Impact of a holistic integrated care package on clinical and psychosocial outcomes for people with lower limb disorders due to Podoconiosis, Lymphatic Filariasis & Leprosy in Awi Zone, Ethiopia.

Oumer Ali Ahmed

PHD 2021

Impact of a holistic integrated care package on clinical and psychosocial outcomes for people with lower limb disorders due to Podoconiosis, Lymphatic Filariasis & Leprosy in Awi Zone, Ethiopia.

Oumer Ali

A thesis submitted in partial fulfilment of the requirements of the University of Brighton and the University of Sussex for a programme of study undertaken at Brighton and Sussex Medical School for the degree of Doctor of Philosophy

In collaboration with

Centre for Innovative Drug Development and Therapeutic Trials in Africa (CDT-Africa), College of Health Sciences, Addis Ababa University

December 2021

This work was Supervised by:

Dr Maya Semrau,

Senior research fellow in implementation research at Brighton & Sussex Medical School, UK

Professor Abebaw Fekadu,

Professor of Psychiatry and head of Center for Innovative Drug Development and Therapeutic trials for Africa, College of Health Sciences, Addis Ababa University

Dr Abraham Tesfaye,

Post-doctoral fellow at Center for Innovative Drug Development and Therapeutic trials for Africa, College of Health Sciences, Addis Ababa University

Prof Gail Davey,

Professor of Global Health Epidemiology, Brighton & Sussex Medical School, UK

Abstract

Background

Podoconiosis, lymphatic filariasis (LF) and leprosy are neglected tropical diseases (NTDs) that cause lymphoedema. Morbidity management and disability prevention (MMDP) services have been shown to reduce their physical impacts, but little is known both about how to address the psychosocial needs of patients and how to integrate services into the primary care unit and scale up these interventions in the resource-limited countries where they are most needed.

Objectives

To evaluate the clinical (physical), mental health and psychosocial outcomes of an integrated holistic care package for lower limb disorders due to podoconiosis, LF and leprosy in north-western Ethiopia, and to determine the fidelity of implementation of the integrated care package. These objectives were set following a systematic review to identify gaps in knowledge surrounding disability, psychosocial and mental health outcomes of people affected by podoconiosis, LF and leprosy.

Methods

For the systematic review we searched papers reporting on disability, psychosocial and mental health outcomes of these three NTDs. Peer-reviewed articles were searched and extracted from Medline, PsychInfo, Global Health and Embase. Data were extracted and narratively summarized, as the studies were heterogenous and used different outcome measures. The review has been published.

After baseline data collection, a holistic integrated care package was piloted as part of the EnDPoINT (Excellence in Disability Prevention Integrated across Neglected Tropical Diseases) project in Gusha district, Awi zone, Ethiopia. To assess the acceptability, scalability and sustainability of the care package and barriers to its implementation, a qualitative study was conducted. The qualitative data analysis results have been published.

We quantitatively assessed the impact of the care package at three months and twelve months post-initiation by using validated measurement tools. For this, mixed effect linear regression and mixed effect logistic regression were conducted; with a fixed effect for time point and a random effect for participant. The cohort study results have been accepted for publication.

Results

During the systematic review, fourteen studies provided evidence on the disability associated with leprosy, podoconiosis or LF. Ten studies provided evidence on the association with mental health or psychosocial outcomes. High burden of mental illness was reported, with prevalence varying from 12.6% to 71.7%.

During the baseline study, among the 251 patients with lymphoedema who were included, 119 (47.4%) had moderate to severe depression and overall quality of life (QOL) was poor (mean ± SD DLQI score: 11.4 ± 4.2). Disability was significantly associated with depression (β=0.26; 95% CI: 0.19, 0.33) and poor quality of life (β=−0.08; 95%CI: −0.15, −0.01).

In the qualitative study, the integrated lymphoedema care package resulted in improved awareness of the causes, treatment and prevention of lymphoedema and in reduced stigma and discrimination. Barriers to integrated care were unrealistic patient expectations, inadequate dissemination across health workers, and poor transportation access

In the quantitative follow-up study, we found significant improvements in both physical and psychosocial outcomes. There was reduction in acute adenolymphangioadenitis (ADLA) (adjusted odds ratio [aOR] was -2.1; 95% confidence interval [CI] -2.5, -1.79; p<0.001), and overall level of disability (mean reduction in WHODAS 2.0 score -11.0; 95% CI -12.1, -9.9; p<0.001). Significant improvements were also notified in QOL (mean difference in adjusted DLQI score -7.2; 95% CI -7.9, 6.5; p<0.001), and depression (mean PHQ-9 score -7.2; 95% CI -7.9, -6.5; p<0.001).

Conclusion

There is high burden of disability, and poor psychosocial and mental health outcomes associated with podoconiosis, LF and leprosy. Health professionals, decision makers and patients believed the integrated lymphoedema care package to be acceptable, and potentially scalable and sustainable. Following implementation of the integrated holistic care package there was significant improvement in both physical and psychosocial-mental health outcomes

This research provides evidence that the EnDPoINT care package is effective across a range of physical and psychosocial outcomes. Following itsscale-up and cost-effectiveness assessment in three more districts, we recommend it to be scaled up to other endemic districts in Ethiopia and elsewhere.

Key words: Podoconiosis, Lymphatic Filariasis (LF), Leprosy, Lymphoedema, Depression, Quality of Life, Stigma, Discrimination, Integration

Table of contents

List of figures

List of tables

List of acronyms

AAU: Addis Ababa University

ADLA: acute dermatolymphangioadenitis

AOR: Adjusted Odds Ratio

ANOVA: Analysis of variance

BSMS: Brighton and Sussex Medical School

CDT-Africa: Centre for innovative Drug development and Therapeutic trials in Africa

CES-D: The Centre for Epidemiologic Studies Depression

CI: Confidence Interval

CIDI: Composite International Diagnostic Interview

CR: Community representative

DAWLY: Disability Adjusted Working Life Years

DISC: Discrimination and Stigma scale

DLQI: Dermatology Life Quality Index

DM: Decision maker

EHF: Eye, Hand, and Feet

EnDPoINT: Excellence in Disability Prevention Integrated across Neglected Tropical Diseases

FALs: Functional Activity Limitations

FGD: Focus Group Discussions

GHQ-30: General Health Questionnaire-30

HEW: Health Extension Worker

HP: Health Professional

ISMI: Internalized stigma related to mental illness

ISRL: Internalized stigma related to lymphoedema

KIIs: Key Informant Interviews

LF: Lymphatic Filariasis

LMIC: Low- and Middle-Income Countries

MINI-Plus: The Mini-International Neuropsychiatric Interview

NTDs: Neglected Tropical Diseases

OR: Odds Ratio

P Scale: Participation scale

PHQ-9: Patient Health Questionnaire 9 items

SALSA: Screening Activity Limitation and Safety Awareness Scale

SD: Standard Deviation

SE: Standard Error

SRQ-20: Self-Reporting Questionnaire-20

TOT: Training of Trainers

TOC: Theory of Change workshops

WHO: World Health Organisation

WHODAS: World Health Organisation Disability Assessment Schedule

WHO-DG: WHO Disability Grade

WHO-QOL-BREF: WHO quality of life brief score

Acknowledgements

I am extremely grateful to my supervisors Professor Gail Davey, Dr. Maya Semrau, and Professor Abebaw Fekadu for their exemplary guidance throughout this PhD project. I have benefitted greatly from your wealth of knowledge and experience. Your encouraging words and thoughtful, detailed feedback have been very important to me. I am also grateful to Dr. Abraham Tesfaye for the guidance and support. I would like to thank my panel members Dr. Charlotte Hanlon and Dr. Kebede Deribe for their valuable inputs and suggestions throughout this project.

I would like to acknowledge the National Institute of Health Research (NIHR) for funding the EnDPoINT project. It is a great opportunity for getting a fund for neglected tropical diseases affecting poor and disadvantaged communities. I would like to appreciate Brighton and Sussex Medical School and the Centre for Innovative Drug Development and Therapeutic Trials for Africa (CDT Africa) for giving me the PhD opportunity. I also want to appreciate the facilitation of training courses that were highly relevant and of a practical nature which helped me to develop my research proposal, to do effective data analysis, and manuscript write up. Moreover, I greatly acknowledge the University of Brighton and University of Sussex libraries where I got most of the relevant articles. I am also grateful to the Addis Ababa University librarian where I got some of the articles. I am thankful to the Armauer Hansen Research Institute for all the support during the past three and half years. I am also grateful to Global Health Research Unit admin staff for the proper organisation and management of project activities; my special thanks go to the NIHR Global Health Research Centre Programmes Manager, Clare Callow.

I want to acknowledge technical staff of the Ethiopian Ministry of Health, Amhara Regional Health Bureau, Awi zone health department, and Gugsa Shikudad health office for their active role during the situational analysis , FGDs, KIIs, ToCs, and implementation of the project. I also want to acknowledge members of the EnDPoINT consortium who so kindly took time out of their schedules to participate in our research and make this project possible. The role of the Gugsa Shikudad district NTD focal person in the implementation of the project was tremendous, however his sudden death is heart breaking.

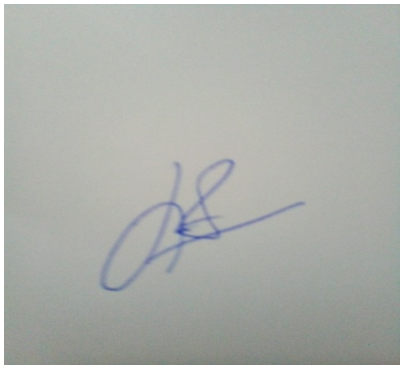
I am grateful to the data collectors for their commitment during both the rainy season and walking long distances in areas that were not accessible by car. I specifically acknowledge the

field coordinator, Abdulkadir and the project coordinator, Mersha Kinfe, for nicely organising and coordinating the field activities. I am also thankful to the study participants for devoting their time in a relatively long interview. My sincere thanks go to the CDT Africa project advisor, Dr Asrat Mengiste, for his continuous advice and guidance. I am very grateful to Professor Stephen Bremner for his guidance on statistical analysis.

I am grateful to my family whose constant love and support keep me motivated and confident. Finally, I thank GOD Almighty for making my dream real.

Authors declaration

I declare that the research contained in this thesis, unless otherwise formally indicated within the text, is the original work of the author. The thesis has not been previously submitted to these or any other university for a degree and does not incorporate any material already submitted for a degree.

Signed _ 

Dated___19 December 2021

Oumer Ali Ahmed

CHAPTER ONE

BACKGROUND

1.0 Overview

In this chapter, I will outline the aetiology, epidemiology, clinical manifestations and management of each of the three neglected tropical diseases (NTDs) the Excellence in Disability Prevention Integrated across Neglected Tropical Diseases (EnDPoINT) project focuses on. I will then give an overview of psychosocial and mental health consequences of these NTDs, explain what is meant by 'care packages' and 'integration of care' before developing the rationale for my study.

NTDs are diverse in biological and transmission characteristics, and predominantly affect populations in low and middle-income countries (LMICs) in sub-Saharan Africa, Asia and Latin America. They predispose to long term disability and poverty [1]. The factors which contribute to the neglect of these diseases include social stigma, marginalization, extreme poverty of the affected population, and the low mortality rate of the illnesses [2]. NTDs affect more than one billion people worldwide and the mortality rate is about 300,000 per year [3]. Despite the low mortality rate, the disability adjusted life years (DALY) that measures disease burden is massive; DALYs due to NTDs amount to about 26.06 million life years globally [4].

Lymphoedema is a chronic condition which affects the lymphatic system, and its manifestation are swelling of body tissues, mainly the arms and the legs. In tropical countries, lymphoedema is mainly caused by lymphatic filariasis (LF), podoconiosis, and leprosy; which are all NTDs.

Podoconiosis, LF and leprosy are also associated with disability and poor psychosocial and mental health outcomes. Podoconiosis is associated with physical disability and depression [5, 6], as well as mental distress [7] and poor quality of life [8]. LF is also associated with depression [9]. Moreover, leprosy is associated with disability [10, 11], poor quality of life [12, 13] and mental disorder [14, 15]. Thus, the management of these diseases should be holistic, i.e. should include both physical and psychosocial care.

My PhD research addresses how best to provide integrated holistic care for people with lymphoedema due to podoconiosis, LF or leprosy in Ethiopia. My PhD was embedded within

the EnDPoINT project, which had three phases as shown in Figure 1.1 below. Phase 1 involved the development of a holistic integrated care package for three NTDs, namely podoconiosis, LF and leprosy. The care package was holistic because it included both physical and psychosocial care components. In Phase 2, the care package that was developed during Phase 1 was piloted in one cluster of Guagsa Shikudad district, Awi zone, Amhara Region, north-western Ethiopia. In Phase 3, the care package was implemented and scaled-up in three districts in Awi zone. This phase involved implementing what had been learned during Phase 2 to a higher number of districts (three districts). My PhD work is based on Phase 2 (see Figure 1.1) of the EnDPoINT project. My analysis focuses on baseline, 3 month and 12 month follow up assessments, and particularly on disability, psychosocial and mental health outcomes, using a mixed methods approach.

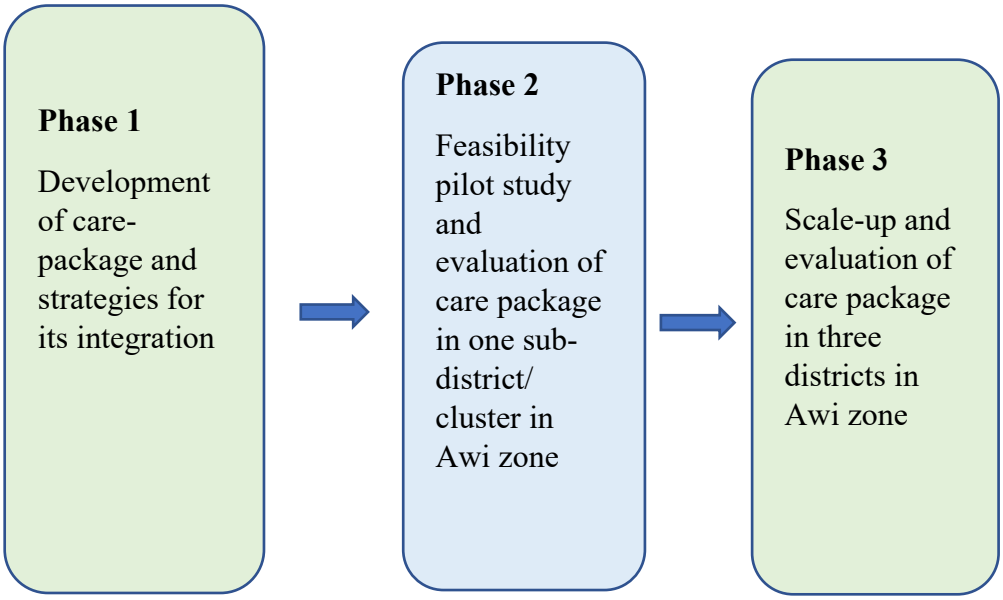


Figure 1. 1 Phases of the EnDPoINT project

1.1 Podoconiosis

1.1.1 Aetiology of podoconiosis

The term podoconiosis was coined by Ernest Price; it arises from a Greek word 'podos' which means foot and 'konos' which means dust. The disease develops when people are exposed to red clay soils derived from alkalic volcanic rock; it occurs in areas of high altitude

(above 1000 meters) and high rainfall (above 1000mm). The soil is slippery during wet times and tends to stick to the feet if allowed to dry [16]. Bare footed farmers are particularly at risk, but the risk is for anyone with prolonged exposure to red clay soil [17]. Colloid-size particles can penetrate the skin of the sole by microtrauma or they can directly enter through the lumen of sweat ducts [16]. In the development of podoconiosis there is evidence for the role of mineral particles with the background of genetic susceptibility [18]. Genome-wide studies have shown a significant association between podoconiosis and single-nucleotide polymorphisms within the HLA class II region of HLA-DQA1, HLA-DQB1, and HLA-DRB1. This association of HLA class II suggests that podoconiosis is a T-cell–mediated inflammatory disease [19].

1.1.2 Epidemiology of podoconiosis

Community based studies have shown the onset of podoconiosis in the first and second decade and advanced progression up to six decades post exposure. Podoconiosis is found in highland areas of tropical Africa, Central America and northwest India [17]. In Africa, podoconiosis presence has been identified in 12 countries, with complete consensus in six countries: Cameroon, Ethiopia, Kenya, Tanzania, Rwanda and Uganda. Consensus is reached based on a report from health organisations, from peer reviewed journals, and from surveys. There was strong evidence for presence of podoconiosis in four countries: Burundi, Cape Verde, São Tome and Prıncipe and Sudan. There was also moderate evidence of presence of podoconiosis in Equatorial Guinea and Nigeria [20].

In Asia, podoconiosis has been reported in two countries. In India there was very strong evidence for presence, and in Indonesia there is moderate evidence for presence of podoconiosis. Similarly, podoconiosis has been reported in three countries in Latin America: Brazil, Ecuador and Mexico, in all with moderate evidence for presence of podoconiosis [20].

In Ethiopia, in 2015, there were about 1.5 million cases of podoconiosis (the total population of Ethiopia is estimated to be 100 million) and the disease was endemic in 345 districts out of the surveyed 775 districts. In the same calendar year, nearly 36 million people were living in areas with podoconiosis prevalence exceeding 1% [21].

1.1.3 Pathogenesis of podoconiosis

The response of living tissues when challenged by crystalline silica is phagocytosis of the particles by macrophages. Multiple aggregates of macrophages or granuloma in the cortex of the node was noticed and fibroblasts were present at the periphery in experimental animals. Silica particles were seen both in macrophages as well as free in the cytoplasm [22, 23].

In a study in experimental animals, the main pathology was enormous collagen surrounded by macrophages. The lymph vessel lumen was obstructed by aggregates of macrophages, lymphocytes and giant cells; reticulin fibres were also observed within the lumen of the lymphatic vessel [22]. Thus, the silica in early stage disease leads to obliterative lymphangitis and if left untreated for prolonged time, leads to fibrosis which further impedes lymphatic flow. The degree of obstruction was directly related with the duration of exposure [22].

1.1.4 Clinical manifestations of podoconiosis

Clinical manifestations are classified into early symptoms and late ones. There are three kinds of early symptoms which may occur in isolation or together: burning sensation which is usually intense, itching sensation of the foot which is either intermittent or persistent, and splaying of the forefoot [24] [25]. Early signs are subtle, however early recognition helps early intervention and prevention of progression of the disease. Early signs are as follows: Swelling of the foot with plantar oedema [25]; the swelling starts in one foot several months earlier than the other leading to asymmetrical swelling. In addition to this there are skin changes such as: lichenification (thickened skin) due to repeated scratching, increased skin markings, transcutaneous ooze of serum, and mossy papules as the surface of the skin produces excess keratin which resembles 'moss' that is hard and rough to touch or quite soft [24, 25].

According to Price (1990) the late signs of podoconiosis are two different types of swelling which are: 1) soft and fluid ('water bag') type, and 2) hard or fibrotic ('leathery' type), which is usually associated with multiple hard skin nodules (Price,1990- cited in [17]).

Acute dermato-lymphangio-adenitis (ADLA) is an acute inflammation that is both a complication and an aggravating factor for lymphoedema. The causative agents are similar to ADLA due to other types of lymphoedema like that of filarial lymphoedema. The main clinical

manifestations of ADLA are fever, chills, malaise, diffuse inflammation and limb swelling [26].

1.1.5 Diagnosis of podoconiosis

The diagnosis of podoconiosis is clinical using typical clinical manifestations in the correct geographical context. The diagnosis is by exclusion, to distinguish from filarial and leprotic lymphoedema. Features that help distinction from filarial lymphoedema include swelling in the foot being the first symptom rather than elsewhere in the leg, and bilateral but asymmetric swelling usually confined to the lower leg. Filarial lymphoedema is usually unilateral and the swelling extends above the knee [17]. To differentiate from leprotic lymphoedema, in podoconiosis lymphoedema there is preservation of sensation and no trophic ulcer, thickened nerves or hand involvement. [17]

Community workers' clinical diagnosis was highly predictive of podoconiosis in a study in an endemic area which used midnight thick film examination and BinaxTM antigen cards to rule out lymphatic filariasis. [27]

1.1.6 Control measures of podoconiosis

Evidence suggests that primary prevention should consist of avoidance of prolonged contact between the skin and irritant red clay soils. This can be achieved through health education on the use of footwear or covering of floor surfaces in areas of red clay soil. This is the core primary prevention strategy. For primary or secondary prevention, daily washing with soap and water and application of antiseptics and emollients are important. Emollients soften the skin, preserve the skin barrier function, prevent skin cracking, and thus prevent infection. The other secondary prevention modalities are: use of socks and shoes, compression using short-stretch elastic bandages, elevation of the limb at night, and exercise. For advanced lymphoedema, in addition to the secondary prevention measures, surgical management including removal of nodule is recommended [17, 25, 28].

1.2 Lymphatic filariasis

1.2.1 Aetiology of lymphatic filariasis

Lymphatic filariasis is named because the main sites in which adult worms are found are the lymphatic vessels of the extremities and the male genitalia. There are three filarial

nematodes which are implicated in human infection, and of these, two are responsible for lymphatic filariasis. *Wuchereria bancrofti* causes nearly 90% of infection, whereas *Brugia spp* are the causative agents for the remaining 10%; *Brugia Malayi* distribution is restricted to southeast Asia and a closely related species, *Brugia timori,* is restricted to south-eastern Indonesia [29, 30].

The parasite has two forms: adult worms and larvae; the adult worms live in afferent lymphatics (and lymph nodes) and the larvae or microfilariae circulate in the peripheral blood [30]. The adult worms can reproduce actively for 5-8 years in lymphatics producing millions of microfilaria or larvae that migrate to the blood vessels, where they reach peak concentration coinciding with the feeding habit of the mosquito vector, enabling transmission to other susceptible human hosts [29].

1.2.2 Epidemiology of lymphatic filariasis

As of mid-2013, worldwide, LF was endemic in 72 countries, and 120 to 129 million people were infected. Among these, an estimated 40 million developed overt clinical manifestation, either hydrocele (scrotal swelling) or lymphoedema [30]. Lymphatic filarial disease is the second leading parasitic cause of disability, with disability-adjusted life years (DALYs) estimated to be 5.549 million [31].

The vectors for the LF parasites belong to four genera: *Aedes, Anopheles, Culex or Mansonia*. In these vectors, the parasite develops into human infective stage (L3). During subsequent blood meals, the larvae enter through the scratch wound made by the mosquito bite. In the human body, the larvae undergo two more moults to complete the cycle and progress to adult form [32].

Globally, after 13 years of mass drug administration (MDA) programmes, the global prevalence of LF has been reduced from 3.55% to 1.47%, which is almost a 59% reduction. At the same time, the global prevalence of microfilaraemia was 0.79%, that of hydrocele, 0.42%, and that of lymphoedema, 0.36%. MDA is a modality of preventive chemotherapy in which anti-helminthic drugs are administered to eligible populations irrespective of the infection status. By 2013, after 13 years of MDA, there were 67.88 million cases: including 36.45 million cases of microfilaraemia, 19.43 million cases of hydrocele and 16.68 million cases of lymphoedema. Among these cases, 64% are in Sub-Saharan Africa and 32% are in the South

East Asian region [33]. In Ethiopia, 75 of 658 surveyed districts were found to be endemic for LF in 2013. Including the previously known 37 districts, a total of 112 endemic districts in Ethiopia (or nearly 12 million people) are at risk of LF [34].

1.2.3 Pathogenesis of lymphatic filariasis

The pathogenesis of LF is not well understood. Potential factors are the host innate and adaptive responses secondary to the dead or dying adult worms. These effects also lead to lymphangitis and lymphadenitis with associated swelling and pain [32, 35]. Another potential inducer of inflammation is the symbiont bacteria Wolbachia [36]. The resulting lymphatic dysfunction and damage progresses to hydrocele and lymphoedema in some patients [29].

The death of adult worms may result in episodes of acute filarial lymphangitis (AFL) or may remain subclinical and result in no clinical complaints by the patient [35, 37]. People harbouring adult worms may develop lymphangiectasia, which either remains subclinical or develops to overt chronic disease. This lymphangiectasia could further weaken lymphatic function and predispose to bacterial infection. This recurrent bacterial infection is a critical factor for the development of lymphoedema and subsequent development of elephantiasis [35]. Elephantiasis is characterized by marked enlargement of the parts affected, especially of the legs. The word ‘elephantiasis’ is prejudicial and potentially stigmatising, so should be dropped in favour of the more neutral ‘lymphoedema’.

1.2.4 Clinical manifestations of lymphatic filariasis

The incubation period of LF may vary from two to more than ten years, and some microfilaraemic individuals can remain asymptomatic throughout life. Symptoms may be either acute or chronic. The acute illness is usually manifested as adenolymphangitis, which is followed one or more decades later by chronic obstructive lesions [38].

In LF due to *Wuchereria bancrofti,* the main clinical features are hydrocele, lymphoedema, and chyluria, whereas in that due to *Brugia spp* hydrocele is less common. In both cases, the most commonly affected lymph nodes are: inguinal, axillary and epitrochlear nodes [35].

There are two distinct acute clinical syndromes resulting from LF, acute dermatolymphangioadenitis (ADLA) and acute filarial lymphangitis (AFL). AFL is caused by the death of adult worms, whereas ADLA is caused by superimposed bacterial infection. According to Dreyer et al [39] "The syndrome of ADLA is characterized by a plaque-like area of relatively diffuse (sub)cutaneous and inflammation with or without ascending lymphangitis and/or satellite adenitis. A distal skin lesion that served as the point of entry for the bacteria that probably cause the clinical episode can be identified. Prostration, high fevers, chills and other systemic manifestations of bacteraemia or, in rare cases, of severe sepsis are common during the acute episode. ADLA can be unilateral or bilateral. The acute attack is often accompanied or followed by distal oedema of the affected leg. The latter may (partially) regress, but recurrent ADLA is a common cause of chronic lymphoedema and elephantiasis."

In contrast, as described by Dreyer et al [39], AFL presents as "a circumscribed inflammatory nodule or cord in the arms, legs or the breast (in women) centred around adult worms in a lymphatic vessel. When the adult worms are located in lymph node, acute filarial adenitis may occur. Bacterial entry lesions are rarely present, systemic manifestations are mild or absent, and the acute episode is seldom accompanied or followed by distal lymphoedema. Exfoliative dermatitis, common during ADLA episodes, was not observed in patients with AFL."

1.2.5 Diagnosis of lymphatic filariasis

Diagnosis of filarial infection is based on detection of microfilariae in Giemsa-stained thick blood films using microscopy. The blood should preferably be taken at night because of the mainly nocturnal microfilaremia of *W. bancrofti* infection [29, 40].
Identification of microfilaremia can also be conducted by measuring the parasite antigen using rapid format cards based on immuno-chromatographic techniques. These tests are used to assess the endemicity of LF, as well as to determine baseline prevalence rates before national control programmes and to assess the effectiveness of a control program after rounds of MDA [34, 40]. Late in the clinical scenario of either lymphoedema or hydrocele the chance of getting either positive microscopy or positive antigen-based diagnostics is less likely.

1.2.6 Control measures of lymphatic filariasis

For prevention of transmission and control of LF, MDA is recommended. The two important anti-microfilarial drugs are ivermectin and Diethylcarbamazine (DEC). The anti-microfilarial effect of these drugs is strengthened by albendazole, which has an effect on both the adult worm and microfilaria [29, 41]. Apart from MDA, there is also evidence of the efficacy of Doxycycline, especially on its sterility effect on the bacterial endosymbiont-Wolbachia and microfilaricidal activity [36]. Vector control is one of the secondary strategies to prevent LF. Long-lasting insecticide impregnated bed nets (LLIN) and indoor residual spraying help to tackle the mosquito vector [42].

1.3 Leprosy

1.3.1 Aetiology of leprosy

Leprosy is a chronic infectious disease and the causative organism is a mycobacterium called *Mycobacterium leprae*. The organism reproduces slowly with an incubation period of more than two years [43]. *M. leprae* is an acid-fast obligate intracellular bacillus which has a strong tropism to the peripheral nervous system (mainly Schwann cells) and the reticuloendothelial system. The replication of the organism takes a very long time, from 11 to 13 days [44]. The organism grows best at temperatures between 25 and 30^{o}C. Thus this mycobacterium has a predilection for colder areas of the body such as: the skin, nasal mucosa and peripheral nerves [44].

1.3.2 Epidemiology of leprosy

Globally, the number of leprosy cases on treatment at the end of 2020 were 129,192, with the rate of cases per million population being 16.6. There was a reduction in new cases by 37.1% as compared to the 2019 data [45]. One of the reasons for the reduction of cases in 2020 as compared to 2019 was the reduced reporting of cases due to the COVID-19 pandemic. The number of children among new cases were 8629, which corresponds to 6.8% of all new cases [45]. In Ethiopia, in 2020, a total of 2591 new leprosy cases were registered and among these,

the majority were Multi-Bacillary (MB). The proportion of children among new cases of leprosy was 15.1%, and 14.8% of new cases of leprosy had grade II disability (high disability) at diagnosis during the same calendar year [45].

Most infected individuals will not develop overt disease. Patients with lepromatous leprosy are relatively infectious compared to those patients with tuberculoid leprosy [46]. The mode of transmission of leprosy remains unclear but it is widely believed that transmission occurs through respiratory droplets [43]. The transmission is more common in family members who have close and prolonged contact with the infected person having high bacterial load. Moreover, the development of disease depends on the immunocompetence of the infected person [43, 46].

1.3.3 Pathogenesis of leprosy

There are three main pathological forms of leprosy including tuberculoid leprosy, lepromatous leprosy and borderline leprosy forms. Patients with the tuberculoid form have strong cell-mediated immunity and relatively few lesions with no detectable mycobacteria. However, patients with lepromatous leprosy have weak cell mediated immunity, are anergic to M. leprae and have multiple skin lesions with mycobacteria present in smear exam. In between these two forms is the borderline form which has its own sub-types with some cell mediated immunity and multiple skin lesions [44, 47]. In tuberculoid leprosy, there is intense inflammation, whereas this inflammation is less remarkable in lepromatous leprosy. Histologically in leprosy there are granuloma filled by epithelioid histiocytes, multinucleated giant cells, and CD4+ T cells that secrete interferon [44].

The pathology due to M. leprae depends on the genetic constitution of the host, specifically it depends on the HLA class II major histocompatibility gene. HLA-DQ1 is mostly linked with lepromatous leprosy, while HLA-DR2 and HLA-DR3 are linked with tuberculoid leprosy [44].

1.3.4 Clinical manifestations of leprosy

The majority of infected individuals will not develop overt disease; only 5-10% of individuals will develop clinical manifestations and these manifestations depend on the host's genetically determined immune response towards M. leprae [46, 48]. Leprosy leads to lesions on the limbs, skin, peripheral nerves and eyes. Loss of sensation, thickened peripheral nerves, numbness, weakness of the extremities, and ulcers on anaesthetic hands and feet are also features of leprosy. In severe cases it can lead to disability several years after the onset of the disease [43, 49]. The clinical scenarios are further classified into two based on World Health organisation (WHO) guidelines: paucibacillary when there are up to five skin lesions, and multibacillary when there are more than five skin lesions [47]. The disease is complicated by two immunologic reactions, type I reactions and type II reactions [47].

1.3.5 Diagnosis of leprosy

The diagnosis of leprosy is clinical. Making a clinical diagnosis is usually straightforward; despite this there is lack of a good point-of-care test to confirm the diagnosis. Diagnosis can be easily done if one of the following is present [47-49]:

a. Hypopigmented or reddish skin lesions (patches) with definite sensory loss
b. Thickened peripheral nerves
c. Acid-fast bacilli on skin smears or biopsy material.

NB. In the borderline and lepromatous leprosy spectrum, patients may not have sensory loss.

1.3.6 Leprosy control measures

Leprosy is a curable disease; early diagnosis and early treatment will prevent disability. To prevent transmission, active contact tracing is recommended. For contacts, health education, counselling and examination for signs and symptoms is advisable. The standard treatment for leprosy is MDT, the first line of treatment consisting of three drugs for multibacillary leprosy (rifampicin, clofazimine, and dapsone) and two drugs for paucibacillary leprosy (rifampicin and dapsone). The recommended treatment duration for multibacillary leprosy is 12 months and for paucibacillary is 6 months [43, 46-48]. As part of control of leprosy there should be

proper screening of contacts and administration of prophylaxis to eligible contacts. The recommended prophylaxis medication is a single dose of rifampicin [50].

1.4 Overview of psychosocial and mental health outcomes

1.4.1 Case definitions

The definition of the term ‘psychosocial’ in the Oxford English dictionary as cited in International Journal of Epidemiology is [51] “pertaining to the influence of social factors on an individual’s mind or behaviour, and to the interrelation of behavioural and social factors”.

The concept of psychosocial wellbeing emerged from the WHO definition of health as 'a state of complete physical, mental, and social well-being, and not merely the absence of disease and infirmity'. Social factors affect psychosocial factors which in turn affect psychological factors. The psychological factors affect individuals’ health through either a change in biological or behavioural conditions [51]. In this study the psychosocial outcomes included assessment of quality of life, social support, stigma and discrimination.

Psychosocial and mental health outcomes relevant to my study are defined below, along with the causes and mitigation mechanisms.

Quality of Life is defined by WHO as “individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” [52]. This is affected by “physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment” [52]

Mental health is defined by WHO as “a state of wellbeing in which an individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and is able to make a contribution to his or her community. In this positive sense, mental health is the foundation for individual well-being and the effective functioning of a community”, cited in [53]

Health-related stigma is defined by Weiss and Ramakrishna [54] as follows: “a social process or related personal experience characterised by exclusion, rejection, blame, or devaluation that results from experience or reasonable anticipation of an adverse social judgment about a person

or group identified with a particular health problem. It may adversely affect public health policy and individual health status."

According to WHO, **psychosocial and mental health distress** are defined as follows:
"Psychological distress comprises the worry, fears, sadness and insecurity often experienced by people with an NTD and the associated stigma. It can result in reduced social functioning and self-isolation." [55]

"**Mental health conditions** are characterized by changes in thoughts, perceptions, emotions or behaviour that affect relationships and the ability to perform expected social roles and can cause significant functional impairment. Some examples include depression, anxiety, harmful use of alcohol and other psychoactive substances."[55]

1.4.2 Types of stigma, and causes of NTD related stigma

There are different forms of stigma including internalized-stigma, enacted stigma, and anticipated stigma. Internalized -stigma arises when the affected person is ashamed and holds negative attitudes about his/her value, which may reduce the tendency to reveal symptoms, seek care, demand rights or try to be included in the household or community [56]. Enacted stigma is the experience of discrimination such as abuse, loss of employment or prejudicial attitudes, while anticipated stigma is the perceived fear of enacted stigma [57].

The causes of stigma for people with NTDs may be (amongst others): appearance, fear of contagion, being a burden to the family and the inability to fulfil the expected role in the community [58].

1.4.3 Potential management of stigma

Mitigation strategies for stigma and discrimination have been addressed at different levels. Multi-component stigma reduction programmes have been shown to be most effective at reducing stigma. First, to target the health problem by early diagnosis and treatment. Next, to implement public health measures to control the disease. Early diagnosis and treatment for

cure cannot be the only modalities since not all cases of NTDs can be prevented, and some people could already be disabled at the time of diagnosis [54, 59].

Further strategies include addressing stigmatisers through proper health education and information dissemination to the public at large. Also, to address the emotional impact of stigma through proper counselling, establishment of peer support groups (self-help groups) and enhancing community conversation. In addition to this, managing associated mental health conditions is recommended. It is also advisable to improve livelihoods, to implement social inclusion, and to empower affected individuals through community based and community led projects. Finally, communicating with decision makers through advocacy, lobbying and facilitating research support on diseases of poverty or NTDs may all contribute to wider stigma reduction [54, 59].

1.4.4 Epidemiology of depression

Depression is the mental health outcome that was included in our study. Globally, depression is the leading cause of mental health related illness and affects 300 million individuals worldwide. It can impede individuals from working to their full capacity and is associated with premature mortality secondary to suicide, self-harm and other illnesses [60, 61]. Major depression impairs psychosocial functioning and leads to poor quality of life. Moreover, WHO has ranked major depression as the third largest cause of burden of disease worldwide and projects it to rank first by 2030 [61, 62].

The lifetime risk of depression is 15-20%, which means that almost one in five people suffer an episode at some point in their lifetime. It is one of the most common conditions treated in primary health care units - nearly 10% of all primary health care visits are related to depression [62-64]. The estimated prevalence of depression in Ethiopia is 9.1% [65].

1.4.5 Diagnosis of depression – according to DSM-V

The two main classificatory diagnostic systems, the Diagnostic and Statistical Manual of Mental Disorders [DSM], and International Classification of Diseases [ICD], mainly rely on the identification of a number of key symptoms as shown in Figure 1.2.

According to DSM-V and the American Psychiatric Association, depression is characterized by the following: The symptoms can vary from mild to severe and are shown in *Figure 1.2:*

Figure 1.2 Characterization of depression symptoms. For a diagnosis of major depressive disorder, the individual needs to present with five or more of these symptoms nearly every day during a 2-week period.

Symptoms must last at least two weeks and must represent a change in previous level of functioning for a diagnosis of depression. For a diagnosis of major depressive disorder, the individual needs to present with five or more of these symptoms nearly every day during a 2-

week period, provided at least one of these symptoms is a fundamental one [62]. The fundamental symptoms are depressed mood and anhedonia [62].

Notably, none of the symptoms are pathognomonic of depression, and do occur in other psychiatric and medical illnesses. Thus, the definition of depression as a disorder is based on symptoms forming a syndrome and causing functional impairment [62]. For instance, some of the symptoms of depression are similar to mental distress and sometimes it is difficult to differentiate between the two. In our study we used the PHQ-9 tool to screen depressive symptoms. A limitation of this tool is that, as it can detect transient depression, it can sometimes overestimate the outcome. Moreover, where there are comorbidities, whether some of the symptoms (like loss of energy or fatigue) are due to the comorbid illness or due to the depression is difficult to categorize. Despite this, screening for depression is relevant and important, as in many primary care settings, patients presenting with multiple disorders that include depression often do not get diagnosed, and even if they do, treatment may be focused on other chronic diseases [66].

1.4.6 Management of depression

The pathways for appropriate management of depression include - a timely proper diagnosis, health education and patient engagement, initiation of pharmacotherapy or psychotherapy, close follow up, strict adherence mechanisms, assessment of treatment effectiveness, and follow-up and management of medication side effects [64].

The objective of depression management is usually complete remission of the above stated symptoms. The treatment modality is either psychological therapy, pharmacotherapy or both. Together with psychological and pharmacotherapy, social intervention addressing self-skill training which enhances social and emotional competencies may be recommended. Before initiation of any form of pharmacotherapy it is important to stop any medication which lowers mood, address any substance abuse, and apply general supportive measures including sleep hygiene, regular physical exercise, and healthy nutrition [62].

Details on the association between psychosocial and mental health outcomes and the three NTDs studied in this thesis are described in *Chapter two.*

1.5 Overview of care package and integrated care

A care package is a disease control and management modality composed of various mechanisms. Care packages can be developed by referring to grey literature, peer reviewed literature, by conducting Theory of Change workshops, or by conducting key informant interviews and focus group discussions. A holistic care package is one which includes both physical and psychosocial interventions. Care package development was found to be successful previously in the PRIME project (PRogramme for Improving Mental health carE) which was conducted in five low- and middle-income countries: Ethiopia, India, Nepal, South Africa and Uganda. The aim of PRIME was to develop, implement, evaluate and scale up mental health care plans in districts at the primary health care level [67]. The care package is described further in *Chapter three*.

A health system-based definition of integration is: "Integrated health services: health services that are managed and delivered so that people receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease-management, rehabilitation and palliative care services, coordinated across the different levels and sites of care within and beyond the health sector, and according to their needs throughout the life course", cited in [68]

A social science-based definition of integration is: "Integration is a coherent set of methods and models on the funding, administrative, organizational, service delivery and clinical levels designed to create connectivity, alignment and collaboration within and between the cure and care sectors. The goal of these methods and models is to enhance quality of care and quality of life, consumer satisfaction and system efficiency for people by cutting across multiple services, providers and settings. Where the result of such multi-pronged efforts to promote integration lead to benefits for people the outcome can be called 'integrated care'." Also cited in [68]

These definitions are a bit broader than what we used in our study. However, the health system-based definition aligns with the clinical aspects of the care package, whereas the social science-based definition mainly aligns with the program management and psychosocial aspects of the care package.

The WHO 2021-2030 NTD roadmap advocates for provision of integrated care. The integrated delivery of community-based interventions for helminthic NTDs in co-infected

communities has been shown to result in reduced prevalence of NTDs and more effective control with greater coverage compared to routine vertical delivery [69]. Moreover, integrated interventions have been found to be more feasible and cost effective than vertical care [69]. Integrated community-based interventions for non-helminthic NTDs have also been shown to lead to a reduction in incidence and burden of these NTDs, and to result in extended coverage and sustained community acceptance [70]. Similarly, integrated interventions for skin NTDs have been found to be effective and efficient in relation to reduction of NTD-related morbidity, alleviation of poverty [71], and have resulted in capacity building, awareness creation and motivation of health workers [71]. Conversely, integrated care may have some limitations, including loss of specialized expertise due to loss of vertical care, lack of adequate trained staff, and staff turnover following training [71].

Systematic reviews [72-74] have shown that stigmatized chronic skin NTDs are associated with comorbid mental health conditions and more so than other chronic diseases [66]. Integration of care which includes mental health and psychosocial care alongside physical health care, across these NTDs at primary health care level, is therefore increasingly recommended.

