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 (£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 morbidity, 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, 300 000 people affected by leprosy and 5.6 million at risk of infection with LF. 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. 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. 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. 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. 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. 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 2019 and purchasing power parity (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), a dermatology-specific quality of life instrument, that had previously been translated into Amharic and validated among patients with podoconiosis in southern Ethiopia. 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. 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. 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 bootstrap 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 aim of the training was 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 Gugusa Shikudaud 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 identification 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           | 14 500         | 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            | 3600           | 2160                      | 965                           |
| 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)**                |       |          |                |                |                          |                             |
| **Cost per supervisor**                     |       |          |                |                |                          |                             |
|                                            |       |          |                |                |                          |                             |
| **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)**                |       |          |                |                |                          |                             |
| **Cost per supervisor**                     |       |          |                |                |                          |                             |
|                                            |       |          |                |                |                          |                             |
| **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)**                |       |          |                |                |                          |                             |
| **Cost per trainee**                        |       |          |                |                |                          |                             |
|                                            |       |          |                |                |                          |                             |
| **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)**                    |       |          |                |                |                          |                             |
| **Cost per participant**                    |       |          |                |                |                          |                             |
|                                            |       |          |                |                |                          |                             |
| **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)**                    |       |          |                |                |                          |                             |
| **Cost per participant**                    |       |          |                |                |                          |                             |
|                                            |       |          |                |                |                          |                             |
| **Total cost of implementation activities** |       |          |                |                |                          |                             |

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            | 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 | 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%
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 visits.

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|
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        |    |      |                         |     |
| Hospital attendance                 | 16 | 6.8  | 6.7                     | 14.6|
| Hospital stay                       | 6  | 2.6  | 16.5                    | 21.7|
| Use of medication and care products |    |      |                         |     |
| 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    |

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 comprehensive care package for people with podoconiosis was demonstrated in the Gojjam Lymphoedema Best Practice Trial (GoLBeT), which was conducted in northern Ethiopia. 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. 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 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.

An earlier cohort study conducted in southern Ethiopia included a 12-month health facility-based intervention for people with podoconiosis. 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. The effectiveness of a home-based lymphoedema management intervention for people with LF was shown in a study conducted in Burkina Faso. 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. 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. 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.

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. 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 Lalghad Leprosy Hospital and Services Centre, Janakpur, Nepal. 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.
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 successful 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 GoLBetT trial, where the cost of care supplies was 529 ETB per person, including shoes. 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.

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