiotics and antidepressants. The total cost of the healthcare supplies was 204 388 Ethiopian birr (ETB) (£12 263), or 870 ETB (£52) per person.

Socio-economic characteristics of study participants

Study participants were subsistence farmers and their family members representing the economically deprived rural population of Gusha cluster. The participants were 18–89 y of age, 50.2%

Table 3. Socio-economic characteristics of participants (n=235)

Characteristics	n	%
Gender		
Male	118	50.2
Female	117	49.8
Age group (years)		
18–25	13	5.5
26–35	35	14.9
36–45	44	18.7
46–55	49	20.9
56–65	50	21.3
>65	44	18.7
Education		
Formal education	11	4.7
3 y	2	0.9
4 y	3	1.3
5–10 y	6	2.6
No formal education (can read and write)	56	23.8
No formal education (illiterate)	168	71.5
Marital status		
Never married	14	6.0
Married	157	66.8
Divorced	35	14.9
Widowed	29	12.3
Kebele		
Urban	4	1.7
Rural	231	98.3
Employment situation		
Farming	197	83.8
Work in the home and childcare	35	14.9
Study	2	0.9
Unemployed	1	0.4
Number of children		
0	24	10.2
1	15	6.4
2	21	8.9
3	30	12.8
4	29	12.3
5	34	14.5
6	37	15.7
7	21	8.9
8	11	4.7
9	8	3.4
10	4	1.7
13	1	0.4
Source of drinking water		
Tap/standpipe	161	68.5
Protected well	3	1.3
Unprotected well	1	0.4
Protected spring	38	16.2
Unprotected spring	31	13.2
Surface water	1	0.4
Toilet facilities		
Private	128	54.5
Shared with other households	105	44.7

Table 3. continued

Characteristics	n	%
No facility	2	0.9
Type of toilet facilities (n=233)		
Pit latrine, ventilated (VIP)	1	0.4
Pit latrine, with slab	97	41.6
Pit latrine, without slab	135	57.9
Roof material (n=234)		
Steel	228	97.4
Grass	6	2.6
Floor material		
Mud	235	100
Kitchen		
In a separate room	191	81.3
No separate room	44	18.7
Cooking fuel		
Wood	233	99.2
Charcoal	1	0.4
Butane gas	1	0.4
Home facilities		
Electricity	66	28.1
Radio	24	10.2
Television	1	0.4
Telephone (landline)	1	0.4
Telephone (mobile)	20	8.5
Refrigerator	0	0
Land and livestock ownership		
Land	205	87.2
Cows	142	60.4
Horses	28	11.9
Donkeys	35	14.9
Sheep	69	29.4
Goats	6	2.6
Chickens	57	24.3
No livestock	80	34.0
Corral for cattle (n=155)		
Yes	85	54.8
No	70	45.1

were males and 71% of participants had no formal education. The median number of children per household was five. Only 28% of households had electricity, 10% had a radio, 0.4% had a television and nobody owned a refrigerator. A total of 87% of the population were land owners and 66% kept livestock. The detailed socio-economic characteristics of the population sample are shown in Table 3.

Use of healthcare services by participants

Table 4 summarises the use of healthcare services by study participants within the last year. The majority of study participants (80.4%) did not seek professional help with respect to their lower limb disorder. Only 8.9% attended a doctor, with an average of one visit per year, 19.1% of patients had contact with a nurse, 18.3% visited a pharmacy and 13.6% of patients had laboratory

Table 4. Use of healthcare services by study participants with lower limb disorder (n=235)

Contacts with healthcare specialists	n	%	Mean number of contacts	SD
Doctor	21	8.9	1.1	1.7
Nurse	45	19.1	7.2	29.9
Pharmacy	43	18.3	3.8	12.8
Laboratory	32	13.6	0.8	0.6
No contacts	189	80.4		
Hospital attendance and stay	n	%	Mean number of days	SD
Hospital attendance	16	6.8	6.7	14.6
Hospital stay	6	2.6	16.5	21.7
Use of medication and care products	n	%		
Medication	23	9.8		
Care products (e.g. soap, bandages, disinfectant)	121	51.5		
Traditional remedies	1	0.4		

Table 5. Out-of-pocket expenses associated with lower limb disorder (per year, n=235)