I developed a conceptual framework towards the beginning of my PhD research, based on a systematic and traditional literature review, as well as inputs from the stakeholders during the Theory of Change workshops (See *Figure 1.3*). Details about the Theory of Change workshops are described in *Chapter three.*

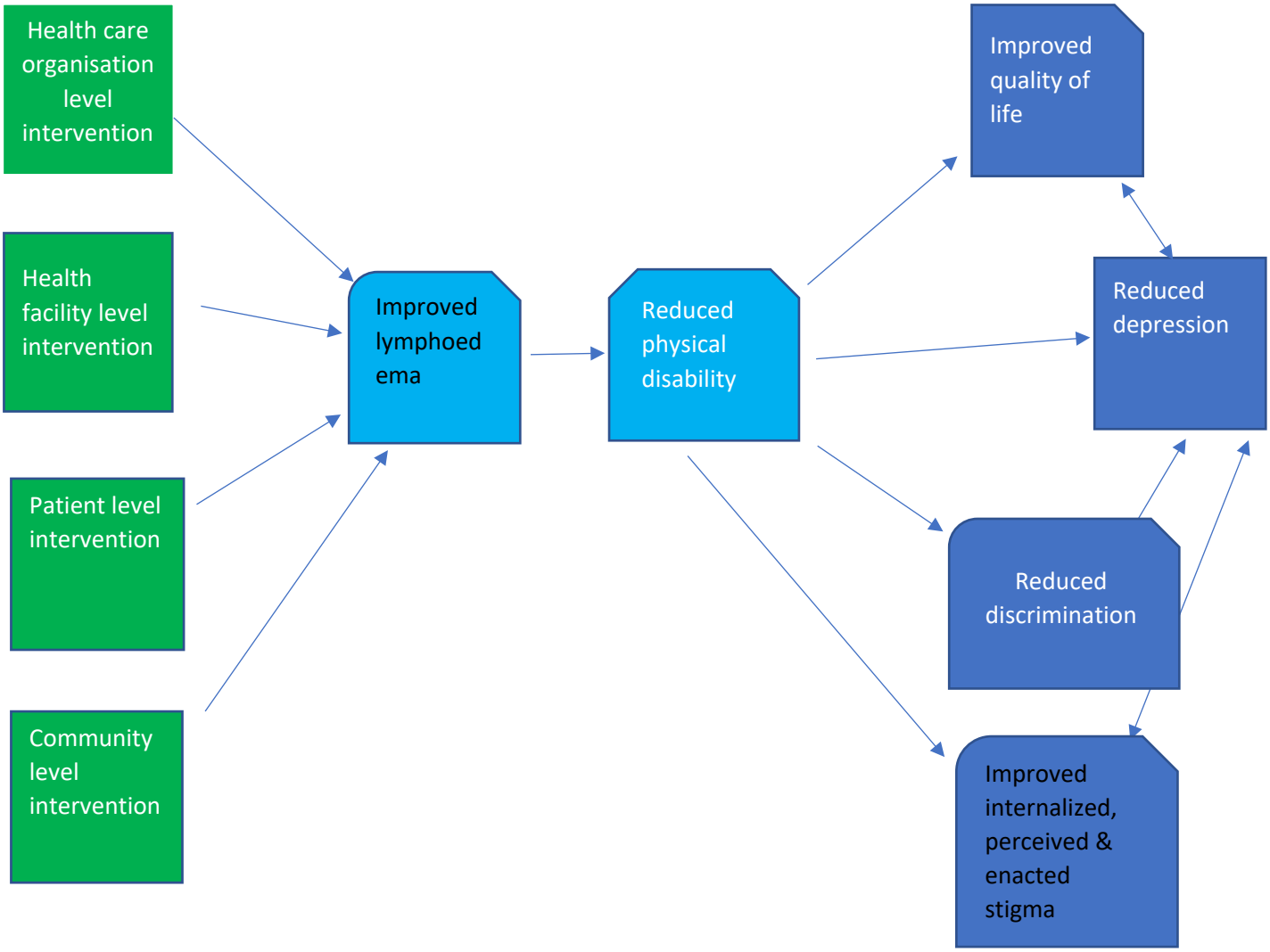


Figure 1. 3 Conceptual framework

1.6 Rationale for the study

Although lower limb disorders secondary to podoconiosis, LF and leprosy lead to significant disability, increased depression, low quality of life and decreased productivity, studies have shown that only a few health facilities in Ethiopia provide services for these diseases. Moreover, physical care is not often integrated with psychosocial care. Even though these three NTDs have different aetiologies and pathogenesis mechanisms, all can affect the lower limb which in turn leads to disability and reduced productivity. In the EnDPoINT project within which this study was embedded, an integrated holistic care package was developed and evaluated, whereby services were integrated into government-run primary health care units and then the clinical, psychosocial and mental health outcomes were assessed. After this, the care package has been scaled up to other endemic districts (not part of my PhD).

1.7 Objective of the study

1.7.1 Overall aim:

To evaluate the clinical (physical), mental health and psychosocial outcomes of an integrated holistic (physical and psychosocial) care package for lower limb disorders secondary to podoconiosis, LF and leprosy in Awi zone, Amhara region, north-western Ethiopia.

1.7.2 Specific objectives

a. To conduct a systematic review on disability, psychosocial and mental health status secondary to podoconiosis, LF and leprosy.
b. To determine the clinical (physical) outcomes of affected persons due to the integrated holistic care package.
c. To determine the psychosocial and mental health outcomes of affected persons due to the integrated holistic care package.
d. To determine factors (demographic, social and economic) that contribute to the clinical (physical), mental health and psychosocial outcomes of the affected persons.

1.8 Research Questions

a. Does the care package result in improved physical outcomes for patients with podoconiosis, LF and leprosy?
b. Does the care package result in improved psychosocial and mental health outcomes for patients with podoconiosis, LF and leprosy?
c. Are there any demographic, social or economic factors that influence these clinical (physical) and psychosocial outcomes?

1.9 Phases of the PhD project

This PhD project had three phases: - preparation phase, pilot implementation, and evaluation phase. In the preparation phase, I conducted a systematic review to assess the existing evidence on the association between NTDs and psychosocial and mental health outcomes. Then, as part of Phase 2 of the EnDPoINT project, we assessed the baseline psychosocial and mental health outcomes of lymphoedemadue to podoconiosis, LF, and leprosy. Subsequently, the integrated holistic care package was implemented in Gusha cluster of Guagsa Shikudad district, Awi zone, North-Western Ethiopia. Finally, we assessed the impact of the intervention using a mixed methods approach: qualitative (Focus Group Discussions, Key Informant Interviews) and quantitative (mixed effects linear regression and mixed effects logistic regression).

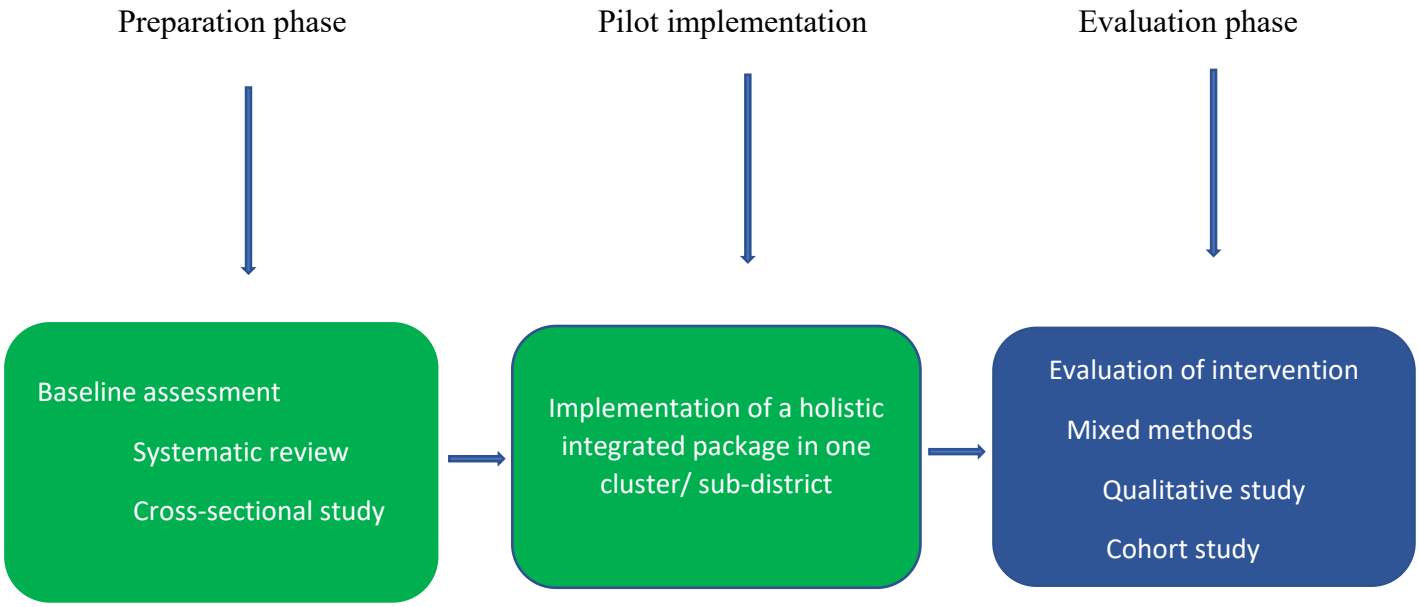


Figure 1. 4 Phases of the PhD project

CHAPTER TWO

SYSTEMATIC REVIEW

The impact of podoconiosis, lymphatic filariasis and leprosy on disability and mental wellbeing: a systematic review

In this chapter I present an overview, methodology, results, and discussion of a systematic review on the impact of podoconiosis, lymphatic filariasis and leprosy on disability and mental wellbeing. In the methods part I describe the eligibility criteria, the literature search, study selection, and data extraction and analysis. In the results section at first I describe the disability and psychosocial outcomes due to leprosy. Then, the disability and psychosocial outcomes due to podoconiosis. Finally, I describe the disability and psychosocial outcomes due to lymphatic filariasis. Following the results section, the discussion part on the physical, psychosocial and mental health impact of the three NTDs is addressed.

The result of systematic review has been published, with details of publication as follows:

Ali O, Mengiste A, Semrau M, Tesfaye A, Fekadu A, Davey G. The impact of podoconiosis, lymphatic filariasis and leprosy on disability and mental wellbeing: a systematic review. PLOS NTDs. 2021; 15(7): e0009492. https://doi.org/10.1371/journal.pntd.0009492

2.1 Overview

The three NTDs addressed in this review are leprosy, podoconiosis and lymphatic filariasis (LF). These three conditions were selected because they are priority NTDs in Ethiopia and because this review was carried out as part of an implementation research study on integrating care for these three conditions (the EnDPoINT programme). Despite the high prevalence and apparent physical and psychosocial burdens imposed by leprosy, podoconiosis and LF, there is a gap in the literature in identifying specific disability, psychosocial and mental health outcomes in a systematic way. Though the three diseases have different aetiologies and pathogenesis, all lead to leg deformity which profoundly affects productivity (though LF and

leprosy affect other parts of the body too). Due to this, potential integration of care for these diseases at primary health care level is a possibility.

Other systematic reviews were conducted earlier by Litt *et al* [53] but which did not address podoconiosis related mental health conditions, whereas one by Somar *et al* [75] is a recent one but addressed only leprosy related mental health outcomes.

The research question of the review was: What are the prevalent disabilities, psycho-social and mental health effects to be considered in order to develop a holistic physical and psychosocial care package for those affected by leprosy, podoconiosis and lymphatic filariasis?

The objective was to determine the disability outcomes secondary to LF, podoconiosis and leprosy, as well as the psychosocial-mental health outcomes secondary to these conditions. This review was conducted prior to developing a holistic physical and psychosocial care package for individuals affected with podoconiosis, lymphatic filariasis or leprosy.

2.2 Methods

2.2.1 Eligibility criteria

Eligible studies were those addressing the NTDs podoconiosis, LF or leprosy, or any combination of these. The outcome measures focussed upon for these diseases were disability and psychosocial or mental health outcomes. We only included articles with outcomes measured using standard tools. Only studies published in English, for which the full text was available, were included. There was no restriction on publication year. Studies that were not published in peer-reviewed scientific journals, or were either purely qualitative studies or animal studies, were excluded.

The protocol is available at the National Institute for Health Research PROSPERO International prospective register of systematic reviews (identifier: CRD42019128400) (see Appendix 4).

2.1.2 Literature search

From July to August 2019, studies were identified by systematic search of four electronic databases: Medline, Global Health, PsycINFO and Embase. Additionally, we included one article published by one of the co-authors that had yet to be indexed in any of the literature databases searched. We used search terms for NTDs; for disability, psychosocial and mental health outcomes; and countries endemic for at least one of the three NTDs.

The following search terms were used in all four databases, where we searched the main domains and their synonyms. The search terms for NTDs were “podoconiosis” OR “lymphatic filariasis” OR “leprosy” OR “elephantiasis” OR "elephantiasis, filarial". The search terms for disability, psychosocial and mental health outcomes included: “disability” OR “functioning” OR “mental distress” OR “depression” OR “alcohol abuse” OR “substance abuse” OR “psychosocial” OR “anxiety disorder” OR “common mental disorder” OR “mood disorder” OR “distress” OR “major depression” OR "depressive disorder" OR “alcohol” OR “substance” OR “anxiety” OR “mental disorder”. The list of endemic countries for leprosy and lymphatic filariasis were taken from recent WHO reports [76, 77], and for podoconiosis from a recent systematic review [78]; all of these countries were also included as search terms.

2.1.3 Study selection

Studies that were identified through the database searches underwent a two-stage screening process. First, two reviewers (OA & AM) screened the titles and abstracts using Endnote reference manager to remove duplicates and identify eligible articles based on the inclusion and exclusion criteria. Following the selection of articles through the title and abstract review, the full text articles were reviewed by the same two reviewers. After the two reviewers independently screened all articles, they met to achieve consensus on inclusion/exclusion of each article. The details are depicted in Figure 2.1.

2.1.4 Data extraction and analysis

The following data were extracted from studies that fulfilled inclusion and exclusion criteria: the disability, psychosocial, and mental health outcomes due to three NTDs; the outcome measures, and the number of studies conducted using the tool or the outcome measure (see Table 2.1)

The quality assessment mechanism was adapted from the Evidence for Policy and Practice Information and Co-ordinating Centre [79] and included six quality criteria: - aims clearly stated, design appropriate to the stated objectives, justification given for sample size, evidence provided of reliability or validity of measures used, statistics accurately reported, and sample selection relatively unbiased (i.e. where steps such as random sampling had been taken).

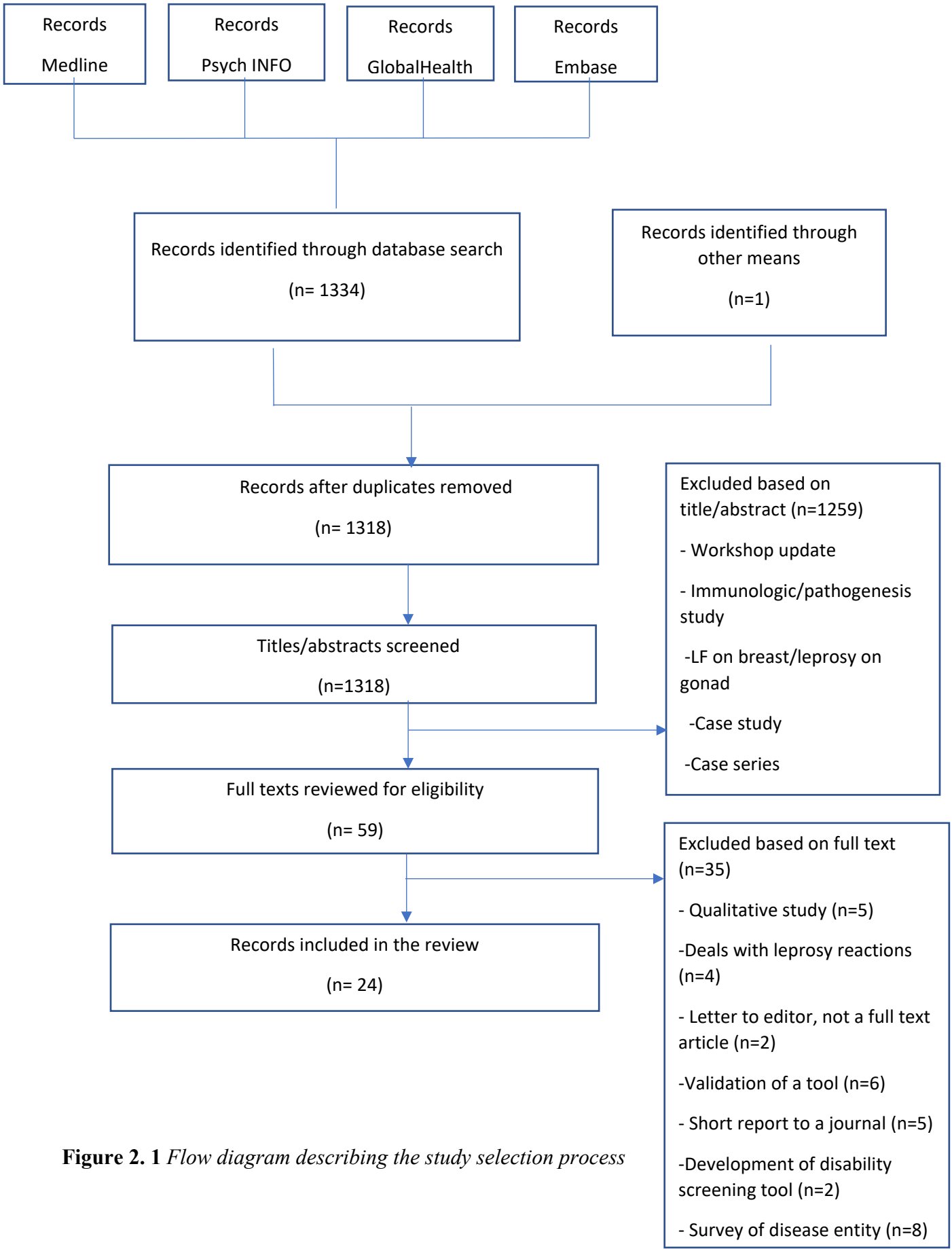


Figure 2. 1 *Flow diagram describing the study selection process*

Table 2. 1 : Profile of the disability, psycho-social and mental health outcomes found among those affected by leprosy, podoconiosis and lymphatic filariasis, and the outcome measures used in the studies.

	Leprosy	Tool used (no. of studies)	Podoconiosis	Tool used (no. of studies)	Lymphatic filariasis	Tool used (no. of studies)	Total
Disabilities	Hand and feet deformity	EHF scale (3)					
	Disability and	WHO tool (6)	Disability	WHODAS (1)	Disability	8 domain/5-level (8D5L) survey tool (1)	
	Activity limitations	SALSA (4)			Limitation of activities	Functional measure (1)	
	Disability adjusted life work years	DALY (1)					
	Social participation	P scale (2)					
	Total	16		1	1	2	20
Psycho-social	Quality of life	WHO-QoL brief (2)	Quality of life	WHO-QoL brief (1)	Quality of life	Short-Form (SF-36) (1)	
	-	-	-	-	-	-	
	Total	1		1		2	4
Mental health	Depression	CES-D (1)	Depression	PHQ-9 (2)	Depression	CIDI (1)	

	Mental distress	SRQ-20 (2)	Mental distress	Kessler-10 (1)	Current mental health status	SRQ-20 (1)	
	Psychiatric disorders	MINI-plus (1)			Mental Health conditions	GHQ-30 (1)	
	Mental health conditions	GHQ-30 (1)					
	Total	5		3		3	11

2.2 Results

We identified 1334 articles: 1247 articles from Medline, 47 articles from PsycINFO, 14 articles from Global Health and 26 from Embase. After removing duplicates, 1318 articles were reviewed, of which 59 were included based on the title-abstract review. The full texts of these 59 articles were then reviewed, of which 23 were accepted for inclusion. One recent article known to the authors was retrieved through Google Scholar. The full text was unavailable for three articles. A summary of the data extracted from the reviewed studies is shown in the data extraction table (See Appendix 3).

2.2.1 Description of studies included

The 24 studies included in this review were published between 1980 and 2019. Several study designs were used, including cross-sectional, case-control and prospective studies. The majority of studies employed a cross-sectional study design. A significant number of the studies (n=10) were conducted in Africa, and about half of these (n=6) were conducted in Ethiopia. Besides Africa, most studies were conducted in Asia (n=8) and half of these (n=4) were from India. Six studies were conducted in Latin America. Among the articles included for review, 16 dealt with leprosy, four with podoconiosis, and another four with LF.

The aims were clearly stated in all articles included in this review, the design was appropriate to the stated objectives in 22/24 papers (92%), proper justification was given for the sample size in 12/24 (50%), evidence for reliability or validity of measures was provided in 17/24 (71%), statistics were accurately reported in 20/24 (83%), and sample selection was relatively unbiased in 15/24 (63%).

The description of outcome measures used in the articles selected for this review are included in Table 2.2.

Table 2. 2 Description of outcome measures

Name of scale	Number of items	What the scale measures	Condition the tool has been used for	How it is scored	Source reference
WHO-DG (WHO disability grade)	3	This scale measures disability based on the WHO definition of disability in leprosy	To measure leprosy related disability	Grade 0 implies no disability, grade 1 implies patients only have loss of sensation, and grade 2 indicates there is visible deformity.	[80]
EHF (Eye, Hand and Feet)	12	The EHF score is the sum of disability of both eyes, and both hands and feet in leprosy patients	To measure leprosy related disability	The scores range from 0 to 12. A higher score is associated with high grade of disability.	[81]
DAWLY (disability adjusted working life years)	NA	This estimates the number of productive years lost due to the disability, and can be termed disability adjusted productive work years lost or DAWLY)	Measures productivity years lost due to disability	The number of lost productive years due to disability recorded.	[82]
WHODAS II (WHO disability schedule)	12	The WHODAS II tool was developed by WHO to measure general disability.	To measure disability in podoconiosis cases and controls	Questions relate to concentration, physical activities of daily life and social interactions over the last 30 days. Higher	[83]

				scores are related to higher disability.	
SALSA (Screening Activity Limitation and Safety Awareness Scale)	20	The SALSA scale measures activity limitations and risk awareness in patients who have or have had a disease with peripheral neuropathy, as in leprosy. The scale includes assessment of the eyes, hands (skills and labour), feet (mobility) and self-care.	To measure activity limitation related to leprosy	SALSA scores range from 10 to 80, with 10–24 allocated to patients without significant limitations; 25–39 for mild limitations; and 40–49, 50– 59 and 60–80 for moderate, severe and very severe limitations, respectively.	[84]
Participation scale	18	The Participation scale is composed of 18 items, which measures activities of social participation.	To measure social participation restriction in leprosy patients	Scores range from 0 to 90. The higher the score, the more severe the participation restriction. The levels of restriction are classified as: no restriction (0 to 12), mild restriction (13 to 22), moderate restriction (23 to 32), severe restriction (33 to 52) and extreme restriction (53 to 90).	[85]
WHO-QOL-BREF (WHO quality of life)	26	The WHOQOL-BREF was developed by the WHO as a shortened version of the quality of life measure WHOQOL-100 and it assesses quality of life.	To measure quality of life in podoconiosis and leprosy cases	The WHOQOL-BREF uses a 5-point scale for each answer, and these are scored positively, with higher values indicating a higher quality of life.	[86]
PHQ-9 (The Patient Health Questionnaire)	9	The Patient Health Questionnaire (PHQ-9) is used to screen depression.	To measure depression in podoconiosis cases	The four response categories refer to the amount of time the symptom was present from ‘not at all’ (0) to ‘nearly every day’ (3). Higher scores are associated with more severe	[87]

				forms of depression. Those who screen positive (with a score of 5 and above) can be further interviewed using the CIDI.	
CIDI (Composite International Diagnostic Interview)	9	A fully structured non-clinical interview designed for use in general population surveys or other study designs where clinical ratings are not practical. It can also be used for clinical purposes and is designed to assess mental disorders.	To assess depression in LF cases	Symptoms have been present during the same 2-week period and at least one of the symptoms is either depressed mood or loss of interest or pleasure. Each symptom assessed as "change from previous functioning" corresponding to each symptom (e.g. "more than usual", "less than usual").	[88]
CES-D (The Centre for Epidemiologic Studies Depression)	20	CES-D scale is a brief self-report scale which was developed to measure self-reported symptoms associated with depression experienced in the past week.	To assess depression in leprosy cases	It contains 20 items with 0-3 sub-items covering the major components of depression. Higher scores indicate more severe depression.	[89]
Kessler-10	10	The Kessler-10 scale is a 10-item screening tool which measures the likelihood of some	To measure podoconiosis related mental distress	There are ten questions, each scored out of five. Higher mental distress scores	[90]

		form of common mental disorder, such as depression or anxiety.		indicate an increased probability of having depression or an anxiety disorder.	
MINI-Plus (The Mini-International Neuropsychiatric Interview)	10	MINI-Plus is a short, structured diagnostic psychiatric interview for Diagnostic and Statistical Manual of Mental Disorders, fourth Edition (DSM-IV) disorders. It is a short and accurate measure designed for clinical trials, epidemiologic research and outcome tracking in non-research settings.	To assess psychiatric diagnosis in leprosy cases	The questionnaire comprises ten Likert-type statements scored from 0 = do not agree at all, to 3 = agree fully.	[91]
SRQ-20 (The Self-Reporting Questionnaire)	20	SRQ was developed by the WHO to screen for psychiatric disturbance in primary health care settings in low-income countries.	To assess mental distress in leprosy cases and other dermatologic illnesses	It can be used as a first-stage screening instrument for the second-stage clinical interview. The questions ask about features of common mental disorders, particularly anxiety and depression. If the participant thinks the question applies to him/her, they will answer yes, and otherwise the answer will be no.	[92]
GHQ-30 (The General Health Questionnaire-30)	30	GHQ-30 is a measure of the current mental health status of individuals.	To measure the mental health status of LF and leprosy patients and controls	The GHQ-30 has 4 response categories for each of the 30 questions: better than usual, same as usual, less than usual, and much less than usual. The scoring method	[93]

				is categorised into a dichotomous response (“0” for the first 2 options and “1” for either of the second 2 options).	

2.2.2 Disability, psychosocial and mental health status due to leprosy, podoconiosis or lymphatic filariais

2.2.3 Prevalence of leprosy-related disability

A study in Brazil included 84 patients with leprosy and found 81% with multibacillary lesions. Less than half of the patients (41.7%) had no disability at the time of the study, although 36.9% had not been evaluated for disability [94]. Another study, this time from India, showed high rates of disability with 147 (86%) of the subjects having grade 2 (visible deformity) and four (2.3%) grade 1 disability [95]. A study in Mexico among 223 study participants affected by leprosy reported that disabilities, as assessed by the WHO-DG and EHF, affected 32% of participants [96, 97]. Another study in 104 people affected by leprosy in Brazil found 20 (19.2%) patients with Grade 2 leprosy-related deformities [97]. Similarly, a study in Ethiopia among 513 people affected by leprosy showed that 65.9% had disability; 40.2% had grade I disability and 25.7% had grade II disability [98]. A study conducted in Indonesia among 1,358 leprosy-affected individuals showed that most impairment was associated with the feet (47%), followed by hands (31%) and eyes (11%) [99].

In contrast with the above studies, a study in Ethiopia reported a lower prevalence of grade 2 disability among new cases, with the proportion of Grade II disability being 3.9%. This prevalence was lower than the national average, which was 10% [100]. A cross-sectional study in Brazil used EHF score in 282 leprosy-affected individuals, and reported the maximum degree of physical incapacity (12 points), in only one case. The others presented from 0 to 8 points, and 11.3% people presented at least two compromised segments (which is considered a disability) [101]. A group of researchers in Brazil used the SALSA scale to measure activity limitation among 84 leprosy-affected individuals. More than half of the participants (53.6%)

did not have any activity limitations, 32.1% had mild limitations, 10.7 % had moderate limitation, 3.4% had severe limitation, and none of the subjects had developed very severe limitations [94].

Another study in Brazil showed a mean SALSA score of 4.8 points (SD = 7.84), with scores equal to or higher than 25 points in 84 (29.8%) people [101]. A very severe limitation score was identified in five (1.8%) people. However, among people with limitations, the mild form was most prevalent, with 68 (24.0%) cases [101]. A study from Mexico reported that 57.8% of people affected by leprosy had some limitations in activities as assessed by the SALSA scale, with most (39%) being slight limitations [102]. A study from Brazil amongst people affected by leprosy reported a median SALSA score of 31.0 (25.0–41.5) , with 24% having no significant FALs (functional activity limitations), 50% mild, 8.7% moderate, 5.8% severe and 11.5% very severe FALs [97]. Another study conducted in Mexico assessed social participation among leprosy-affected individuals. Among the cases, 35.4% presented with some degree of restriction in social participation, with a median score of 8 [96].

2.2.4 Severity of leprosy-related disability and associated factors

A study from India found that education, occupational status, income and duration since diagnosis had statistically significant associations ($p<0.05$) with disability [95]. After controlling for the effect of other variables, not having an education, a longer duration of the disease and having experienced surgery were significantly associated with disability [95]. Patients with duration of symptoms of 6 to 12 months and greater than 24 months were more likely to develop disability, AOR 2.13 (CI 1.14-3.96), $p = 0.017$ and >24 months AOR 2.491 (CI 1.31-4.72), $p = 0.005$. Signs of nerve damage and reversal reactions were also associated with higher disability rates, AOR 13.1 CI (8.07- 21.25), $p <0.001$, and 1.85 (CI 1.03-3.33), $p = 0.038$, respectively [98]. A univariate analysis showed significant correlation between the WHO-DG and the SALSA scale score (p-value, 0·001) [102].

The SALSA scale was used to categorise outcomes into absence (score <25) or presence (score ≥25) of activity limitations. Using multiple logistic regression, there were significantly more activity limitations for women, for people with low incomes, and for people who reported pain. People who reported lesions that they considered to be significant also had greater limitations, as did having a physical disability as classified by the WHO-DG [102].

There was an association between the presence of disabilities and FALs ($p = 0.001$) [97]. Increasing SALSA scores were also associated with decreasing quality of life, in terms of the physical ($r = -0.68$; $p<0.001$), psychological ($r = -0.28$; $p = 0.003$), social ($r = -0.21$; $p = 0.03$) and environmental ($r = -0.47$; $p<0.001$) domains of the WHOQoL-BREF [97]. Impairment status did not change significantly during treatment. Before treatment with standard MDT, 31% of people already had grade 1 impairment and 31% had grade 2 impairment [99]. At RFT (Release from Treatment), 27% had grade 1 and 32% had grade 2 impairment. However, 2 to 5 years after RFT, 26% of the participants had grade 1 impairment and 49% had grade 2 impairment. This difference was statistically highly significant [99].

Another study reported the association between participation and activity limitation among people affected by leprosy. The mean participation score was 24.4 points (SD = 7.8), ranging from 16 to 68 points. The maximum SALSA score is 60-80 points which corresponds to very severe limitation. Among the cases reporting restriction of participation, mild restriction was common. Restriction of participation was significantly associated with activity limitation ($p < 0.0001$) [101]. In the univariate analysis, any reported poor physical and mental health was associated with social restriction ($p = 0.001$ in both cases). There was less restriction of social participation among people who did not present with disabilities (p-value = 0·001). Severe activity limitations and/or the highest level of anticipated stigma was associated with a much higher level of participation restriction (13.8 and 20.8 points, respectively) [96].

When SALSA scale scores were examined by degrees of disability, a paradox emerged with some patients with grade 0 physical disability having mild or moderate activity limitation scores. Equally, some patients with grade 2 physical disability had activity scores in the 'without limitations' or 'mild limitations' categories [94]. This might be explained as follows: as WHO DG measures only leprosy-related disability, individuals having other possible impairments such as old age might contribute to the disability. Patients with leprosy reactions were seven times more likely to develop activity limitations than those without reactions. Patients who developed physical disability were four times more likely to develop limitations in activities of daily living than those who had no disability [94].

The DALY concept has been adapted to estimate the number of productive years lost due to disability, called disability adjusted productive work years lost or disability adjusted working life years (DAWLY). A study in India among leprosy-affected individuals found the overall mean DAWLY (± SE) to be 28.6 (±0.67), indicating a significant ($p<0.05$) reduction of

13.4 years or 31.9% from the ideal productive period of 42 years [82]. The EHF score was used to assess leprosy-related disability in a study conducted in Ethiopia. Disability as measured by EHF score was significantly positively associated with mental distress [103].

2.2.5 Psychosocial and mental health status due to leprosy

A comparative cross-sectional study of leprosy patients and healthy controls in Bangladesh assessed quality of life and reported significantly lower scores among leprosy patients for both genders (p=0.01). Factors associated with decreased quality of life were the presence of perceived stigma, fewer years of education, the presence of deformities, and a lower annual income[13].

A study from India assessed mental health outcomes of leprosy and found that psychiatric disturbances tended to increase with the duration of leprosy, although the trend did not reach statistical significance. Psychiatric disturbance was more common in patients with physical deformity, and this was statistically significant. The prevalence rate of psychiatric disturbance among leprosy patients was about 9.9%. This prevalence rate was much greater than in the general population in the area in which the study was conducted [104].

A case-control study conducted among people affected by leprosy, patients with tinea versicolor and healthy controls in Nigeria, used the General Health Questionnaire (GHQ) score to evaluate mental health outcomes. The mean GHQ scores were significantly higher in the leprosy group than in the two control groups. The analysis of variance for the three groups mean showed a statistically significant difference (ANOVA 19.83, $p < 0.001$) in psychiatric morbidity [105]. A psychiatric diagnosis was more commonly made among people affected by leprosy (58%) compared to those with tinea versicolor (18.2%) or healthy controls (14.8%) [105]. The most commonly reported psychiatric disorders were depressive disorder and anxiety disorder.

A cross-sectional comparative study conducted in Ethiopia among people affected by leprosy assessed the association between leprosy and mental distress, using the SRQ-20 scale. The overall prevalence of mental distress in the study population was 34.6%. Among people with leprosy, the prevalence was 52.4%, compared to 7.9% in the non-leprosy patients. After controlling for other socio-demographic variables, people with leprosy had a 7.14 fold higher

risk of mental distress than non-leprosy patients [103]. When the level of disability increased, the risk of mental distress also seemed to increase. Overall, 18.5% of people affected by leprosy had suicidal ideation while only 6.3% of the non-leprosy patients reported such thoughts in the previous month. However, the investigators thought leprosy patients might over-report symptoms of mental distress as a way of seeking attention from health care providers [103]. Another study, this time from Bangladesh, used the same mental health scale and found similar results. Moreover, the SRQ scores were highly correlated with total quality of life scores and physical and psychological domain scores [106].

The Centre for Epidemiologic Studies for Depression scale (CES-D) was used to assess the association between leprosy and depression in Bangladesh. The median CES-D score for leprosy patients was 28.0, while that of the control group was 12.0 ($p<0.001$). As disability grade advanced, the total CES-D score also increased [89].

Another study assessed mental health outcomes of people affected by leprosy in Brazil using the MINI-Plus. Among 120 study participants, 71.7% had at least one psychiatric diagnosis. Of those with at least one diagnosis (86 patients), 20.8% fulfilled the criteria for one diagnosis, 21.7% had two diagnoses and the remaining 29.2% had three or more psychiatric diagnoses. The diagnosis of major depressive disorder was the most common. Of all patients, 37 (30.8%) were diagnosed with current depression and 39 (32.5%) had depression in the past [91].

2.2.6 Disability due to podoconiosis

A comparative cross-sectional study among podoconiosis patients and healthy neighbourhood controls in Ethiopia reported that the median WHODAS II score was significantly higher in podoconiosis cases compared to their healthy neighbours. The mean number of days in the past 30 days in which individuals were totally unable to carry out usual activities, or unable to work because of any health condition was 3.1 (±4.3) in the podoconiosis group and 0.2 (±1.1) in the healthy neighbour group ($p<0.001$) [107]. Having ALA (acute adenolymphangioadenitis) in the past month had a statistically significant effect on depression score ($p=0.002$). However, stage of disease did not have a significant impact on the depression score [107].

2.2.7 Psychosocial and mental health status due to podoconiosis

In another study from Ethiopia, people with podoconiosis had significantly lower mean overall quality of life scores than healthy controls, with a mean difference of −12.35 (95% CI: -13.87 to −10.83). This was also seen in all four sub-domains (physical, psychological, social and environmental, p<0.001) [108]. Factors associated with below-average quality of life scores included experiencing high levels of stigma (OR=3.71, 95% CI: 2.19 to 6.27), being illiterate (OR=2.07, 95% CI: 1.36 to 3.21), having additional co-morbidities (OR=2.12, 95% CI: 1.19 to 4.06), and being unmarried [108].

The study described under 'disability outcomes' above showed depressive symptoms to be significantly more common among people with podoconiosis (34/269, 12.6%) than their healthy neighbours (2/268 = 0.7%, p-value <0.001). Among participants with podoconiosis, 5.2% were considered at high risk of suicide, whereas only 0.4% of their healthy neighbours were (p<0.001) [107]. In the multivariable logistic regression model, people with podoconiosis had 11.4 times higher odds of having an elevated depressive symptom score than people without podoconiosis (95% CI 2.4–53.4) [107].

Another group of researchers examined mental distress among people with podoconiosis in northern Ethiopia. The mean K10 score was 15.92 (95% CI: 15.27 to 16.57) in people with podoconiosis and 14.49 (95% CI: 13.85 to 15.12) in healthy neighbourhood controls (average K10 scores 1.43 points higher [95% CI: 0.52 to 2.34]). Although not linear, there was a significant difference (p=0.001) in the mean K10 scores across podoconiosis disease stages [90].

Depressive symptoms measured using a PHQ-9 cut off of 5 were common amongst people with podoconiosis and lower limb lymphoedema of other cause in Cameroon. More than one-third of participants (38.5%) presented with at least some degree of depressive symptoms, though the large majority of these were classified as having mild depression [6]. There were no significant differences in levels of depressive symptoms between people with podoconiosis (mean = 3.38, SD = 3.5) and those with lower limb lymphoedema of other cause (mean = 3.65, SD = 2.82) (p = 0.73) [6].

2.2.8 Disability due to lymphatic filariasis

Researchers used an eight-domain five-level score (score ranging from 1=no problem to 5=extreme problem) in LF lymphoedema cases in Malawi. The majority of participants (60%) reported that they had no problem (score=1). Approximately half of participants (51%) stated that they needed some form of assistance with their self-care, though this was mostly when they were facing acute adenolymphangitis attacks [109]. The mean overall disability score using this newly developed scale among lymphoedema cases was 13.9 with a range of 8 to 34. Pearson's correlation coefficient analyses showed a significant negative association ($p<0.01$) between overall disability score and the maximum distance participants were able to walk ($r= -0.436$; $p <0.001$) and the hours they were able to work in an average day ($r=-0.388$; $p<0.001$) [109].

A study of 372 people with LF in south India described several functional outcomes. About 31% of the interviewed patients and 35% of the control group felt that filariasis definitely or possibly hindered an affected person from doing domestic tasks, which included cooking, washing, cleaning and preparing children for school [110]. During the quantitative interviews, about 28% of the patients reported altered activity and 5% gave up their work. All activities were significantly more affected in patients with acute adenolymphangitis than in other groups [110] .

2.2.9 Psychosocial and mental health status due to lymphatic filariasis

A comparative cross-sectional study of people with filariasis lymphoedema and healthy controls in Sri Lanka measured quality of life using the Short-Form-36 (SF-36). Patients experienced poorer physical functioning, more role limitations as a result of physical health problems, less emotional well-being, poorer social functioning, and more pain than healthy controls [93]. There was no association between any of the domains of the SF-36 and the number of acute adenolymphangitis attacks suffered during the past one year, the total number of acute adenolymphangitis attacks suffered during the entire duration of disease, or the maximum duration of lymphoedema among patients [93]. However, in the general health domain of the SF-36, cases unexpectedly reported a better general health status compared to controls [93].

This study also measured the mental health condition of the two groups using the GHQ-30. The GHQ-30 score demonstrated mental wellbeing in 67.2% of controls, which was significantly better than that of patients (36.2%, $p < 0.001$) [93]. Among patients, there was no association between GHQ-30 score and suffering at least one acute adenolymphangitis attack during the entire duration of the disease, the maximum grade of lymphoedema, the total number of acute adenolymphangitis attacks suffered during the entire duration of the disease or duration of lymphoedema or the maximum grade of lymphoedema ($p > 0.05$) [93].

A cross-sectional study from Nigeria examined the association between lymphatic filariasis and depression. Among study cases, 19 (20%) met the criteria for depression, using the CIDI, with the severity of depression being mild in 42.1%, moderate in 31.6% and severe in 26.3%. The percentage of those found to be depressed among people with lymphatic filariasis (20%) was higher than the reported prevalence of depression among adults in the general population in Nigeria (3.1–5.2%) [111]. Logistic regression analysis revealed that history of mental illness (OR 40.8, $p = 0.008$), duration of the illness between 11–20 years (OR 5.0, $p = 0.079$), unemployment (OR 12.7, $p = 0.003$) and low self-esteem (OR 0.09, $p = 0.004$) were predictive of depression in the cohort [111].

2.3 Discussion

Leprosy, podoconiosis and LF are diseases of poverty associated with high level of disability. In addition, there was high levels of psychosocial and mental health impairment. This was shown in diverse studies from Africa, Asia and South America. The three NTDs on which this review focuses all affect the lower limb resulting in progressive swelling or lymphoedema, deformity and potential disability. In addition to these lower limb changes, leprosy also affects the skin, peripheral nerves, eyes, and hands. In the case of LF, in addition to lower limb changes, the upper limb, breast or scrotum may also be affected, leading to lymphoedema or hydrocele. However, podoconiosis is limited to the lower limb leading to progressive swelling or lymphoedema.

Among the studies included in this review, the majority (n=16**)** dealt with leprosy, and an equal number of articles (n=4 each) addressed podoconiosis and LF. Concerning the quality of the included studies, aims were clearly stated in all included papers, the design was appropriate to the study in 92% of studies, evidence was provided of reliability or validity of

measures in 71%, and statistics were accurately reported in 83% of the studies. However, sample selection was relatively unbiased in only 63% of the studies and a justification for the sample size was given in only 50% of studies.

We were unable to perform a meta-analysis, because the studies included in this review were highly heterogeneous and used different outcome measures. Another limitation is that we only reviewed articles written in English. However, one strength is that most of the outcome measures are robust instruments with a long history of use both in studies and in clinical practice.

A range of degrees of disabilities secondary to the reviewed NTDs were reported in 14 studies [82, 94-103, 107, 109, 110]. Ten studies reported a significant association between being affected by the selected NTDs and psychosocial and mental health outcomes [6, 89-91, 103-107, 111].

The prevalence of grade 2 disability varied from 3.9% in Ethiopia [100] to 86% in India [95], though a study in Ethiopia in the same calendar year reported grade 2 disability of 25.7% [98]. The reason for this discrepancy could be that the study in Ethiopia was conducted among new cases of leprosy whereas the study in India was conducted among leprosy-affected individuals who had longer duration of disease. Longer duration of the disease is associated with severity of disability [95, 98]. The authors also suggested that an aggressive control program using early diagnosis, early treatment and full integration of the previously vertical program might have resulted in lower grade 2 disability [100]. It is worth highlighting that the 3.9% grade II disability is well below the national average, which was 10% [100].

An interesting study by Rao et al., reported the extent of the loss of productivity among people affected by leprosy, who experience on average a loss of one third of their productive years [82]. Leprosy is significantly associated with activity limitation as measured by the SALSA scale [94, 97, 99, 101, 102]. Physical disability is also significantly associated with activity limitation [94] [96]. The severity of activity limitation and high levels of anticipated stigma were significantly associated with reduced participation [99, 101]. Increased activity limitation was associated with decreased quality of life [97]. An increase in the level of disability also increased the risk of depression [89] and mental distress [103]. This is to be expected among people affected by such a chronic and disabling disease [103]. Podoconiosis patients had high disability score as measured by WHODAS II. The mean number of days in

which the podoconiosis cases were unable to do their routine activities or unable to work was 3.1 days per month [107]. In the case of leprosy there was nearly 33% loss of productivity, whereas in the case of podoconiosis the loss was about 10 %. Although different tools were used to measure productivity, it appears that the loss of productivity due to leprosy-related disability is much higher than that in podoconiosis. A study among LF patients showed that 28% of the patients reported altered activity and 5% gave up their work completely [110] .

Among the studies included, four revealed the effect of NTDs on quality of life or general health status. In three of them, quality of life was reduced significantly [97, 106, 108]. In contrast, one study reported that people affected by LF had a better general health status than apparently healthy controls [93]. It is possible that the selection of controls was responsible for this finding – the apparently healthy individuals who accompanied the filarial patients may have been long-term burned-out caregivers. This could also be explained by the disability paradox, as surveys have shown that people with disabilities report a quality of life which is either as good as or even better than that of non-disabled people [112].

Several mental disorders are associated with NTDs ranging from mild panic disorders to generalized anxiety and major depressive disorders. A significant association between leprosy and mental disorders was reported in six articles [89, 91, 103-106]. There was also a significant association between mental disorders and podoconiosis [6, 90, 107], and between mental disorders and LF [93, 111]. The risk of suicide was significantly higher in study participants with podoconiosis (5.2%) than their healthy neighbours (0.4%) [107]. Suicidal ideation was also higher among leprosy patients: 18.5% of people affected by leprosy had suicidal ideation as compared to only 6.3% patients affected by other skin diseases [103].

A recent systematic review assessed the impact of leprosy on mental wellbeing, which found that leprosy affected individuals are at risk of poor psychosocial and mental health outcomes. The reported psychosocial outcomes were fear, shame, low self-esteem, loneliness, sadness, anger and low quality of life [75]. |Several mental health conditions were reported in the review, such as depression, anxiety disorders, mental distress and suicide (thoughts and attempts). The most commonly reported mental health condition was depression and the second most common was anxiety disorder [75].

NTDs such as LF, leprosy, buruli ulcer, cutaneous leishmaniasis, onchocerciasis, trypanosomiasis and neurocysticercosis are associated with stigma and discrimination. Individuals affected by these NTDs are at risk of exclusion from participating fully in society, reduced access to health and social services, exclusion from employment opportunities, restrictions in exercising civil and political rights, increased disability and poor mental health conditions [53]. Poor mental health may be a consequence of physical disability, social stigmatization and subsequent marginalization. Both LF and leprosy are significantly associated with depression. People with NTDs are also at risk of suicide, suicide attempt or suicidal thoughts [53]. To eliminate NTDs as public health problem, we should not only target the active NTD infection, but also address the associated psychosocial impairments [113] .

The mental health outome most often reported by studies was depression [6, 89, 91, 105, 107, 111], with mental distress – which is a state of poor mental wellbeing that can involve a range of different symptoms, including symptoms of depression and anxiety – second [90, 91, 103, 105]. This suggests the importance of provision of access to mental health screening and of appropriate mental health interventions to people affected by these three NTDs [111].

In conclusion, there is extensive physical disability due to leprosy, podoconiosis and LF. Poor quality of life is common amongst people affected by each of these three NTDs. Reduced mental wellbeing (mainly depression and mental distress) is common amongst people affected by leprosy, podoconiosis and LF. To prevent long term disability due to leprosy, podoconiosis and LF, early case finding and early management of cases is needed. Integrated physical, psychosocial and mental health interventions are vital for the management of leprosy, podoconiosis and LF. In addition to physical impairment there are psychosocial and mental health impairments unless there is early holistic care intervention. As there is similarity in both physical and psychosocial and mental health outcomes among persons affected with podoconiosis, LF and leprosy, we believe integration of services at the primary health care unit is vital. Thus, awareness creation among decision makers and community representatives, and proper training of health care workers who are working in primary health care units, is highly relevant.

CHAPTER THREE

METHODOLOGY

In this chapter I describe the methodology relevant to my PhD study. This includes details of methods of both Phase 1 and Phase 2 of the EnDPoINT project. These Phases have been described diagrammatically in *Chapter 1*. Phase 1 included development of the care package, which was a vital input to Phase 2. Phase 2 of EnDPoINT corresponds to Phase 2 of the MRC's framework on complex interventions. According to MRC framework : Phase 1 is devlopment, phase 2 is feasibility/piloting, phase 3 is implementation , and phase 4 is evaluation [114]. Phase 2 involved employment of the holistic care plan at four levels of the health system and evaluation of its implementation. Phase 2 was conducted in one cluster/sub-district (Guagusa Shikudad district) in Awi zone.

In this chapter, after describing the development of the care package (Phase 1), I describe: the study area, study population, data collection and management, assessment tools, data analysis, and ethical clearance relevant to Phase 2, i.e. to my PhD study.

3.1 Development of a care package

The EnDPoINT care package is part of a care plan for the three NTDs administered at the individual, health facility, community, and health care organisation level for the betterment of the affected community. The care package is holistic, and so comprises both physical and psychosocial care including basic lymphoedema care, counselling and mental wellbeing care.

To prepare this holistic care package, a number of steps were taken during Phase 1 of EnDPoINT. These included a situational analysis, a document review, three Theory of Change (ToC) workshops, care plan preparation with validation workshops and a qualitative study. The aim of the situational analysis was to understand the local context for the development of the integrated holistic care package. Document review was conducted to get updated information to develop the integrated holistic care package. The ToC workshops aimed to get inputs from experts, policy makers and the affected community in a participatory and structured way so that the causal pathways that needed to be changed and the reasons behind this were addressed. Care plan validation workshops were conducted in order to fine-tune the draft care package and the training materials, as well as to get comments from the local context. The main

objective of the qualitative study was to determine the feasibility, acceptability, and appropriateness of the draft care package in terms of its integration into government-run health services.

The situational analysis was done by desk review and interviewing officials in the FMOH (Federal Ministry of Health), ARHB (Amhara Regional Health Bureau) and Awi zone health department. Document review of national and international guidelines on NTDs and mental health, and local and international peer reviewed journals was also conducted.

Three ToC workshops were conducted and I was actively involved in the planning and delivery of all three. ToC is a participatory structured thinking process for program design and evaluation. It helps to build a causal pathway of what needs to change and why. It provides a clear explanation of the mechanisms of change through which complex intervention leads to real-world impact. The process is evidence-based, and the rationale for each link or pre-condition in the causal pathway of the whole process leading to outcomes is also evidence based [115].

A good ToC should be clear, credible, logical, based on evidence, and arrived at by consultation among appropriate stakeholders. These stakeholders first need to agree on the real-world impact they need to achieve. Then, they work backwards from long term outcomes on potential causal pathways and changes required leading to short term and mid-term outcomes that can be achieved in the existing context by using available resources. Other components of ToC are: indicators, interventions, outcome measurements, and encouraging stakeholder buy-in to the study. ToC, if applied properly and consistently, can be of great help in understanding complex interventions and strengthening the approach suggested in the MRC guidance for complex health interventions. The information gathered through ToC workshops is essential in developing complex interventions that are more likely to be effective, sustainable, and scalable [114, 116, 117].

The participants in the EnDPoINT ToC workshop were from a range of organizations including: universities (Addis Ababa University, Brighton and Sussex Medical School (BSMS) and Imperial College, London), the Ethiopian Ministry of Health, and non-governmental organizations working on podoconiosis, leprosy and LF (International Orthodox Christian Charities, Ethiopian National Association of Persons Affected by Leprosy [ENAPAL], National Podoconiosis Action Network [NaPAN]). Moreover, staff from the project

implementation region, zone, district, and health facility were included, and community representatives participated actively. The first and third ToCs were conducted in Addis Ababa whereas the second one was conducted in the capital city of Amhara regional state, Bahirdar. Following the ToC workshops, a ToC map was developed (See Appendix 5) [117, 118].

A baseline qualitative study was also conducted to get input for fine tuning of the care package. Focus group discussions were conducted among three groups of individuals representing decision makers, health professionals and community representatives. Key informant interviews were also conducted among similar groups of individuals.

Based on the above-mentioned strategies, a care plan was prepared which addressed interventions at four levels: that of the health organization, the health care facility, the community, and the patient. Care plan validation workshops were conducted in Addis Ababa and Bahirdar. Based on the care plan, an integrated guideline addressing podoconiosis, LF, leprosy and common mental disorders was prepared and peer evaluated and then training was conducted in Guagsa Shikudad district, Awi zone. Below is a summary of the training and other activities delivered at each level. The interventions at each level of care have been summarized in *Figure 3.1.*

Health service organisation interventions: this included high level awareness-raising and mobilization training; Training of Trainers in morbidity management and disability prevention for podoconiosis, LF and leprosy, as well as co-morbid mental health conditions; and Training of Trainers on supportive-supervision, mentoring, and coaching. To ensure proper management of the program, program management support was also part of the intervention.

Health facility interventions: this mainly involved capacity building, i.e. Training of Trainers in morbidity management and disability prevention for podoconiosis, LF and leprosy, as well as co-morbid mental health care. In addition to this, provider supply chain management training was delivered. Awareness-raising activities for health facility staff and general attendees of the health centre were conducted. The main activities at the health facility were case finding, assessment, treatment initiation, clinical mentoring and health facility worker supportive supervision.

Community interventions: This included capacity building for community health workers and Health Extension Workers (HEWs) in morbidity management and disability prevention for podoconiosis, LF and leprosy. In addition to this, awareness-raising workshops were held, and other activities included Community Conversations, information dissemination, community-based case finding and referral by HEWs, patient follow up visits by HEWs, community-based rehabilitation and community health workers supportive-supervision.

Patient level interventions: This had six main components: hygiene (regular twice-daily washing), skin care (applying emollients), wound care (antiseptics), patient counselling, management of co-morbid mental conditions, health education on disease prevention, and stigma reduction through regular sessions at health centres and through patient self-help groups. The care package helps in secondary prevention or prevention progression of lymphoedema due to repeated acute attacks Those with mild depression were offered counselling only, and some of those with moderate or severe forms received anti-depressants based on an assessment by health professionals. The details of interventions at each level of care are described in a separate holistic care plan document (See Appendix 6).

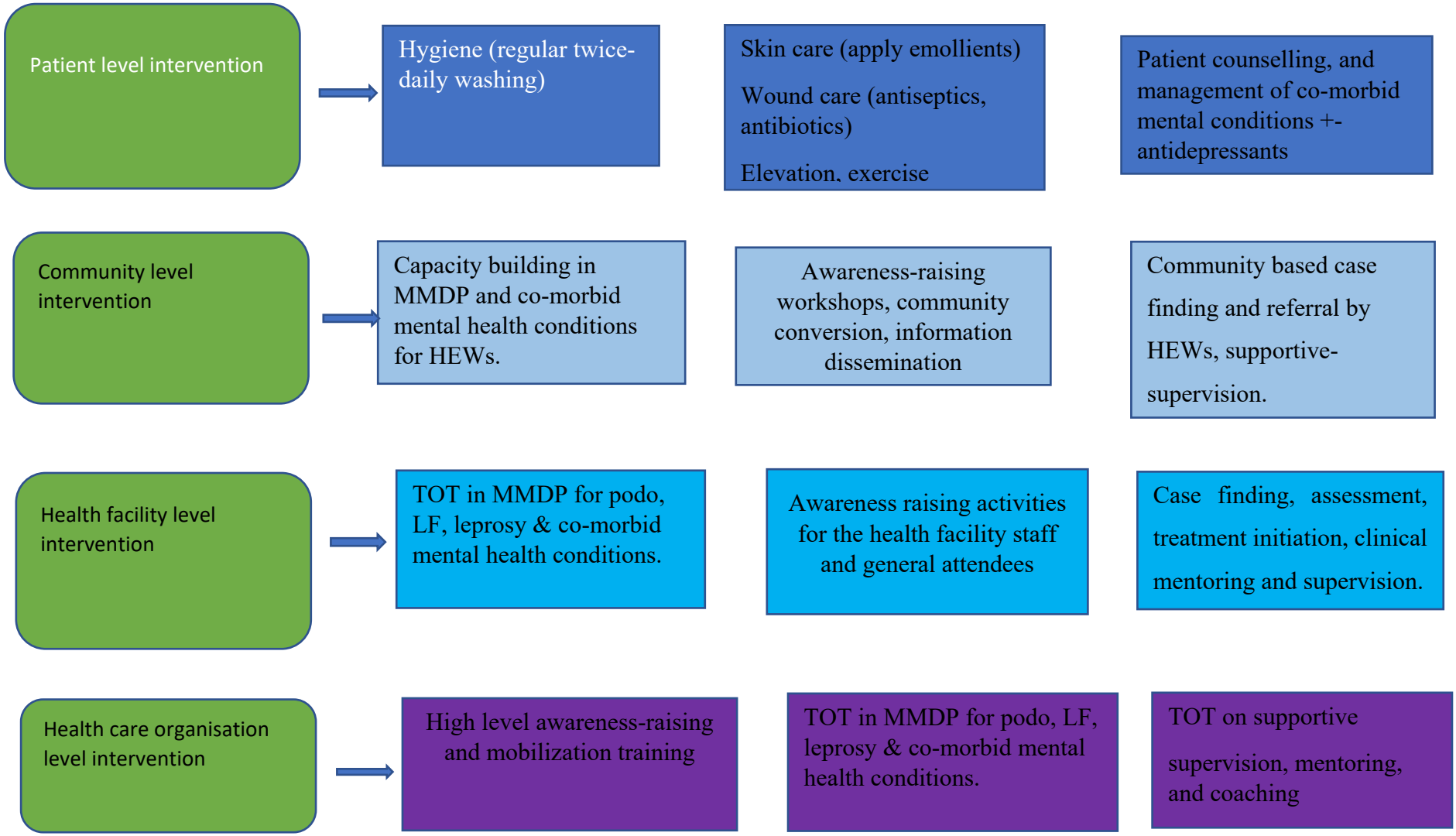


Figure 3. 1 Overview of the EnDPoINT care package, with different levels of care: Patient, community, health facility, and health care organization level interventions

The EnDPoINT care package was based on prior evidence of limb care for the three diseases. Both podoconiosis and LF lymphoedema require similar provision of health care, and the World Health Organization (WHO) has suggested a minimum package of care for managing morbidity and preventing disability. The WHO-recommended basic lymphoedema management activities include limb washing, skincare, wound-care (applying creams and dressings), elevation, exercise, and the protection of feet with appropriate footwear. A pragmatic randomized controlled trial of this simple, inexpensive package of lymphoedema self-care for people with podoconiosis was found to be effective previously in reducing the frequency and duration of acute dermatolymphangioadenitis. The authors recommended its implementation by the governments of endemic countries [26].

The similarities between the basic interventions for LF and leprosy include daily home-based self-care; avoidance of injury; skin and wound care; prevention of contractures; compliance with footwear advice and interventions to prevent activity limitation. Other morbidity management interventions that may be needed for both groups include advice and support for caregivers; surgery to address impairments; schemes for economic upliftment; advocacy and social mobilisation [119].

EnDPoINT Phase 2: Study Methodology

3.2 Study area

The study was conducted in Awi zone, which is divided into seven districts and is one of the ten zones of the Amhara region, north-western Ethiopia. This zone was selected as it is co-endemic for the three diseases and because so far there had not been interventions to address the three diseases**.**

According to the Ethiopian Census of 2007, Awi zone has a population of 982,942 (with each district having populations of between 8000 and 31,500); the total population is currently likely to be around 1.2 million. Among these, 87.5% of the population live in rural areas and 12.5% in urban areas. The latter are spread across 13 towns in Awi zone, of which Dangila (around 25,000 population), Chagni (23,000), Injebara (21,000) and Gimijabet

(11,000) are the largest; all other towns in the zone had populations of less than 10,000 in 2007. Injebara is the administrative centre. On average, there were 4.6 people living in each household in Awi zone in 2007. The majority of the population are from the Age-Awi (59.8%) and Amhara (38.4%) ethnic groups, and their first language is primarily Amarigna (53.4%) and Agew-Awinigigna (45.0%). The majority of the population are Ethiopian Orthodox Christians (94.4%), with a minority being Muslim (4.5%) or of other religions.

The study was conducted in the Gusha cluster of the Awi Zone (Figure 3.2).

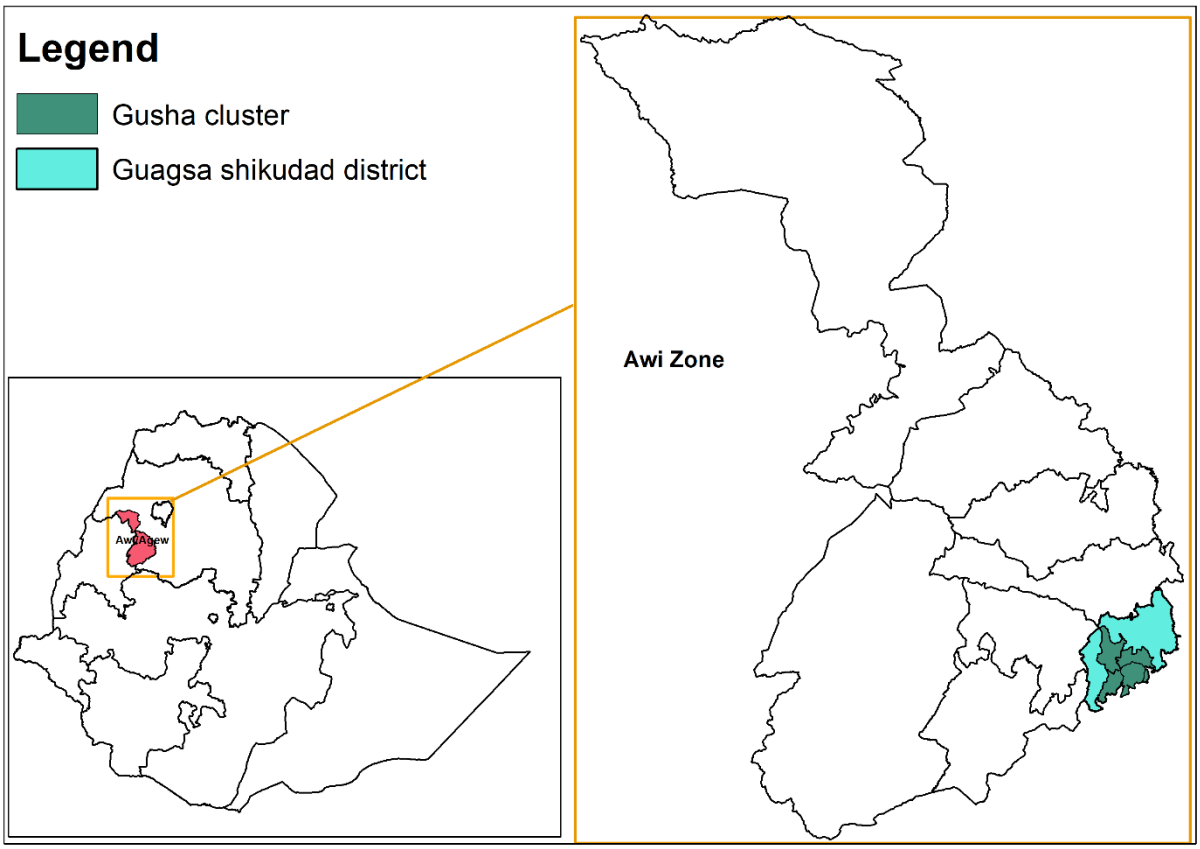


Figure 3. 2 Map of Ethiopia, Amhara Region, including Guagsa Shikudad District (Gusha cluster) in the Awi Zon

3.3 Study population for quantitative study

The study participants (adults over 18 years of age) were identified by Health Extension Workers, who registered potential lymphoedema cases at the health post. Then, they linked them to Gusha Health Center. At the health centres, health professionals screened lymphoedema cases and diagnosed them. Patients were excluded from the study if they expected to leave the study site during the study period, had nodular disease preventing use of shoes (these individuals were referred for nodulectomy), or had complex wounds (these individuals were referred for specialist care). Those who fulfilled the inclusion criteria and consented were enrolled into the study.

3.4 Study design of the quantitative study

A longitudinal non-comparative (pre-post) study design was conducted. After baseline data collection, the holistic care package was implemented. Then, data were collected at three months and at 12 months post initiation of intervention (the 'cohort' study).

As this research is part of the Phase 2 pilot study of the EnDPoINT project**,** all lymphoedema patients who were willing (consented) and who fulfilled the inclusion /exclusion criteria in the pilot sub-district (Gusha cluster) were enrolled in the study. In total, there were 251 study participants. Sample size was calculated for Phase 3 of EnDPoINT but this was not part of my PhD work

Randomised controlled trials (RCTs) are prospective studies that measure effectiveness of new interventions or treatments by randomly allocating study participants in to either treatment or control groups. In RCTs the study population receiving the programme or policy intervention is chosen at random from the eligible population, and a control group is also chosen at random from the same eligible population [120-122]. RCTs help in obtaining evidence in cause-effect relationships of interventions. RCTs are often blinded so that investigators and/ or study participants do not know what intervention each participant is receiving and this helps in further reducing bias [120-122].

RCTs can be individualized or cluster randomized trials. In cluster randomized trials, a group of participants instead of individual participants are randomized. Cluster RCTs have an advantage in terms of administrative convenience, ethical considerations, and ease of application at the cluster level [121]. RCTs have shortcomings including: high cost in terms

of time and money; problems with generalizability, as those who consented might not be representative of the general population; and risk of loss to follow-up [122].

In our study we preferred an observational before- and after (pre-post) longitudinal study, as it is unethical to withhold MMDP treatment to persons with lymphoedema. Moreover, to our knowledge there is no alternative community-based lymphoedema management protocol. We believe it is also unethical to withhold psychosocial interventions, as this can result in mental ill-health including suicidality.

3.5 Data collection and management of the quantitative study

Experienced data collectors were recruited and trained on how to use the study tools and how to extract information from both written and electronic health records (See Appendix 7). These trained community data collectors administered the validated questionnaires that had been translated into the local language of Amharic.

Regular supervision of the data collection process was carried out by the investigating team. Onsite supervision and feedback were given to the data collectors. All completed questionnaires and tools were checked for consistency, completeness, clarity and accuracy. Data were collected by smart phone using Open Data Kit, free software developed to allow data collection using Android mobile devices and data submission to an online server. After collection, data were transferred to an Excel data sheet for cleaning and verification, before being exported to STATA version 14 (College station, Texas 77845, USA) for analysis.

Patient demographics (sex, age) and socioeconomic characteristics (residence, education level, marital status, children, religion, employment status and relative income) were recorded using a pretested structured questionnaire.

The following physical/clinical outcomes were measured: limb circumference, wound condition, presence of nodules, presence of infection, the stage or grade of the affected limb, frequency of acute attacks and degree of disability. In addition, the following psychosocial outcomes were assessed: quality of life, internalized stigma, discrimination and depressive symptoms of the participants. These data were collected at baseline, three months and 12 months after the initiation of interventions to measure the outcomes of the integrated care package.

The largest point of swelling below the knee **circumference** was measured in cm using measuring tape [123]. The presence of **wounds** was checked during health facility visits by observation. The presence of nodules or infection was also checked during health facility visits by observation. Frequency of **acute attacks** per month was collected by asking participants the number of acute attack episodes over the last month. The **disability** assessment was done using the World Health Organization Disability Assessment Schedule tool (WHODAS version 2.0) [124].

The **quality of life** of patients was assessed using the Dermatology Life Quality Index (DLQI) [125]. **Depressive symptoms** of patients were assessed using the Patient Health Questionnaire-9 (PHQ-9) [126]. **Suicidal ideation and attempt** was measured using the Composite International Diagnostic Interview scale (CIDI) [127]. **Social support** was measured using the Oslo social support scale (Oslo-3) [128]. **Internalized stigma** was measured using a modified version of the internalized stigma scale for mental illness (ISMI/ISRL) [129, 130]. **Enacted stigma and discrimination** was measured using the Discrimination and Stigma scale (DISC-12) [131]. The socio-demographic and economic factors contributing to the clinical and psychosocial outcomes were assessed using a pretested **structured questionnaire.**

3.6 Assessment tools

The DLQI has previously been validated and translated into the official Ethiopian language, Amharic [132] and used to assess quality of life in podoconiosis patients in Southern Ethiopia. The DLQI was developed to measure quality of life in a range of skin conditions [5] and has been translated and used in a range of skin conditions in both high- and low-income countries [21]. The DLQI consists of 10 questions covering several dimensions of life quality, including pain, embarrassment, interference with activities, and social and sexual relationships. The DLQI has been used in patients with filarial lymphoedema in Guyana [22] and India [23]. Low DLQI scores suggest high QOL, and vice versa.

The World Health Organization Disability Assessment Schedule tool (WHODAS version 2.0) was used to measure disability [133]. The WHODAS 2.0 has also been translated into Amharic and used to assess disability due to severe mental disorders in rural Ethiopia [134]. The WHODAS was developed to measure disability and to assess the following: standing for long periods such as 30 minutes, taking care of household responsibilities, learning

a new task, joining community activities, effect of health problems on emotions, concentrating for 10 minutes, walking a long distance (one kilometre, or equivalent), getting dressed, maintaining a friendship and maintaining day-to-day work. The possible WHODAS range is 12-60, where higher scores reflect greater disability,

The PHQ-9 has previously been translated independently into Amharic by two Ethiopian psychiatrists and then back-translated into English, and the final version obtained by expert consensus [87]. The criteria for validity of the PHQ-9 for detecting depression have been demonstrated among medical out-patients at a referral hospital in Addis Ababa, Ethiopia, and at a PHC unit in Butajira, Ethiopia [135](20). The PHQ-9 is a widely used depression screening scale within primary health care in high-income countries and has also been validated in LMICs [135]. The nine items of the PHQ follow the Diagnostic and Statistical Manual (DSM) version IV [136] diagnostic criteria for a depressive episode. Each question requires participants to rate the frequency of a depressive symptom experienced in the two weeks prior to evaluation. These items include: 1) Little interest or pleasure in doing things, 2) depressed mood, 3) insomnia or hypersomnia, 4) fatigue or loss of energy, 5) appetite disturbances, 6) guilt or worthlessness, 7) diminished ability to think or concentrate, 8) psychomotor agitation or retardation, and 9) suicidal thoughts. Scores for each item range from 0 (“not at all”) to 3 (“nearly every day”) with a total score ranging from 0 to 27. Higher scores represent high level of depressive symptoms [126, 136]. The PHQ-9 contains one additional item (item 10) which assesses functional impairment, also based on a three point scale (not difficult at all, somewhat difficult, very difficult and extremely difficult) [126, 136].

The Composite International Diagnostic Interview (CIDI) scale was used to measure suicidal ideation, suicidal plan, and suicide attempts. There are four main questions including, during the past one month: did you think a lot about death?; did you feel so low you thought a lot about committing suicide?; did you make a plan as to how you might do it?; did you attempt suicide? [127]. Presence of suicidal ideation, suicidal planning, and suicidal attempt in the past one month was recorded. The CIDI has been used to measure suicidal ideation and suicide attempts among HIV-infected individuals [137]. The CIDI has also been used in studies in the community and at primary health facilities in LMICs, including Ethiopia, with the study aim of determining the 12-month prevalence of suicidal ideation, plans and attempts, as well as associated risk factors [127].

The Oslo Social Support tool (Oslo-3) was used to measure social support [128]. It is a very brief scale which assesses the number of close confidantes, perceived level of concern from others, and perceived ease of getting help from neighbors. The total score ranges from 3–14 and higher scores represent better social support. The scores can be categorized in three levels: 3–8=poor social support, 9–11=moderate social support, and 12–14=strong social support [128]. The internal consistency in a population based in Germany was 0.64, which was considered acceptable as the scale is very brief with only 3 items [128]. The Oslo-3 scale has been used in Ethiopia in a study that examined the prevalence of and factors associated with depression among patients with HIV/AIDS [138], as well as a study addressing the prevalence and predictors of depression among pregnant women [139].

Internalized stigma is a product of the internalization of public stigma which is measured using an internalized stigma scale (ISMI). It was first developed for mental illness. It contains 29 Likert items and five subscales: Alienation; Stereotype Endorsement; Perceived Discrimination; Social Withdrawal; and Stigma Resistance. The 29-item ISMI had an internal consistency reliability coefficient of alpha 0.90. The test–retest reliability coefficient was 0.92 [130]. This tool has also been used to assess internalized stigma in leprosy-affected individuals. Investigators used a 28-item scale for leprosy-affected persons, by replacing the word ‘mental illness’ in the statements by ‘leprosy’. This study in leprosy-affected individuals showed internal consistency of 0.96 and test–retest reproducibility of 0.62 [129]. The ISMI was previously translated into Amharic and was used to study internalized stigma among schizophrenia patients. Three different Amharic versions were developed by three senior psychiatry residents and a senior psychiatrist; after this, a consensus version was developed in a group discussion including two other senior psychiatrists. The consensus version was back translated by a consultant psychiatrist. The inter-rater agreement was good (Kappa = 0.76). The Cronbach’s alpha based on standardised items was also good (0.92) [140]. In this study, we used an 11-item ISRL (Internalized Stigma Related to Lymphoedema) scale. The 29-item ISMI scale originally developed for mental illness was adapted by experts in lymphoedema to produce an 11-item scale, ISRL, relevant to lymphoedema. The possible range of the score is 11 (less stigma) – 44 (more stigma). It is to be noted that this scale should be interpreted with caution, as it has not been formally validated.

The Discrimination and Stigma Scale (DISC) assesses the behavioural aspect of stigma and discrimination and is an interview-based measure which collects qualitative and

quantitative data. The DISC assesses study participants' stigma and discrimination experience in various areas of life including work, education, parenting, housing, leisure, and relationships. It is graded using a Likert scale from 0 "not at all" to 3 "a lot". Its interpretation uses four ordinal categories based on DISC mean scores: <1 minimal discrimination; 1–1.5 low discrimination; 1.5–2 moderate discrimination; and 2+ high discrimination. It has internal consistency or Cronbach's α of 0.78, inter-rater reliability Lin's ρc= 0.89, p<0.001 and overall test–retest reliability Lin's ρc 0.88, p<0.001 [131]. The DISC has been used in a similar setting to that of Ethiopia, in Kenya, where it was used to examine the feasibility of the WHO mhGAP-intervention guide in reducing experienced discrimination in people with mental disorders [141]. It has also been used in a study conducted in Ethiopia that examined rural vs urban residence and experience of discrimination among people with severe mental illnesses [142]. The 22-question discrimination section of the original DISC-12 was modified as described in a previous Ethiopian study by removing two items believed not to be applicable to the rural Ethiopian setting of the study, and two items with low item-factor loading [142].

3.7 Data analysis of the quantitative study

For baseline data analysis (see *Chapter four*), descriptive analysis was performed for sociodemographic factors, clinical and psychosocial explanatory and outcome variables.

In the baseline data analysis, depression (measured using the PHQ-9) and QOL (measured using the DLQI) were the primary outcome measures. There are four categories of depression, based on severity, using PHQ-9 cut-offs: <5=no depression, 5–9=mild depression, 10–14=moderate depression, 15–19=moderately severe depression and 20–27=severe depression [126]. For diagnosis of depression, the PHQ-9 with a cut-off of 10 has shown good sensitivity and specificity, however, a cut off of 5 had lower sensitivity and specificity [143]. The best DLQI score is 0 (high quality of life) and the worst score is 30 (low quality of life) [125].

Linear regression analysis was used to examine the association between explanatory variables and depression measured by the PHQ-9 and QOL measured by the DLQI. For the DLQI, linear regression is preferable to logistic regression as this outcome is a continuous variable. However, the PHQ-9 could be considered either as a continuous or a categorical variable, using a cut-off point level to classify it into two forms (depression vs. no depression).

The continuous outcome variable is preferable to get more statistical power, so the data were analyzed using linear regression models. For both the PHQ-9 and the DLQI, explanatory variables with an association of $p<0.2$ in the bivariate analysis were included in the multivariate linear regression model. In the multivariate linear regression model, those explanatory variables with association at $p<0.05$ were considered statistically significant. Logistic regression or linear regression were used to determine the associations between socio-demographic or economic factors and either clinical or psychosocial outcomes.

For the cohort data (see *Chapter six*) we compared the impact of the care package at three months and twelve months post-initiation of interventions. Quantitative measurements such as: count of wounds, count of nodules, count of infection, frequency of acute attacks, mean DLQI, mean WHODAS, mean PHQ-9, mean Oslo-3, mean ISRL, and mean DISC were calculated between the baseline and three months, as well as between the baseline and 12 months post-initiation of treatment. For this, mixed effect linear regression and mixed effect logistic regression were conducted with a fixed effect for time point and a random effect for participant. For the outcome measures with continuous outcomes, we employed mixed effects linear regression models with a fixed effect with adjustment for potential confounders. Mixed effect linear regression is preferable to generalized linear regression, as it yields more statistical power and more precision. This is attained as mixed effect linear models consider both between-person and within-person variation. The adjustment for potential confounders is relevant as it helps to get more accurate or less biased results. For the outcomes with dichotomous results, the analysis used mixed effect logistic regression models with adjustment for potential confounders. Mixed effect logistic regression is preferable to simple logistic regression, as it yields more statistical power and more precision. The adjustment for potential confounders is vital as it helps to get more accurate or less biased results.

Ninety-five percent confidence intervals (95% CIs) were calculated for the mean difference between baseline and three months, and then between baseline and final measurements. Both the baseline cross-sectional data, and the cohort data were analysed using STATA software version 14.0.

3.8 Study design of the qualitative study

For the qualitative study (see *Chapter five),* Focus Group Discussions (FGD) and Key Informant Interviews (KII) were conducted. The details have been described below. During Phase 2 of the EnDPoINT implementation, alongside quantitative evaluations, qualitative methods were used to collect data through key informant interviews (KIIs) and focus group discussions (FGDs). Sample size was determined by a data saturation approach, that is, data collection was continued until either sufficient information had been obtained or further data collection failed to generate additional themes. The more information the sample holds, with respect to the aim of the study, the lower the sample size required [144, 145].
We used purposive sampling techniques - members of the EnDPoINT research team contacted key stakeholders from regional health bureau, zonal health department, district health office, health care units, community and affected individuals, and asked them to participate in the FGDs or KIIs. The potential candidates were contacted based on their roles and those who were willing to participate, signed informed consent and participated in interviews or discussions.

3.9 Data collection procedures for the qualitative study

We conducted four FGDs with health professionals, decision makers, community representatives and patients. We also conducted ten KIIs with the head and vice head of the District Health Office, the District NTD focal person, the District leprosy focal person, the head of the Health Centre, the NTD focal person for the Health Center, patients, and health extension workers (HEWs). All participants who were approached consented to participate.

The qualitative data collection was conducted in January 2020. A semi-structured interview guide was used. Interviews were conducted in the local language, Amharic. The PhD candidate and two other researchers from the EnDPoINT team conducted the interviews. All participants were encouraged to contribute and be heard. Patients and non-patients participated in separate focus groups. There were six to eight participants per group, and the duration of the discussion was between 40 minutes and 1 hour.

We also conducted 10 KIIs. The KIIs lasted between 30 and 40 minutes each. We made sure that the interviews were conducted at places chosen by the participants. Prior to the interviews, we spent time chatting with participants to make them feel comfortable with the interview process and to build rapport. During the interviews, we engaged with participants

sensitively, with empathy and care. The FGDs and KIIs were conducted in the local language (Amharic) using an interview guide, audio recorded, transcribed, translated to English, and checked for accuracy prior to coding.

First, we developed an English version of the interview guide and then translated it into the local language, Amharic. In addition to the interview guide, we developed a focus group discussion guide which included an introduction, detailed instructions for the discussions, how to close sessions and post-discussion activities. Please see Appendix 8 for the interview and focus group guide.

3.10 Data Analysis of the qualitative study

All interviews were transcribed verbatim and translated into English by researchers from Addis Ababa University who are bilingual in Amharic and English. The audio-recorded interviews were transcribed and translated into English before coding. The accuracy of all transcripts was checked by comparing them with the audio-recorded interviews. The analysis was conducted in English. Coding was done using NVivo 12 plus by the PhD candidate and one EnDPoINT research team member, and was further reviewed by the remaining research team to ensure consistency with the codes and data. Thematic analysis was used, starting with predefined themes in the interview guides, and open and axial coding was followed to identify new themes emerging from the data. Pre-determined themes were based on the guiding questions (See Appendix 8) developed following the three Theory of Change (TOC) workshops during Phase 1. A conceptual framework was developed following the TOC workshops; the main components of the framework were - program resources, capacity building, case identification, service delivery, long-term outcome and impact of the intervention

3.11 Ethical clearance

Ethical approval for Phases 1 and 2 was obtained from the Research Governance and Ethics Committee (RGEC) of the Brighton & Sussex Medical School (references ER/BSMS9D79/1 and ER/BSMS9D79/2), and the College of Health Sciences, Addis Ababa University Institutional Review Board (IRB) (reference 061/18/CDT). Written informed consent was obtained from study participants, who were informed that they were free to withdraw from the study at any stage. The information sheet and consent forms are included in Appendix 1 and 2.

CHAPTER FOUR

A cross-sectional (baseline) study to evaluate depression and quality of life among patients with lymphoedema due to podoconiosis, lymphatic filariasis and leprosy

4.1 Overview of introduction

In this chapter, I summarise the cross-sectional study conducted at baseline prior to intervention using the care packages. I give a brief overview of the objectives, methods, results and discussion.

The objective of this study was to characterize the baseline depression and quality of life (QOL) of people with lymphoedema due to podoconiosis, LF or leprosy in Ethiopia, prior to assessment of the impact of an integrated holistic physical, mental health and psychosocial care package. Specifically, the study aims were to: i) determine the prevalence of depression among people with lymphoedema due to podoconiosis, LF or leprosy; ii) measure the QOL among people with lymphoedema caused by podoconiosis, LF or leprosy; and iii) determine the sociodemographic factors that contribute to depression and QOL in this population. The detailed background has been described in *Chapter one.*

The result of baseline study has been published with details of publication as follows:
Ali O, Deribe K, Semrau M, Mengiste A, Kinfe M, Tesfaye A, Bremner S, Davey G, Fekadu A. A cross-sectional study to evaluate depression and quality of life among patients with lymphoedema due to podoconiosis, lymphatic filariasis and leprosy. *TRSTMH*. 2020; 114(12): 983-994. doi:10.1093/trstmh/traa130

4.2 Overview of methods

The detailed methodology has been described in *Chapter three*, but here I summarise methods relevant to the quantitative analysis.

Descriptive analysis was performed for sociodemographic factors, clinical and psychosocial explanatory, and outcome variables. Depression (measured using PHQ-9) and

QOL (measured using DLQI) were the primary outcome measures. There are four categories of depression, based on severity, using PHQ-9 cut-offs: <5=no depression, 5–9=mild depression, 10–14=moderate depression, 15–19=moderately severe depression and 20–27=severe depression [126]. For diagnosis of depression, the PHQ-9 with a cut-off of 10 has shown good sensitivity and specificity, however, a cut off of 5 had lower sensitivity and specificity [143]. The best DLQI score is 0 and the worst score is 30 [125]. Linear regression analysis was used to examine the association between explanatory variables and depression measured by the PHQ-9 and QOL measured by the DLQI. For both the PHQ-9 and DLQI, explanatory variables with an association of $p<0.2$ in the bivariate analysis were included in the multivariate linear regression model. In the multivariate linear regression model, those explanatory variables with association at $p<0.05$ were considered statistically significant.

4.3 Results

4.3.1 Demographic and socioeconomic characteristics at baseline

A total of 251 patients with lymphoedema associated with LF, podoconiosis or leprosy were included in the study. Their mean age was 51.9 (range 18–88) years (Table 4.1). Among the study participants, 52.6% were female, 99.6% lived in a rural area, 66.2% were illiterate, 67.7% were married, all were Orthodox Christians, and 77.3% were farmers (Table 4.1).

Table 4.1 Demographic and socioeconomic characteristics of patients with lymphoedema participating in the baseline study (N=251)

Characteristic	Participants
Sex	
Female	132 (52.6)
Male	119 (47.4)
Residence	
Urban	1 (0.4)
Rural	250 (99.6)
Age (years), mean (range)	51.9 (18–88)
Age category (years)	
18–24	10 (4.0)
25–34	25 (10.0)
35–44	40 (15.9)
45–54	55 (21.9)
55–64	57 (22.7)
≥65	64 (25.5)
Education	
Illiterate	156 (62.2)
Literate	95 (37.8)
Marital status	
Never married	25 (10.0)
Married	170 (67.7)

Divorced	27 (10.8)
Widowed	29 (11.6)
Religion, Christian	251 (100)
Employment status	
Salaried	2 (0.8)
Self-employed	2 (0.8)
Farming	194 (77.3)
Housework	47 (18.7)
Not working	4 (1.6)
Other[a]	2 (0.8)
Relative income	
Very low	40 (15.9)
Low	106 (42.2)
Middle	99 (39.4)
High	6 (2.39)
Have children	
Yes	223 (88.8)
No	28 (11.2)

Data are n (%) participants unless stated otherwise. Percentages may not add up to 100 due to rounding.

[a] One daily labourer and one unable to work due to disability.

4.3.2 Clinical and psychosocial characteristics at baseline

Among the study population, 93.6% had a history of acute attack. The mean ± standard deviation (SD) number of acute attacks (acute dermatolymphangioadenitis) in the month prior to the survey was 2.4 ± 2.6. Only 15.5% of participants had ever received treatment for their leg lymphoedema, and only 8.4% of participants were currently receiving treatment or administering self-treatment at the time of enrolment (Table 4.2).

The prevalence of depression with a PHQ-9 cut-off of 10 was 47.4% (119/251 participants). Considering the severity of depression, 39.0% of participants were classed as having mild depression, 29.9% moderate, 11.2% moderately severe and 6.4% severe depression (Table 4.3). The mean ± SD DLQI was 11.4 ± 4.2. Lymphoedema had a very large effect on the patient's QOL in 53.4% of cases and a moderate effect in 30.7% of cases (Table 4.3).

Assessment of other psychosocial characteristics showed that 65.3% had poor social support, 27.5% had moderate social support, and only 7.2% had strong social support (Table 4.3). The mean ± SD WHODAS score for disability was 29.6 ± 8.8, the mean ± SD number of days over the last 30 days where the person was unable do their usual activities or work was 6.3 ± 4.7 days, and the mean ± SD number of days where they cut back or reduced their usual activities was 3.7 ± 2.7 (Table 4.3).