Expenses	n	%	Mean cost, ETB	SD, ETB
Hospital care				
Paid hospital stay	12	5.1	401	379
Travel	8	3.4	274	335
Additional medication during hospital stay	7	3.0	407	707
Additional food during hospital stay	5	2.1	165	88
Overnight stay for accompanying person	7	3.0	239	343
Food for accompanying person	10	4.3	205	149
Medication and care products				
Medication	23	9.8	188	143
Care products (e.g. soap, bandages, disinfectant)	91	38.7	150	145
Traditional remedies	1	0.4	130	N/A
Money borrowed from family/relatives/community	91	38.7	8779	8542

tests. Medication was used by 9.8% of study participants and only half of the sample used hygiene or skin care products for lower limb problems. Traditional remedies were rarely used (<1%).

Out-of-pocket expenses

Out-of-pocket expenses included additional spending associated with attending hospital, buying medication and borrowing money from family, relatives or the community to meet their health needs and the needs of their families (Table 5). People staying in a hospital contributed on average 401 ETB (£24; PPP-based) per year to their care. They also reported expenses related to travel and subsistence during hospital visits, as well as expenses incurred by accompanying persons (Table 5). The participants spent on average 188 ETB (£11) on buying medication and 150 ETB (£9) on purchasing hygiene and care products. Approximately 40% of households including people with lower limb disorders

had to borrow money from family, relatives or the community in the past year in order to meet their needs (Table 4).

Health outcomes of the intervention

A summary of health outcomes at baseline and the 3-month follow-up is provided in Table 6. There was a significant improvement in dermatologic quality of life at 3 months compared with baseline, as demonstrated by a 46% decrease in the mean DLQI scores (lower scores indicate better outcomes). There was an improvement in self-reported disability as measured using the WHODAS 2.0 (35% decrease in the mean score). Frequency distributions of DLQI and WHODAS 2.0 scores at baseline and the 3-month follow-up are shown in Figure 1. There were reductions in the number of days with symptoms over the last month, days off usual activities or work and days with reduced activity due to lower limb disorder, all of which were statistically significant (Table 6).

Table 6. Health outcomes at baseline and the 3-month follow-up

Outcome	Baseline		3 months		Difference	
	Mean	SD	Mean	SD	Mean	95% CI*
DLQI	14.9	6.3	8.1	6.1	-6.9	-7.9 to -5.7
WHODAS 2.0	29.6	8.8	19.2	6.7	-10.4	-11.8 to -9.1
Days with symptoms	12.4	6.2	5.6	6.1	-6.8	-7.9 to -5.7
Days unable to work	6.3	4.7	2.4	3.7	-3.9	-4.6 to -3.1
Days with reduced activity	3.6	2.7	1.6	2.0	-2.0	-2.4 to -1.6

Lower DLQI and WHODAS 2.0 scores indicate better outcome.

*Derived using non-parametric bootstrapping.

Discussion

The economic assessment of the community-based holistic care package for people with lower limb disorder caused by LF, podoconiosis or leprosy demonstrated a high level of potential effectiveness of the intervention in improving dermatologic quality of life, reducing disability and the number of days off work at the 3-month follow-up. Previously the effectiveness of a community-based physical care package for people with podoconiosis was demonstrated in the Gojjam Lymphoedema Best Practice Trial (GoLBeT), which was conducted in northern Ethiopia.⁵ The 12-month GoLBeT intervention included training in foot hygiene, skin care, bandaging, exercises and the use of socks and shoes, supported by lay community assistants. The study showed a decrease in the incidence of ADLA episodes and days off work due to disability and an improvement in dermatologic quality of life captured using the DLQI. The cost of delivering the intervention to patients was 1890 ETB per person and the cost of healthcare supplies was 529 ETB per person.⁵ However, the GoLBeT study did not show an improvement in disability, also measured using the WHODAS 2.0. There are several explanations for recording an impact on disability within EnDPoINT, but not within GoLBeT. First, it is possible that a lack of impact on disability in GoLBeT represents a false negative finding. Second, the difference may reflect a greater reduction in days off work or usual activities recorded within EnDPoINT compared with GoLBeT. Third, it may reflect the addition of mental health and psychosocial components to this holistic care approach. In EnDPoINT the participants were assessed by a mental health professional and counselling and antidepressants were provided where necessary. The prescribers were trained by psychiatrists, including clinical attachments at a specialist centre, supervision and mentoring support. Antidepressants are part of the treatment protocol for depression in the WHO Mental Health Gap Action Programme Intervention Guide developed for primary care.³⁰