Table 4.2 Clinical characteristics of patients with lymphoedema participating in the baseline study (N=251)

Variable	Participants
Type of case with lymphoedema	
Lymphatic filariasis/podoconiosis	246 (98.0)
Leprosy	5 (2.0)
Has your leg ever suddenly become hot, red and painful? (i.e. an acute attack)	
Yes	235 (93.6)
No	16 (6.4)
How often does your leg become hot, red and painful? (i.e. acute attack), (n=235)	
Every week	62 (26.4)
Every 2 weeks	58 (24.7)
Every month	48 (20.4)
Every 3 months	31 (13.2)
Every 6 months	19 (8.1)
Every year	11 (4.7)
≥1 year	6 (2.6)
Number of acute episodes in the month prior the survey, mean ± SD (range)	2.4 ± 2.6 (0–20)

Have you ever received treatment for your leg lymphoedema?	
Yes	39 (15.5)
No	212 (84.5)
Are you currently receiving treatment for, or self-treating your leg(s)?	
Yes	21 (8.4)
No	230 (91.6)
Where did you receive/are you receiving treatment? (n=39)	
Government clinic	27 (69.2)
Non-governmental clinic	6 (15.4)
Self-treatment	4 (10.3)
Traditional healer	1 (2.6)
Other	1 (2.6)

Data are n (%) participants unless stated otherwise. Percentages may not add up to 100 due to rounding.

Table 4.3 Mental health and psychosocial characteristics of patients with lymphoedema participating in the baseline study (N=251)

Variable	Participant
Mean PHQ-9 (SD)	10.1 (5.2)
Depressive Symptoms (based on PHQ-9 <5 Scores), n (%)	
Not depressed	34 (13.5)
Depressed	217 (86.5)
Level of Depressive Symptoms (based on PHQ-9 Scores), n (%)	
No depression (0–4)	34 (13.5)
Mild (5–9)	98 (39.0)
Moderate (10–14)	75 (29.9)
Moderately severe (15–19)	28 (11.2)
Severe (20–27)	16 (6.4)
Depressive Symptoms (based on PHQ-9 <10 Scores), n (%)	
Not depressed	132 (52.6)
Depressed	119 (47.4)
Social support (based on Oslo-3)	
Poor social support	164 (65.3)
Moderate social support	69 (27.5)
Strong social support	18 (7.2)
Disability measure (based on WHODAS), mean ± SD	
WHODAS score	29.6 ± 8.8 (median, 28.0)
How many days in the past 30 days have these difficulties been present?	12.4 ± 6.2

How many days in the past 30 days were you totally unable carry out your usual activities?	6.3 ± 4.7
How many days in the past 30 days did you cut back or reduce your usual activities?	3.7 ± 2.7
Quality of Life (DLQI score), mean ± SD	11.4 ± 4.2
DLQI effect on patients' life, n (%)	
No effect (0–1)	4 (1.6)
Small effect (2–5)	27 (10.8)
Moderate (6–10)	77 (30.7)
Very large (11–20)	134 (53.4)
Extremely large (21–30)	9 (3.6)
DLQI sub-scale, mean ± SD	
Symptoms and feelings[a]	3.4 ± 1.4
Daily activities[a]	2.3 ± 1.7
Leisure[a]	1.8 ± 1.4
Work and school[b]	2.4 ± 1.1
Personal relationships[a]	1.1 ± 1.3
Treatment[b]	0.7 ± 0.9

Data are n (%) participants unless stated otherwise. Percentages may not add up to 100 due to rounding.

[a] Maximum value of subscale = 6.

[b] Maximum value of subscale = 3.

DLQI; Dermatology Quality of Life Index; Oslo-3: Oslo Social Support tool; PHQ-9: Patient Health Questionnaire-9; WHODAS: World Health Organization Disability Assessment Schedule tool (WHODAS version 2.0).

Using the CIDI scale, 12.4% of the 251 study participants had suicidal thoughts, 9.2% reported planning suicide, and 7.6% reported a suicide attempt (Table 4.4). None of the participants with suicidal ideation, suicidal planning or suicidal thought had accessed any form of treatment for this (Table 4.4).

Table 4.4 Suicidal ideation and suicide attempts, assessed using the CIDI, among patients with lymphoedema participating in the baseline study (N=251)

Variable	**Number (%) participants**
Suicidal ideation in the last 1 month	
Yes	31 (12.4)
No	220 (87.6)
Suicide planning in the last 1 month	
Yes	23 (9.2)
No	228 (90.8)
Suicide attempts in the last 1 month	
Yes	19 (7.6)
No	232 (92.4)
Among those who attempted suicide, frequency of attempt (n=19), mean ± SD (range)	1.9 ± 0.9 (1–5)
Received any treatment for thinking about or attempting take your own life?	
Yes	0
No	31 (100)

Data are n (%) participants unless stated otherwise. Percentages may not add up to 100 due to rounding.

CIDI: Composite International Diagnostic Interview.

4.3.3 Factors associated with depression

In the bivariate linear regression analysis, sex, age, educational status, employment status, marital status, social support and relative income were significantly associated with depression (Table 4.5). However, in the multivariate linear regression analysis none of these sociodemographic factors were significantly associated with depression. In the multivariate linear regression model, there was a positive, statistically significant, association between disability, as measured by the WHODAS, and depression, as measured by the PHQ-9 (β=0.26; 95%CI: 0.19, 0.33) (Table 4.6).

Table 4.5 Bivariate analysis using depression, assessed using the PHQ-9 scale, as a continuous outcome variable (N=251)

	PHQ-9 mean ± SD	Beta (95%CI)	p-value[a]
Sex			
Male	9.2 ± 5.4	−1.54 (-2.81, −0.27)	0.02
Female (reference)	10.7 ± 4.8	1.0	
Age (continuous)	10.0 ± 5.2	0.05 (0.01, 0.08)	0.03
Education			
Illiterate	10.8 ± 5.4	2.32 (1.03, 3.62)	<0.001
Literate (reference)	8.5 ± 4.4	1.0	
Marital status			
Currently married	9.5 ± 5.2	−1.44 (−2.81, −0.08)	0.04
Currently not married (reference)	10.9 ± 5.0	1.0	
Employment			
Employed[b]	10.2 ± 5.5	0.90 (−0.71, 2,42)	0.28
Not employed (reference)	9.3 ± 3.20	1.0	
Relative income			
Very low and Low (reference)	11.3 ± 5.3	1.0	<0.001
Middle and high	8.2 ± 4.4	−3.11 (−4.35, −1.87)	
Acute attack frequency (n=235)			
Every week/2 weeks/month (reference)	10.2 ± 5.1	1.0	
≥3 months	9.3 ± 5.1	−0.92 (−2.39, 0.53)	0.21
Acute attack (continuous)	10.0 ± 5.2	0.01 (−0.24, 0.26)	0.93

Have you ever received treatment for your leg lymphoedema?			
No (reference)	9.8 ± 5.1	1.0	0.35
Yes	10.7 ± 5.6	0.84 (−0.93, 2.61)	
Are you currently receiving treatment for, or self-treating your leg(s)?			
No (reference)	10.0 ± 5.1	1.0	0.82
Yes	9.7 ± 5.9	−0.27 (−2.59, 2.05)	
Social support (based on Oslo-3)			
Poor social support (ref)	5.9 ± 5.2	1.0	
Moderate social support	9.0 ± 4.9	−1.76 (−3.17, −0.35)	0.01
Strong social support	10.8 ± 3.5	−4.85 (−7.29, −2.41)	<0.001
Disability assessment based on WHODAS (continuous)	11.8 ± 5.1	0.31 (0.25, 0.37)	<0.001
DLQI (cont.)	10.0 ± 5.2	−0.04 (−0.17, 0.09)	0.52

[a] Linear regression was used to examine the association between explanatory variables and depression measured by the PHQ-9; explanatory variables with an association of $p<0.2$ in the bivariate analysis were included in the multivariate linear regression model.

[b] Salaried, self-employed and farming.

DLQI; Dermatology Quality of Life Index; Oslo-3: Oslo Social Support tool; PHQ-9: Patient Health Questionnaire-9; WHODAS: World Health Organization Disability Assessment Schedule tool (WHODAS version 2.0).

Table 4.6 Multivariate linear regression analysis using depression, assessed using the PHQ-9 scale, as a continuous outcome variable (N=251)

	PHQ-9, mean ± SD	Beta (95%CI)	p-value[a]
Sex			
Male	9.2 ± 5.4	1.0	
Female	10.7 ± 4.8	0.39 (−1.02, 1.80)	0.59
Age (continuous)	10.0 ± 5.2		
Education			
Illiterate	10.8 ± 5.4	1.0	
Literate	8.5 ± 4.4	0.01 (−0.03, 0.05)	0.67
Marital status			
Currently married	9.5 ± 5.2	1.0	
Currently not married	10.9 ± 5.0	0.07 (−1.30, 1.43)	0.92
Relative income			
Very low and low	11.3 ± 5.3	1.0	
Middle and high	8.2 ± 4.4	−1.17 (−2.42, 0.09)	0.07
Social support (based on Oslo-3)			
Poor social support (reference)	5.9 ± 5.2	1.0	
Moderate social support	9.0 ± 4.9	−0.83 (−2.09, 0.41)	0.19
Strong social support	10.8 ± 3.5	−2.07 (−4.27, 0.13)	0.07
Disability assessment based on WHODAS (continuous)	11.8 ± 5.1	0.26 (0.19, 0.33)	< 0.001

[a] Linear regression was used to examine the association between explanatory variables and depression measured by the PHQ-9; explanatory variables with an association of p<0.2 in the bivariate analysis were included in the multivariate linear regression model. In the multivariate

linear regression model, those explanatory variables with association at $p<0.05$ were considered statistically significant.

Oslo-3: Oslo Social Support tool; WHODAS: World Health Organization Disability Assessment Schedule tool (WHODAS version 2.0).

4.3.4 Factors associated with quality of life

In the bivariate linear regression analysis, none of the sociodemographic factors, history of acute attack, or frequency of attack in the past month were associated with QOL, as measured by the DLQI (Table 4.7). In the multivariate linear regression model, currently receiving treatment was significantly associated with improved QOL (β=−3.05; 95% CI −5.25, −0.85). Social support was also significantly associated with improved QOL; using poor social support as reference, participants with moderate social support had β=−2.27; 95% CI −3.66, −0.89, and those with strong social support had β=−2.87; 95% CI:−5.35, −0.38. Additionally, disability was significantly associated with QOL (β=−0.08; 95% CI: −0.15, −0.01) (Table 4.8).

Table 4.7 Bivariate analysis using quality of life, assessed using the DLQI, as a continuous outcome variable (N=251)

	DLQI, mean ± SD	Beta (95%CI)	p-value[a]
Sex			
Male	12.4 ± 5.3	1.24 (−0.02, 2.49)	0.05
Female (reference)	11.2 ± 4.8	1.0	
Age (continuous)	11.8 ± 5.1	−0.006 (−0.05, 0.04)	0.76
Education			
Illiterate	11.3 ± 4.9	−1.17 (−2.47, 0.12)	0.08
Literate (reference)	12.5 ± 5.4	1.0	
Marital status			
Currently married	11.8 ± 5.2	0.06 (−1.29, 1.41)	0.93
Currently not married (reference)	11.7 ± 4.8	1.0	
Employment			
Employed[b]	11.9 ± 5.1	0.82 (−0.72, 2.37)	0.24
Not employed (reference)	11.1 ± 5.0	1.0	
Relative income			
Very low and low (reference)	11.8 ± 4.9	1.0	
Middle and high	11.6 ± 5.3	−0.22 (−1.50, 1.06)	0.74
Acute attack frequency (n=235)			
Every week/2 weeks/month (reference)	11.8 ± 5.1	1.0	
Three-month and above	11.8 ± 4.9	−0.02(−1.45, 1.42)	0.98

Acute attack (continuous)	11.8 ± 5.1	0.07 (−0.19, 0.31)	0.61
Have you ever received treatment for your leg lymphoedema?			
No (reference)	11.9 ± 5.0	1.0	
Yes	11.0 ± 5.4	−0.94 (−2.68, 0.80)	0.29
Are you currently receiving treatment for, or self-treating your leg(s)?			
No (reference)	12.0 ± 5.1	1.0	
Yes	9.2 ± 4.2	−2.74 (−4.99, −0.48)	0.02
Social support (based on Oslo-3)			
Poor social support (reference)	12.4 ± 4.7	1.0	
Moderate social support	10.5 ± 5.2	−1.93 (−3.35, −0.52)	0.008
Strong social support	10.7 ± 7.2	−1.67 (−4.13, 0.78)	0.18
Disability assessment based on WHODAS (continuous)	11.8 ± 5.1	−0.06 (−0.13, 0.01)	0.11
PHQ-9 (continuous)	11.8 ± 5.1	−0.04 (−0.16, 0.08)	0.52

[a] Linear regression was used to examine the association between explanatory variables and quality of life measured by DLQI; explanatory variables with an association of $p<0.2$ in the bivariate analysis were included in the multivariate linear regression model.

[b] Salaried, self-employed and farming.

DLQI; Dermatology Quality of Life Index; Oslo-3: Oslo Social Support tool; PHQ-9: Patient Health Questionnaire-9; WHODAS: World Health Organization Disability Assessment Schedule tool (WHODAS version 2.0).

Table 4.8 Multivariate linear regression (DLQI-as an outcome variable) (N=251)

	Beta (95%CI)	*P*-Value
Sex (N=251)		
Male	-1.0 (-2.34 to 0.36)	0.15
Female (Ref)		
Education (N =251)		
Illiterate	0.75 (-0.64 to 2.14)	0.29
Literate(Ref)		
Are you currently receiving treatment for, or self-treating your leg(s)? (N=251)		
No (Ref)		
Yes	-3.05 (-5.25 to -0.85)	0.007*
Social support (based on Oslo-3) (N=251)		
Poor social support (Ref)		
Moderate social support	-2.27 (-3.66 to -0.89)	0.001*
Strong social support	-2.87 (-5.35 to -0.38)	0.024*
Disability assessment based on WHODAS (continuous) (N=251)	-0.08 (-0.15 to -0.01)	0.035*
*Significant		

4.4 Discussion

The present study demonstrated high levels of depression and low QOL among study participants with lymphoedema associated with LF, podoconiosis or leprosy. Disability, as assessed by the WHODAS, was the factor most significantly associated with depression in this population. A high proportion of patients (47.4%) reported moderate to severe depressive symptoms. QOL was significantly associated with current treatment, social support, and disability.

Among study participants, 12.4% had suicidal thoughts, 9.2% reported suicidal planning, and 7.6% reported suicide attempts. This is lower than among HIV positive individuals, among whom the lifetime prevalence of suicidal ideation was 26% and that of suicide attempt 13% [137]. Moreover, suicidal ideation was significantly associated with major depressive disorder [137]. A similar prevalence of suicidal ideation (10.3%) and relatively lower rate of suicidal planning (2.2%) was reported previously in a study in five LMICs among community/healthcare seeking populations presenting at primary care facilities.[127]

An association between depression and lymphoedema due to podoconiosis, LF or leprosy has also been reported by other researchers. A comparative cross-sectional study in Northern Ethiopia showed a higher prevalence of depression, measured using the PHQ-9 scale, among patients with podoconiosis (12.6%) compared with their apparently healthy neighbours (0.7%) [107]. Another cross-sectional study among people living with LF in Nigeria, which used the PHQ-9 and CIDI to measure depression, found a higher prevalence of depression (20%) among LF-affected individuals than the reported 'background' prevalence among the general adult population in Nigeria (3.1–5.2%) [111]. A study in Cameroon used the PHQ-9 scale to demonstrate a high prevalence of depressive symptoms (38.5%) among individuals with lower limb lymphoedema (predominantly due to podoconiosis), although the majority had mild depression [6]. Similarly a study in Rwanda reported high prevalence of depression (68.5%) among participants with lower limb lymphoedema using the PHQ-9 as outcome measure [146]. Studies on individuals affected by leprosy have also reported a high burden of depression [89, 105]. For example, the prevalence of psychiatric morbidity among leprosy patients in Nigeria was found to be 58% and most cases had depression [105].

Poor socioeconomic status might contribute to the high burden of depression among the study participants. Only 2.4% of study participants belonged to the high relative income group in our study. However, despite an association between relative income and depression, this was not statistically significant (p=0.07). It is possible that lack of treatment for lymphoedema (as found in 85.5% of participants) led to disease progression, which itself may have led to depressive symptoms. Stigma and discrimination due to lymphoedema may also have contributed to the high prevalence of depressive symptoms.

QOL was moderately compromised in one-third of cases and severely compromised in about half of patients in the present study; the mean ± SD DLQI score was high at 11.4 ± 4.2. Similar results were reported in a previous intervention study from Guyana among people affected by LF lymphoedema, showing a baseline mean DLQI of 10.9 [147]. In contrast, a study from India among LF lymphoedema cases reported a relatively low mean DLQI value of 2.7 (SD 4.4) [148], indicating better QOL than was observed in the present study. Other studies have measured QOL using the World Health Organization Quality of Life questionnaire (WHOQoL-BREF) and found that people with podoconiosis had significantly poorer QOL than controls [108]. In a study in Bangladesh, the WHOQoL-BREF score was lower among people affected by leprosy than controls [106]. A cross-sectional study in Brazil among leprosy-affected individuals also reported low WHOQoL-BREF scores [97]. Here, we demonstrated that patients currently on treatment had a better QOL than those who were not, implying that emphasis should be given to early diagnosis and management of cases.

The only factor significantly associated with depression among people with lymphoedema was higher disability score. Similarly, a study from northern Ethiopia among patients with podoconiosis showed that increased disability, as measured by the WHODAS, was associated with increased depression among patients with podoconiosis [107]. A study conducted in Bangladesh on leprosy-affected individuals also showed a significant association between disability, as measured by the WHO disability grade, and depression as measured by the Centre for Epidemiologic Studies Depression scale [89].

Disability was inversely related to QOL, i.e. lower disability scores were associated with higher QOL. This suggests that prevention of disability due to lymphoedema may also prevent depression and improve QOL. Study participants with better social support had better QOL. Similar results have been reported in previous studies. A study in Iran among people living with HIV showed a significant association between QOL, as measured by the Short-

Form-36 (SF-36), and social support [149]. Whilst we are not aware of any other studies on NTDs that have shown an association between social support and QoL, this association has been demonstrated for other conditions. There was an association between QOL, as measured by the WHOQOL-BREF, and social support in a study on hospitalized schizophrenia patients in Malaysia [150], while disability was inversely related to QOL, and improvement in disability was associated with improved QOL. Disability, measured using the WHODAS, was significantly associated with QOL, measured by the SF-36, in study participants with mental disorder [151] and QOL, assessed by the WHOQOL-BREF, was significantly associated with disability among leprosy patients in Northeastern Brazil [97].

There were some limitations to the current study. Firstly, the study design was cross-sectional in nature, making it difficult to determine a direction of association between presumed explanatory variables and depression or QOL. Secondly, although most of the tools including the PHQ-9, DLQI and WHODAS, have been validated in Ethiopia, despite their use in studies in other parts of the world, the Oslo-3 scale has not been validated in Ethiopia. Thirdly, we did not measure all factors that might be associated with depression, e.g. family history of mental illness, wealth index or co-morbidities, or factors that might affect QOL, such as wealth index and co-morbidities.

4.5 Conclusion

Our findings indicate a considerable burden of depression and poor QOL among study participants with lymphoedema due to podoconiosis, LF or leprosy. Therefore, a holistic package of care that addresses the physical, mental, social and psychological needs of people with lymphoedema is warranted. Interventions targeting morbidity management and disability prevention of these three NTDs should integrate best practices in addressing the mental, social and psychological aspects of these diseases.

CHAPTER FIVE

A qualitative study on the implementation of a holistic care package for control and management of lymphoedema: Experience from a pilot intervention in Northern Ethiopia

5.1 Overview of introduction

In the previous chapter I described the baseline quality of life and depression status of people affected by podoconiosis, LF or leprosy in Ethiopia. This chapter covers a post-intervention qualitative impact assessment of an integrated holistic care package for persons affected with the stated three NTDs. In this chapter, I briefly give an overview of the introduction and methods, and then explain the results in more detail. These are divided into: burden of lymphoedema on affected individuals, burden due to stigma and discrimination, misconceptions about podoconiosis, LF, and leprosy, perceptions about integration of the holistic care package into the primary health system, perceived barriers to integration of the holistic care package, acceptability of the care package, outcomes of the holistic care package, perceptions about scalability of care, and perceptions about sustainability of care. I then give an overall discussion and conclusion. Overall, this chapter's aim is 1) to assess implementation fidelity by determining the integrated care package's acceptability, scalability, sustainability and the barriers to its implementation; 2) to assess specific program outcomes, including reduction of misconceptions, reduction of stigma and improvement of clinical outcomes.

The result of qualitative study has been published, with details of publication as follows:
Ali O, Kinfe M, Semrau M, Tora A, Tesfaye A, Mengiste A, Davey G, Fekadu A. A qualitative study on the implementation of a holistic care package for control and management of lymphoedema: Experience from a pilot intervention in Northern Ethiopia. *BMC Health Services Research*. 2021; 21:1065. https://doi.org/10.1186/s12913-021-07088-7

5.2 Overview of methods

A holistic integrated care package was developed and interventions were implemented at the health care organization, health facility, patient and community levels. To assess the impact of the intervention, a qualitative study was conducted in January 2020. This included four focus

group discussions (29 participants) with decision makers, health professionals, patients, and community representatives. We also conducted 10 KIIs with the heads of zonal and district health offices, the NTD focal person, the TB (tuberculosis) and Leprosy focal person, the Head of the health centre, health professionals and HEWs (Health Extension Workers). Sample size was determined by a data saturation approach, that is, data collection was continued until further data collection failed to generate additional themes. The more information the sample holds, with respect to the aim of the study, the lower the sample size required [144, 145]. We used a semi-structured interview guide, and a detailed guide on how to conduct the focus group discussions. Please see Appendix 8 for the interview and focus group guide. The detailed methodology has been described in *Chapter three.*

5.3 Results

Among the 39 study participants, 29 were male and 10 were female; the age range was 24 to 62 years. Among these, six were single and 33 were married. They belonged to various professional categories: five Public health experts (MPH), seven health officers (BSc), six clinical nurses (BSc), two public health nurses (diploma), one druggist (diploma), two Health Extension Workers (HEWs), and sixteen farmers. All except one (who was Muslim) belonged to the Orthodox Christian religious group. Ten people participated in the KIIs and 29 participated in the FGDs.

A range of themes and sub-themes were identified. Themes included burden of lymphoedema on affected individuals, misconceptions about NTDs, stigma and its mitigation, advantages of integrated care for NTDs, acceptability of the care package, outcomes of treatment, scalability and sustainability of care, while sub-themes included integration of care across NTDs, psychosocial care integrated with limb care, barriers and solutions to implementing the integrated care package, acceptability by patients and caregivers, acceptability by health care workers and acceptability by decision makers. The predetermined themes included stigma and its mitigation, advantages of integrated care for NTDs, acceptability of the care package, outcomes of treatment, and scalability of care. The themes that emerged during the analysis included burden of lymphoedema on affected individuals, misconceptions about NTDs, and sustainability of the care package.

5.3.1 Burden of lymphoedema on affected individuals

Health burden

Podoconiosis, LF and leprosy can all lead to lymphoedema complicated by acute attacks, which are characterised by severe pain, fever, chills and difficulty walking.

> Before starting the treatment, I felt chills and rigor whenever I returned from work. I couldn't even eat food because of the pain. I take a cup of coffee but am still in pain. That is the acute attack, which causes severe damage to our health and effectiveness in work. [FGD Participant, 47 year old female patient]

> The last two years were especially difficult for me; it gets difficult even to get out of my house. My family worried about me, others blame me that I fell while working. I feel weak. [FGD participant, 49 year old male patient]

Psychosocial burden

NTDs not only have devastating physical outcomes, but also tremendous social, psychological and mental health outcomes. Undermining personal dignity and exclusion from decision making roles and social activities were common experiences of lymphoedema-affected individuals. These experiences had a negative impact on the mental health of lymphoedema patients. As some participants stated,

> In our workplace our work-mates used to belittle us due to our condition. They
>
> didn't consider us equal for social or political positions, which is painful.
>
> [FGD participant, 58 year old female decision maker (DM)]

> People with this problem definitely have mental health problems or these might happen in their lifetime. These mental health problems are neglected as there is not even one psychiatric professional in the health centre. [Decision maker,
>
> 31-year-old male]

Economic burden

Participants also reported that NTDs have a significant impact on the economy of the family and there is a possibility that more than one person in a family is affected by these diseases.

> In a single family there may be three or four affected individuals. The affected individuals are poor as they can't work due to disability. Even if they have farmland, they can't cultivate it, rather they go begging. [FGD participant, 50 year old female community representative (CR)]

Burden due to stigma and discrimination

The community tend to stigmatize and discriminate against individuals affected by lymphoedema, a highly visible condition. They avoid marriage to individuals affected by lymphoedema, as they believe the disease will pass to their offspring.

> There were a husband and wife with huge leg swelling in the neighbourhood, two years back she prepared '*Tela*' (a local alcoholic beverage) and took it to the church to celebrate a holiday, but people refused to drink what she had brought. [FGD participant, 47 year old male patient]

> Even in the case of marriage proposal, if the man has a leg problem, the woman's family do not allow their daughter to go to his family. They think that either the disease will be transmitted directly to their daughter or passed genetically to their grandchild. [FGD participant, 48 year old female CR]

The stigmatization is not only from the unaffected community but also from the patients themselves.

> The problem is not only from the other side, patients also isolate themselves fearing that the bad smell would disturb other people, so it is a two-way problem. [FGD participant, 28 year old male Health Professional (HP)]

5.3.2 Misconceptions about podoconiosis, LF and leprosy

For podoconiosis, most of the patients participating in the interviews thought that is was caused by a curse. Few mentioned barefoot contact with the soil for a long period of time as a cause.

> People believe that podoconiosis is caused by a curse from God - even though they can afford to buy shoes, they don't want to buy and wear them. However, had they known that walking bare footed is the cause of this illness, they will prioritize shoes even above food and drink. [FGD participant, 51 year old female CR]

Be it podoconiosis, LF or leprosy, most people did not understand that it could be prevented or treated medically. Similar to podoconiosis, they believed that LF and leprosy were caused by a curse from God. Most did not believe that leprosy is caused by a bacteria and LF by a parasite.

> Previously, there was no awareness about the disease; they considered themselves inferior to everybody and they thought the diseases had no cure but now we follow them and they know that if they preserve their hygiene there is a cure and it doesn't transmit through blood lines. [HEW, 28-year-old female]

> Some people think that we brought this on ourselves as we did something wrong that God didn't like. It is a matter of education: those who are illiterate think like that, but the ones with some knowhow show us empathy and support in everything. [FGD participant, 47 year old male patient]

The misconceptions around podoconiosis, LF and leprosy are not limited to patients - there have been reports of misconceptions even among health professionals regarding the treatment of the disease [152]. NTDs, especially podoconiosis, are inadequately addressed in health professionals' training curricula.

> I am a focal person at the health center. First, when I came to this profession, to tell you the truth, I was treating only other cases, and also the acute attack cases came due to this problem. We didn't understand their [patients with podoconiosis] problem, despite providing pain relief for them. In addition, there was nothing that we got from the curriculum too. We didn't know whether they will get improvement by foot hygiene. But at this time, after attending the training, first we know about it and we also create awareness in the community too. So, I believe that we will solve the problem. [Decision maker, 28 year old male]

> I was shocked when I heard that there are about 251 cases [of lymphoedema] at Gugsa cluster. I mean, sometimes we do see those cases even though we don't differentiate specifically whether it is podo or lymphatic filariasis as both of them have similar differential diagnoses, we may not specifically know the case. Moreover, I may not have the reference book at the table, so, that means I may mis-diagnose the case at that time. Therefore, it is necessary to have an orientation. [FGD participant, 35 year old male HP]

5.3.3 Perception on integration of the holistic care package into the primary health system

Perception of decision makers about integration of lymphoedema care

To operationalise the EnDPoINT project, advocacy activities were started at the leadership level. Training on integrated care of the three NTDs and psychosocial care was provided to health professionals. Then awareness-raising workshops were conducted in health facilities. Community awareness was addressed through facilitated Community Conversations.

> It is good to do things in an integrated way as you can save more time and resources. Therefore, integrating the care package of the three diseases in Gusha health centre proves we can achieve that. It saves much needed time and money, the pilot project shows we achieve the three cares in one. As I am a leprosy officer I gained good experience, got a lot knowledge that I didn't have before.

> Therefore, the integration of the treatment package was good and effective which needs to continue. [Decision maker, 37 year old male]

> Each of the diseases is currently included in the check list and I can tell you that they are being supported and the service is being provided. Even though these diseases were neglected during the previous times, at present, they are being included in the program. Hence, I think it will be strengthened more in the future and we will work more by collaborating with partner organizations to make the program more successful and to make sure the community benefits from it. [Decision maker, 42 year old male]

Perception of health professionals about integration of mental health care

Patients with lymphoedema stigmatise themselves and feel inferior compared to their healthy counterparts. Due to this, they are at risk of mental distress. Thus, integration of lymphoedema care with psychosocial and mental health care is very important.

> Patients live stressed life and I don't think that they feel good internally because they think they are discriminated against by others or may think they are inferior to others because they aren't able to do what others can do for a living, so including a psychological intervention benefits them more. [FGD participant, 62 year old male DM]

Considering the local health condition, previously mental health services were given only at hospital level, not at health centre level. However, through the CDT-Africa/EnDPoINT project, mental health training has been given to health centre-level healthcare professionals. A three-day theoretical training and five-day practical training was delivered.

> Mental health services were not being provided in health centres, it was totally an ignored work. [FGD participant, 55 year old male DM]

> Mental health problems are neglected, there is not even one psychiatric professional at the health centre. At *woreda* level, training to give an integrated service was given to health professionals working in the health centres. This training was given for those who work on morbidity management to support the psychosocial and mental health care. Therefore, I believe the psychosocial

> work is a vital part of the treatment package and goes hand-in-hand with the treatment and prevention work. [Decision maker, 31 year old male]

5.3.4 Perceived barriers to integration of the holistic care package

Unrealistic expectations

One of the barriers to implementing integrated care comes from the patients themselves. After providing the health education and delivering start-up supplies to practice self-treatment, it is expected that patients continue to receive the services covering the costs necessary. However, they expect the cost of supplies to be covered by the government.

> There are a lot of patients who are currently enrolled in the service and there are patients who got help before. Several patients want everything to be covered by the government, they want the government to give them all services for free. Maybe this will be a challenge. [Health professional, 30 year old male]

Inadequate dissemination across health workers

Another barrier is lack of cooperation from officers and health workers at the health center, as they consider the work to be only for the trained focal persons and heads.

> There is a low level of awareness among health workers, except those who attended the training, since health professionals didn't learn much about podoconiosis or LF from their college time. [Decision maker, 37 year old male]

Poor transport access

A further challenge is lack of transport. Either patients are poor and cannot afford transport to the health centre where the integrated lymphoedema care is given, or are too disabled to walk because of the leg swelling.

> While they want to come here, they can't find transport and may spend the night on the street. Since these patients are poor, they don't have money for a 'bajaj' [A form of taxi with three wheels that can carry up to five passengers]. So my

> first request is to bring the service to health post level. [FGD participant, 57 year old male CR]

5.3.5 Acceptability of care package

Perception of patients

Patients were very comfortable with the integrated care package. They described how much relief the self-treatment brought. They acknowledged the government and the project for reaching them with such effective measures. They asked for more education and that the counselling services be continued. They were ready to purchase the materials necessary for long term management themselves.

> First, the package has much more acceptance after patients have gone through the agony of suffering and see that it is better and more comfortable. They are accepting it very well and they are also strengthening the association by contributing money. [The package] is accepted by both the patients and their caregivers. [HEW, 26 year old female]

> The patients say 'GOD came to us, we were created as human but were not living like humans, but now we have become human again". For your information the names of our self-help groups are very unique. For example, one of the names is "Fetari Dereselign" which means "the almighty God reached for us", there is no satisfaction like this. [Decision maker, 31 year old male]

Perception of health care workers

Capacity building activities were delivered to health professionals, health extension workers and district officers. Following this, there was tremendous motivation in the health sector to implement the integrated lymphoedema package, and the providers gave special priority to the program. The health professionals were very happy about integrated care and they said that there had never been a job that gave them more satisfaction than this one.

> The providers are delivering compassionate and respectful care. When demonstrating foot care they kneel and wash the feet. Previously they may have cleaned and cared for wounds, but not washed a patient's feet. This project teaches us to be more humble and compassionate to our patients, to tackle problems more thoroughly. It is good to do things in an integrated way as you can save more time and resources. The integration of the three diseases gives us great experience for other diseases. [Decision maker, 37 year old male]

> Now every patient you get will bless you. Every one we find is blessing us. This will push you to do more work. You will never have a reason to stop working while they are blessing you for what you did. So the health professionals are committed. The health professionals at the health centre will go to each *kebele* [The smallest administrative unit consisting about 1000 head of households] and observe patients' progress covering their own transport cost. [Decision maker, 31year old male]

Perception of decision makers

Decision makers reported how impressed they were with the levels of collaboration seen in the community around the integrated lymphoedema package. They saw the introduction of the package as an opportunity for local government to get behind services clearly appreciated by the community.

> I have been noticing the effectiveness of integration. After project initiation, all responsible bodies from zone to *kebele* level have been actively participating and helping us. When we go out to *kebele* level to conduct supportive supervision, [community] leaders and health extension workers are doing a great job in collaboration. [FGD participant, 28 year old male HP]

> This is a condition that the government itself has previously neglected. But now attention is given, and using this attention as a good opportunity, the management is committed to make the service available and to help the community address the situation. [Decision maker, 31 year old male]

5.3.6 Outcomes of the holistic care package

Improved awareness about the cause, treatment and prevention of lymphoedema

Respondents noted increased understanding of lymphoedema and strategies to prevent it compared with the pre-intervention package situation.

> Now people understand the cause and that it is possible to treat the disease. Everyone is urging the community not to go barefoot and to keep their feet clean. Even in the farming areas, they wear plastic boots. [FGD participant, 48 year old male patient]

Healthcare workers facilitated the establishment of self-help groups. These groups contain eight to twelve patients, and have a chairperson, secretary and audit officer. Each member contributes a specified amount of money each month. The main role of the self-help group is health education including disease prevention, health promotion, and stigma reduction.

> I participated in the training for trainers of self-help groups. After my training, I have been closely following the members of our association. We use the association to educate each other and follow our progress. Following our education, we have been practicing washing our feet and skin care, which has brought many changes. People who have sleepless nights before are now enjoying their times peacefully. [FGD participant, 47 year old male patient]

Improved lymphoedema condition

Proper continuation of lymphoedema care resulted in considerable reduction of pain, of frequency of acute attacks and of the extent of swelling.

> By now there is no problem at all. I was in pain all days of the month before I started this treatment, but now I haven't had a single day of illness after following the advice from health workers. I follow every procedure as recommended and that makes everything well. Now I can wear size 40 shoes, while previously I couldn't even wear size 43 shoes. [FGD participant, 47 year old male patient]

Continued lymphoedema care also resulted in increased productivity and improved quality of life.

> After I started this treatment, thank God, I am in peace. Unfortunately, our fathers didn't get this opportunity. Now I am farming equally as my friends do. Thank you so much, you help us a lot and [the package] improves our quality of life. [FGD participant, 49 year old male patient]

> Some could barely move outside their home before starting treatment, but now they go out and do their business just like a normal person. Their feeling of shame about participating in social occasions because of the smell has gone. [Decision maker, 37 year old male]

Reduced stigma and discrimination

Patients and community members described changes in levels of stigma and discrimination they faced following implementation of the integrated care package.

> Previously, people had a tendency not to eat the food we prepared. Now this education and community conversation comes. We use our knowledge to convince them, and some are changed for the good. [FGD participant, 47 year old male patient]

> My sister used to prepare food to be served in the church but while the men ate it, the women did not. That hurt my feelings deeply. Now we've started this treatment and help each other with the self-help group, we wear our shoes and go out as equals to anyone around. My sister is following treatment closely and by now she is in a near normal condition. Recently in church, I have witnessed the girls who used to refuse the food take it as normal, and I feel happy to see that. [FGD participant, 53 year old male patient]

5.3.7 Perception on scalability of care

Patients, healthcare workers and decision makers all considered the integrated package to be successful and urged its wider introduction. Patients pointed to wider relief of suffering and returning more people to full lives in society, while decision makers stressed the importance they placed in the scientific rigour with which the package had been implemented and evaluated.

> It would be good if this organization could work in other districts. While working on these activities, I believe that the health office will take the initiative to work in other areas which have similar problems. So, it will be very important for the community if you scale up the program to other districts so as to help the community to get rid of this problem and have healthy and productive citizens. [FGD participant, 52 year old male DM]

> We appreciate the follow up you are conducting on the progress of the patients. You are doing it in scientific manner, which is nice. You are helping the patients and relieving many sufferings. We even expect the Ministry of Health to take this idea and scale it up nationwide. [Decision maker, 32 year old male]

5.3.8 Perception on sustainability of care

One of the activities intended to ensure sustainability of the package was the Training of Trainers (TOT) for health professionals. Those who took part in the TOT were expected to cascade training to the remaining health care workers. This aims to protect against high turnover among healthcare workers, which has been a problem for the sustainability of other new healthcare interventions.

> It is good to see as many health workers as possible trained in this to ensure the sustainability of the work after the project phases out. For us we will try to use every level of government to sustain it. [FGD participant, 57 year old male CR]

Another factor that might influence sustainability is the ability and motivation of patients to continue buying the simple consumables needed (for example, soap and ointment). Most of the

supplies for hygiene-based lymphoedema management are easily accessible, for those with extensive swelling, shoes of an appropriate size are not available in any local shops.

> The community has the awareness and they can even purchase the materials by themselves. Previously it was the organization that provides the materials. And they [patients] are so happy with the change they witnessed and consider it sustainable. [Health professional, 28 year old male]

> We can find soap, Vaseline and other materials in the local shops, but shoes of our size are difficult to find, so that is the main problem to be addressed by the government. [FGD participant, 53 year old male patient]

Integrating lymphoedema care into the existing Health Extension Program (HEP) is another factor vital to the sustainability of the intervention. Decision makers suggested that since cost is one of the challenges for sustainability, incorporating the intervention into the HEP might reduce the long-term cost.

> The government is trying to accommodate specific programs into the Health Extension Program. For example, personal hygiene is among the packages of the HEP, so we can take podo, LF, leprosy, skin care and washing practice and then contextualize them with the existing Health Extension Programs. The HEP is one of the most sustainable programs the government has, so we can use it to solve both the sustainability and budget issues. There are some efforts to include podoconiosis care in it. [Decision maker, 32 year old male]

5.4 Discussion

In this qualitative study we observed misconceptions about the causes, prevention and treatment of lymphoedema due to podoconiosis, LF and leprosy. In regard to podoconiosis, the affected community believed that it is caused by a curse; although some mentioned that it is hereditary, most did not realise that it is caused by long term barefoot exposure to red clay soil. Podoconiosis is caused by both genetic and environmental factors [17, 18]. Similarly, a common misconception is that LF and leprosy are caused by a curse, when LF is actually

caused by the parasites *Wuchereria bancrofti* and *Brugia spp* and transmitted by mosquitos, whereas leprosy is caused by a bacteria Mycobacterium *leprae*.

Integrated lymphoedema care was a prefered modality of care among our study participants belonging to decision makers and health professionals. Similar to our findings, integrated NTD care was found to be feasible and cost effective previously in reduction of morbidity [69, 71]. Integrated care of NTDs also resulted in reduction of disease burden [69, 70], and increased coverage [69, 70]. In contrast to our findings, integrated care has also been found to have negative effects as it can lead to loss of specialised proficiency and a tendency for lack of adequate trained staff [71]. As lymphoedema due to NTDs results in poor psychosocial and mental health outcomes, integration of lymphoedema care with mental health care at primary health care units is vital [113].

The integrated holistic care package was found to be acceptable by patients. They reported feeling comfortable with the treatment package and witnessed significant improvements associated with their illness. They were happy with the health education and the counselling activities. Though most were ready to purchase the necessary supplies for the long term self-care, a few of them wanted the government to give them the supplies for free. Similar to patients, health professionals found the care package to be acceptable. The gratitude from patients enhanced the motivation of health professionals and they claimed that they had never had any job which gave them greater satisfaction than the integrated holistic care package. Unlike previously, when mental health care for people affected by lymphoedema was neglected, in this study, integrated NTD and mental health care won the support of decision makers, who believed that it made efficient use of the work force.

The outcomes of the integrated holistic care package included improved awareness about the causes, treatment and prevention of lymphoedema**;** improved lymphoedema condition, and reduced stigma and discrimination. Post-intervention, there was enhanced understanding about ways of controlling and preventing lymphoedema. A self-help group was established, leading to increased information sharing and persistent self-care. Appropriate lymphoedema care was followed by reduction of pain [153], decreased frequency of acute attacks [26, 153, 154] and profound reduction of swelling [28]. In addition, it resulted in enhanced productivity and improved quality of life [28]. Post-intervention, patients and community members noticed a reduction in stigma and discrimination.

Though the integrated holistic care package was reported to have advantages by participants, it was also found to have some drawbacks. These include unrealistic expectations by patients, inadequate cooperation of health workers, and poor transportation access. Patients expected the government to cover the cost of the supplies required for integrated lymphoedema care. There was a tendency to push integrated lymphoedema-mental health care activities towards those healthcare professionals who had attended TOTs. As part of the solution, orientation of a wider range of health workers may help develop capacity more sustainably. Finally, patients may have poor transport access to the health centre where the integrated care is available, either because they are poor and cannot afford transportation or because the lymphoedema leads to reduced mobility. Thus, delivering this service at the health post level, nearer to the community, is proposed.

Health professionals, decision makers and patients strongly supported scale-up of the integrated package to the remaining endemic districts in the zone. They even expected the Ministry of Health to scale it up nation-wide. One of the justifications for scalability is the scientific soundness of the implementation and evaluation mechanisms. Another important justification for scale-up is the relief felt by patients that, as their symptoms reduced, they were able to return to their duties and could once more become productive citizens.

The integrated care program is potentially sustainable. Factors which contribute to sustainability include the Training of Trainers (TOT) given to health professionals, the ability of patients to buy the consumables and the potential for integration into the existing health extension program. The TOT provided to the health professionals enabled them to cascade this training to the remaining health professionals in the health facility. This helps to prevent loss of expertise secondary to staff turnover, which often acts as a barrier to the sustainability of newly initiated programs.

Since cost is often a barrier to sustainability, one of the decision makers' recommendations was incorporation of the integrated care package into the existing Health Extension Program (HEP). The HEP is a highly sustainable government program, and lymphoedema care was thought to fit into it well. Another important issue is ability to buy the essential supplies. By the end of the intervention, patients had the awareness, motivation, and ability to buy most of these supplies. The only limiting factor mentioned was availability of shoes appropriate for those with very large swelling, as these were not usually available in the local market.

5.5 Conclusion

The integrated lymphoedema care package supported lymphoedema awareness creation, reduction of stigma and discrimination, and marked improvement in lymphoedema. The care package was found to be acceptable to patients, health professionals and decision makers. We recommend its scale-up to other endemic districts in Ethiopia, and potentially other countries.

CHAPTER SIX

Effects of a community-based holistic integrated care package on clinical and psychosocial outcomes in people with lower limb disorder due to podoconiosis, lymphatic filariasis or leprosy in north-western Ethiopia: a non-comparative cohort study

In this chapter I give a brief overview of the quantitative post-intervention pilot results, as measured at 3 and 12 months after initiation of the care package. I explain the relevant background and methods, including study design, study outcomes (clinical and psychosocial), and data analysis. The results section of this chapter covers the sociodemographic characteristics of participants, as well as the clinical and psychosocial characteristics of participants at baseline and after 3- and 12-months of the care package intervention being initiated. The chapter closes with a discussion and conclusion.

6.1 Overview of background

The neglected tropical diseases (NTDs) lymphatic filariasis (LF), podoconiosis and leprosy can all cause lower limb lymphoedema *(see Chapter one)*. As highly stigmatised conditions, they have a huge impact on the lives of the people they affect, causing physical disability, reducing economic productivity, and impairing mental wellbeing [155-161].

The 'normal' prognosis without intervention is an increase in swelling due to risk of repeated bacterial/fungal infection (acute attack) which leads to an increase in lymphatic flow obstruction and thus aggravation of lymphoedema. The evidence on poor prognosis without intervention is GoLBeT RCT article [26], where the control group (who waited for 1 year for the intervention) showed overall deterioration in number of acute attacks (the primary outcome) from 16.1 events/person-year to 24.5 events/person-year over the 12-month period.

MMDP services have been found to be effective in relieving troubles from the three NTDS. Several studies have demonstrated that simple hygiene-based foot care can reduce limb swelling and improve quality of life [26, 162-166]. This simple hygiene-based self-care can also reduce acute dermato-lymphangio-adenitis (ADLA) [26, 162, 164-167]. Despite the successes of MMDP in various study programmes, the question remains as to how to integrate wide-scale MMDP services into the primary health care units of the resource-limited endemic countries where they are most needed. The other important issue is how to effectively reduce stigma and address the psychosocial and mental health needs of people living with the conditions. Thus, the aim of the EnDPoINT programme was to integrate a holistic integrated care package for people with LF, podoconiosis, and leprosy into the routine Ethiopian health care system [168] in order to address both the physical and psychosocial needs of people living with lower limb disorders. In the study reported in this chapter, the impact of a small-scale pilot of the EnDPoINT intervention on various physical and psychosocial outcome was assessed.

6.2 METHODS

6.2.1 Study design

The detailed methodology has been presented in *Chapter three*. Here, I present a brief overview of the methods specific to this chapter. In order to assess the impact of the EnDPoINT care package in one district, a non-comparative cohort study / pre-post design was used, wherein the physical and psychosocial characteristics of participants were compared between baseline and at 3- and 12-months after initiation of the care package. The care package was delivered to participants between 20th of August 2019 and 1st October 2020. The care package was administrated at different levels of care (*see* ***Figure 3.1***). Because of ethical concerns about withholding treatment, we did not collect comparative prospective data on a control group of patients.

6.2.2 Study outcomes

In this study we assessed the effectiveness of the integrated holistic care package on a number of clinical (physical) and psychosocial outcomes.

6.2.3 Clinical outcomes

The clinical outcomes included: presence of acute 'attack' of ADLA in the last month; average maximum lower limb circumference; average maximum foot circumference; presence of wounds or nodules on either leg; signs of infection on either leg; lymphoedema stage; and disability measured by the WHO Disability Assessment Schedule-2.0 (WHODAS-2.0) score with higher WHODAS score indicating greater disability [169, 170].

6.2.4 Psychosocial outcomes

The following psychosocial outcomes were included. Symptoms of depression were measured using the Patient Health Questionnaire-9 (PHQ-9) [171]. Total scores for the PHQ-9 range from 0 (no depressive symptoms) to 27 (severe depressive symptoms). Quality of life was measured using the Dermatology Life Quality Index (DLQI) score [172]. The minimum score is 0 (no effect of disease on life) and the maximum is 30 (extremely large effect of disease on life). In this study, the DLQI scores reported are likely to be underestimated, since one of the ten questions (Over the last week, how much has your lymphoedema created problems with your partner or any of your close friends or relatives?) had to be excluded due to an error in data collection; the maximum possible score for this study is thus 27.

To evaluate discrimination, the discrimination section of the DISC-12 score [173] was used. The 22-question discrimination section of the original DISC-12 was modified as described in a previous Ethiopian study by removing two items considered to not be applicable to the rural Ethiopian setting of the study and two items with low item-factor loading [142]. Thus, in this study, the possible discrimination scores range from 1-56, with higher scores reflecting more discrimination. An outcome to reflect disease-related stigma was adapted from the Internalized Stigma of Mental Illness Inventory (ISMI) scale [174]. The 29-item ISMI score originally developed for mental illness was adapted by experts in lymphoedema to produce an 11-item score relevant to lymphoedema. It is good to note that this score should be interpreted

with caution, as it has not been formally validated. The range of the score possible in this study was 11 (less stigma) – 44 (more stigma). Social support was measured using the Oslo-3 social support scale (Oslo-3) [175]. Total scores from this brief scale range from 3 to 14, with higher scores representing better social support.

For details of the clinical and psychosocial outcome measures, please see the data dictionary (Please see Appendix 7)

6.2.5 Data analysis

In order to account for repeat measurements over time, we used a mixed effects model that incorporated time as a variable in both mixed effect linear regression and mixed effect logistic regression analysis. Mixed effects regression models with a random effect for participant and fixed effect for time-point were used to assess the statistical significance of trends in outcomes before intervention and at three and 12-months after initiation of the intervention. All models were adjusted for participant sex, age, literacy, relative income, marital status and whether participants had children or not. Logistic regression was used for variables with dichotomous outcomes. Linear regression was used for continuous variables, with robust standard errors estimated for non-normally distributed variables.

6.3 RESULTS

6.3.1 Sociodemographic characteristics of participants

A total of 251 people with lower limb disorders caused by podoconiosis, LF and leprosy were enrolled into the study at baseline. The detailed sociodemographic characteristics of study participants have been described in *Chapter four (Table 4.1).* Here I have summarized the main ones.

The mean age of participants was 51.9 years, with an age range of 18-88 years. Female participants accounted for 52.6% of the total (132/251). Most participants lived in rural areas (99.6%; 250/251). Literacy levels were low, with only 37.8% (95/251) able to read or write, and only 5.6% (14/251) reporting to have received any formal education. Most participants

worked in farming (77.3%; 194/251). Relative to others in their community, 15.9% (40/251) rated their income as very low, 42.2% (106/251) as low, 39.4% (99/251) as middle and 2.4% (6/251) as high. All participants identified as Christian. One hundred and seventy (67.7%) were married, and 223 (88.8%) had children.

Participants were followed up at 3-months and 12-months after the start of the intervention. Twenty-six participants (10.4%) were lost to follow-up between baseline and 12-months. No sociodemographic characteristics were significantly associated with loss-to-follow-up.

6.3.2 Clinical characteristics of participants at baseline

Among those enrolled into the study, 98.0% (246/251) had LF or podoconiosis and 2.0% had leprosy. At baseline, only 21 participants (8.4%) reported to have been receiving treatment for their lower limb disorder, and physical characteristics were generally poor (Table 6.1).

Two hundred participants (79.7%) had suffered from an attack of ADLA in the last month. Signs of infection were observed in 13.1% (33/251). Nodules and wounds were observed in 19.5% (49/251) and 2.8% (7/251), respectively. Mean maximum lower limb circumference was 26.8 cm (standard deviation (SD) 4 cm) and mean maximum foot circumference was 27.8 cm (SD 2.9 cm).

Mean lymphoedema by podoconiosis stage was 2.7 (SD 1.5), with stage 2 representing below-knee swelling not reversible overnight with or without nodules below ankle, and stage 3 below-knee swelling not reversible overnight with nodules above ankle [176].

The mean WHODAS-2.0 score, a measure of disability, was high at 29.6 (SD 8.8) [43].

Table 6.1 Clinical characteristics of participants at baseline and after 3- and 12-months of receiving the study care package.

	Baseline N=251	After intervention	
		Three months N=234	Twelve months N=225
Diagnosis, n (%)			
Lymphatic filariasis/podoconiosis	246 (98.0)	231 (98.7)	221 (98.2)
Leprosy	5 (2.0)	3 (1.3)	4 (1.8)
Currently receiving treatment, n (%)	21 (8.4)	234 (100)	225 (100)
Maximum lower limb circumference, mean (SD)	26.8 (4.0)	25.0 (4.0)	24.9 (3.7)
Maximum foot circumference, mean (SD)	27.8 (2.9)	25.7 (2.8)	25.5 (2.6)
Presence of wounds, n (%)	7 (2.8)	5 (2.1)	2 (0.9)
Presence of nodules, n (%)	49 (19.5)	16 (6.8)	3 (1.3)
Signs of infection, n (%)	33 (13.1)	12 (5.1)	4 (1.8)
Lymphoedema stage, mean (SD)	2.7 (1.5)	2.3 (1.4)	2.4 (1.4)
Acute attack of ADLA in last month, n (%)	200 (79.7)	40 (17.1)	17 (7.6)
Number of ADLA attacks in last month, mean (SD)	2.2 (2.5)	0.5 (1.5)	0.1 (0.5)
Disability (WHODAS-2.0), mean (SD)[a]	29.6 (8.8)	19.2 (6.7)	18.8 (6.5)

a. Possible range of disability (WHODAS-2.0) scores: 12-60; higher scores reflect increased disability.
SD: standard deviation; WHODAS-2.0: World Health Organisation Disability Assessment Schedule-2.0; ADLA: acute dermatolymphangioadenitis.

6.3.3 Clinical characteristics of participants after 3- and 12-months of care package intervention

All clinical measures tended to improve 3- and 12-months after initiating the integrated holistic study care package (Table 6.1).

The proportion of participants having an acute attack of ADLA in the last month decreased significantly from 79.7% at baseline, to 17.1% at 3-months and 7.6% at 12-months. In a mixed effects logistic regression model adjusted for sociodemographic characteristics (Table 6.2), the adjusted odds ratio (aOR) for having any ADLA attack in the last month was 0.03 at 3-months (95% confidence interval [CI] 0.01, 0.07; p<0.001) and 0.01 at 12-months (95% CI 0.004, 0.02; p<0.001).

The mean *number* of ADLA attacks in the last month decreased significantly from 2.2 (SD 2.5) at baseline to 0.5 (SD 1.5) at 3-months (mean reduction -1.71, 95% confidence interval [CI] -2.10, -1.33; p<0.001). At 12-months, the mean number of ADLA attacks in the last month was 0.1 (SD 0.5), a mean reduction of -2.12 compared to baseline (95% CI -2.45, -1.79; p<0.001).

Signs of infection were observed in 13.1% of participants at baseline, compared to 5.1% at 3-months, and 1.8% at 12-months. These reductions in infection yielded significant aORs of 0.17 at 3-months (95% CI 0.06, 0.47; p=0.001) and 0.08 at 12-months (95% CI 0.02, 0.27; p<0.001). The proportion of participants with nodules was also significantly reduced across time-points (19.5% at baseline vs. 6.8% at 3-months vs. 1.3% at 12-months; aOR [3-months] 0.13; 95% CI 0.05, 0.39; p<0.001; aOR [12-months] 0.02; 95% CI 0.00, 0.28; p=0.005). Wounds were observed less frequently after the intervention (2.8% at baseline vs. 2.1% at 3-months vs. 0.9% at 12-months), however these changes were *not* statistically significant (aOR [3 months] 1.39; CI 0.19, 10.23; p=0.744; aOR [12-months] 0.16; 95% CI 0.02, 1.79; p=0.138).

Average maximum lower limb and foot circumference were both found to be significantly reduced after both 3- and 12-months of follow-up in an adjusted mixed-effects linear regression model. After 12 months, the adjusted mean reduction in lower limb circumference was 2.0 cm (95% CI 1.8cm, 2.3 cm; p<0.001), and in foot circumference was 2.3 cm (95% CI 2.0 cm, 2.5 cm;

p<0.001). Disease stage also showed a modest but significant reduction after care package implementation (adjusted mean reduction at 12-months 0.3; 95% CI 0.2, 0.4; p<0.001).

Disability (WHODAS 2.0) scores improved from 29.6 at baseline to 19.2 at 3-months and 18.8 at 12-months. The adjusted mean reduction in disability scores at 3-months and 12-months were 10.2 (95% CI 9.0, 11.4; p<0.001) and 11.0 (95% CI 9.9, 12.1; p<0.001), respectively.

Table 6.2 Assessing the impact of the study care package on clinical outcomes after 3- and 12-months.

	After 3-months of intervention			After 12-months of intervention		
Linear regression: continuous outcomes	**Mean difference in outcome compared to baseline**	**95% CI**	**p-value**	**Mean difference in outcome compared to baseline**	**95% CI**	**p-value**
Mean maximum lower limb circumference (cm)	-1.96	-2.29, -1.64	<0.001	-2.02	-2.26, -1.77	<0.001
Mean maximum foot circumference (cm)	-2.21	-2.46, -1.96	<0.001	-2.28	-2.53, -2.04	<0.001
Mean ADLA attacks in last month	-1.71	-2.10, -1.33	<0.001	-2.12	-2.45, -1.79	<0.001
Disease stage	-0.32	-0.43, -0.22	<0.001	-0.27	-0.37, -0.19	<0.001
Disability score (based on WHODAS 2.0)[a]	-10.22	-11.42, -9.02	<0.001	-10.97	-12.08, -9.87	<0.001
Logistic regression: dichotomous outcomes	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**
ADLA attack in last month (yes v. no)	0.03	0.01, 0.07	<0.001	0.01	0.004, 0.02	<0.001
Presence of wounds (yes v. no)	1.39	0.19, 10.23	0.744	0.16	0.02, 1.79	0.138
Presence of nodules (yes v. no)	0.13	0.05, 0.39	<0.001	0.02	0.00, 0.28	0.005
Signs of infection (yes v. no)	0.17	0.06, 0.47	0.001	0.08	0.02, 0.27	<0.001

NB. Mixed-effect linear and logistic regression modelling with random effect for participant and fixed effect for time-point; adjusted for participant age, sex, literacy, marital status, relative income rating, and presence of children.

[a.] Possible range of disability (WHODAS-2.0) scores: 12-60; higher scores reflect increased disability. *OR: odds ratio; CI: confidence interval; ADLA: acute dermatolymphangioadenitis; WHODAS-2.0: World Health Organisation Disability Assessment Schedule-2.0.*

6.3.4 Psychosocial characteristics of participants at baseline

Similar to physical characteristics, psychosocial characteristics of study participants at baseline were generally poor (Table 6.3).

There was evidence that the lower limb disorders the participants suffered from had at least a moderate effect on their quality-of-life at baseline, with a mean adjusted DLQI score of 10.9 (SD 4.5). Further, the majority of patients (86.5%; 217/251) were found to have at least mild depressive symptoms (PHQ-9 score $\geq$5), and a large proportion (47.4%; 119/251) had at least moderate depression. The mean PHQ-9 score at baseline was 10.0 (SD 5.2).

The mean stigma score (adapted ISMI) at baseline was 27.7 (SD 6.8; possible range 11-44; greater scores represent greater stigma). The mean baseline discrimination (adapted DISC-12) score was 7.6 (SD 7.6; possible range 1-56; greater scores represent greater discrimination).

Using the Oslo-3, at baseline the majority of participants were found to have poor social support (65.3%; 164/251). The mean Oslo-3 was 7.2 (SD 2.9), where the possible range is 3-14 and higher scores represent increased social support.

Table 6.3 Psychosocial characteristics of participants at baseline and after 3- and 12-months of receiving the study care package.

	Baseline N=251	After intervention	
		Three months N=234	Twelve months N=225
Quality-of-life score (adjusted DLQI), mean (SD)[a]	10.9 (4.5)	4.0 (4.3)	3.8 (4.1)
Depressive symptom score (PHQ-9), mean (SD)[b]	10.0 (5.2)	5.0 (4.9)	5.1 (4.9)
Presence of at least moderate depressive symptoms (PHQ-9≥10), n %	119 (47.4)	60 (25.6)	37 (16.4)
Disease-related stigma score (adapted ISMI), mean (SD)[c]	27.7 (6.8)	23.9 (8.2)	23.9 (6.4)
Diseased-related discrimination score (adapted DISC-12), mean (SD)[d]	7.6 (7.6)	5.7 (6.6)	4.7 (6.0)
Social support score (Oslo-3), mean (SD)[e]	7.2 (2.9)	7.6 (2.8)	7.8 (2.9)
Social support category (Oslo-3), n %			
Poor (3-8)	164 (65.3)	153 (65.3)	140 (62.2)
Moderate (9-11)	69 (27.5)	59 (25.2)	55 (24.4)
Strong (12-14)	18 (7.2)	22 (0.9)	31 (13.2)

a. Higher scores reflect worse quality-of-life; possible range 0-27. b. Higher scores reflect a higher frequency of depressive symptoms; possible range 0-27. c. Higher scores reflect increased experience of stigma; possible range 11-44. d. Higher scores reflect increased experience of discrimination; possible range 1-56. e. Higher scores reflect increased social support; possible range 3-14. *SD: standard deviation; DLQI: Dermatology Life Quality Index; PHQ-9: Patient Health Questionnaire-9; ISMI: internalised stigma related to mental illness; DISC-12: discrimination score-12; Oslo-3: Oslo social support score*

6.3.5 Psychosocial characteristics of participants after 3- and 12-months of care package intervention

Psychosocial outcomes were reassessed at three and 12-months after initiation of the integrated holistic care package. As for clinical characteristics, there was a trend towards improvement in all outcomes (Table 6.3).

Quality-of-life (adjusted DLQI) scores improved from 10.9 at baseline to 4.0 at 3-months and 3.8 at 12-months. In an adjusted mixed effects linear regression model (Table 6.4), the mean improvement in quality-of-life score after 3-months was 6.9 (95% CI 6.2, 7.6; p<0.001), and after 12-months was 7.2 (95% CI 6.5, 7.9; p<0.001).

Depressive symptom (PHQ-9) scores were also found to be significantly improved. The prevalence of depression (PHQ-9 cut off point of 10) was reduced from 47. 4% at baseline, to 25.6% at three months, and then to 16.4% at 12-month post initiation of the intervention. In an adjusted mixed effects linear regression model (Table 6.4), the mean improvement as measured by mean PHQ-9, from baseline to 3-months scores decreased by an adjusted mean of 5.0 (95% CI 4.1, 5.8; p<0.001) and from baseline to 12-months by 5.1 (95% CI 4.3, 5.9; p<0.001).

Levels of self-reported stigma faced by participants decreased, with stigma scores (adapted ISMI) falling significantly by a mean of 3.8 (95% CI 2.6, 5.0; p<0.001) between baseline and 3-months and by 3.9 (95% CI 2.9, 4.9; p<0.001) between baseline and 12-months.

Discrimination scores (adapted DISC-12) similarly decreased significantly from 7.6 at baseline to 5.7 at 3-months and 4.7 at 12-months. The mean improvement in score after 12-months of the care package was 3.2 (95% CI 2.1, 4.3; p<0.001).

Social support scores (Oslo-3) were 7.2 at baseline, 7.6 at 3-months, and 7.8 at 12-months. Although there was a modest trend to improvement at 3-months, this was *not* statistically significant at this time-point (adjusted mean 0.4; 95% CI -0.1, 0.8; p=0.11). From baseline to 12-months, however, the trend gained significance (adjusted mean 0.6; 95% CI 0.2, 1.0; p=0.00).

Table 6.4 Assessing the impact of the study care package on psychosocial outcomes after 3- and 12-months.

	After 3-months of intervention			After 12-months of intervention		
	Mean difference in score compared to baseline	**95% CI**	**p-value**	**Mean difference in score compared to baseline**	**95% CI**	**p-value**
Quality-of-life score (adjusted DLQI)	-6.93	-7.64, -6.22	<0.001	-7.18	-7.88, -6.48	<0.001
Depressive symptom score (PHQ-9)	-4.96	-5.78, -4.14	<0.001	-5.06	-5.85, -4.26	<0.001
Disease-related stigma score (adapted ISMI)	-3.79	-4.99, -2.59	<0.001	-3.87	-4.86, -2.87	<0.001
Disease-related discrimination score (adapted DISC-12)	-2.22	-3.42, -1.04	<0.001	-3.22	-4.31, -2.12	<0.001
Social support score (Oslo-3)	0.36	-0.08, 0.80	0.106	0.61	0.18, 1.03	0.005

NB. Mixed-effect logistic regression modelling with random effect for participant and fixed effect for time-point; adjusted for participant age, sex, literacy, marital status, relative income rating, and presence of children.

CI: confidence interval; DLQI: Dermatology Life Quality Index; PHQ-9: Patient Health Questionnaire-9; ISMI: internalised stigma related to mental illness; DISC-12: discrimination score-12; Oslo-3: Oslo social support scale-3.

6.4 Discussion

6.4.1 Overview of findings

In this study we found that the EnDPoINT integrated holistic care package was associated with significant improvements in most of the physical (clinical) and psychosocial outcomes for people with lymphoedema caused by podoconiosis, LF, and leprosy in Awi zone, north-western Ethiopia.

There was a profound improvement in lymphoedema after both three and 12-months post initiation of the EnDPoINT integrated holistic care package. There were significant reductions in lower limb (leg) and foot size, frequency of attacks of ADLA, the presence of nodules, signs of infection, lymphoedema stage and overall level of disability. Wounds were also less frequent after the intervention, although this reduction was not statistically significant. Overall, physical benefits of the training in self-care to promote foot hygiene over the 12-month period were comparable to those reported in similar studies over similar timeframes [163, 167]. Similarly, there was a significant improvement in psychosocial outcomes as described below, subsequent to the description of the specific physical outcomes.

6.4.2 Findings related to physical outcomes

There was a modest but significant improvement in lymphoedema stage at both three and 12-month post intervention as compared to baseline (from mean stage of 2.7 at baseline to 2.4 at 12-month follow up; $p<0.001$). Another study in southern Ethiopia showed a significant mean reduction in stage of the disease from 2.1 at baseline to 1.4 at 12-month post initiation of treatment [28]. Similar findings were also reported in a study conducted in India where a community-based lymphoedema management programme resulted in a significant improvement in lymphoedema stage post intervention as compared to baseline [177]. The same holds true for a study conducted

in Bangladesh where hygiene based lymphoedema resulted in a significant improvement in lymphoedema stage [178].

In our study, we also found a significant decrement (improvement) in lower limb circumference (both for leg and foot) at both three- and 12-month post intervention as compared to baseline. The leg circumference was reduced from 26.8 cm at baseline to 24.9 cm at 12-month post initiation of intervention ($p<0.001$). Moreover, the foot circumference was reduced from 27.8 cm at baseline to 25.5 cm at 12-month post initiation of intervention ($p<0.001$). Another study in southern Ethiopia showed a comparable mean reduction in lower limb circumference from 26.2 cm at baseline to 24.2 cm at 12 month post-initiation of treatment [28]. Similar findings were reported in a study conducted among lymphoedema cases in Bangladesh in which there was a significant but modest reduction in limb circumference post initiation of intervention [178].

We also observed a significant improvement in ADLA at both three and 12-months post initiation of the integrated holistic care intervention. We found a substantial improvement in frequency of ADLA (from 2.2 episodes at baseline to 0.1 episodes at 12-months post initiation of the intervention, $p<0.001$). A significant reduction in ADLA was also reported post hygiene-based lymphoedema care in a previous randomized controlled trial (RCT) among podoconiosis-affected individuals in Ethiopia [26], as well as in an observational (cohort) study among LF lymphoedema cases in Haiti [179]. In the earlier study from Ethiopia, the efficacy of the intervention in reducing episodes of ADLA was better in men than women, whereas in our study there was no significant difference between the two genders. In the latter scenario of LF-related lymphoedema in Haiti, ADLA incidence was 1.56 episodes per person-year at the time when applying compression bandage was a routine practice. However, when hygiene and skin care were systematically emphasized and bandaging discouraged, ADLA incidence decreased to 0.48 episodes per person year ($p<0.0001$) [179]. Similarly, in India, community-based basic lymphoedema management resulted in a 35% lower rate of ADLA episodes post-intervention compared to baseline [177]. A significant reduction in frequency (and duration) of acute attacks following a community-based hygiene-based lymphoedema programme was also reported from Bangladesh [178]. A systematic review and meta-analysis on hygiene-based lymphoedema management in LF-related lymphoedema resulted in a significant reduction of ADLA as well. Following the meta-analysis, it

was suggested that simple basic lymphoedema care could result in a reduction of about 14 million episodes of ADLA annually [180].

Although it is challenging to compare, the impact of the EnDPoINT intervention on the frequency of ADLA attacks appears greater than that reported in the RCT conducted in a similar Ethiopian setting [26]. This randomized controlled trial (GoLBeT trial), by using simple community-based hygiene-based lymphoedema management as intervention in eastern Gojjam-Ethiopia, aimed to assess the impact of a foot care package in people with podoconiosis. The study found that ADLA incidence was approximately 20% lower in the intervention arm compared to the control arm. In comparison, mean ADLA episodes self-reported in the last month in this study improved from 2.2 at baseline to 0.1 at follow-up, an approximately 95% decrease.

The apparent differences in effect size on ADLA frequency may be due to several factors. First, as previously discussed, this study was non-randomised, so it is possible there may be other factors that have affected ADLA frequency outside of the intervention itself. Second, the patient cohorts in the two studies were different, as GoLBeT only recruited people with at least stage two podoconiosis, whereas this study recruited those with podoconiosis, LF and leprosy of any disease stage. Third, the way ADLA frequency was measured differed. GoLBeT gave patients diaries to record ADLA episodes and reviewed these quarterly, whereas EnDPoINT relied on patients to recall the number of ADLA episodes they had had in the last month. Finally, it may be that the difference in effect size is a result of the EnDPoINT intervention truly being more effective in reducing ADLA incidence. Whilst the care packages for promoting foot hygiene are similar, it is plausible that addressing the *psychosocial* needs of people with the diseases could have resulted in improved self-motivation and social support for performing daily self-care. This will be an important area for future research, including qualitative studies to understand the potential impact of improved mental health on lower limb care.

In our study, we found a significant improvement in perceived disability status both at three month and 12-month post initiation of the integrated holistic care intervention. The disability score was profoundly improved from the baseline level of 29.6 to 18.812 month post initiation of intervention. Similar results were reported in a study conducted in India where there was a significant reduction in disability scores from baseline to 24 months following simple hygiene-based lymphoedema care [181]. In our study the mean number working days lost due to disability

was reduced from 6.3 days at baseline to 2.3 days at 12 months post initiation of the integrated intervention. Similar to our results, in the study conducted in India, at 12-month post-intervention lymphoedema-affected persons lost 2.5 fewer work days per month as compared to baseline [181].

In contrast to our study, in the GoLBeT trial there was no statistically significant difference in the disability score between the immediate treatment group and control group [182]. This difference might be due to the baseline disease stage of affected individuals. In GoLBeT, podoconiosis-affected individuals with disease stage two and above was the inclusion criteria, whereas in our study (EnDPoINT) individuals affected by podoconiosis, LF or leprosy with any stage of disease was the criteria for enrolment in the study. The other possible explanation could be that in EnDPoINT the intervention was at four different levels of care: patient, community, health facility and health care organisation. Finally, the inclusion of psychosocial interventions in the EnDPoINT care package may have contributed to adherence to foot care, reduction of lymphoedema, and then reduction of disability.

6.4.3 Findings related to psychosocial outcomes

The psychosocial benefits of the EnDPoINT integrated holistic care package included a significant improvement in quality-of-life, reduced levels of depression, and reduced experiences of stigma and discrimination. After 12-months, a modest but significant increase in social support was also noted. However, three-month post-intervention there was no statistically significant change in social support; this is not surprising given that a substantial change in social support would not be expected in such a short period of time due to its complex nature. The regular self-help group and Community Conversation meetings could contribute to increasing social support in the long term, as shown as a modest increase in social support after the 12-month post-initiation of the integrated care package.

We found a significant improvement in quality of life at both three and 12-months post initiation of the integrated holistic care package. At 12-months post-initiation of the intervention, the mean DLQI value was markedly improved (from a baseline value of 10.9 to 3.8 post intervention). Similar results have been reported in a previous study conducted in southern Ethiopia

in which the mean DLQI value was reduced (i.e. quality of life improved) from 21.1 at baseline to 6.1 at 12 months post-intervention [28]. For nearly 96% of patients there was a change of 10 DLQI points or more [28]. In the aforementioned GoLBeT trial, just by using simple community-based hygiene-based lymphoedema management as intervention, the mean quality of life was better in the immediate treatment group (mean DLQI of 9.1) as compared to controls or the delayed treatment group (mean DLQI of 11.2) [182]. A hygiene and skin care regimen for lymphoedema cases in Guyana in South America also resulted in a significant improvement in quality of life; the mean improvement 12 months post-intervention was 6.8 points [147]. Thus, from these studies we can propose that a hygiene and skin care-based lymphoedema management program in the primary care unit improves the quality of life of affected individuals.

There are a number of reasons why the EnDPoINT intervention resulted in improved quality of life (as measured by the DLQI). Firstly, the reduced clinical severity of the disease condition (in particular a reduction in acute attacks and swelling size), leading to an increased ability to work and perform daily routines. Secondly, the empowerment associated with a proper understanding of the disease condition and the ability to manage it individually with home care activities. Finally, the networks that were formed through the established self-help groups and Community Conversations had their own encouraging impacts in improving quality of life.

There was a significant reduction in stigma and discrimination both at three and 12-months post-initiation of the integrated holistic care package intervention. The internalized stigma as measure by ISRL score was significantly improved (from mean value of 27.7 at baseline to 23.9 at 12-month post initiation of the integrated care package). In addition, discrimination as measured by mean DISC score was significantly improved (from 7.6 at baseline to 4.7 at 12-months-post initiation of treatment).

Although we are not aware of any study that has examined a hygiene and skin care-based lymphoedema care package's impact on stigma and discrimination, several authors have reported the association between stigma and discrimination and NTDs. Two studies conducted in Ethiopia, one in the South and another in the North, showed a significant association between podoconiosis and stigma [57, 183]. Elsewhere, in the Dominican Republic, Ghana, Togo and India, studies have reported a significant association between LF-related lymphoedema and stigma [184-186]. A systematic review assessing the links between stigma and NTDs including podoconiosis, LF, Buruli

ulcer, onchocerciasis, schistosomiasis, leishmaniasis, Chagas disease, trachoma, soil-transmitted helminthiasis (STH) and human African trypanosomiasis also showed a significant association between the reviewed NTDs and stigma [58]. The association between leprosy and stigma has, for example, been reported in a cross-sectional study conducted in Indonesia and in another review article [187, 188].

We observed a significant improvement in depressive symptoms at both three and 12-months post initiation of the integrated holistic care package. The prevalence of depression (PHQ-9 cut-off score of 10) was reduced from 47.4% at baseline to 16.4% at 12-month post-initiation of the intervention. Depressive symptoms were profoundly improved 12 months post intervention, as measured by mean PHQ-9 score. The PHQ-9 score was reduced (i.e. depressive symptoms were improved) to 5.1 from the baseline value of 10.0. To our knowledge, there is only one study which has examined the impact of a hygiene and skin care-based NTD-related lymphoedema intervention on depressive symptoms, though there are abundant articles determining the impact of NTD on depression and other mental health outcomes, including mental distress. According to a systematic review, in Togo, implementation of a national lymphoedema management program resulted in a significant reduction in depression [180]. In studies conducted in various countries, a high burden of depression was reported among study participants affected by one of the three NTDs that were included in our research. Among podoconiosis patients, prevalence for depression has been reported to be in the range of 12.6% to 68.5% [5, 6, 9, 146]. For LF, a qualitative study in South India resulted in 97% of the interviewed patients reporting depression or a feeling of inferiority. They had a tendency to compare themselves with their healthy counterparts which lead to sadness [189]. Similarly, in Togo, LF patients had about a 70% risk of depression when rated on the Duke Anxiety–Depression scale (DUKE-AD score >30) [185]. Among various leprosy affected populations, the prevalence of depression or mental disorders has been reported to be between 12.5% and 76%, despite the use of different study tools to measure depression in the various reviewed studies [53].

The suicidal ideation rate among our study participants was very high at baseline. There was improvement in prevalence of suicidal thought/ideation from 12.4% at baseline to 7.9% 12-months post initiation of the intervention. Similarly, suicidal planning was reduced from 9.2% at baseline to 3.1% at 12-months post initiation of the intervention. Interestingly, suicidal attempts

were reduced from 7.6% at baseline to 0% (nil) at 12-months post-initiation of the intervention. An association between various NTDs and suicidal ideation, suicidal planning, and suicidal attempts has been reported in an earlier systematic review [53]. Further, in a study conducted in Ethiopia, the risk of suicide was 5.2% among study participants having podoconiosis as compared to 0.4% among healthy neighbours [5]. Suicidal ideation was also reported by LF-affected individuals in qualitative studies conducted in Siri Lanka and India [190, 191]. In Japan, 41 leprosy-affected individuals had committed suicide since a leprosarium was established [192]. Similarly suicidal ideation has been reported in 18% of leprosy-affected study participants in a study conducted in central Ethiopia [193].

Interestingly, most of the improvements in psychosocial outcomes were observed between baseline and 3-months, and there was limited further improvement between three and 12-months post initiation of the holistic integrated care package. These results suggest that even over a short period of time, substantial improvements can be made in mental wellbeing. The positive impact on psychosocial outcomes associated with the EnDPoINT care package is likely to have resulted both directly from the components of the interventions designed to address low mood and reduce community-level stigma and discrimination, and indirectly through improvements in clinical disease that result from improved foot care.

As this study was not randomised, any significant trends seen over the study timeframe can only ever be *assumed* to be a result of the intervention itself. However, theoretical plausibility and previous literature support a causal link between the EnDPoINT care package and the improvements in physical and psychosocial outcomes [26, 162-166]. Physical benefits are presumed to result from improved health education, daily lower limb self-care and provision of a simple supply package (see Figure 6.1). The positive impact on psychosocial outcomes is proposed to stem both directly from the components of the intervention designed to address low mood and reduce community-level stigma, and indirectly through improvements in clinical disease and disability (see Figure 6.1).

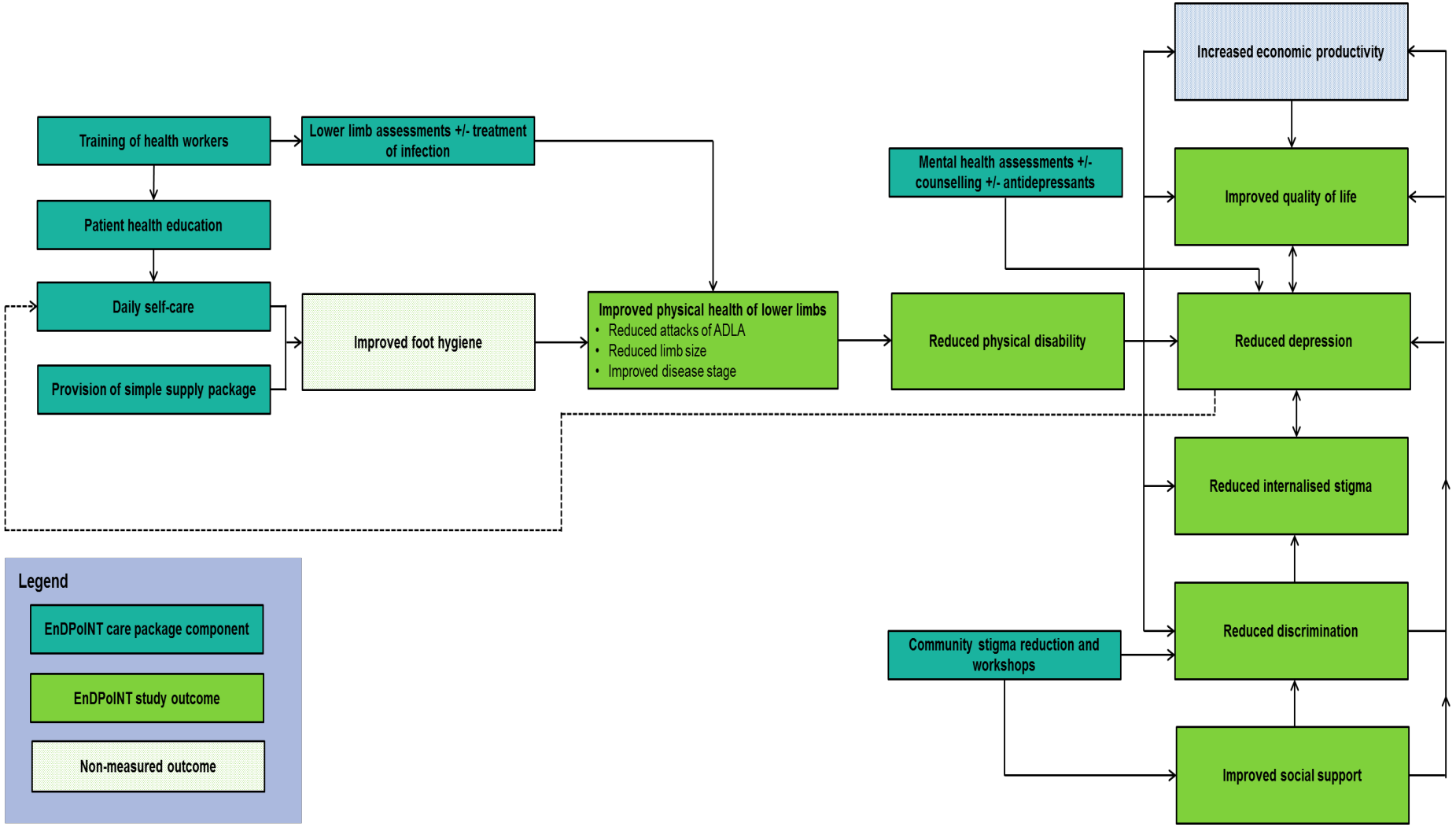


Figure 6.1 Theoretical framework for understanding the impact of the various components of the EnDPoINT intervention on study outcomes

6.4.4 Limitations of the study

We expected a reasonable number of leprosy cases, as the site is co-endemic for the three NTDs namely podoconiosis, LF, and leprosy. However, the number of leprosy cases at enrolment was only five. This may be because leprosy is at the elimination stage in Ethiopia and thus the number of leprosy cases may be low in the study district . Another reason might be that leprosy patients may not be willing to be managed together with LF and podoconiosis patients**,** as in the qualitative study we observed that leprosy patients do stigmatize podo-LF patients and vice-versa . Our results may not be as generalisable/applicable to leprosy patients as to LF and podoconiosis patients. And that it would be good to explore the reasons for the low numbers of leprosy patients in future research.

Another limitation of this study is that it was not randomised. Therefore, although strong theoretical plausibility and previous literature support a causal link [26, 162-166], any significant trends seen over the timeframe can only be *assumed* to be a result of the intervention itself. A further limitation of the study is that many of the psychosocial outcomes were assessed by scoring scales. Whilst these scales are mostly well established and validated, they are unlikely to capture the full complexity of the outcomes they aim to measure. Further qualitative work will be needed to better understand the effects of the intervention on these measures.

Aside from the clinical examination of lymphoedema status, all results were based on interviewing individuals affected by one of the three stated NTDs. In addition, results involving the one-month frequency of ADLA episodes may be subject to recall bias. Another limitation of this study is the lack of a control group, i.e. a subset of comparable patients who did not receive an integrated holistic care intervention. We did not include a control population in this study as it would be unethical to withhold knowledge of lymphoedema management techniques from patients with lymphoedema, as is recommended by WHO in all endemic countries. To evaluate the effectiveness of the intervention over time, we considered the baseline assessments before the intervention was initiated as the comparison group.

6.4.5 Conclusion

Despite the above limitations, in conclusion, this study provides convincing evidence that the EnDPoINT care package is effective in improving the clinical and psychosocial health of people living with podoconiosis, LF or leprosy in north-western Ethiopia. This simple integrated approach is feasible even in remote rural areas, and appears ideal for scaling up to other endemic regions in Ethiopia and internationally. The results of the evaluation of the care package across three more districts in north-western part of Ethiopia in Phase III of the EnDPoINT project are eagerly awaited to provide important further information on the cost-effectiveness and scalability of integrated MMDP and psychosocial care services in Ethiopia.

CHAPTER SEVEN

Discussion and Conclusion

7.1 Overview.

In this chapter, I provide an overview of the chapter, principal findings of my PhD study, limitations of the study, strengths of the study, future directions, and the overall conclusions of the study.

The three NTDs addressed in this study, namely: podoconiosis, LF, and leprosy, are diseases of poverty which are significantly associated with high levels of disability, and psychosocial and mental health impairments. These associations have been reported in diverse studies from endemic countries in Africa, Asia and South America. After a systematic review linking disability, psychosocial and mental health status with podoconiosis, LF and leprosy, the project focussed on two important outcomes: a/ clinical (physical) outcomes of affected persons after implementation of the integrated holistic care package. b/ the psychosocial and mental health outcomes of affected persons after implementation of the integrated holistic care package. The factors associated with clinical and psychosocial-mental health outcomes were also determined.

7.2 Principal findings

7.2.1 Findings of systematic review and baseline assessment

The first chapter provided background information for the study, whereas the second chapter described a systematic review of the disability and psychosocial impacts of podoconiosis, LF, and leprosy. The findings of the systematic review are briefly summarised here. Among the reviewed articles, 14 revealed an association of these NTDs with disability [82, 94-103, 107, 109, 110], and ten studies revealed an association between the reviewed NTDs and psychosocial and mental health impairments [6, 89-91, 103-107, 111].

Widely ranging prevalence of leprosy grade II disability was reported (ranging from 4 to 86%). Factors contributing to this wide range include different health systems approaches, for example a horizontal disease control program with active case finding and an integrated

intervention, versus the less effective vertical program [100] [95] [98]. Disability secondary to leprosy results in a loss of nearly one-third of economically productive years [82]. There is a significant association between leprosy and activity limitation [94, 97, 99, 101, 102]. Stigma and discrimination are associated with limited social participation [99, 101], and high degrees of disability are associated with high risk of depression [89] and mental distress [103]. Additionally, all reviewed NTDs are significantly associated with compromised quality of life [97, 106, 108].

Although several mental disorders, ranging from mild panic disorders to generalized anxiety and major depressive disorders, are associated with NTDs, the most commonly reported was depression [6, 89, 91, 105, 107, 111], and then mental distress [90, 91, 103, 105]. In addition, suicide ideation and attempts were significantly higher in study participants with podoconiosis and leprosy as compared to their healthy fellow citizens [107, 194]. This clearly suggests the relevance of proper mental health assessment and provision of appropriate mental health interventions to people affected by these three NTDs [111].