An earlier cohort study conducted in southern Ethiopia included a 12-month health facility-based intervention for people with podoconiosis.⁹ The intervention included education on aetiology and prevention of podoconiosis; daily washing of feet with soap, water and antiseptics; regular use of emollient; elevation of the limb at night and emphasis on consistent wearing of shoes. The intervention was shown to be effective in decreasing

leg circumference and improving dermatologic quality of life measured using the DLQI.⁹

The effectiveness of a home-based lymphoedema management intervention for people with LF was shown in a study conducted in Burkina Faso.³¹ The project included training in lymphoedema management and the provision of medication and hygiene supplies. The intervention was effective in reducing the incidence of ADLA episodes.

A community-level intervention including self-care, compression therapy and integrative treatment was conducted for people with LF in South India.³² The study reported a statistically significant reduction in thigh-level volume, a decrease in the number of inflammatory episodes and a statistically significant improvement in LF-specific quality of life.

A study conducted in northeast Nigeria compared three interventions for people with LF, including community-based care, patient self-care and health facility-based care.³³ The study found that the community-based approach was more culturally acceptable and effective in the management of lymphoedema and the reduction of ADLA episodes. The cost of the intervention per participant varied from US\$7.2 for community-based care to US\$16.7 for facility-based care over 12 months.³³

A community-based study for people with LF in Odisha state, India involved training patients in leg washing and the use of topical antibiotic and antifungal treatments.³⁴ The programme evaluation based on an economic model showed high cost-effectiveness of the programme, with a cost per patient of US\$10.00–12.50 over 24 months.

There are a limited number of studies addressing limb management in people affected by leprosy. A study assessing the feasibility of integration of self-care for filarial lymphoedema into existing community leprosy self-help groups was conducted in the Lalgadh Leprosy Hospital and Services Centre, Janakpur, Nepal.³⁵ A semi-structured questionnaire was used to elicit information on participant knowledge of management of their condition, access to services and attitudes towards the integration of filariasis and leprosy care services. On average, leprosy-affected participants were more knowledgeable of self-care techniques and practiced them 2.5 times more frequently than LF-affected participants. There was a high level of stigma towards the alternate condition in both (leprosy and LF) groups.³⁵

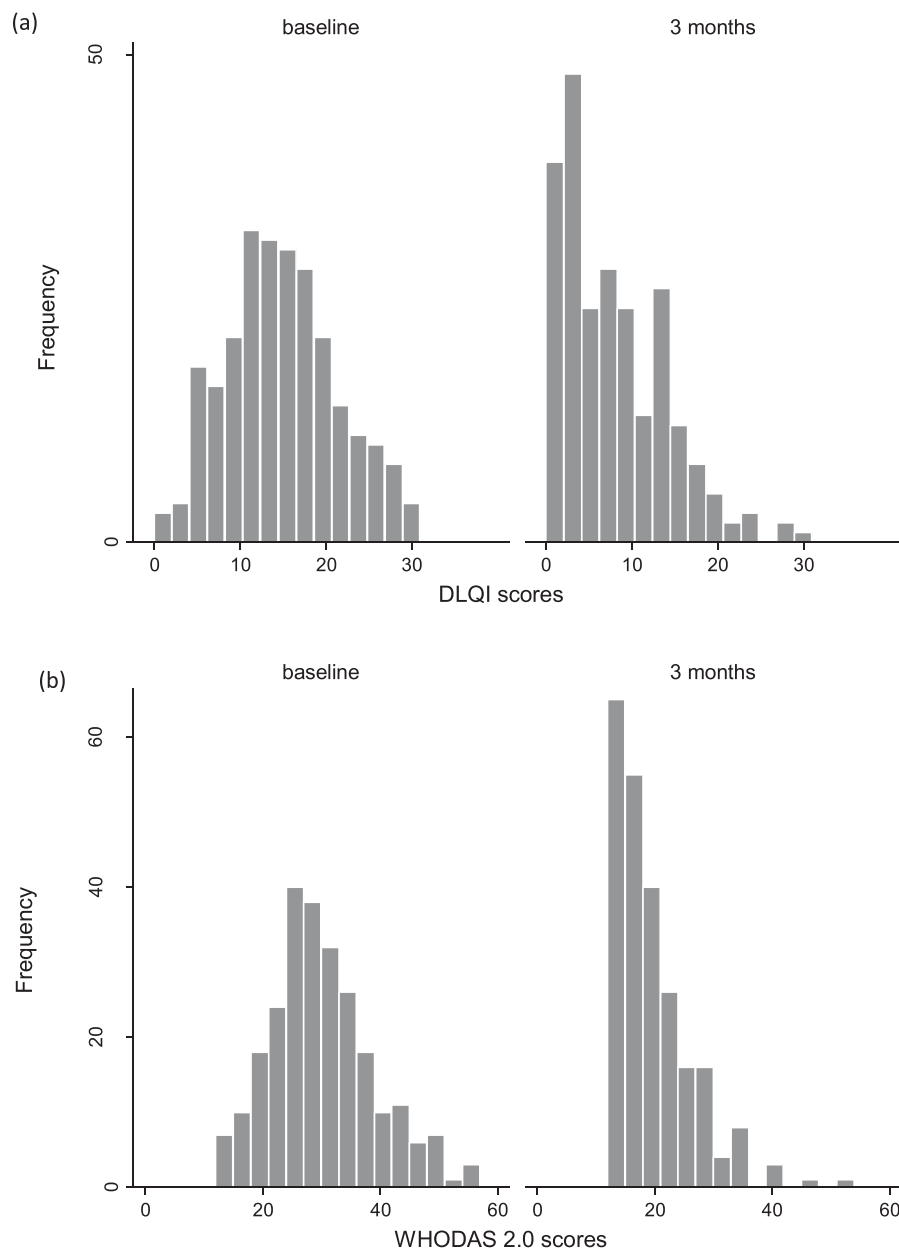


Figure 1. Frequency distribution of (a) DLQI and (b) WHODAS 2.0 scores at baseline and 3 months post-intervention.

While the effectiveness of lymphoedema management programmes has been demonstrated, awareness of morbidity management and disability prevention is very low in the general population and among decision makers. The rural population in Ethiopia is especially difficult to reach given that 72% of households have no electricity, 90% no radio and 99.6% no television. The successful integration of lymphoedema management into routine healthcare requires involvement at many levels, including the District Health Office; District Administration Office; District Education Office; District Labour and Social Affairs Office; Women, Youth and Children’s Affairs Office; religious organisations; local administration; charities; volunteer organisations and community and patient associations. Our study demonstrates that suc-

cessful implementation can be achieved via a range of activities, including training and awareness-raising events, workshops, self-help groups, supportive supervision, staff secondments and advisory board meetings. In addition to lymphoedema management, our package also includes mental health and psychosocial components, such as case detection, assessment, treatment initiation, patient counselling and coping skills acquisition. A separate article will focus on the mental health outcomes from this study, including anxiety and depression, alcohol consumption, suicidal ideation, social support, discrimination and stigma.

We estimated that the cost of implementation activities in one subdistrict in Awi zone in Ethiopia was 204 388 ETB (£12 263) and the average cost of care supplies and medication was 870 ETB

(£52) per patient, including custom-made shoes (570 ETB [£34] per person). These numbers are in line with our findings from the GoLBeT trial, where the cost of care supplies was 529 ETB per person, including shoes.⁵ It should be mentioned that a large proportion of the implementation costs are incurred upfront, therefore the cost of the intervention will decrease when the healthcare package is fully adopted. Our future scale-up study in three other districts in northwest Ethiopia will provide more information on costs and cost-effectiveness of the care package.

Conclusions

The piloting of this healthcare package demonstrated high potential effectiveness of the intervention in improving health-related quality of life and disability and reducing time out of economic activity due to illness.

Authors' contributions: All authors contributed to the manuscript and have read and approved the final version. NH and MK led the writing of the manuscript. AF and GD are the principal investigators of the EnDPoINT study. MK, OA, AT, AM and AA are responsible for the implementation of the study in Ethiopia. MS led the implementation aspects of the study, SB led the statistical elements and NH led the economic assessment.