The third chapter dealt with details of the assessment tools, and qualitative and quantitative methodologies. The fourth chapter dealt with the baseline assessment of depression and quality of life and the factors associated with these outcome variables. Cross-sectional assessment of the baseline data revealed high levels of depression and reduced quality of life (QOL) among study participants with lymphoedema associated with LF, podoconiosis or leprosy. Nearly 47% of our study participants reported symptoms of moderate to severe depression. This ties in with previous studies that also found high prevalence of depression, ranging between 12.6% and 68.5% [5, 146] [89, 105]. The factors that contribute to high prevalence of depression could be poor socio-economic status, as well as stigma and discrimination due to disfigurement and subsequent disability. Among the explanatory variables studied here, only disability was significantly associated with depression. Similar findings have been reported among podoconiosis cases in Ethiopia [5], and leprosy cases in Bangladesh [89].

QOL was severely affected in about half of the study participants. This was in line with previously conducted studies in which QOL was reduced among patients with lymphoedema due to podoconiosis [108], LF [147], and leprosy [106]. Quality of life improved when a participant was on treatment, when they had good social support, and when the disability score

was lower. The implication is that early diagnosis and treatment of lymphoedema is vital for improvement of QOL.

7.2.2 Evaluation of the intervention by qualitative methods

The fifth chapter described the qualitative assessment of the EnDPoINT intervention, which involved FGDs and KIIs. The main findings of the qualitative study were as follows. We noticed misconceptions around the cause, prevention, and therapeutic modalities of lymphoedema due to podoconiosis, LF, and leprosy. Some patients and community members believed that podoconiosis was caused by a curse and the majority did not know that it was caused by long term exposure to irritant red clay soil. There is evidence that podoconiosis is caused by this environmental exposure and genetic predisposition [17, 18]. LF is caused by the parasites *Wuchereria bancrofti* and *Brugia spp* and transmitted by mosquitos, whereas leprosy is caused by a bacterium, *Mycobacterium leprae*.

According to the qualitative study, following the integrated holistic care package, there was profound improvement in awareness about the causes, treatment and prevention of lymphoedema**.** In addition to this, there was an improvement in lymphoedema condition of affected persons, and reduction in stigma and discrimination. The establishment of a peer support group may have contributed to the increased information dissemination and adherence to self-care. Our findings are supported by those of studies conducted in similar settings, where integrated NTD care resulted in reduction of morbidity [69, 71] and reduction of disease burden [69, 70].

The integrated holistic care package was found to be acceptable by patients, health professionals, and decision makers. At the same time, they recommended scaling up of integrated care to other endemic districts in Awi zone. Some of them even expected the Ministry of Health to scale it up nationwide.

Despite the acceptability and perception of scalability, there were barriers to implementation. Some of the lymphoedema-affected individuals had poor transportation access to the health centre where the integrated care was provided. Moreover, among health workers there was a tendency to push lymphoedema care towards the TOT trained professionals. These

barriers might be tackled by cascading the training to most health professionals, and further decentralisation of the service to more accessible health posts.

The integrated holistic care package was considered to be potentially sustainable. Factors contributing to sustainability included cascading the TOT provided to healthcare workers to newly recruited health professionals. Another factor was integration of foot care into the existing Health Extension Program, which is one of the most sustainable programs of the Ethiopian government. The awareness created through health education, and the health promotion activities at the community level also contributed to the sustainability of the care package.

During the qualitative study, we observed that persons affected by podoconiosis and LF lymphoedema had stigmatizing attitudes towards persons affected by leprosy and vice versa. Thus, we need to work further on stigma reduction activities through self-help or peer support groups and community conversation to alleviate such issues for better integration of podoconiosis- LF care with leprosy care. This should also be explored in further detail in future research.

7.2.2 Evaluation of the intervention by quantitative methods

The sixth chapter examined the impact of the EnDPoINT intervention using quantitative methods in the form of a non-comparative cohort study. The integrated holistic care intervention resulted in a significant improvement in both physical and psychosocial outcomes for people with lymphoedema caused by podoconiosis, LF, or leprosy in Awi zone, north-western Ethiopia. The improvement was profound at both three and 12-months post initiation of the integrated holistic care intervention. Concerning the details, the integrated intervention resulted in significant improvement in physical outcomes including: reduction in lower limb (leg and foot) size, reduction in signs of infection, reduction in frequency of acute attacks, reduction in lymphoedema stage, and reduction in overall level of disability. The presence of wounds also declined though the improvement was not statistically significant. Similarly, there was a significant improvement in psychosocial and mental health outcomes. There was a significant improvement in the following psychosocial and mental health outcomes: improvement in quality-of-life, reduction in levels of depression, and reduction of experiences of stigma and discrimination. The physical benefits and the improvement in quality

of life are similar to studies previously conducted in similar settings and over similar time frames [163, 167].

One of the most relevant parameters by which to assess the impact of NTD related lymphoedema intervention is frequency of ADLA. In our study, the mean number of ADLA episodes in the last month was significantly reduced from 2.2 episodes at baseline to 0.1 episodes at 12-months post initiation ($p<0.001$). Following the lymphoedema intervention, similar results (reduction in ADLA episodes) were reported in the earlier GoLBeT randomized clinical trial (RCT) [26] and an observational cohort study [179]. Other community-based lymphoedema management packages in south-east Asia resulted in significant reduction of ADLA frequency [177] [178]. This evidence has been summarised in a systematic review and meta-analysis of the effect of hygiene-based care in LF-related lymphoedema which documented a significant reduction of ADLA (68% reduction) [180].

There was an apparent difference in effect size in ADLA episode between our study and the GoLBeT RCT. The potential reason for this has been explained in detail in *Chapter six.* We assume the main difference between the EnDPoINT and GoLBeT findings lies in the integration of psychosocial care with limb care in EnDPoINT, which presumably resulted in increased self-motivation for continued foot care which directly resulted in reduction of ADLA. The role of psychosocial and mental health care for proper lower limb care is a future area for research, including qualitative studies.

In addition to the significant improvement in limb size, significant reduction in presence of infection and lymphoedema stage, there was a significant improvement in perceived disability. The disability score as measured by the WHODAS was reduced from the baseline level of 29.6 to a 12-month level of 18.8 ($p< 0.001$). The mean number of working days lost due to disability was reduced from 6.3 days at baseline to 2.3 days at 12 months. Improvement of disability has also been reported in a study conducted in India, where the impact of the hygiene-based lymphoedema package was assessed 24 months post intervention and the improvement was statistically significant ($p<0.0001$) [181]. In this Indian study, after 12 months of intervention, the lymphoedema-affected persons lost 2.5 fewer work days as compared to the baseline ($p <0.001$) [181]. However, in contrast to our study, in the GoLBeT trial there was no statistically significant difference in disability between study and control groups [182]. The possible explanation for the varied results between the GoLBeT and EnDPoINT studies has been explained in *Chapter six*.

In our study, post integrated holistic care intervention there was a significant improvement in quality of life, from a DLQI score of 10.9 at baseline to 3.8 after 12 months ($p<0.001$). Improvement in quality of life following a community-based hygiene and skin care intervention for lymphoedema has been reported in other studies conducted in Ethiopia and South America [182] [147] [28]. The improvement in quality of life can be related to improvement of physical outcomes such as decreased limb circumference, reduced infection, reduction of acute attacks, and improvement of disability. Also, indirectly, the increase in quality of life could have resulted from continued community conversation, peer support group (self-help group) discussion, and community awareness raising activities which resulted in alleviation of stigma and discrimination.

At baseline the prevalence of depression was very high (47.4%). Similarly, high burden of depression has been reported among podoconiosis [146], LF [185], and leprosy cases [53] in studies conducted in Rwanda, Togo, and Nigeria respectively. In our study, there was a significant improvement in depressive symptoms, the prevalence of depression being reduced from 47.4% at baseline to 16.4% at 12-months. The mean PHQ-9 score was also reduced (improved) significantly following the integrated holistic care package ($p< 0.001$). Similarly, in Togo a significant improvement in depressive symptoms following instigation of a national community-based lymphoedema management program was reported [180].

The improvement in depression might be explained indirectly by the notified improvement in physical or clinical outcomes. It might also be due to community- and patient-level interventions (through community conversation and self-help groups) by reduction in internalized stigma and enacted stigma and/or discrimination. In addition, direct impact may have been due to the health facility level psychosocial and mental health interventions.

As I was brought up and completed primary-secondary school in endemic districts, I have similar concern and views as that of the affected community. I was expecting a significant improvement in some of the outcome variables and no significant improvement in some other variables. However, there was a statistically significant improvement in almost all outcome variables. The only variable which did not show a statistically significant improvement was presence of wounds. There was an improvement, but it was not statistically significant; this may be because at baseline there was a low number of lymphoedema cases with presence of

wounds. What especially impressed me a lot is an improvement in psychosocial outcomes including stigma-discrimination and quality of life in such a short period of time.

Generalizability of the findings depend on the Phase III part of the EnDPoINT study. In Phase III we are determining the scalability and cost-effectiveness of the care package in addition to determining the effectiveness of the intervention. In Phase II, which involved my PhD work, we witnessed improvements in both the effectiveness of the intervention and in implementation outcomes. Both the qualitative and the quantitative studies showed improvements in outcome measures. There was improvement in both clinical/physical and psychosocial-mental health outcomes. The care package was found to be acceptable, and potentially scalable and sustainable. Following the Phase III part of the EnPoINT study in three districts, we expect its scalability to other endemic districts in Ethiopia and elsewhere.

The theory which developed from this study is the role of psycho-social care in proper foot care and reduction of lower limb lymphoedema morbidity. We developed this, as we witnessed more significant improvements in lymphoedema related complications when psychosocial care was integrated with limb care as compared to studies that only implemented limb care. Future studies should work on the role of psychosocial-mental health care on proper lower limb care. To understand the complex nature of this, qualitative study designs should be part of the research.

7.3 Limitations of the studies

The limitations of each study have been described in respective chapters. The relatively low number of leprosy cases in the cohort is a concern. This may limit the generalizability to leprosy affected individuals as compared to persons affected by podoconiosis and LF. The potential reasons for low number of leprosy cases in the study district has been described in *Chapter six*. Future studies should address the reason for low number of leprosy cases.

The major limitation is the lack of control groups. The justification behind this is that it would be unethical to withhold treatment in confirmed cases. The other justification is that there is no alternative treatment for lymphoedema due to the stated NTDs. We considered

baseline data as the comparison and compared the baseline data with post intervention data. Another limitation is that using recollected frequency of ADLA over the last month may have resulted in recall bias. Finally, most of the psychosocial and mental health outcomes were measured by scoring scales. Despite the tools being well established and validated, their use might limit assessment of the full complexity of mental health outcomes.

7.4 Strengths of the study

This study had several strengths, including that it was the first to assess -

a. Integration of leprosy foot care with podoconiosis-LF lymphoedema care

b. Integration of physical limb care (MMDP) with psychosocial and mental health care

c. Integration of podoconiosis-LF-leprosy holistic care into the routine primary health care (PHC) activities.

We also used a multicomponent approach in developing the care package: review of grey literature, systematic literature review, document review, qualitative study, Theory of Change workshops (with input from experts in NTDs, mental health experts, public health professionals, FMOH NTD officers, zonal/regional/district health officers/ NTD focal person, community representatives, NGOs working on NTDs). The input from all these stakeholders was used in the development of the integrated holistic care package.

One further strength is that we used validated tools, and electronic data collection techniques which helped us in daily validation of the correctness of the data.

7.5 Future directions

Scale up of the EnDPoINT care package is being conducted in three districts in Awi zone in Ethiopia and we are awaiting the scalability, sustainability, and cost-effectiveness outcomes of the care package. One of the next priorities is to present the results of the

EnDPoINT project to the Ministry of Health, WHO and other stakeholders who are working on NTDs.

Training of primary health care unit health workers on lymphoedema MMDP and common mental disorders should be emphasised. In LMICs there is shortage of mental health professionals, thus task shifting to BSc nurses and health officers is recommended. Training of health professionals on common mental disorders as recommended by WHO using the mhGAP intervention guide is highly relevant. In addition to the theoretical part, there should be a practical attachment in hospitals with mental health specialists. Mental health professionals should routinely supervise and mentor health professionals working in PHC. For proper management of lymphoedema and co-morbid mental disorders we need to ensure the availability of supplies and essential medicines at the PHC level.

Following the Phase III part of EnDPoINT, we expect to recommend integration of lymphoedema services into PHC, and expansion of basic mental health services to other PHC services in Ethiopia. Moreover, we hope that lymphoedema care and mental health care services will be integrated and provided in other endemic countries at PHC level. Potential pilot studies need to be conducted in other endemic countries in order to get inputs for proper scaling up of MMDP, and psychosocial and mental health care in PHC units.

In the future, following the determination of its scalability and cost-effectiveness in a larger number of endemic districts (EnDPoINT Phase III), it would be good to consider conducting research on integration of additional skin-related NTDs like leishmaniasis, onchocerciasis and scabies. This recommendation is in line with the WHO 2021-2030 NTD Roadmap.

7.6 Conclusion

Lymphoedema due to NTDs results in disability, as well as poor psychosocial and mental health outcomes. Both the qualitative and the quantitative studies provide convincing evidence that the EnDPoINT care package is effective in improving the clinical and psychosocial and mental health outcomes of people living with podoconiosis, LF, and leprosy in north-western Ethiopia. Thus, integration of lymphoedema care with mental health care is

recommended. The MMDP and psychosocial and mental health care should be delivered at primary health care unit level in endemic districts.

The findings of our study led to Phase III of the EnDPoINT project, in which the simple integrated holistic care package was scaled up into three more districts in north-western Ethiopia. Following the scale up and cost-effectiveness assessment part of the Phase III study, we expect that integrated MMDP and psychosocial and mental health care could be implemented in other endemic districts in Ethiopia and internationally.

REFERENCES

1. Hotez PJ, Molyneux DH, Fenwick A, Kumaresan J, Sachs SE, Sachs JD, et al. Control of neglected tropical diseases. New England Journal of Medicine. 2007;357(10):1018-27.
2. Liese B, Rosenberg M, Schratz A. Programmes, partnerships, and governance for elimination and control of neglected tropical diseases. The Lancet. 2010;375(9708):67-76.
3. Molyneux DH, Savioli L, Engels D. Neglected tropical diseases: progress towards addressing the chronic pandemic. The Lancet. 2017;389(10066):312-25.
4. Hotez PJ, Alvarado M, Basáñez M-G, Bolliger I, Bourne R, Boussinesq M, et al. The global burden of disease study 2010: interpretation and implications for the neglected tropical diseases. PLoS Negl Trop Dis. 2014;8(7):e2865.
5. Bartlett J, Deribe K, Tamiru A, Amberbir T, Medhin G, Malik M, et al. Depression and disability in people with podoconiosis: a comparative cross-sectional study in rural northern Ethiopia. International health. 2016;8(2):124-31.
6. Semrau M, Davey G, Beng AA, Ndongmo WPC, Njouendou AJ, Wanji S, et al. Depressive symptoms amongst people with podoconiosis and lower limb lymphoedema of other cause in Cameroon: a cross-sectional study. Tropical medicine and infectious disease. 2019;4(3):102.
7. Mousley E, Deribe K, Tamiru A, Tomczyk S, Hanlon C, Davey G. Mental distress and podoconiosis in Northern Ethiopia: a comparative cross-sectional study. International health. 2015;7(1):16-25.
8. Mousley E, Deribe K, Tamiru A, Davey G. The impact of podoconiosis on quality of life in Northern Ethiopia. Health and Quality of Life Outcomes. 2013;11(1):122.
9. Obindo J, Abdulmalik J, Nwefoh E, Agbir M, Nwoga C, Armiya'u A, et al. Prevalence of depression and associated clinical and socio-demographic factors in people living with lymphatic filariasis in Plateau State, Nigeria. PLoS neglected tropical diseases. 2017;11(6):e0005567.
10. Ganesan DK, Muthunarayanan L. Is disability in leprosy still a burden? A cross-sectional study in a rural block in Tamil Nadu, India. Transactions of The Royal Society of Tropical Medicine and Hygiene. 2018;112(1):31-5.
11. Shumet T, Demissie M, Bekele Y. Prevalence of disability and associated factors among registered leprosy patients in all Africa tb and leprosy rehabilitation and training centre (ALERT), Addis Ababa, Ethiopia. Ethiopian journal of health sciences. 2015;25(4):313-20.
12. Santos VS, Oliveira LS, Castro FD, Gois-Santos VT, Lemos LM, Ribeiro MdC, et al. Functional activity limitation and quality of life of leprosy cases in an endemic area in Northeastern Brazil. PLoS neglected tropical diseases. 2015;9(7):e0003900.
13. Tsutsumi A, Izutsu T, Islam AM, Maksuda A, Kato H, Wakai S. The quality of life, mental health, and perceived stigma of leprosy patients in Bangladesh. Social science & medicine. 2007;64(12):2443-53.
14. LEEKASSA R, BIZUNEH E, ALEM A. Prevalence of mental distress in the outpatient clinic of a specialized leprosy hospital. Addis Ababa, Ethiopia, 2002. Lepr Rev. 2004;75:367-75.
15. Erinfolami AR, Adeyemi JD. A case control study of psychiatric morbidities among subjects with leprosy in Lagos, Nigeria. The International Journal of Psychiatry in Medicine. 2009;39(1):89-99.
16. Price E, Bailey D. Environmental factors in the etiology of endemic elephantiasis of the lower legs in tropical Africa. Tropical and geographical medicine. 1984;36(1):1-5.
17. Davey G, Tekola F, Newport MJ. Podoconiosis: non-infectious geochemical elephantiasis. Transactions of the Royal Society of Tropical Medicine and Hygiene. 2007;101(12):1175-80.
18. Davey G, GebreHanna E, Adeyemo A, Rotimi C, Newport M, Desta K. Podoconiosis: a tropical model for gene–environment interactions? Transactions of the Royal Society of Tropical Medicine and Hygiene. 2007;101(1):91-6.
19. Tekola Ayele F, Adeyemo A, Finan C, Hailu E, Sinnott P, Burlinson ND, et al. HLA class II locus and susceptibility to podoconiosis. New England Journal of Medicine. 2012;366(13):1200-8.

20. Deribe K, Simpson H, Cano J, Pigott DM, Weaver ND, Cromwell EA, et al. Mapping the global distribution of podoconiosis: Applying an evidence consensus approach. PLoS neglected tropical diseases. 2019;13(12):e0007925.
21. Deribe K, Cano J, Giorgi E, Pigott DM, Golding N, Pullan RL, et al. Estimating the number of cases of podoconiosis in Ethiopia using geostatistical methods. Wellcome open research. 2017;2.
22. Fyfe N, Price E. The effects of silica on lymph nodes and vessels—a possible mechanism in the pathogenesis of non-filarial endemic elephantiasis. Transactions of the Royal Society of Tropical Medicine and Hygiene. 1985;79(5):645-51.
23. Price E, Henderson W. The elemental content of lymphatic tissues of barefooted people in Ethiopia, with reference to endemic elephantiasis of the lower legs. Transactions of the Royal Society of Tropical Medicine and Hygiene. 1978;72(2):132-6.
24. Nenoff P, Simon JC, Muylowa GK, Davey G. Podoconiosis–non-filarial geochemical elephantiasis–a neglected tropical disease? JDDG: Journal der Deutschen Dermatologischen Gesellschaft. 2010;8(1):7-13.
25. Fuller LC. Podoconiosis: endemic nonfilarial elephantiasis. Current opinion in infectious diseases. 2005;18(2):119-22.
26. Negussie H, Molla M, Ngari M, Berkley JA, Kivaya E, Njuguna P, et al. Lymphoedema management to prevent acute dermatolymphangioadenitis in podoconiosis in northern Ethiopia (GoLBeT): a pragmatic randomised controlled trial. The Lancet Global health. 2018;6(7):e795-e803.
27. Desta K, Ashine M, Davey G. Predictive value of clinical assessment of patients with podoconiosis in an endemic community setting. Transactions of the Royal Society of Tropical Medicine and Hygiene. 2007;101(6):621-3.
28. 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 neglected tropical diseases. 2010;4(11):e902.
29. Taylor MJ, Hoerauf A, Bockarie M. Lymphatic filariasis and onchocerciasis. The Lancet. 2010;376(9747):1175-85.
30. Nutman TB. Insights into the pathogenesis of disease in human lymphatic filariasis. Lymphatic research and biology. 2013;11(3):144-8.
31. Fenwick A. The global burden of neglected tropical diseases. Public health. 2012;126(3):233-6.
32. Pfarr K, Debrah A, Specht S, Hoerauf A. Filariasis and lymphoedema. Parasite immunology. 2009;31(11):664-72.
33. Ramaiah K, Ottesen EA. Progress and impact of 13 years of the global programme to eliminate lymphatic filariasis on reducing the burden of filarial disease. PLoS Negl Trop Dis. 2014;8(11):e3319.
34. Rebollo MP, Sime H, Assefa A, Cano J, Deribe K, Gonzalez-Escalada A, et al. Shrinking the lymphatic filariasis map of Ethiopia: reassessing the population at risk through nationwide mapping. PLoS Negl Trop Dis. 2015;9(11):e0004172.
35. Dreyer G, Noroes J, Figueredo-Silva J, Piessens W. Pathogenesis of lymphatic disease in bancroftian filariasis:: a clinical perspective. Parasitology today. 2000;16(12):544-8.
36. Taylor MJ, Hoerauf A, Townson S, Slatko BE, Ward SA. Anti-Wolbachia drug discovery and development: safe macrofilaricides for onchocerciasis and lymphatic filariasis. Parasitology. 2014;141(1):119-27.
37. Figueredo-Silva J, Noroes J, Cedenho A, Dreyer G. The histopathology of bancroftian filariasis revisited: the role of the adult worm in the lymphatic-vessel disease. Annals of Tropical Medicine & Parasitology. 2002;96(6):531-41.
38. Partono F. The spectrum of disease in lymphatic filariasis. Filariasis. 1987;127:15-31.
39. Dreyer G, Medeiros Z, Netto MJ, Leal NC, de Castro LG, Piessens WF. Acute attacks in the extremities of persons living in an area endemic for bancroftian filariasis: differentiation of two syndromes. Transactions of the Royal Society of Tropical Medicine and Hygiene. 1999;93(4):413-7.

40. Ramzy RM, El Setouhy M, Helmy H, Ahmed ES, Abd Elaziz KM, Farid HA, et al. Effect of yearly mass drug administration with diethylcarbamazine and albendazole on bancroftian filariasis in Egypt: a comprehensive assessment. The Lancet. 2006;367(9515):992-9.
41. Ottesen E, Duke B, Karam M, Behbehani K. Strategies and tools for the control/elimination of lymphatic filariasis. Bulletin of the world Health Organization. 1997;75(6):491.
42. Belete Mengistu KD, Kebede F, Martindale S, Hassan M, Sime H, Mackenzie C, et al. The national programme to eliminate lymphatic filariasis from Ethiopia. Ethiopian medical journal. 2017;55(Suppl 1):45.
43. Smith CS, Noordeen SK, Richardus JH, Sansarricq H, Cole ST, Soares RC, et al. A strategy to halt leprosy transmission. The Lancet Infectious Diseases. 2014;14(2):96-8.
44. Eichelmann K, González SG, Salas-Alanis J, Ocampo-Candiani J. Leprosy. An update: definition, pathogenesis, classification, diagnosis, and treatment. Actas Dermo-Sifiliográficas (English Edition). 2013;104(7):554-63.
45. WHO. Weekly Epidemiological Record, 2021, vol. 96, 38 [full issue]. Weekly Epidemiological Record= Relevé épidémiologique hebdomadaire. 2021;96(38):461-76.
46. Fischer M. Leprosy–an overview of clinical features, diagnosis, and treatment. JDDG: Journal der Deutschen Dermatologischen Gesellschaft. 2017;15(8):801-27.
47. Rodrigues LC, Lockwood DN. Leprosy now: epidemiology, progress, challenges, and research gaps. The Lancet infectious diseases. 2011;11(6):464-70.
48. Walker SL, Lockwood DNJ. Leprosy Clinics in Dermatology 2007;25:165-72. doi: 10.1016/j.clindermatol.2006.05.012.
49. Britton WJ, Lockwood DNJ. Leprosy. Lancet. 2004;363:1209-19.
50. Richardus JH, Tiwari A, Barth-Jaeggi T, Arif MA, Banstola NL, Baskota R, et al. Leprosy post-exposure prophylaxis with single-dose rifampicin (LPEP): an international feasibility programme. The Lancet Global Health. 2021;9(1):e81-e90.
51. Martikainen P, Bartley M, Lahelma E. Psychosocial determinants of health in social epidemiology. Oxford University Press; 2002.
52. WHO. WHOQOL: measuring quality of life. 1997. Geneva: WHO. 1997.
53. Litt E, Baker MC, Molyneux D. Neglected tropical diseases and mental health: a perspective on comorbidity. Trends in parasitology. 2012;28(5):195-201.
54. Weiss MG, Ramakrishna J. Stigma interventions and research for international health. The Lancet. 2006;367(9509):536-8.
55. WHO. Mental health of people with neglected tropical diseases: towards a person-centred approach. 2020.
56. Kuper H. Disability, mental health, stigma and discrimination and neglected tropical diseases. Transactions of The Royal Society of Tropical Medicine and Hygiene. 2021;115(2):145-6.
57. Deribe K, Tomczyk S, Mousley E, Tamiru A, Davey G. Stigma towards a neglected tropical disease: felt and enacted stigma scores among podoconiosis patients in Northern Ethiopia. BMC Public Health. 2013;13(1):1-8.
58. Hofstraat K, van Brakel WH. Social stigma towards neglected tropical diseases: a systematic review. International health. 2016;8(suppl_1):i53-i70.
59. Kuper H. Neglected tropical diseases and disability—what is the link? Transactions of The Royal Society of Tropical Medicine and Hygiene. 2019;113(12):839-44.
60. Herrman H, Kieling C, McGorry P, Horton R, Sargent J, Patel V. Reducing the global burden of depression: a Lancet–World Psychiatric Association Commission. The Lancet. 2019;393(10189):e42-e3.
61. Patel V, Chisholm D, Parikh R, Charlson FJ, Degenhardt L, Dua T, et al. Addressing the burden of mental, neurological, and substance use disorders: key messages from Disease Control Priorities. The Lancet. 2016;387(10028):1672-85.
62. Malhi GS, Mann JJ. Course and prognosis. Lancet. 2018;392:2299-312.

63. Ansseau M, Dierick M, Buntinkx F, Cnockaert P, De Smedt J, Van Den Haute M, et al. High prevalence of mental disorders in primary care. Journal of affective disorders. 2004;78(1):49-55.
64. Unützer J, Park M. Strategies to improve the management of depression in primary care. Primary Care: Clinics in Office Practice. 2012;39(2):415-31.
65. Hailemariam S, Tessema F, Asefa M, Tadesse H, Tenkolu G. The prevalence of depression and associated factors in Ethiopia: findings from the National Health Survey. International journal of mental health systems. 2012;6(1):1-11.
66. Moussavi S, Chatterji S, Verdes E, Tandon A, Patel V, Ustun B. Depression, chronic diseases, and decrements in health: results from the World Health Surveys. The Lancet. 2007;370(9590):851-8.
67. Lund C, Tomlinson M, De Silva M, Fekadu A, Shidhaye R, Jordans M, et al. PRIME: a programme to reduce the treatment gap for mental disorders in five low-and middle-income countries. PLoS Med. 2012;9(12):e1001359.
68. Goodwin N. Understanding integrated care. International journal of integrated care. 2016;16(4).
69. Salam RA, Maredia H, Das JK, Lassi ZS, Bhutta ZA. Community-based interventions for the prevention and control of helmintic neglected tropical diseases. Infectious diseases of poverty. 2014;3(1):1-17.
70. Das JK, Salam RA, Arshad A, Maredia H, Bhutta ZA. Community based interventions for the prevention and control of Non-Helmintic NTD. Infectious diseases of poverty. 2014;3(1):1-12.
71. Mitjà O, Marks M, Bertran L, Kollie K, Argaw D, Fahal AH, et al. Integrated control and management of neglected tropical skin diseases. PLoS neglected tropical diseases. 2017;11(1):e0005136.
72. Singh GP. Psychosocial aspects of Hansen's disease (leprosy). Indian Dermatology Online Journal. 2012;3(3):166.
73. Ton TG, Mackenzie C, Molyneux DH. The burden of mental health in lymphatic filariasis. Infectious diseases of poverty. 2015;4(1):1-8.
74. Bennis I, De Brouwere V, Belrhiti Z, Sahibi H, Boelaert M. Psychosocial burden of localised cutaneous Leishmaniasis: a scoping review. BMC Public Health. 2018;18(1):1-12.
75. Somar P, Waltz M, van Brakel W. The impact of leprosy on the mental wellbeing of leprosy-affected persons and their family members–a systematic review. Global Mental Health. 2020;7.
76. WHO. Weekly Epidemiological Record 2018. Weekly Epidemiological Record. 2019;94(41):457-72.
77. WHO. Global leprosy update, 2018. Weekly Epidemiological Record. 2019;94(35/36):389-411.
78. Deribe K, Cano J, Trueba ML, Newport MJ, Davey G. Global epidemiology of podoconiosis: A systematic review. PLoS neglected tropical diseases. 2018;12(3):e0006324.
79. Oakley A, Gough D, Oliver S, Thomas J. The politics of evidence and methodology: lessons from the EPPI-Centre. Evidence & Policy: A Journal of Research, Debate and Practice. 2005;1(1):5-32.
80. Brandsma JW, Brakel WV. WHO'disability'grading: Operational definitions. Leprosy review. 2003;74(4):366-73.
81. Van Brakel WH, Reed NK, Reed DS. Grading impairment in leprosy. Leprosy review. 1999;70:180-8. doi: 10.5935/0305-7518.19990021.
82. Rao PS, Darlong F, Timothy M, Kumar S, Abraham S, Kurian R. Disability adjusted working life years (DAWLYs) of leprosy affected persons in India. The Indian journal of medical research. 2013;137(5):907-10. Epub 2013/06/14. PubMed PMID: 23760375; PubMed Central PMCID: PMCPMC3734681.
83. Luciano JV, Ayuso-Mateos JL, Aguado J, Fernandez A, Serrano-Blanco A, Roca M, et al. The 12-item world health organization disability assessment schedule II (WHO-DAS II): a nonparametric item response analysis. BMC medical research methodology. 2010;10(1):45.
84. Group SCS, Group SCS. The development of a short questionnaire for screening of activity limitation and safety awareness (SALSA) in clients affected by leprosy or diabetes. Disability and rehabilitation. 2007;29(9):689-700.

85. Van Brakel WH, Anderson AM, Mutatkar R, Bakirtzief Z, Nicholls PG, Raju M, et al. The Participation Scale: measuring a key concept in public health. Disability and rehabilitation. 2006;28(4):193-203.
86. Skevington SM, Lotfy M, O'Connell K. The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL group. Quality of life Research. 2004;13(2):299-310.
87. Hanlon C, Medhin G, Selamu M, Breuer E, Worku B, Hailemariam M, et al. Validity of brief screening questionnaires to detect depression in primary care in Ethiopia. Journal of affective disorders. 2015;186:32-9.
88. Gelaye B, Williams MA, Lemma S, Deyessa N, Bahretibeb Y, Shibre T, et al. Diagnostic validity of the composite international diagnostic interview (CIDI) depression module in an East African population. The International Journal of Psychiatry in Medicine. 2013;46(4):387-405.
89. Tsutsumi A, Izutsu T, Akramul Islam MD, Amed JU, Nakahara S, Takagi F, et al. Depressive status of leprosy patients in Bangladesh: association with self-perception of stigma. Leprosy review. 2004;75(1):57-66. Epub 2004/04/10. PubMed PMID: 15072127.
90. Mousley E, Deribe K, Tamiru A, Tomczyk S, Hanlon C, Davey G. Mental distress and podoconiosis in Northern Ethiopia: a comparative cross-sectional study. International health. 2015;7(1):16-25. Epub 2014/07/27. doi: 10.1093/inthealth/ihu043. PubMed PMID: 25062906; PubMed Central PMCID: PMCPMC4236095.
91. Rocha-Leite CI, Borges-Oliveira R, Araújo-de-Freitas L, Machado PRL, Quarantini LC. Mental disorders in leprosy: An underdiagnosed and untreated population. Journal of Psychosomatic Research. 2014;76(5):422-5. doi: 10.1016/j.jpsychores.2014.02.006. PubMed PMID: 2014-09510-001.
92. Beusenberg M, Orley JH, Organization WH. A User's guide to the self reporting questionnaire (SRQ. World Health Organization, 1994.
93. Wijesinghe RS, Wickremasinghe AR. Physical, psychological, and social aspects of quality of life in filarial lymphedema patients in Colombo, Sri Lanka. Asia-Pacific journal of public health. 2015;27(2):Np2690-701. Epub 2012/02/07. doi: 10.1177/1010539511434140. PubMed PMID: 22308536.
94. Aben-Athar C, Lima SS, Ishak R, Vallinoto ACR. Assessment of the sensory and physical limitations imposed by leprosy in a Brazilian Amazon Population. Revista da Sociedade Brasileira de Medicina Tropical. 2017;50(2):223-8. Epub 2017/06/01. doi: 10.1590/0037-8682-0493-2016. PubMed PMID: 28562759.
95. Ganesan DK, Muthunarayanan L. Is disability in leprosy still a burden? A cross-sectional study in a rural block in Tamil Nadu, India. Transactions of the Royal Society of Tropical Medicine and Hygiene. 2018;112(1):31-5. Epub 2018/03/23. doi: 10.1093/trstmh/try021. PubMed PMID: 29566236.
96. Nardi SM, Paschoal VD, Zanetta DM. Social participation of people affected by leprosy after discontinuation of multidrug therapy. Leprosy review. 2011;82(1):55-64. Epub 2011/06/08. PubMed PMID: 21644472.
97. Santos VS, Oliveira LS, Castro FD, Gois-Santos VT, Lemos LM, Ribeiro Mdo C, et al. Functional Activity Limitation and Quality of Life of Leprosy Cases in an Endemic Area in Northeastern Brazil. PLoS Negl Trop Dis. 2015;9(7):e0003900. Epub 2015/07/02. doi: 10.1371/journal.pntd.0003900. PubMed PMID: 26132166; PubMed Central PMCID: PMCPMC4489006.
98. Shumet T, Demissie M, Bekele Y. Prevalence of Disability and Associated Factors among Registered Leprosy Patients in All Africa Tb and Leprosy Rehabilitation and Training Centre (ALERT), Addis Ababa, Ethiopia. Ethiopian journal of health sciences. 2015;25(4):313-20. Epub 2016/03/08. doi: 10.4314/ejhs.v25i4.4. PubMed PMID: 26949295; PubMed Central PMCID: PMCPMC4762969.
99. van Brakel WH, Sihombing B, Djarir H, Beise K, Kusumawardhani L, Yulihane R, et al. Disability in people affected by leprosy: the role of impairment, activity, social participation, stigma and discrimination. Global health action. 2012;5. Epub 2012/07/25. doi: 10.3402/gha.v5i0.18394. PubMed PMID: 22826694; PubMed Central PMCID: PMCPMC3402069.

100. Abraham Agidew YG, Fikre Enquselassie, Abiy Hiruye, Miliard Derbew, Dereje Mammo, Abiyou Muhiye. Magnitude of Disability and Associated Factors among Patients in Boru Medda Hospital, South Wollo Zone, Amhara Region, Ethiopia. Ethiopian medical journal. 2015;(2).
101. Monteiro LD, Alencar CH, Barbosa JC, Novaes CC, da Silva Rde C, Heukelbach J. Limited activity and social participation after hospital discharge from leprosy treatment in a hyperendemic area in North Brazil. Revista brasileira de epidemiologia = Brazilian journal of epidemiology. 2014;17(1):91-104. Epub 2014/06/05. PubMed PMID: 24896785.
102. Nardi SM, Paschoal VD, Zanetta DM. Limitations in activities of people affected by leprosy after completing multidrug therapy: application of the SALSA scale. Leprosy review. 2012;83(2):172-83. Epub 2012/09/25. PubMed PMID: 22997693.
103. Leekassa R, Bizuneh E, Alem A. Prevalence of mental distress in the outpatient clinic of a specialized leprosy hospital. Addis Ababa, Ethiopia, 2002. Leprosy review. 2004;75(4):367-75. Epub 2005/02/03. PubMed PMID: 15682974.
104. Kumar JH, Verghese A. Psychiatric disturbances among leprosy patients. An epidemiological study. International journal of leprosy and other mycobacterial diseases : official organ of the International Leprosy Association. 1980;48(4):431-4. Epub 1980/12/01. PubMed PMID: 7193658.
105. Erinfolami AR, Adeyemi JD. A case control study of psychiatric morbidities among subjects with leprosy in Lagos, Nigeria. International journal of psychiatry in medicine. 2009;39(1):89-99. Epub 2009/08/05. doi: 10.2190/PM.39.1.g. PubMed PMID: 19650532.
106. Tsutsumi A, Izutsu T, Islam AM, Maksuda AN, Kato H, Wakai S. The quality of life, mental health, and perceived stigma of leprosy patients in Bangladesh. Social science & medicine (1982). 2007;64(12):2443-53. Epub 2007/03/27. doi: 10.1016/j.socscimed.2007.02.014. PubMed PMID: 17382441.
107. Bartlett J, Deribe K, Tamiru A, Amberbir T, Medhin G, Malik M, et al. Depression and disability in people with podoconiosis: a comparative cross-sectional study in rural Northern Ethiopia. International health. 2016;8(2):124-31. Epub 2015/06/27. doi: 10.1093/inthealth/ihv037. PubMed PMID: 26113669; PubMed Central PMCID: PMCPMC4604655.
108. 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. Epub 2013/07/23. doi: 10.1186/1477-7525-11-122. PubMed PMID: 23866905; PubMed Central PMCID: PMCPMC3726315.
109. Martindale S, Mkwanda SZ, Smith E, Molyneux D, Stanton MC, Kelly-Hope LA. Quantifying the physical and socio-economic burden of filarial lymphoedema in Chikwawa District, Malawi. Transactions of the Royal Society of Tropical Medicine and Hygiene. 2014;108(12):759-67. Epub 2014/10/02. doi: 10.1093/trstmh/tru154. PubMed PMID: 25270880.
110. Ramaiah KD, Kumar KN, Ramu K, Pani SP, Das PK. Functional impairment caused by lymphatic filariasis in rural areas of south India. Tropical medicine & international health : TM & IH. 1997;2(9):832-8. Epub 1997/10/07. PubMed PMID: 9315041.
111. Obindo J, Abdulmalik J, Nwefoh E, Agbir M, Nwoga C, Armiya'u A, et al. Prevalence of depression and associated clinical and socio-demographic factors in people living with lymphatic filariasis in Plateau State, Nigeria. PLoS Negl Trop Dis. 2017;11(6):e0005567. Epub 2017/06/02. doi: 10.1371/journal.pntd.0005567. PubMed PMID: 28570585; PubMed Central PMCID: PMCPMC5453421.
112. Albrecht GL, Devlieger PJ. The disability paradox: high quality of life against all odds. Social science & medicine. 1999;48(8):977-88.
113. Bailey F, Eaton J, Jidda M, van Brakel WH, Addiss DG, Molyneux DH. Neglected tropical diseases and mental health: progress, partnerships, and integration. Trends in parasitology. 2019;35(1):23-31.
114. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337.

115. De Silva MJ, Breuer E, Lee L, Asher L, Chowdhary N, Lund C, et al. Theory of change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. Trials. 2014;15(1):1-13.
116. Breuer E, De Silva MJ, Fekadu A, Luitel NP, Murhar V, Nakku J, et al. Using workshops to develop theories of change in five low and middle income countries: lessons from the programme for improving mental health care (PRIME). International journal of mental health systems. 2014;8(1):1-13.
117. Tesfaye A, Semrau M, Ali O, Kinfe M, Tamiru M, Fekadu A, et al. Development of an integrated, holistic care package for people with lymphoedema for use at the level of the Primary Health Care Unit in Ethiopia. PLoS neglected tropical diseases. 2021;15(4):e0009332.
118. Semrau M, Ali O, Deribe K, Mengiste A, Tesfaye A, Kinfe M, 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(10):e037675.
119. Pryce J, Mableson HE, Choudhary R, Pandey BD, Aley D, Betts H, 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(1):201.
120. Kendall J. Designing a research project: randomised controlled trials and their principles. Emergency medicine journal: EMJ. 2003;20(2):164.
121. Zabor EC, Kaizer AM, Hobbs BP. Randomized controlled trials. Chest. 2020;158(1):S79-S87.
122. Hariton E, Locascio JJ. Randomised controlled trials—the gold standard for effectiveness research. BJOG: an international journal of obstetrics and gynaecology. 2018;125(13):1716.
123. Health. FDRoEMo. Lymphatic Filariasis and Podoconiosis Morbidity Management and Disablity Prevention Guidelines 2016.
124. WHO WHO. WHO Disability Assessement Schedule 2018 [cited 2018 15 September].
125. Finlay AY, Khan G. Dermatology Life Quality Index (DLQI)—a simple practical measure for routine clinical use. Clinical and experimental dermatology. 1994;19(3):210-6.
126. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. Journal of general internal medicine. 2001;16(9):606-13.
127. Jordans M, Rathod S, Fekadu A, Medhin G, Kigozi F, Kohrt B, et al. Suicidal ideation and behaviour among community and health care seeking populations in five low-and middle-income countries: a cross-sectional study. Epidemiology and psychiatric sciences. 2018;27(4):393.
128. Kocalevent R-D, Berg L, Beutel ME, Hinz A, Zenger M, Härter M, et al. Social support in the general population: standardization of the Oslo social support scale (OSSS-3). BMC psychology. 2018;6(1):31.
129. Rensen C, Bandyopadhyay S, Gopal PK, Van Brakel WH. Measuring leprosy-related stigma–a pilot study to validate a toolkit of instruments. Disability and Rehabilitation. 2011;33(9):711-9.
130. Ritsher JB, Otilingam PG, Grajales M. Internalized stigma of mental illness: psychometric properties of a new measure. Psychiatry research. 2003;121(1):31-49.
131. Brohan E, Clement S, Rose D, Sartorius N, Slade M, Thornicroft G. Development and psychometric evaluation of the Discrimination and Stigma Scale (DISC). Psychiatry research. 2013;208(1):33-40.
132. Henok L, Davey G. Validation of the Dermatology Life Quality Index among patients with podoconiosis in southern Ethiopia. British Journal of Dermatology. 2008;159(4):903-6.
133. World Health Organisation. WHO Disability Assessment Schedule 2.0 2018 [23 April 2020]. Available from: https://www.who.int/classifications/icf/whodasii/en/.
134. Habtamu K, Alem A, Medhin G, Fekadu A, Dewey M, Prince M, et al. Validation of the World Health Organization disability assessment schedule in people with severe mental disorders in rural Ethiopia. Health and quality of life outcomes. 2017;15(1):64.