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References

- 1 Tekola F, Mariam DH, Davey G. Economic costs of endemic non-filarial elephantiasis in Wolaita zone, Ethiopia. *Trop Med Int Health*. 2006;11(7):1136–44.
- 2 Mousley E, Deribe K, Tamiru A, Davey G. The impact of podoconiosis on quality of life in northern Ethiopia. *Health Qual Life Outcomes*. 2013;11:122.
- 3 Bartlett J, Deribe K, Tamiru A, et al. Depression and disability in people with podoconiosis: a comparative cross-sectional study in rural northern Ethiopia. *Int Health*. 2016;8(2):124–31.
- 4 van't Noordende AT, Aycheh MW, Schippers A. The impact of leprosy, podoconiosis and lymphatic filariasis on family quality of life: a qualitative study in northwest Ethiopia. *PLoS Negl Trop Dis*. 2020;14(3):e0008173.
- 5 Hounsou N, Kassahun MM, Ngari M, et al. Cost-effectiveness and social outcomes of a community-based treatment for podoconiosis lymphoedema in the East Gojjam zone, Ethiopia. *PLoS Negl Trop Dis*. 2019;13(10):e0007780.
- 6 Mues KE, Deming M, Kleinbaum DG, et al. Impact of a community-based lymphedema management program on episodes of adenolymphangitis (ADLA) and lymphedema progression—Odisha State, India. *PLoS Negl Trop Dis*. 2014;8(9):e3140.
- 7 Tora A, Davey G, Tadele G. A qualitative study on stigma and coping strategies of patients with podoconiosis in Wolaita zone, southern Ethiopia. *Int Health*. 2011;3(3):176–81.
- 8 Hofstraat K, van Brakel WH. Social stigma towards neglected tropical diseases: a systematic review. *Int Health*. 2016;8(Suppl 1):i53–70.
- 9 Sikorski C, Ashine M, Zeleke Z, Davey G. Effectiveness of a simple lymphoedema treatment regimen in podoconiosis management in southern Ethiopia: one year follow-up. *PLoS Negl Trop Dis*. 2010;4(11):e902.
- 10 Negussie H, Molla M, Ngari M, et al. Lymphoedema management to prevent acute dermatolymphangioadenitis in podoconiosis in northern Ethiopia (GoLBeT): a pragmatic randomised controlled trial. *Lancet Glob Health*. 2018;6(7):e795–803.
- 11 Douglass J, Mableson HE, Martindale S, Kelly-Hope LA. An enhanced self-care protocol for people affected by moderate to severe lymphedema. *Methods Protoc*. 2019;2(3):77.
- 12 Davey G, Burrige E. Community-based control of a neglected tropical disease: the mossy foot treatment and prevention association. *PLoS Negl Trop Dis*. 2009;3(5):e424.
- 13 Mengitsu B, Shafi O, Kebede B, et al. Ethiopia and its steps to mobilize resources to achieve 2020 elimination and control goals for neglected tropical diseases webs joined can tie a lion. *Int Health*. 2016;8(Suppl 1):i34–52.
- 14 Federal Ministry of Health of Ethiopia. National masterplan for neglected tropical diseases (NTDs). Addis Ababa: Ministry of Health; 2013.
- 15 Federal Ministry of Health of Ethiopia. Elimination of neglected tropical diseases (NTDs) in Ethiopia. Available from: <https://www.eliminatedschisto.org/sites/gsa/files/content/secondments/2020-02-18/191019%20Final%20WASH-NTD%20Woreda%20toolkit-%20English.pdf> [accessed 10 August 2020].
- 16 Deribe K, Cano J, Giorgi E, et al. Estimating the number of cases of podoconiosis in Ethiopia using geostatistical methods. *Wellcome Open Res*. 2017;2:78.
- 17 International Federation of Anti-Leprosy Associations (ILEP). Home page. Available from: <https://www.ilepfederation.org/> [accessed 10 August 2020].
- 18 Federal Ministry of Health of Ethiopia. Second Edition of National Neglected Tropical Diseases Master Plan. Available from: <https://www.afro.who.int/sites/default/files/2019-04/Second%20Edition%20of%20National%20Neglected%20Tropical%20Diseases%20Master%20Plan%2C%202016.pdf> [accessed 23 September 2020].
- 19 Deribe K, Brooker S, Pullan R, et al. Epidemiology and individual, household and geographical risk factors of podoconiosis in Ethiopia:

- results from the first nationwide mapping. *Am J Trop Med Hyg.* 2015;92(1):148–58.
- 20 Kebede B, Martindale S, Mengistu B, et al. Integrated morbidity mapping of lymphatic filariasis and podoconiosis cases in 20 co-endemic districts of Ethiopia. *PLoS Negl Trop Dis.* 2018;12(7):e0006491.
 - 21 Semrau M, Ahmed OA, Deribe K, et al. EnDPoINT – protocol for an implementation research study to integrate a holistic package of physical health, mental health and psychosocial care for podoconiosis, lymphatic filariasis and leprosy into routine health services in Ethiopia. *BMJ Open.* 2020;10:e037675.
 - 22 ODK. ODK Collect. Available from: <https://docs.getodk.org/collect-intro/> [accessed 10 August 2020].
 - 23 Exchange Rates.org.uk. Ethiopian birr to British pound spot exchange rates for 2019. Available from: <https://www.exchangerates.org.uk/ETB-GBP-spot-exchange-rates-history-2019.html> [accessed 10 August 2020].
 - 24 Evidence for Policy and Practice Information and Co-ordinating Centre. CCEMG – EPPI-Centre cost converter. Available from: <https://eppi.ioe.ac.uk/costconversion/default.aspx> [accessed 10 August 2020].
 - 25 Cardiff University Department of Dermatology. DLQI instructions for use and scoring. Available from: <http://sites.cardiff.ac.uk/dermatology/quality-of-life/dermatology-quality-of-life-index-dlqi/dlqi-instructions-for-use-and-scoring> [accessed 10 August 2020].
 - 26 Henok L, Davey G. Validation of the Dermatology Life Quality Index among patients with podoconiosis in southern Ethiopia. *Br J Dermatol.* 2008;159(4):903–6.
 - 27 World Health Organization. WHO Disability Assessment Schedule 2.0 (WHODAS 2.0). Available from: http://www.who.int/classifications/icf/more_whodas/en/ [accessed 10 August 2020].
 - 28 Habtamu K, Alem A, Medhin G, et al. Validation of the World Health Organization Disability Assessment Schedule in people with severe mental disorders in rural Ethiopia. *Health Qual Life Outcomes.* 2017;15(1):64.
 - 29 Briggs AH, Gray AM. Handling uncertainty in economic evaluations of healthcare interventions. *BMJ.* 1999;319(7210):635–8.
 - 30 World Health Organization. mhGAP intervention guide – version 2.0. Available from: <https://www.who.int/publications/i/item/mhgap-intervention-guide—version-2.0> [accessed 10 August 2020].
 - 31 Jullien P, Somé J, Brantus P, et al. Efficacy of home-based lymphoedema management in reducing acute attacks in subjects with lymphatic filariasis in Burkina Faso. *Acta Trop.* 2011;120(Suppl 1):S55–61.
 - 32 Narahari SR, Bose KS, Aggithaya MG, et al. Community level morbidity control of lymphoedema using self care and integrative treatment in two lymphatic filariasis endemic districts of South India: a non randomized interventional study. *Trans R Soc Trop Med Hyg.* 2013;107(9):566–77.
 - 33 Akogun OB, Badaki JA. Management of adenolymphangitis and lymphoedema due to lymphatic filariasis in resource-limited north-eastern Nigeria. *Acta Trop.* 2011;120(Suppl 1):S69–75.
 - 34 Stillwaggon E, Sawers L, Rout J, et al. Economic costs and benefits of a community-based lymphedema management program for lymphatic filariasis in Odisha state, India. *Am J Trop Med Hyg.* 2016;95(4):877–84.
 - 35 Pryce J, Mablesen HE, Choudhary R, et al. Assessing the feasibility of integration of self-care for filarial lymphoedema into existing community leprosy self-help groups in Nepal. *BMC Public Health.* 2018;18:201.