135. Gelaye B, Williams MA, Lemma S, Deyessa N, Bahretibeb Y, Shibre T, et al. Validity of the patient health questionnaire-9 for depression screening and diagnosis in East Africa. Psychiatry research. 2013;210(2):653-61.
136. Diagnostic D. statistical manual of mental disorders. . Washington DC, American Psychiatric Association. 1995.
137. Badiee J, Moore DJ, Atkinson JH, Vaida F, Gerard M, Duarte NA, et al. Lifetime suicidal ideation and attempt are common among HIV+ individuals. Journal of affective disorders. 2012;136(3):993-9.
138. Duko B, Geja E, Zewude M, Mekonen S. Prevalence and associated factors of depression among patients with HIV/AIDS in Hawassa, Ethiopia, cross-sectional study. Annals of general psychiatry. 2018;17(1):45.
139. Bisetegn TA, Mihretie G, Muche T. Prevalence and predictors of depression among pregnant women in debretabor town, northwest Ethiopia. PloS one. 2016;11(9).
140. Assefa D, Shibre T, Asher L, Fekadu A. Internalized stigma among patients with schizophrenia in Ethiopia: a cross-sectional facility-based study. BMC psychiatry. 2012;12(1):239.
141. Mutiso V, Pike K, Musyimi C, Rebello T, Tele A, Gitonga I, et al. Feasibility of WHO mhGAP-intervention guide in reducing experienced discrimination in people with mental disorders: a pilot study in a rural Kenyan setting. Epidemiology and psychiatric sciences. 2019;28(2):156-67.
142. Forthal S, Fekadu A, Medhin G, Selamu M, Thornicroft G, Hanlon C. Rural vs urban residence and experience of discrimination among people with severe mental illnesses in Ethiopia. BMC psychiatry. 2019;19(1):340.
143. Fekadu A, Medhin G, Selamu M, Giorgis TW, Lund C, Alem A, et al. Recognition of depression by primary care clinicians in rural Ethiopia. BMC family practice. 2017;18(1):56.
144. Morse JM. The significance of saturation. QUALITATIVE HEALTH RESEARCH. 1995;5(2):147-9.
145. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: guided by information power. Qualitative health research. 2016;26(13):1753-60.
146. Semrau M, Davey G, Bayisenge U, Deribe K. High levels of depressive symptoms among people with lower limb lymphoedema in Rwanda: a cross-sectional study. Transactions of The Royal Society of Tropical Medicine and Hygiene. 2020;114(12):974-82.
147. McPherson T. Impact on the quality of life of lymphoedema patients following introduction of a hygiene and skin care regimen in a Guyanese community endemic for lymphatic filariasis: A preliminary clinical intervention study. Filaria Journal. 2003;2(1):1-5.
148. Babu B, Nayak A, Rath K, Kerketta A. Use of the Dermatology Life Quality Index in filarial lymphoedema patients. Transactions of the Royal Society of Tropical Medicine and Hygiene. 2006;100(3):258-63.
149. Charkhian A, Fekrazad H, Sajadi H, Rahgozar M, Abdolbaghi MH, Maddahi S. Relationship between health-related quality of life and social support in HIV-infected people in Tehran, Iran. Iranian journal of public health. 2014;43(1):100.
150. Munikanan T, Midin M, Daud TIM, Rahim RA, Bakar AKA, Jaafar NRN, et al. Association of social support and quality of life among people with schizophrenia receiving community psychiatric service: a cross-sectional study. Comprehensive psychiatry. 2017;75:94-102.
151. Al-Yahya AH, Raya Y, El-Tantawy A. Disability due to mental disorders and its relationship to severity of illness and quality of life. International journal of health sciences. 2011;5(2 Suppl 1):33.
152. Yakob B, Deribe K, Davey G. Health professionals' attitudes and misconceptions regarding podoconiosis: potential impact on integration of care in southern Ethiopia. Transactions of the Royal Society of Tropical Medicine and Hygiene. 2010;104(1):42-7.
153. Stocks ME, Freeman MC, Addiss DG. The effect of hygiene-based lymphedema management in lymphatic filariasis-endemic areas: a systematic review and meta-analysis. PLoS Negl Trop Dis. 2015;9(10):e0004171.
154. Akogun O, Badaki J. Management of adenolymphangitis and lymphoedema due to lymphatic filariasis in resource-limited North-eastern Nigeria. Acta tropica. 2011;120:S69-S75.

155. Weiss MG. Stigma and the social burden of neglected tropical diseases. PLoS Negl Trop Dis. 2008;2(5):e237. doi: 10.1371/journal.pntd.0000237. PubMed PMID: 18478049; PubMed Central PMCID: PMCPMC2359851.
156. Ali O, Deribe K, Semrau M, Mengiste A, Kinfe M, Tesfaye A, et al. A cross-sectional study to evaluate depression and quality of life among patients with lymphoedema due to podoconiosis, lymphatic filariasis and leprosy. Trans R Soc Trop Med Hyg. 2020;114(12):983-94. doi: 10.1093/trstmh/traa130. PubMed PMID: 33190154; PubMed Central PMCID: PMCPMC7738660.
157. Kebede B, Martindale S, Mengistu B, Kebede B, Mengiste A, F HK, 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. doi: 10.1371/journal.pntd.0006491. PubMed PMID: 29965963; PubMed Central PMCID: PMCPMC6044548.
158. 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. doi: 10.1111/j.1365-3156.2006.01658.x. PubMed PMID: 16827714.
159. 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. doi: 10.1371/journal.pntd.0008173. PubMed PMID: 32155158; PubMed Central PMCID: PMCPMC7083326.
160. 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. doi: 10.1016/j.inhe.2011.06.006. PubMed PMID: 24038367.
161. Yakob B, Deribe K, Davey G. High levels of misconceptions and stigma in a community highly endemic for podoconiosis in southern Ethiopia. Trans R Soc Trop Med Hyg. 2008;102(5):439-44. doi: 10.1016/j.trstmh.2008.01.023. PubMed PMID: 18339411.
162. Douglass J, Mableson H, Martindale S, Jhara ST, Karim MJ, Rahman MM, et al. Effect of an Enhanced Self-Care Protocol on Lymphedema Status among People Affected by Moderate to Severe Lower-Limb Lymphedema in Bangladesh, a Cluster Randomized Controlled Trial. J Clin Med. 2020;9(8). doi: 10.3390/jcm9082444. PubMed PMID: 32751676; PubMed Central PMCID: PMCPMC7464742.
163. 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. doi: 10.1371/journal.pntd.0000902. PubMed PMID: 21152059; PubMed Central PMCID: PMCPMC2994920.
164. Mues KE, Deming M, Kleinbaum DG, Budge PJ, Klein M, Leon JS, 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. doi: 10.1371/journal.pntd.0003140. PubMed PMID: 25211334; PubMed Central PMCID: PMCPMC4161333.
165. Budge PJ, Little KM, Mues KE, Kennedy ED, Prakash A, Rout J, et al. Impact of community-based lymphedema management on perceived disability among patients with lymphatic filariasis in Orissa State, India. PLoS Negl Trop Dis. 2013;7(3):e2100. doi: 10.1371/journal.pntd.0002100. PubMed PMID: 23516648; PubMed Central PMCID: PMCPMC3597476.
166. Addiss DG, Louis-Charles J, Roberts J, Leconte F, Wendt JM, Milord MD, et al. Feasibility and effectiveness of basic lymphedema management in Leogane, Haiti, an area endemic for bancroftian filariasis. PLoS Negl Trop Dis. 2010;4(4):e668. doi: 10.1371/journal.pntd.0000668. PubMed PMID: 20422031; PubMed Central PMCID: PMCPMC2857874.
167. Hounsome N, Kassahun MM, Ngari M, Berkley JA, Kivaya E, Njuguna P, 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. doi: 10.1371/journal.pntd.0007780. PubMed PMID: 31644556; PubMed Central PMCID: PMCPMC6808421.

168. Ali O, Deribe K, Semrau M, Mengiste A, Kinfe M, Tesfaye A, et al. A cross-sectional study to evaluate depression and quality of life among patients with lymphoedema due to podoconiosis, lymphatic filariasis and leprosy. Transactions of The Royal Society of Tropical Medicine and Hygiene. 2020;114(12):983-94.
169. Tekola F, Ayele Z, Mariam DH, Fuller C, Davey G. Development and testing of a de novo clinical staging system for podoconiosis (endemic non-filarial elephantiasis). Tropical Medicine & International Health. 2008;13(10):1277-83.
170. Habtamu K, Alem A, Medhin G, Fekadu A, Dewey M, Prince M, et al. Validation of the World Health Organization disability assessment schedule in people with severe mental disorders in rural Ethiopia. Health and quality of life outcomes. 2017;15(1):1-11.
171. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606-13. doi: 10.1046/j.1525-1497.2001.016009606.x. PubMed PMID: 11556941; PubMed Central PMCID: PMCPMC1495268.
172. Finlay AY, Khan GK. Dermatology Life Quality Index (DLQI)--a simple practical measure for routine clinical use. Clin Exp Dermatol. 1994;19(3):210-6. doi: 10.1111/j.1365-2230.1994.tb01167.x. PubMed PMID: 8033378.
173. Thornicroft G, Brohan E, Rose D, Sartorius N, Leese M, Group IS. Global pattern of experienced and anticipated discrimination against people with schizophrenia: a cross-sectional survey. Lancet. 2009;373(9661):408-15. doi: 10.1016/S0140-6736(08)61817-6. PubMed PMID: 19162314.
174. Ritsher JB, Otilingam PG, Grajales M. Internalized stigma of mental illness: psychometric properties of a new measure. Psychiatry Res. 2003;121(1):31-49. doi: 10.1016/j.psychres.2003.08.008. PubMed PMID: 14572622.
175. Kocalevent RD, Berg L, Beutel ME, Hinz A, Zenger M, Harter M, et al. Social support in the general population: standardization of the Oslo social support scale (OSSS-3). BMC Psychol. 2018;6(1):31. doi: 10.1186/s40359-018-0249-9. PubMed PMID: 30016997; PubMed Central PMCID: PMCPMC6050647.
176. Tekola F, Ayele Z, Mariam DH, Fuller C, Davey G. Development and testing of a de novo clinical staging system for podoconiosis (endemic non-filarial elephantiasis). Trop Med Int Health. 2008;13(10):1277-83. doi: 10.1111/j.1365-3156.2008.02133.x. PubMed PMID: 18721188; PubMed Central PMCID: PMCPMC2992944.
177. Mues KE, Deming M, Kleinbaum DG, Budge PJ, Klein M, Leon JS, et al. Impact of a community-based lymphedema management program on episodes of adenolymphangitis (ADLA) and lymphedema progression-Odisha state, India. PLoS neglected tropical diseases. 2014;8(9):e3140.
178. Douglass J, Mableson H, Martindale S, Jhara ST, Karim MJ, Rahman MM, et al. Effect of an enhanced self-care protocol on lymphedema status among people affected by moderate to severe lower-limb lymphedema in Bangladesh, a cluster randomized controlled trial. Journal of clinical medicine. 2020;9(8):2444.
179. Addiss DG, Louis-Charles J, Roberts J, LeConte F, Wendt JM, Milord MD, et al. Feasibility and effectiveness of basic lymphedema management in Leogane, Haiti, an area endemic for bancroftian filariasis. PLoS neglected tropical diseases. 2010;4(4):e668.
180. Stocks ME, Freeman MC, Addiss DG. The effect of hygiene-based lymphedema management in lymphatic filariasis-endemic areas: a systematic review and meta-analysis. PLoS neglected tropical diseases. 2015;9(10):e0004171.
181. Budge PJ, Little KM, Mues KE, Kennedy ED, Prakash A, Rout J, et al. Impact of community-based lymphedema management on perceived disability among patients with lymphatic filariasis in Orissa State, India. PLoS neglected tropical diseases. 2013;7(3):e2100.
182. Hounsome N, Kassahun MM, Ngari M, Berkley JA, Kivaya E, Njuguna P, et al. Cost-effectiveness and social outcomes of a community-based treatment for podoconiosis lymphoedema in the East Gojjam zone, Ethiopia. PLoS neglected tropical diseases. 2019;13(10):e0007780.
183. Tora A, Davey G, Tadele G. A qualitative study on stigma and coping strategies of patients with podoconiosis in Wolaita zone, Southern Ethiopia. International Health. 2011;3(3):176-81.

184. Person B, Bartholomew LK, Gyapong M, Addiss DG, van den Borne B. Health-related stigma among women with lymphatic filariasis from the Dominican Republic and Ghana. Social Science & Medicine. 2009;68(1):30-8.
185. Richard SA, Mathieu E, Addiss DG, Sodahlon YK. A survey of treatment practices and burden of lymphoedema in Togo. Transactions of the Royal Society of Tropical Medicine and Hygiene. 2007;101(4):391-7.
186. Ramanathan P, Prabhakar R, Ananthan VA. Perception of social stigma among patients attending a filariasis morbidity control clinic in South India. International Journal of Community Medicine and Public Health. 2020;7(11):4604.
187. Van Brakel WH, Sihombing B, Djarir H, Beise K, Kusumawardhani L, Yulihane R, et al. Disability in people affected by leprosy: the role of impairment, activity, social participation, stigma and discrimination. Global health action. 2012;5(1):18394.
188. Sermrittirong S, Van Brakel WH. Stigma in leprosy: concepts, causes and determinants. Leprosy review. 2014;85(1):36-47.
189. Suma T, Shenoy R, Kumaraswami V. A qualitative study of the perceptions, practices and socio-psychological suffering related to chronic brugian filariasis in Kerala, southern India. Annals of Tropical Medicine & Parasitology. 2003;97(8):839-45.
190. Krishna Kumari A, Harichandrakumar K, Das L, Krishnamoorthy K. Physical and psychosocial burden due to lymphatic filariasis as perceived by patients and medical experts. Tropical Medicine & International Health. 2005;10(6):567-73.
191. Wijesinghe R, Wickremasinghe A, Ekanayake S, Perera M. Physical disability and psychosocial impact due to chronic filarial lymphoedema in Sri Lanka. Filaria Journal. 2007;6(1):1-8.
192. Nishida M, Nakamura Y, Aosaki N. Prevalence and characteristics of depression in a Japanese leprosarium from the viewpoints of social stigmas and ageing. A preliminary report. Leprosy review. 2006;77(3):203-9.
193. Leekassa R, Bizuneh E, Alem A. Prevalence of mental distress in the outpatient clinic of a specialized leprosy hospital. Addis Ababa, Ethiopia, 2002. Leprosy review. 2004;75(4):367-75.
194. Nishida M, Nakamura Y, Aosaki N. Prevalence and characteristics of depression in a Japanese leprosarium from the viewpoints of social stigmas and ageing. A preliminary report. Leprosy review. 2006;77(3):203-9. Epub 2006/12/19. PubMed PMID: 17172000.

Appendices

Appendix 1- Information sheet and consent form (English version)

AP 1.2 Participant information sheet –

Development of a care package for patients with lymphoedema (leg-swelling disease) in Awi zone, Ethiopia

Dear Participant,

My name is ……, and I am working with CDT-Africa, Addis Ababa University and the Brighton and Sussex Medical School in the UK.

We are inviting you to take part in our research study. Before you decide whether to take part, we would like you to understand why the study is being done and what it would involve for you if you took part. One of our team will go through the information with you and answer any questions you may have. This will probably take about 20 minutes. You will be given a copy of this information sheet to keep.

You can talk to friends and family about the study if you wish before deciding whether to take part. Ask us if there is anything that is not clear or if you would like more information.

1. **What is the purpose of the study?**

We are developing a care package for people with one of three types of leg-swelling disease: podoconiosis and lymphatic filariasis (LF) and leprosy. The care package that we are developing will include both physical and mental health care interventions for people with these conditions. The care package will eventually be integrated into the state health care system in a few districts in Awi zone in Ethiopia as part of the project.

2. **Who is organising and funding the study?**

The study is funded by the National Institute for Health Research (NIHR). This is a funding body based in the UK, which aims to improve people's health and care services.

3. Why have I been invited?

We are inviting you into the study because we are studying a care package for patients who are having either podoconiosis, lymphatic filariasis (LF) or leprosy.

Do I have to take part?

No. It is up to you to decide whether or not you wish to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will ask you to sign a consent form.

4. What will I have to do if I take part?

If you decide to take part in the study, you would take part in an interview that would be carried out by a member of our team. During the interview, we would ask you questions about your socioeconomic and disease status. We will also make physical examination and some measurements.

5. What are the possible benefits of taking part?

This study will probably not have any direct benefits for you. However, by helping us develop a care package for people with podoconiosis, lymphatic filariasis (LF) and leprosy, hopefully people with these conditions will be cared for and treated better through the state health system in Ethiopia in the future.

6. Are there any possible disadvantages or risks of taking part?

There are no disadvantages to taking part in the study. If you decide not to take part, any treatment you may be receiving will not be affected in any way.

7. What about confidentiality?

All information that is collected during this study will be kept on a password protected database and will be kept strictly confidential. All data will be stored securely. We will not ask you to tell us any personal or sensitive information. The data will be kept in a locked cupboard.

At the end of this study, the information you tell us may be used by other researchers, but they will not be able to identify you in any way.

8. What will happen if I do not want to carry on with the study?

You are free to withdraw from the study at any time and without giving a reason. You may withdraw your information from the study at any time until the data have been combined with that of the other participants. If you decide to withdraw or not to join the study, this will not affect any standard of care you may be receiving. We will also be happy to discuss with you what will happen to any data that has been collected up to the point of your withdrawal from the study.

9. What if there is a problem?

We do not expect that any problems will occur during the study. However, if you do have any concerns about any aspect of this study or complaints about the way you have been treated during the study or possible harm you might suffer, please ask to speak with a member of our team who will do their best to answer your questions. Our team's contact details are provided at the end of this sheet.

10. **Harm**

The Universities of Brighton and Sussex have insurance in place to cover their legal liabilities in respect of this study.

11. What will happen to the results of the study?

The results from the study will be used to inform the development of the care package. It is also likely that the results will be written up and published in a scientific journal. The results would be anonymised, so you would not be identifiable in any publication.

12. Who has approved this study?

This study has received ethical approval from the Brighton and Sussex Medical School Research Governance and Ethics Committee (BSMS RGEC) and the Institutional Review Board of the College of Health Sciences of Addis Ababa University.

13. **Contact Details:**

- Dr Oumer Ali
  Email: O.A.Ahmed@bsms.ac.uk
  Mobile: +251911408208

- Dr Abebaw Fekadu
  Email: abebaw.fekadu@aau.edu.et
  Mobile: +251912894975

- Dr. Solomon Abay
  Mobile: 0941222169
  Institutional Review Board, College of Health Science, Addis Ababa University.

Thank you for taking the time to read this information sheet

AP 1.4 Consent form

Title of Project: Development of a care package for patients with lymphoedema (leg-swelling disease) in Awi zone, Ethiopia

Name of Researchers: Prof Gail Davey and Prof Abebaw Fekadu

	Please initial box
I confirm that I have read or has been read for me and understood the information dated **<insert date> (<Insert Version Number>)** for the study 'Development of a care package for patients with lymphoedema in Awi zone, Ethiopia'. I have had the chance to read the information and ask questions about the study and am satisfied with the answers I have been given.	☐
I understand that my participation in this study is voluntary and that I am free to stop at any time, and I do not have to give a reason for doing so. I understand that if I ask to stop the study my medical care and legal rights will not be affected in any way.	☐
I understand that occasionally an external regulator or funding body may ask to look at the data for this study to check that it is being run correctly.	☐
I understand that information about me recorded during the study will be kept in a safe database. If data are given to others, my personal details will be removed. Data will be kept for 5-10 years after the results of this study have been published.	☐
I agree my interview / the focus group discussion *(delete as appropriate)* to be recorded.	☐
I agree to take part in the above study.	☐
I understand that if something goes wrong I can report it to one of the project staff or the study coordinators at the address given on the participant information sheet.	☐

_____ _____

_____

Name of Participant | Date | Signature

_ _

I have explained the information in this document and encouraged the participant to ask questions and provided adequate time to answer them.

_________________________ ________________ _____________________

Name of Researcher or Person Seeking Consent (If different from researcher) | Date | Signature

When completed: 1 copy for the participant; 1 copy for the researcher site file

Appendix 2: Information sheet and Consent form (Amharic version)

አባሪ 2.1 ፡ የለውጥ ንድፈ -ሃሳብ ወርክሾፕ ጥናት ተሳታፊዎች የመረጃ ቅጽ

የጥናቱ ርዕስ፡ በአዊ ዞን ኢትዮጵያ የእግር ማበጥ በሽታ የጤና እንክብካቤ ፓኬጅን ማዘጋጀት

ውድ የጥናቱ ተሳታፊዎች

ስሜ.....ይባላል፣ የምሰራውም በኢዲስ አበባ ዮኒቨርሲቲ በሚገኘው ሲዲቲ አፍሪካ እና እንግሊዝ አገር በሚገኘው ብራይተንና ሱሴክስ የህክምና ትምህርት ቤት ተመራማሪዎች በትብብር በሚካሄድ የጥናትና ምርምር ፕሮጀክት ነው፡፡

በዚህ የጥናትና ምርምር ፕሮጀክት እንዲሳተፉ ለመጋበዝ እንወዳለን፡፡ ይህ ጥናትና ምርምር ለመሳተፍ ወይም ላለመሳተፍ ከመወሰንዎ በፊት ጥናቱ ለምን እየተካሄደ እንደሆነና በጥናቱ በሚኖርዎ ተሳትፎ ምን እንደሚጠበቅብዎት መረዳት ጠቃሚ ነው፡፡ የዚህ ጥናት ቡድን አባላት የቀረበውን መረጃ ያነብልዎታል ወይም የቀረበውን መረጃ ጊዜ ወስደው በጥንቃቅ ያንብቡ ፡፡ በተጨማሪም ለጥያቄዎ መልስ ይሰጦዎታል፡፡ ይህ በግምት 20ደቂቃ ይወስዳል፡፡ የጥናቱ ተሳታፊዎች የመረጃ ቅጽ አንድ ኮፒ ይሰጥዎታል፡፡

አስፈላጊ ነው ብለው ካሰቡም በጥናቱ ከመሳተፎ በፊት ከጓደኞች፤ ቤተሰብ አና ከሌሎች ሰዎች ጋር ይወያዩበት፡፡ ማንኛውም ግልጽ ያልሆነ ነገር ካለ ወይም ተጨማሪ መረጃ ከፈለጉ እባክዎን ይጠይቁን፡፡

1. **የዚህ ጥናትና ምርምር ፕሮጀክት አላማ ምንድነው?**

የዚህ ጥናትና ምርምር አላማ ለሶስቱ የእግር ማበጥ በሽታች (ፖዶኮነሲስ፤ ሊንፍ ፊላሪያሲስ እና ሰጋደዌ) የጤና እንክብካቤ ፓኬጅ ማዘጋጀት ነው፡፡ የምናዘጋጀው የእንክብካቤ ፓኬጅ በዚህ በሽታ ለታመሙ የአካላዊና አእምራዊ የጤና እንክብካቤ አገልግሎቶችን ለመስጠት የሚያስችል ይሆናል፡፡ በሂደትም የተዘጋጀው የእንክብካቤ ፓኬጅ በተወሰኑ የአዊ ዞን ወረዳዎች ባሉ የመንግስት የጤና እንክብካቤ ስርአት ውስጥ የሚካተት ይሆናል ይህም የጥናቱትና ምርምሩ አካል ነው፡፤

2. **ጥናቱን በገንዘብ የሚደግፈው ድርጅት ማን ነው?**

ይህንን ጥናትና ምርምር በገንዘብ የሚደግፈው ድርጅት እንግሊዝ አገር የሚገኘው ብሄራዊ የጤና ምርምር ተቋም ነው፡፡ አላማውም የህብረተሰብ ጤናና የጤና አንክብካቤ አገልግሎት ማሻሻል ነው፡፡

3. **በዚህ ጥናት እንድሳተፍ ለምን ተጋበዝኩኝ?**

በዚህ ጥናት እንዲሳተፉ የተጋበዙት ምክንያት የእግር ማበጥ በሽታ (ፖዶኮነሲስ፤ ሊንፍ ፊላሪያሲስ ወይም ሰጋደዊ) ህመም ስላለብዎት ነው፡፡

4. **የግድ በዚህ ጥናት መሳተፍ ይኖርብኛል?**

አይደልም፡፡ በዚህ ጥናት የሚኖርዎ ተሳትፎ ሙሉ በሙሉ በእርሶዎ ፍቃደኝነት ላይ የተመሰረተ ነው፡፡ ስለጥናቱ አስፈላጊው መረጃ ገለጻ እናደርግሎታለን፤ በጥናቱ ለመሳተፍ ከወሰኑ የፍቃደኝነት መጠይቅ ፎርም እንዲፈርሙ እንጠይቆዎታለን፡፡

5. **በዚህ ጥናት ብስማማ ምን ይጠብቀኛል?**

በዚህ ጥናት ለመሳተፍ ከተስማሙ በጥናት ቡድኑ አባላት መጠይቅ ይቀርብሎታል፡፡ በቃለ መጠይቁ ጊዜ አጠቃላይ የማህበራዊና ኢኮነሚያዊ ጥያቄ እንጠይቆዎታለን፡፡ እንዲሁም አካላዊ ምርመራና ልኬት እናደርጋለን፡፡

6. **በዚህ ጥናት መሳተፍ ሊያስገኛቸው የሚችለው ጠቀሜታዎች ምንድናቸው?**

በዚህ ጥናት በመሳተፎ ቀጥተኛ ሊያገኙት የሚችሉት ጥቅም የለም፡፡ነገር ግን የፖዶኮነሲስ፤ ሊንፍ ፊላሪያሲስ እና ሰጋደዌ እንክብካቤ ፓኬጅ እንዲዘጋጅ በመርዳትዎ በዚህ ህመም የተጠቁ ሰዎች ወደፊት በኢትዮጵያ የመንግስት የጤና ስርዓት የተሻለ እንክብካቤና ህክምና እንደሚያገኙ ተስፋ ይደረጋል፡፡

7. በዚህ ጥናት መሳተፍ ሊያስከትላቸው የሚችለው ጉዳቶች ምንድናቸው?

በዚህ ጥናት በመሳተፍ ሊመጣ ይችላል ተብሎ የሚገመት ምንም አይነት ጉዳት የለም፡፡ በጥናቱ ላለመሳተፍ በመወሰኖ በማንኛውም መንገድ እያገኙ ያሉት ህክምና ካለ የሚያሳጡዎት የለም፡፡

8. ለጥናቱ ከምሰጠው መረጃ በመነሳት ሌሎች ሰዎች ማንነቴን ሊያውቁ ይችላሉ (የጥናቱ ሚስጥራዊነት)?

በዚህ ጥናት የተሰበሰቡ ማንኛቸውም መረጃ በቁልፍ በታሰረ የመረጃ-ቋት ውስጥ በጥብቅ ሚስጥር የሚቀመጥ ይሆናል፡፡ ማንኛውም መረጃ ደህንነቱን በጠበቀ ሁኔታ ይቀመጣል፡ማንኛውም የግል ወይም ጥንቃቄ የሚፈልግ መረጃ የማይጠየቁ መሆኑን እንገልጻለን፡፡

ከዚህ ጥናት በኋላ እርሶዎ የሰጡን መረጃ በሌላ ተመራማሪ ጥቅም ላይ ሊውል ይችላል፡፡ ነገር ግን እርሶዎን በማንኛውም መንገድ ለይቶ ሊያውቅበት የሚችሉበት መንገድ የለም፡፡

9. በዚህ ጥናት ለመቀጠል ባልፈልግ ምን ሊከሰት ይችላል?

ከጥናቱ ምንም ምክንያት መስጠት ሳያስፈልግዎ በማንኛውም ጊዜ ተሳትፎዎን ማቆም ይችላሉ፡፡ የሰጡት መረጃ ከሌሎች የጥናቱ ተካፋዮች ጋር ተዋህዶ እስከ ሚተንተን ድረስ በማንኛውም ጊዜ መረጃዎን ማውጣት ይችላሉ፡፡ ከዚህ ጥናት ለማቋረጥ ወይም ላለመሳተፍ ቢፈልጉ የሚያጡት አገልግሎት የለም፡፡

10. ችግር ካለ ምን ይሆናል?

በዚህ ጥናት ይከሰታል ብለን የምንገምተው ምንም አይነት ጉዳት የለም፡፡ ነገር ግን ስለጥናቱ የትኛውም ሁኔታ ላይ ማንኛውም አሳሳቢ ጉዳይ ካለ ወይም የተስተናገዱበት ሁኔታ ላይ ቅሪታ ካልዎት ወይም ጉዳት ከደረስብዎ፤ እባክዎ የጥናት ቡድኑ አባላትን ያነጋግሩ፡፡ የቡድኑ አባላት አድራሻ በዚህ የመረጃ ቅጽ መጨረሻ ላይ ይገኛል፡፡

11. ጉዳት

ይህ ጥናት በተመለከተ የብራይተንና ሱሲክስ ዩኒቨርሲቲ የህግ ግዲታውን ለመወጣት ኢንሹራንስ (መድህን) አለው፡፡

12. ከጥናቱ የሚገኘው ውጤት ምን ይሆናል?

ከጥናቱ የሚገኘው ውጤት የእንክብካቤ ፓኬጁን ለማዘጋጀት ይረዳል፡፡ ውጤቱም ተጽፎ በሳይንቲፍክ መጽሄት (ጆርናል) የሚታተም ይሆናል፡፡ የጥናቱ ውጤት የግለሰቦች ማንንት በማያሳውቅ መልኩ ስለሚሆን፣ የእርሶዎ ማንነት በማንኛው ህትመት የሚታወቅበት ሁኒታ የለም፡፡

13. ጥናቱን ማን አጸደቀው?

ይህ ጥናትና ምርምር በአዲስ አበባ ዩኒቨርሲቲ የጤና ሳይንስ ኮሌጅ የተቋማዊ ግምገማ ቦርድ እንዲሁም የብራይተንና ሱሲክስ የህክምና ትምህርት ክፍል የጥናት አመራርና የስነምግባር ኮሚቲ ተፈትሾ መሉ ፍቃድ የተሰጠው ነው፡፡

14. ይህንን ጥናትና ምርምር በተመለከተ ተጨማሪ ጥያቄዎች ቢኖሩኝ ማንን ማነጋገር እችላለሁ?

- ዶ/ር ዑመር አሊ
  ኢሜይል፡ O.A.Ahmed@bsms.ac.uk
  ስልክ፡ +251911408208
- ዶ/ር አበባው ፍቃዱ
  ኢሜይል፡ abebaw.fekadu@aau.edu.et
  ስልክ፡+251912894975
- ዶ/ር ዳንኤል አባይ ተቋማዊ ግምገማ ቦርድ
  ጤና ሣይንስ ኮሌጅ አዲስ አበባ ዩኒቨርሲቲ
  ስልክ፡ 0941222169

የመረጃ ቅጹን ጊዚ ወስደው ስላነበቡ እናመሰግናለን

አባሪ 2.4 ፡ የጥናት ተሳታፊ ፈቃደኝነት መጠየቂያ ፎርም

የጥናቱ ርዕስ፡ በአዊ ዞን ኢትዮጵያ የእግር ማበጥ በሽታ የጤና እንክብካቤ ፓኬጅን ማዘጋጀት

		እባክዎ እዚህ ምልክት ያድርጉ
1	*በአዊ ዞን ኢትዮጵያ የእግር ማበጥ በሽታ የጤና እንክብካቤ ፓኬጅን ማዘጋጀት* የተባለውን ጥናት በ.....ቀን የተዘጋጀውን እና ቁጥር.....የሆነውን የመረጃ ቅጽ አንብቤ መረዳቴን አረጋግጣለሁ፡፡ ከመረጃ ቅጽ ያገኘሁትን መረጃም ለመጠቀም እድሉን እግኝቻለሁ እንዲሁም ጥያቄዎች ጠይቄ ሙሉ በሙሉ በሚያረካ መልኩ ተመልሰውልኛል፡፡	
2	ተሳትፎዬ ሙሉ በሙሉ በፍቃደኝነት ላይ የተመሰረተ መሆኑን ተረድቻለሁ እንዲሁም ጥናቱ በሚካሄድበት በማንኛውም ወቅት ምንም ምክንያት ማቅረብ ሳይኖርብኝ ከተሳትፎዬ መውጣት እንደምችል ተረድቼአለሁ፡፡ ተሳትፎዬ ቢቋረጥም የማገኘው የህክምና አገልግሎትና ህጋዊ መብቴ በማንኛውም መንገድ እንደማይጎዳ ተረድቻለሁ፡፡	
3	ተቆጣጣሪ አካላትና ገንዘብ የሚደግፈው ድርጅት ጥናቱ በአግባቡ እየተካሄደ ለማረጋገጥ አልፎ አልፎ መረጃዎችን ሊጠይቁና ሊመለከቱ እንደሚችሉ ተረድቻለሁ፡፡	
4	በጥናቱ ወቅት የተቀዳ/የተመዘገበ እኔን የሚገልጽ መረጃ በአግባቡ በመረጃቋትእንደሚቀመጥ፤ መረጃ ለሌላ አካል ከተሰጠ የእኔ ዝርዝር ማንነት የሚገልጽ መረጃ እንደሚወገድ እና ጥናቱ ከታተመ በኋላ መረጃ ከ5-10 አመት እንደሚቀመጥ ተረድቻለሁ፡፡	
5	ከላይ በተጠቀሰው ጥናት ለመሳተፍ ተስማምቻለሁ	
6	ማንኛውም ጥያቄ ቢኖረኝ በመረጃ ቅጹ ላይ በተገለጸው የዚህ ጥናት አባላት አድራሻ ላይ ሪፖርት ማድረግና ማነጋገር እንደምችል ተረድቻለሁ፡፡	

_____ _____ _____

የተሳታፊ ስም ፊርማ ቀን

በዚህ የጥናት ሰነድ ያሉ መረጃዎችን ለጥናት ተሳታፊ አብራርቻለሁ፤ ጥያቄ እንዲጠይቁ ማበረታታ አድርጌአለሁ እናም ጥያቄዎችን ለመመለስ በቂ ጊዜ ሰጥቻለሁ፡፡

_____ _____ _____

የተመራማሪ/የመረጃ ሰብሳቢ ስም ፊርማ ቀን

ከተሞላ በኋላ፡ አንድ ቅጂ ለጥናት ተሳታፊ፤ አንድ ቅጂ ለተመራማሪ ፋይል መረጃ

Appendix 3. Summary of data extracted from papers for narrative review

No	1st Author year, Country	The NTD concerned	Aims of the study	Study design/setting	Participant	Sample size	Inclusion criteria	Outcome measured	Summary of results
1	Aben-Athar , 2017 Brazil	Leprosy	To evaluate activity limitations of daily life imposed by leprosy through the SALSA scale among leprosy patients	This was a descriptive epidemiological, cross-sectional study with a quantitative approach, Health care setting	Leprosy patients with or without leprosy reactions, 64.3%)were males and 26.2% were in the 31- to 40-year-old age group	84	were under treatment in the selected treatment units, were older than 18 years of age, and had agreed to participate in the study.	WHO disability grade (WHO-DG) SALSA (Screening of Activity Limitation and Safety Awareness	Out of 84 patients, less than half of the patients (41.7%) had no disability at the time of the study, although 31 (36.9%) had not been evaluated for disability. More than half of the participants (53.6%) did not have any activity

									limitations, 27 (32.1%) had mild limitations, and none of the subjects had developed very severe limitations .
2	Agidew , 2015 Ethiopia	Leprosy	The aim was to assess the magnitude of disability and associated factors among leprosy patients after MDT	Cross-sectional study, Health facility setting	Leprosy patients. 72% males and 28% are females. With mean age of 39.3 years	128	Leprosy patients who completed MDT	WHO-DG	The proportion of Grade II disability was 3.9%. All patients discharged with grade 2 disability were from rural areas

3	Bartlett , 2016 Ethiopia	Podoconiosis	To determine the prevalence of depression in individuals with and without podoconiosis, and to investigate the association of depression (as indicated by a high depression score) to disability and podoconiosis.	A comparative cross-sectional design was used, Community setting	People with podoconiosis and from healthy neighbours (The two groups were significantly different in terms of mean age)	542	Individuals with podoconiosis / controls over 18 years of age , accessibility of their homes for data collectors (271 podoconiosis patient &271 controls)	WHODAS (WHO Disability Assessment Schedule) & PHQ-9 (Patient Health Questioner)	The prevalence of depressive symptoms was significantly higher (p-value <0.001) among study participants having podoconiosis (12.6%) compared to their healthy neighbours (0.7%). The median WHODAS II score was significantly higher in people with podoconiosis than in their healthy neighbours.

4	Erinfolami , 2009 Nigeria	Leprosy	To examine the pattern of psychiatric morbidity in leprosy patients in comparison to another dermatological lesion, tinea vesicolor, as well as normal subjects.	Case control study, Health facility setting	Leprosy patients, patients with tinea versicolour, and normal individuals. All control subjects were matched for age and sex with the Leprosy patients	264	Leprosy patients, patients with tinea versicolour and normal individuals who are age above 15 years	GHQ-30 (General Health Questionnaire)and PSE-9 (The Present State Examination)	The mean GHQ scores were significantly higher in the leprosy group than in the two control groups. The analysis of variance for the three groups mean showed a statistically significant difference (ANOVA 19.83, $p < 0.001$) in psychiatric morbidity loading

5	Ganesan ,2018 India	Leprosy	To estimate the prevalence of disability and the factors associated with disability in people affected by leprosy	Cross-sectional study Community setting	Leprosy affected persons . The mean age of the study participants was61.58±12.31y, with an almost equal distribution of males (49.7%) and females (50.3%)	171	Treatment completed leprosy-affected persons ≥18 y of age, those willing to participate	WHO disability grading scale	WHO disability grading showed that 147 (86%) of the subjects were grade 2 (visible deformity) and 4 (2.3%) were grade 1.
6	Kumar ,1980 India	Leprosy	The aim is to determine the amount and type of psychiatric disturbances commonly associated with leprosy.	Cross-sectional study, Health facility setting	Leprosy patients under supervision by leprosy control program	540	Not specified (Other than being leprosy patient)	Mental Health Item sheet and the M-R scale of the Cornell Medical Index	The result is 49 0ut of 494 subjects developed psychiatric disturbance, with prevalence rate of 99 per 1000.
7	Leekassa , 2004	Leprosy	The aim was to estimate the 1-	Cross-sectional study	Outpatient Leprosy and other dermatological	786	Leprpsy patients and other		The overall prevalence of mental distress in

	Ethiopia		month prevalence of mental distress, and to investigate whether having leprosy is associated with a higher prevalence of mental distress than other dermatological conditions.	Hospital setting	illnesses. The sex distribution was approximately equal in two groups. Aged between 15 and 70 years of age.		dermatologic illness, Willing to participate	SRQ-20 (Self Reporting Questionnaire) & (EHF) Eye, hand, feet score	the study population was found to be 34·6%. Among people with leprosy the prevalence was 52·4%, compared to 7·9% in the non-leprosy patients. After controlling for other socio-demographic variables , people with leprosy had a 7-fold higher risk of mental distress than non-leprosy patients.

8	Martindale, 2014 Malawi	Lymphatic Filariasis	The aim was to quantify the severity of lymphoedema, the physical restrictions and the socio-economic impact on affected individuals living in an endemic area of Malawi.	a follow-up survey?, community setting	Lymphatic Filariasis Patients. 48 participants were female (70%) and 21 were male (30%). The median age of participants was 60 years, ranging from22 to 90 years of age	69	Lymphoedema cases over 18 years of age	?Functional outcomes (8domains 5 score/8D5L)	The majority of participants (60%) reported that they had no problem (score=1) with the mobility (46/69), self-care (57/69), usual activity (48/69), cognition (63/69) and social participation (64/69) aspects of their daily living. The mean overall disability score of the lymphoedema cases was 13.9 with a

									range of 8 to 34.
9	Montero, 2014 Brazil	Leprosy	The aim was to characterizing the limitation of activities and social participation among people who had been discharged from polychemotherapy for leprosy	Cross-sectional, Community based	Leprosy cases 145 (51.4% were male). The mean age was of 45.8 years old, ranging from 15 and 85 years old	282	Leprosy cases, discharged from treatment, age over 18 years	Eye-hand-foot score, SALSA scale, Scale of social participation.	SALSA score showed 70.2% with no limitation, 24.1 with mild limitation and 3.9 % with moderate limitation. Restriction to social participation was significantly associated with activity limitation. There was a significant association between restricted social participation

									and functional Limitation.
10	Mousley 2013 Ethiopia	Podoconiosis	To understand the effect of podoconiosis on quality of life, thus for establishing the full burden of the disease, planning appropriate services, and ensuring podoconiosis is treated as a high priority condition in local contexts.	Comparative cross-sectional study, Community setting	Podoconiosis patients, healthy neighbours. The two groups were comparable in terms of gender and age	695	Podoconiosis patients and healthy neighbours with age greater than 15 years old	WHO QoL-BREF, Kessler-10 scale, podoconiosis stigma scale	Patients with podoconiosis had significantly lower mean overall QoL scores than the controls, with a mean difference of −12.35 (95% CI: -13.87 to −10.83). This was also seen in all four sub domains (physical, psycho-logical, social and environmental) ($p<0.001$).

11	Mousley , 2015 Ethiopia	Podoco-niosis	The aim was to assess the association between podoconiosis and mental distress	Comparative cross-sectional study, Community setting	Podoconiosis patients and healthy neighbours. Both groups are similar with respect to age and gender.	695	Podoconiosis patients and healthy neighbours; age greater than 15 years old	Kessler-10 (K10) scale; the podoconiosis stigma scale	In univariate linear regression of continuous K10 scores, people with podoconiosis had K10 score 1.43 points higher than healthy controls (95% CI: 0.52 to 2.34).
12	Nardi , 2011 Mexico	Leprosy	The aim was to assess the social participation of leprosy cases after completing the treatment, and to describe the relationship between physical sequelae and the sociodemographic characteristics	cross-sectional descriptive study, community setting	People affected by leprosy, those completed therapy, of these 51·6% were women, the mean age was 54 years	223	People affected by leprosy, irrespective of age or gender	The Participation Scale (PS), 'degree of physical disability' (DPD-WHO), Eye-Hand-Foot (EHF) score	Disabilities, as assessed by the DPD-WHO and EHF, affected 32% (71) of the subjects. Of the interviewees, 35·4% (79) presented with some degree of

									restriction in social participation, with a median PS score of 8 (range 0 to 79).
13	Nardi , 2012 Mexico	Leprosy	The aim was to identify people affected by leprosy with disabilities after completing MDT for leprosy and evaluate their limitations in daily activities using the SALSA scale.	cross-sectional study, community setting	People affected by leprosy, completed therapy, of these 51·6% were women, the mean age was 54 years	223	People affected by leprosy, irrespective of age or gender	WHO-DG, SALSA scale	Thirty-two percent of respondents had disabilities according to the WHO-DG classification (23.4% G1 & 8.6% G2). One hundred and twenty-nine (57·8%) interviewees had some limitations in activities as assessed by the SALSA

									scale with the vast majority (39%) being slight limitations
14	Obindo , 2017 Nigeria	Lymphatic filariasis	The aim was to determine the prevalence and severity of depression and the social and clinical factors associated with depression in individuals with lymphatic filariasis	cross-sectional 2-stage descriptive convenience study design, Health facility setting	lymphatic filariasis cases, the majority, 58 respondents (61.7%), were females	98	lymphatic filariasis cases , irrespective of age	PHQ-9, CIDI	Nineteen respondents (20%) met criteria for depression, using CIDI, with the severity of the depression being Mild (42.1%), Moderate (31.6%) and Severe (26.3%)

15	Ramaiah, 1997 India	Lymphatic filariasis	The aim was to determine the scope of functional impairment due to the disease, and to study the prevalence of chronic disease and incidence of ADL	Qualitative and quantitative methods ? only quantitative reported, Community setting	Lymphatic filariasis cases (172) and healthy controls (200)	372	Lymphatic filariasis cases, age greater than 15 years old	?Functional outcomes	During the quantitative interviews, about 28% of the patients reported altered activity and 5% giving up work altogether. About 66% of all patients and 56% of female patients reporting impairment of occupational activities and travel and domestic activities respectively.

16	Rao, 2013 India	Leprosy	The aim was to investigate the methodology of computing DAWLY in leprosy affected persons as part of a major research on assessment of post-elimination status of leprosy in India	Cross-sectional study, Health care facility setting	Leprosy affected individuals	150	Leprosy affected individuals	DAWLY(disability adjusted working life years)	The overall mean DAWLY (± SE) of the disability adjusted life years was 28.6 (±0.67) which indicated a significant (P<0.05) reduction of 13.4 years or 31.9 per cent from the ideal productive period of 42 years. The 95 per cent of DAWLY confidence interval was 27.22 to 29.88.

17	Rocha-Leite , 2014 Mexico	Leprosy	The aim was to investigate the frequency of mental disorders in leprosy patients from two reference centres in a metropolitan area in Northeastern Brazil.	A descriptive, census and observational nature, Health facility based	leprosy patients, undergoing treatment, the majority were males (52.5%), with an average age of 42.6 years, range (18-79 years)	120	leprosy patients, age greater than 18 years,	Mini-International Neuropsychiatric Interview (MINI-Plus)	The assessment using the MINI-Plus showed that 34 (28.3%) patients did not have any psychiatric diagnosis and 86 (71.7%) had at least one. The diagnosis of major depressive disorder was the most common.

18	Santos, 2015 Brazil	Leprosy	The aim was to describe the relationship of FALs (functional activity limitation) and the QoL of patients with a diagnosis of leprosy in an endemic area of Brazil.	Cross-sectional study, Health care facility setting	Leprosy patients, 56 (53.8%) were male; their median (IQR) age was 48.0 (37.2–58.0) years old	104	Leprosy patient, age >15 years old with , in MDT treatment	SALSA, WHOQoL-BREF	Increasing SALSA scores were associated with decreasing WHOQoL-BREF scores for the physical ($r = -0.68$; $p<0.001$), psychological ($r = -0.28$; $p = 0.003$), social ($r = -0.21$; $p = 0.03$) and environmental ($r = -0.47$; $p<0.001$) scores.

19	Semrau, 2019 Cameroon	Podoconiosis	The aim was to report the prevalence of depressive symptoms amongst people with podoconiosis and lower limb lymphoedema of other cause in Cameroon (Part of large podoconiosis prevalence study)	Comparative cross-sectional, Community setting	Podoconiosis lymphoedema & lower limb lymphoedema of other causes. 50.6 % are males and 49.6 % are females. The mean age are 50.6 years.	83	Podoconiosis lymphoedema & lower limb lymphoedema of other causes	PHQ-9	There were no significant differences in levels of depressive symptoms between people with podoconiosis (mean = 3.38, SD = 3.5) and those with lower limb lymphoedema of other cause (mean = 3.65, SD = 2.82) (p = 0.73), though the only people who reported either moderate or moderately severe depressive

									symptoms had podoconiosis
20	Shumet, 2015 Ethiopia	Leprosy	The aim was to assess the prevalence of disability and associated factors among registered leprosy patients in All African TB and Leprosy Rehabilitation and Training Centre	A cross sectional retrospective record review, Health facility based	Leprosy patients, 63.9% were male and 36.1% were females patients; 43.9% were aged 15 to 30 years, 33.5% were in the age group 30-50	513	Leprosy patients	WHO-DG	338(65.9%) had disability. Two hundred and six (40.2%) had disability grade I and 132 (25.7%) had grade II disability
21	Tsutsumi, 2004	Leprosy	The aim was to investigate the depressive status of leprosy patients as	Comparative cross-sectional study, Community based study	Leprosy patients and healthy individuals. 115 male and 25 female patients	275	Leprosy patients and healthy individuals.	CES-D (The Centre for Epidemiologic Studies	The median CES-D score the patients group is 28.0, while that of the

	Bangladesh		compared to the general public.		but the control group with almost equal number (66 vs 69)			Depression scale)	comparison group is 12.0 ($p<0.001$). As a disability grade advanced the total CES-D score also increased.
22	Tsutsumi, 2007 Bangladesh	Leprosy	The aim was to determine the QOL and general mental health of leprosy patients compared with the general population	cross-sectional, Health care facility setting	Leprosy patients and healthy controls, No significance difference in age was identified between the groups for both genders (37.97 years for pts and 38.52 years for controls)	389	Leprosy patients and healthy controls	WHOQoL-BREF, SRQ, ADL (Activities of daily living)	Total WHOQOL-BREF scores among leprosy patients were significantly lower than among controls for both genders ($p<0.01$). Total SRQ scores of leprosy patients was significantly higher than healthy

									controls for both genders ($p< 0.01$)
23	Van Brakel, 2012 Indonesia	Leprosy	The aim was to assess the extent of disability and its determinants among persons with leprosy-related disabilities after release from MDT	Cross-sectional, Community setting	Leprosy affected individuals 63% of them were males, the mean age was 42.5 years	1358	Leprosy affected individuals Age greater than 10 years	SALSA scale, Social participation scale	Before treatment with standard MDT, 31% of the people already had grade 1 impairment and 31% had grade 2 impairment. About 60 % of participants had limitation in daily activities, similar proportion of participants had problems in participating in social life, and 35% had

									experienced stigma
24	Wijesinghe, 2015 Sri Lanka	Lymphatic filariasis	The aim was to describe and quantify the physical, psychological, and social aspects of the QOL in patients with chronic filarial lymphoedema	Comparative cross-sectional study, Health facility setting	Patients withfilariasis lymphoedema & healthy controls. The majority of patients were greater than 50 years old (68%), female(80 %)	269	Patients withfilariasis lymphoedema & healthy controls. Age greater than 18 years old	The General Health Questionnaire-30 (GHQ-30) and Short Form-36 (SF-36) questionnaires	The GHQ-30 questionnaire revealed that, mental well-being of controls (better than usual; 67.2%) was significantly better than that of patients (36.2%, P < .001)

Appendix 4- Systematic review protocol

Psychosocial and functional (disability) outcome of podoconiosis, lymphatic filariasis and leprosy

Oumer Ali Ahmed, Hattie Sharp, Maya Semrau, Abraham Tesfaye, Asrat Mengiste, Abebaw Fekadu, Gail Davey

Citation

Oumer Ali Ahmed, Hattie Sharp, Maya Semrau, Abraham Tesfaye, Asrat Mengiste, Abebaw Fekadu, Gail Davey. Psychosocial and functional (disability) outcome of podoconiosis, lymphatic filariasis and leprosy. PROSPERO 2019 CRD42019128400 Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42019128400

Review question

1. What are the functional/disablity outcomes secondary to LF, podoconiosis and leprosy

2. What are the psychosocial outcomes secondary to LF, podoconiosis and leprosy?

Searches

Search Engines: PubMed/MEDLINE, COCHRANE, GLOBAL HEALTH database, PsycINFO and EMBASE: The search strategy will be developed in PubMed, and iterative changes will be made to enable optimal search in the other databases.

There is no time restriction as we didn't come across previous review on the same topic. However, there is language restriction (English only), and restriction on studies conducted only in Endemic countries.

The search terms includes - Podoconiosis OR elephantiasis OR leprosy, Disability OR function OR "mental distress" OR depress* OR alcohol OR psychosocial OR Substance OR "Anxiety disorder" OR "common mental disorder" OR "Mood disorder".

On the search term I have added list of endemic countries for podoconiosis, lymphatic filariasis and leprosy. I got the list from World Health Organisation (WHO) website

Search strategy

Types of study to be included

Cross-sectional studies, prospective studies, case-control studies, clinical trials

Condition or domain being studied

Condition: Disablity (functional outcome), mental distress, depression, substance abuse/alcohol

(psychosocial outcomes) secondary to LF, podoconiosis and leprosy.

Participants/population

People with podoconiosis, lymphatic filariasis and leprosy; any age, any gender and any severity with clearly stated disability and psychosocial outcomes. Studies on these NTDs that do not address disability or co-morbid psychosocial disorders will be excluded.

Intervention(s), exposure(s)

Main outcome will be disability and psychosocial outcomes secondary to LF, podoconiosis and leprosy with or without any interventions intended to minimize these outcomes. However, the impact of the intervention will be evaluated separately.

Comparator(s)/control

Not relevant

Context

The focus of the study will be on neglected tropical diseases, specifically LF, podoconiosis. The reason for focusing on theses diseases is they are a group of chronic, disabling, and disfiguring conditions that occur most commonly in the setting of extreme poverty, especially among the rural poor and some disadvantaged urban populations. Despite the substantial disease burden they impose, NTDs have largely been ignored in the global health architecture until recently. We want to understand the gap on disability and psychosocial impacts so that appropriate intervention will be recommended

Main outcome(s)

The main outcomes are disability and depression. The disability will be measured using the World Health

Organisation Disability Assessment Schedule (WHODAS II) , which is a validated disability tool.

WHODAS 2.0 assesses the followings:- standing for long periods such as 30 minutes, taking care of household responsibilities, learning a new task, how much of a problem for joining community activities in the same way as anyone else can, emotional affection by health problems, concentrating for 10 minutes on

doing something, walking a long distance such as a kilometre or equivalent, getting dressed, maintaining a friendship and maintaining day-to-day work.

The other main outcome is depression measured by Patient Health questioner (PHQ-9), a validated mental health assessment tool.

Each question requires participants to rate the frequency of a depressive symptom experienced in the two weeks prior to evaluation. These : 1.Little interest or pleasure in doing things 2.depressed mood, 3.insomnia or hypersomnia, 4.fatigue or loss of energy, 5.appetite disturbances, 6.guilt or worthlessness, 7. diminished ability to think or concentrate, 8. psychomotor agitation or retardation, and 9.suicidal thoughts. Scores range from 0 (“not at all”) to 3 “nearly every day” with a total score ranging from 0 to 27 .

Timing and effect measures

Not applicable

Additional outcome(s)

The secondary outcomes are mental distress/anxiety and alcohol use disorder. Mental distress will be measure by Hamilton Anxiety rating scale (HAM-A) , alcohol use disorder will be measured by FAST.

Timing and effect measures

Not applicable

Data extraction (selection and coding)

a) Authors OA and HS will do the database search and the manual search of the reference lists with additional support from MS and AT

b) OA and HS will screen identified citations independently according to the selection criteria including rapid appraisal of full manuscripts. If no consensus is reached between OA and HS, then MS and AT will review.

c) Excluded articles and reasons for exclusion will be documented.

Risk of bias (quality) assessment

ProProtocol will define the method of literature critique/ appraisal use, and will use PRISMA tool for relevant con content and methodology used in the each of the papers to be reviewed

We will check the followings critically: aims clearly stated, design appropriate to stated objectives, justification for sample size, evidence provided of reliability or validity of measures used and statistics accurately reported.

Strategy for data synthesis

Narrative synthesis will be done using a framework which consists of four elements

1. Assessing the psychosocial and disability outcomes of the 3 NTDS

2. Exploring relationships among studies

3. Assessing the interrelatedness of disabilities among these NTDs

4. Assessing the strength of the synthesis

Analysis of subgroups or subsets

Analysis will be stratified by the three disease entities

Contact details for further information

Oumer Ali Ahmed

O.A.Ahmed@bsms.ac.uk

Organisational affiliation of the review

CDT Africa- Addis Ababa University, Brighton and Sussex Medical School

Review team members and their organisational affiliations

Dr Oumer Ali Ahmed. CDT Africa- Addis Ababa University, Brighton and Sussex Medical School

Ms Hattie Sharp. Brighton and Sussex Medical School
Dr Maya Semrau. Brighton and Sussex Medical School
Dr Abraham Tesfaye. Addis Ababa University

Dr Asrat Mengiste. Addis Ababa University

Professor Abebaw Fekadu. Addis Ababa University, Brighton and Sussex Medical School

Professor Gail Davey. Brighton and Sussex Medical School

Type and method of review

Epidemiologic, Narrative synthesis, Systematic review

Anticipated or actual start date

21 January 2019

Anticipated completion date

20 June 2019

Funding sources/sponsors

The review is part of Excellence in Disability Prevention Integrated across Neglected Tropical Diseases' (EnDPoINT) project work-package 1. The study is supported by National Institute of Health Research. The Funders do not have role in commissioning or advising in the review

Conflicts of interest

Language

English

Country

England, Ethiopia

Published protocol

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Elephantiasis; Elephantiasis, Filarial; Humans; Leprosy

Date of registration in PROSPERO

30 July 2019

Date of publication of this version

30 July 2019

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

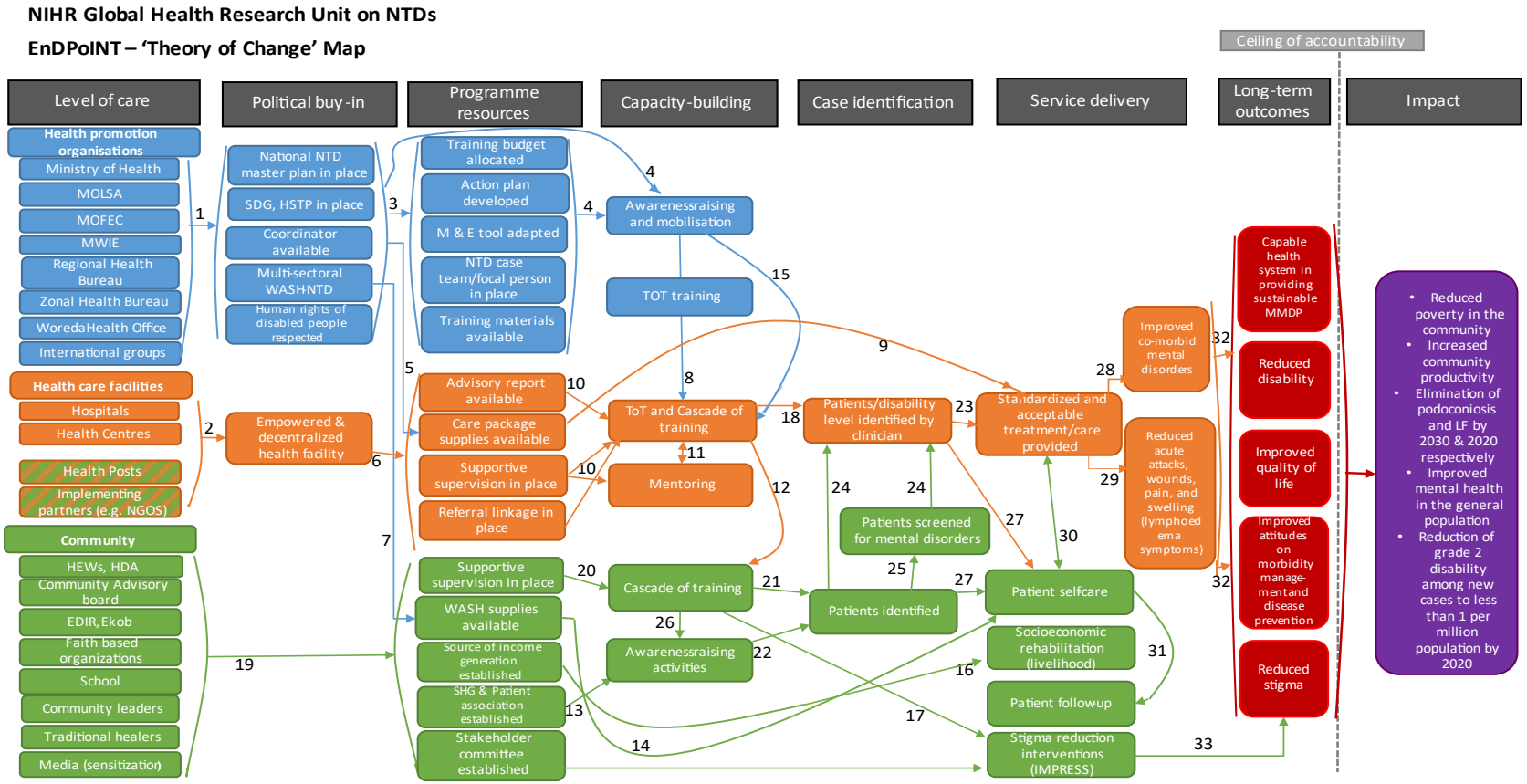
Stage	Started
Completed Preliminary searches	
Yes	No Piloting of the study selection process
No	No Formal screening of search results against eligibility criteria
No	No
Data extraction	No
No Risk of bias (quality) assessment	No
No Data analysis	No
No	

Versions

30 July 2019

R
O

Appendix 5 – Theory of Change map



Assumptions

1a Willingness of stakeholders at health promotion organisation level to participate/engage
2 Willingness of health facility staff to participate/engage
3a Adequate funding available
3b Capacity/resources available to develop action plan
3c Adequate routine data collection
3d Capacity/resources available to adapt M & E tool
4 Availability/willingness of stakeholders to participate in capacity -building activities
5 Adequate structures in place for medical supplies to reach health facilities
6a Possible to make advisory report available
6b Availability of supervisors
7 Organisations such as WASH are willing to collaborate
12 Willingness/engagement of HEWs to participate in training
13 Willingness of stakeholders and patients to engage/participate
14 Structures are in place for WASH supplies to reach patients
15 Health facility staff are willing and available to participate in capacity -building activities
16 Income generation sources/activities sustainable
17 Willingness of community to participate in stigma reduction activities
18/21/22 Training is adequate
19 No opposition from community, e.g. FBO, schools or traditional healers
23a Staff are able to provide care, e.g. sufficient capacity, experience, resources etc.
23b Trained staff remain in post and new staff are trained
24 Community members willing and able to visit health facilities, and to receive treatment
25a Screening mechanisms are adequate
25b Patients consent to being assessed/screened for mental health
26 Willingness of community to participate in awareness -raising activities
27 Patients able to perform self -care, i.e. sufficient capacity
28 Adequate treatment leads to improved mental health outcomes
29 Adequate treatment leads to a reduction in lymphoedema symptoms
30 Patient self-care is adequate
31 Patients consent to follow-up
32a Improved mental health outcomes result in the long -term outcomes
32b Reduced lymphoedema symptoms result in the long-term outcomes
33 Stigma reduction interventions lead to reduced stigma

Interventions

Health promotion organization level

1 Programme management at zonal and district level
4a Conduct participatory sensitization workshops
4b Convene public advisory group
5 Advocate/lobby for medical supplies to be made available in health facilities
7 Ensure that WASH supplies are made available
8a Capacity-building in care provision at health care organisation level (ToT)
8b Capacity -building in supervision at health care organisation level (ToT)

Health care facility level

9a Supply chain management
9b Provide training on supply change management
10a Capacity-building of health facility staff in podoconiosis , LF and leprosy
10b On -site supportive supervision for health facility staff
11 Clinical mentoring for health facility staff
15a Awareness -raising and sensitization workshops for health facility staff
15b Posters in health facilities
15c Health education sessions for attendees of health facilities
18 Case detection by health facility staff
23a Assessment, treatment and care initiation by health facility staff
23b Institutional -based rehabilitation (minor surgery; links with orthopedics , physiotherapy; rehabilitative surgery; shoe makers)
27 Training of patients in self -care

Community level

12 Capacity-building of HEWs and CC facilitators
14 WASH supplies delivered to patients
16 Community- level socio-economic rehabilitation
17a Conduct community conversation (CC) sessions
17b Patient self -help and/or peer support groups
17c Provision of health information by HEWs
17d Educational media campaign
17e Coping skills acquisition / counselling for patients
19 Engage with and sensitise key stakeholders at the community level
20 On -site supportive supervision for HEWs and CC facilitators
21 Active case detection by HEWs
22 Patient self-identification
24 Referrals by HEWs to health facilities
25 Mental health screening by HEWs
26 Conduct awareness-raising sensitization workshops
31 Follow-up home visits by HEWs

Indicators

Health promotion organization level

1 Implementation of programme; MoU signed if necessary; number of meetings with officials
4a Improved attitudes and awareness (qualitative evaluation)
4b Number of times group meets; all key stakeholders included in group
5 Number of health facilities to which medical supplies are made available
7 Number of WASH supplies distributed
8a Improved ability to train others others (pre-post test and teach back evaluation)
8b Improved supervision skills

Health care facility level

9a Number of stock -out days for main supplies
9b Improved KAP post-training compared to pre -training
10a Competence improved post -training compared to pre -training; knowledge, attitude and motivation improved; training activities satisfactory
10b Number of supervision sessions
11 Number of mentoring visits conducted; number/types of skill gaps filled
15a Improved behaviour towards patients (measured through qualitative patient interviews)
15b Number of health facilities with posters in place
15c Number of times health education sessions run
18 Number of patients identified
23a Number of patients assessed and treated
23b Number of patients receiving institutional -based rehabilitation services (minor surgery) and number of patients linked for further institutional rehabilitation
27 Number of patients trained in self -care

Community level

12 Improved KAP post -training compared to pre -training; HEWs satisfied with training materials; community-level intervention packages implemented
14 Number of WASH supplies delivered to patients
16 Increased % of people with severe disability who have access to rehabilitation services
17a Number of CC meetings; positive change in KAP in community
17b Patient self-help groups and/or peer support groups established
17c/d Availability of information leaflets in health posts; number of leaflets distributed; positive change in KAP in community
17e Coping skills acquisition / counselling in place; self-stigma reduced
19 Number of meetings held; number of stakeholders engaged; all relevant stakeholder groups engaged
20 Number of supervision sessions
21 Number of referrals by HEWs to health facilities
22 Number of patients self -identified
24 Number of referrals by HEWs to health facilities
25 Number of patients screened for mental health
26 HEWs satisfied with training materials; increased number of referrals to health post; positive change in KAP in community
31 Patient/families satisfied with home visit; retention in care / missed appointments; appropriate referrals

Appendix 6 – EnDPoINT Care Plan

Care plan for lower limb disorder caused by lymphatic filariasis, podoconiosis, leprosy, and co-morbid mental health disorder

Contents

HEALTH SERVICE ORGANISATION INTERVENTIONS

1.1 High level awareness-raising and mobilisation

Title	Health service Organization (HSO) Intervention 1
Function	Support mobilization or knowledge enhancement
Level	Health service organization level (HSO)
Rationale	Political commitment and 'buy-in' is critical for the successful implementation and sustainability of integrating limb care and co-morbid mental health care into the primary health care services. At present, levelsof awareness about lymphoedema, leprosy, and mental health disorders are very low in the general population and often much the same in health administrators, service co-ordinators, officials and influential persons at thedistrict level. Stigmatising attitudes have a role in perpetuating the neglect oflymphoedema, leprosy, and mental health care in the country.
Package	Awareness-raising workshop
Primary Provide r	HSO Senior staffs
Recipients	FMOH, Bureau, Zonal, and District health, education, agriculture, financelabour & social affairs officials
Intervention objectives	To raise awareness about • Lower limb care and co-morbid mental disorders and their treatability • Raise understanding of the broader public health and developmentbenefits of intervention through treatment of lower limb and co- morbid mental disorders
Activities and style of delivery	Participatory workshop Generate evidence for best practice
Tools	Integrated MMDP (podoconiosis, LF and leprosy, mental health) guidelines,and CC manuals with additional literature on the existing scenario of the cases and project research findings

Training	Half-day workshop
Supervision	Quarterly engagement
Evaluation	Qualitative evaluation of change in attitudes and awareness over time
Gender mainstreaming	We consider gender during selection of participants

1.2 HSO Program management support

Title	HSO Intervention 2
Function	Program management
Level	Health service organization level (HSO)
Rationale	The feasibility and sustainability of delivering lower limb disorder and co-morbid mental health care in PHC are critically dependent on strengthening an integrated NTD programme management at the health system
Package	Program management strengthening
Primary Provider	Health office and NTD team
Recipients	FMOH, Bureau, Zonal, and District health, education, agriculture, financelabour & social affairs officials
Intervention objectives	• Ensure that NTD master plan in place, an action plan on MMDPdeveloped, and inclusion in the district plan • Secure dedicated resources (human and financial) for lower limb careand co-morbid mental health care • Provide reliable MMDP supplies for lower limb care and co-morbidmental health care and MDA for LF • Enhance mechanisms for ensuring access to lower limb care and co-morbid mental health care (e.g. issuing of 'free certificates' for those who are eligible for free care) and avail functioning case identification and referral system in place • Promote human rights of people with disabilities • Ensure regular availability of MMDP training materials and trained health workers at the health centres. • Ensure the inclusion of relevant indicators in the health management information systems (HMIS) for monitoring and evaluation of lower limb disorder and co-morbid mental health care in PHC

1.2 HSO Program management support

Activities and style of delivery	• Working alongside, and in partnership with key personnel in theHSO over the period of project implementation. • Meetings with officials, • Assign coordinator (Zonal and district) • Advocacy work
Tools	MoU and leaflet for advocacy
Training	MMDP and supportive supervision training
Supervision	Quarterly engagement
Evaluation	Qualitative research in programme management capacity on integrated MMDP service delivery
Gender mainstreaming	Ensure collection of gender disaggregating data

1.3 HSO MMDP Capacity-building training

Title	HSO Intervention 3	
Function	Training of trainers on lower limband co-morbid mental health care	Training of trainers on supportive supervision, mentoring, and coaching of lower limb and co-morbid mental healthcare
Level	Health service organization level (HSO)	
Rationale	The high turnover of PHC workers means that it is necessary to build capacity within the district to beable to deliver training to new staff members, thereby ensuring sustainability of the service	Supervision is thought to be important for the sustainable integration of healthintervention into PHC. The health system has supervisory framework for reaching the PHC workers, but supervisors may not haveadequate background in lower limb disorder and co-morbid mental health care
Package	MMDP capacity building for HSO	
Primary Provider	Master trainer	Master trainer
Recipients	HSO NTD, leprosy, and mentalhealth co-ordinators and experts	HSO NTD, leprosy, and co-morbid mentalhealth disorder coordinators
Intervention objectives	To improve the capacity in training health workers at health centre on podoconiosis, LF, leprosy, and co- morbid mental health disorders	To be able to provide supportive supervision to PHC workers to monitor thequality of care
Activities and style of delivery	Training of trainees workshop and Basic training	Training of trainees workshop
Tools	MMDP guideline	FMOH existing supportive supervision document
Training	Six days training	Two days training

1.3 HSO MMDP Capacity-building training

Supervision	Quarterly engagement	
Evaluation	Pre-post-test and teach-back evaluation, attendance	Qualitative research and supervision reportevaluation
Gender mainstreaming	Include promotion of lower limb disorder and mental health of women as an agenda of the HSO	

2. HEALTH FACILITY INTERVENTIONS

2.1 Facility based health worker capacity-building training

Title	HF Intervention 1	
Function	Provider MMDP training	Provider supply chain management training
Level	Health facility – health centre	
Rationale	Health centre level provision of quality of services for lower limb disorders and co-morbid mental health is necessary to manage the diseases and prevent further medical, psychological, economical, and social complications caused by the diseases. This is achieved by training the health staffs with the required knowledge and skills on morbidity management and disability prevention.	Ensuring regular availability of MMDP supplies including MDA drug for lowerlimb disorder and co-morbid mental healthcare is required so as to provide quality services
Package	HF Capacity building training package	
Primary Provider	Master trainer and trainer	Master trainer and trainer
Recipients	Health professional working at health centre	Health Centre staff that receive/manage MMDP supplies
Intervention objectives	• To enable primary care staff to provide competent care to patients with lower limb disorder caused by podoconiosis, lymphatic filariasis and leprosy, and co-morbid mental health	• Improve understanding on basic supply system concept of Ethiopian Pharmaceutical Fund and Supply Agency • Improve knowledge to acquire stock, prevent stock-out, and manage supplies

	• To enhance institutional culture that facilitates continued learning	
Activities andstyle of delivery	Training workshop	Training workshop
Tools	MMDP guideline	PFSA Supply Chain Management training manual
Training	Five days training	One day training
Supervision	Quarterly engagement	
Evaluation	Pre-post-test Satisfaction with training	Pre-post-test
Gender mainstreaming	awareness raising regarding the needs of rural women with disabilities and the challenge they face	

2.2 Facility-based awareness raising and stigma-reduction

Title	HF Intervention 2	
Function	Disease awareness raising andreducing stigma and discrimination among health facility staff	Disease awareness raising and reducingstigma and discrimination among general attendees at the health centre
Level	Health facility – health centre	
Rationale	Studies amongst health workers at the health centre revealed stigmatizing attitudes about persons with severe lower limb disorder and co-morbid mental disorder.	Community disease awareness is very low. Raising awareness in attendees may increase the case finding of lower limb disorder and co-morbid mental health disorder and reduce stigma
Package	Facility-based awareness-raising	
Primary Provider	HSO NTDs focal person and trained health centre health worker	MMDP Trained health centre staff
Recipients	All health centre staff, including security and administrative staff	Attendees at the health centre
Intervention objectives	• To improve awareness about thediseases and MMDP benefits • To reduce stigmatizing attitudes • To raise awareness about benefitsof providing inclusive care	• Learn about symptoms, causes, prevention and treatability of lower limb disorder and co-morbid mental disorders • Reduce stigmatizing attitudes and discriminatory practices – □
Activities and style of delivery	On the job training of all staff to influence institutional culture including patient and caregiver testimonials.	Delivery of health education sessions forattendees Posters in waiting rooms

2.2 Facility-based awareness raising and stigma-reduction

	Posters in health centre	
Tools	MMDP guideline and health education materials	MMDP guidelines and health education materials
Training	Half day participatory awareness-raising and sensitization workshop	30 minute health education training once per week
Supervision	Quarterly engagement	
Evaluation	Pre- post KAP study in health facility workers and beneficiaries (qualitative study)	Number of health education sessions per month Number of health centres with posters in place
Gender mainstreaming	Awareness raising regarding the issue of gender equality and equal treatment	

2.3 Facility based assessment diagnosis and treatment initiation

Title	HF intervention package 3
Function	Case finding, assessment and treatment initiation
Level	Health facility – health centre
Rationale	Health centre level integrated provision of treatment for lower limb disordercases and co-morbid mental health care is necessary to manage the diseases and prevent further medical, psychological, economical, and social complications caused by the diseases
Package	Provision of access to MMDP services
Primary Provider	Health centre nurses and health officers
Recipients	Patients attending the health centre
Intervention objectives	• To provide comprehensive and holistic care for patients with lower limbdisorder and co-morbid mental health disorder • To improve patient quality of life and productivity • To provide patient counselling and co-morbid mental disorder care
Activities and style of delivery	• Patient training in self-care (hygiene, skin care, elevation andexercise, footwear, wound care at the health centres • Patient counselling / coping skills acquisition and co-morbid mentalhealth care • Referral linkage
Tools	MMDP guideline
Training	See HF intervention 1
Supervision	Quarterly engagement

2.3 Facility based assessment diagnosis and treatment initiation

Evaluation	Number of patients identified, assessed and treated for limb care,Number of patients reached with MMDP supplies Number of patients received counselling and co-morbid mental health care. -Clinical and psychosocial patient outcome improvement through qualitativeand quantitative study
Gender mainstreaming	Encourage gender sensitive care

2.4 Clinical Coaching

Title	HF intervention package 4
Function	Mentoring facility-based health workers
Level	Health facility – health centre
Rationale	Clinical mentoring serves as a bridge between class room training and independent-unsupervised clinical practice. Mentoring enables health care workers to practice new skills in clinical settings with the support and guidance of a more specialized and experience clinician.
Package	Clinical mentoring for health centre workers
Primary Provider	A multidisciplinary mentoring team comprised of a psychiatric nurses, senior health care workers on lower limb care, and senior pharmacist
Recipients	Facility-based health workers
Intervention objectives	• To transfer and fill skill gaps on site • To ensure practices are in line with the standards • To provide advice on complex cases
Activities and style of delivery	• On the job mentoring by multidisciplinary mentoring team once permonth
Tools	MMDP guideline
Training	See HF intervention 1. Three days training on Mentorship, coaching and supervision
Supervision	Quarterly engagement
Evaluation	Number of mentoring visits conducted Number/types of skill gap identified and filled
Gender mainstreaming	Equal gender opportunities for beneficiaries will be provided

2.4 Clinical Coaching

2.5 Health facility worker supportive-supervision

Title	HF intervention package 5
Function	Supportive supervision for facility-based health workers and HEWs
Level	Health facility – health centre
Rationale	Supportive supervision has been found to be critical for successful andsustainable delivery of health interventions into primary health care units. Embedding MMDP service supportive supervision to the existing supervision system is part of the integration process
Package	Supportive supervision for health centre workers
Primary Provider	Zonal and district levels supervisors
Recipients	Facility-based health workers
Intervention objectives	• To ensure practice is in line with evidence based guidelines • To identify short-comings and support staff to overcome theseshortcomings • To communicate with various stakeholders (pharmacy, health centrehead, district) to ensure medication supply is constantly in place
Activities and style of delivery	On site supportive supervision
Tools	Supportive supervision checklist
Training	See HF intervention 1. Three days training on Mentorship, coaching and supervision
Supervision	Quarterly engagement
Evaluation	Number of supportive supervision conducted and feedback report

Gender mainstreaming	Supervision will include evaluation whether equal gender opportunities are taking place

3. **COMMUNITY INTERVENTIONS**

3.1 Community health workers capacity-building training

Title	**Community intervention 1**	
Function	MMDP training for HEWs	Community conversation (CC) facilitator training
Level	Community	
Rationale	Health extension workers are paidcommunity-based health workers whose main role is in health promotion and illness prevention. Each 500 households have one HEW. The HEWs have 1 year of training and are in the process of being upgraded. Therefore, to strengthen community works is essential to capacitate HEWS.	Community conversation will help youto achieve reliable and sustainable community cooperation and action. CC is an interactive process through which communities come together to discuss and explore the causes of the diseases and enables them to take preventive measures and care CC facilitators lead the groups discussion and coordinate the conversation process and promote productive group dynamics and participation
Package	Community health worker capacity-building	
Primary Provider	TOT trained trainer	CC facilitators
Recipients	Health professional working at health centre	Community members

Intervention objectives	• To enable health extension workers identify patients with lower limb disorder and co- morbid mental health • To enable health extension workers follow patients during home visit • To enable HEWs to actively participate in community awareness raising • To enable HEWs to conduct adherence monitoring and support	• To generate individual and collectiveresponses through behavioural transformation to enable them to takepreventive measures and care
Activities and dstyle of delivery	Training workshop	Training workshop
Tools	MMDP guideline and FMOH pocket guide	CC manual
Training	Two days training	Two days training
Supervision	Quarterly engagement	
Evaluation	Pre-post-test Satisfaction with the training	Pre-post-test Satisfaction with the training
Gender mainstreaming	All community health workers are women; we will explore the special needs they may have, for example in relation to emotional need and safety needs, particularly in relation to providing care to those with lower limb disorder and co-morbid mental illness	

3.2 Community awareness-raising and stigma reduction

Title	Community intervention 2		
Function	1.Awareness-raising workshops	2.Community Conversation	3.Information dissemination
Level	Community		
Rationale	The community understanding about the cause, care and preventive methods ofthe diseases is low. Furthermore, most people perceive the disease is contagious, hereditary or even supernatural which result in stigmatization of the patient, and the social norm of wearing shoes is not strong. So the community needs to be aware of the diseases and the significance of wearing shoes, advantage of mass drug administration and vector control.		
Package	Community awareness-raising		
Primary Provider	HEWs	CC facilitators	HEWs
Recipients	Health transformation army, edir, schools, churches, mosques	CC members	Health transformation army, edir, schools, churches, mosques
Interventi on objectives	• To increase awareness of the disease and wearing shoes • To reduce stigma and discrimination • To protect human rights of the disabled • To increase case finding, referral and service utilization • To facilitate social reintegration □		
Activities and styleof delivery	Workshop in local vicinity including testimonials from patients / caregivers	Regular CC meetings	Information leaflets, posters in the health

3.2 Community awareness-raising and stigma reduction

	about benefits of care		posts, and mass media
Tools	MMDP guideline and FMOH pocket guide	CC manual	Billboard, poster & leaflets
Training	Half day workshop	Three days training of CC	
Supervision	Quarterly engagement		
Evaluation	• Number of referrals • Change in KAP of community	• Number of CC meetings • Number of referrals • Change in KAP of community	• Availability of posters in health posts • Number of leaflets distributed • Change in KAP of community
Gender mainstreaming	Community awareness raising workshop and CC group members will be selected based on gender and socio-cultural context		

3.3 Active case detection and referral by community health workers

Title	Community intervention 3
Function	Community-based case finding and referral by health extension workers
Level	Community
Rationale	Health extension workers are ideally placed to improve case detection in the community. This approach to case detection fits closely with their expected roles and responsibilities for other disorders. Once established aspart of their role, this has the potential to bring about sustainable improvements in case finding and referrals.
Package	Community health workers case detection and referrals
Primary Provider	Community health workers
Recipients	Patients
Intervention objectives	To identify cases in the community and referral to health centres therebyincrease access to integrate MMDP service
Activities and style of delivery	Case finding of persons with lower limb disorder and co-morbid mental health problems by community health workers
Tools	HEWs pocket guide and checklist
Training	As for HEW capacity-building package
Supervision	Quarterly engagement
Evaluation	Number of appropriate referrals to PHC centre
Gender mainstreaming	There will be no gender bias in case finding and referral

3.4 Patient follow-up visit by HEWs

Title	Community intervention 4
Function	Follow-up visit
Level	Community
Rationale	Visiting patients at their home helps to detect entry lesions early, remind patients & their families on the basic management techniques, and ensure compliance with the basics
Package	Patient follow-up
Primary Provider	HEWs
Recipients	Patients
Intervention objectives	• To improve adherence and quality of home based self-care routine • To remind patients & their families of the basic management techniques • Monitoring of mental state, detecting early signs of acute attacks andreferring for review when needed
Activities and style of delivery	Home visit by health workers to remind patient and their families the basic management techniques and to ensure compliance with self-care routine
Tools	MMDP guideline and HEWs pocket guide
Training	As for HEW capacity-building package
Supervision	Quarterly engagement
Evaluation	Satisfaction of family / person with follow-up visits Lost to follow up rate
Gender mainstreaming	Care takers of female patients may experience higher burden and stigma. These will be explored and addressed

3.4 Patient follow-up visit by HEWs

3.5 Community-based socio-economic rehabilitation

Title	Community intervention 5
Function	Community-level socio-economic rehabilitation (CBR)
Level	Community
Rationale	The potential of people with disabilities from lower limb and co-morbid mental disorders is frequently overlooked and as a result they are often excluded from income, education, employment and working opportunities.The aim of CBR is to help people with disabilities, by establishing community-based programs for physical rehabilitation, social integration, and equalization of opportunities.
Package	Community-based rehabilitation
Primary Provider	HEWs, MOLSA, community support network, other stakeholders
Recipients	Patient with disabilities
Intervention objectives	• To empower people with disabilities through social integration and equalization of opportunities, and become productive member of thecommunity • To engage the family, community, and relevant organizationsinproviding opportunities and support for the disabled.
Activities and style of delivery	Home visit, meeting community leaders. Establishment and follow-up patient self-help group and family supportgroup, and patient association. Community mobilization to support social inclusion and involvement incommunity activities, and support for families
Tools	Manual on Psychosocial and Economic Rehabilitation of patients with Podoconiosis and Lymphatic Filariasis
Training	As for HEW capacity-building package
Supervision	Quarterly engagement

3.5 Community-based socio-economic rehabilitation

Evaluation	Number of people with disability that have access to rehabilitation services and increased productivity
Gender mainstreaming	• Important to be sensitive to the needs of carers of female patients • Often care takers are women and need to mobilise broader support andengagement in care • Encourage gender-sensitive care

3.6 Community health workers supportive-supervision

Title	Community intervention 6
Function	Supportive supervision for community health workers and CC facilitators
Level	Community
Rationale	Supportive supervision has been found to be critical for successful and sustainable delivery of health interventions into primary health care. Basedon the Ministry of Health approach, supportive supervision will be conducted by Zonal and district non-speciality health office staffs.
Package	Community health workers supportive supervision
Primary Provider	District, and health centre levels supervisors HEWs(supervision of other member Health Development Army)
Recipients	Community health workers
Intervention objectives	• To ensure practice is in line with evidence based guidelines • To identify short-comings and overcome these shortcomings
Activities and style of delivery	On site supportive supervision
Tools	MMDP guideline and Supportive supervision checklist
Training	As per HEW capacity-building package
Supervision	N/A
Evaluation	Number of supportive supervision conducted and feedback reports
Gender mainstreaming	• As much as practicable, equal gender opportunities for beneficiaries will be provided

4. Cross-cutting

4.1 Community advisory group

Title	Cross-cutting intervention 1
Function	Community and stakeholder participation in development and monitoring of health service
Level	Cross-cutting
Rationale	Community Advisory Group (CAG) participants, who are recruited from the same community as the patient population, can provide valuable insightinto the underlying dynamics of the implementation. These complex issuesinclude cultural beliefs and values that can inform critical aspects of intervention design, as well as patients' perspectives of healthcare deliveryin. The CAG can help maximize the chances that the interventions will succeed. Running an effective community advisory group is listening to the community members themselves and recognizing that they are the experts when it comes to understanding the beneficiary perspective
Package	Community advisory group
Primary Provider	Advisory group members
Recipients	HSO, HF, and community workers and the project
Intervention objectives	To advises the public health service on community issues and in relation to its communication with the communities it serves
Activities and style of delivery	• Identify key community organizations that should be represented. • Outline the process for identifying which Health care organizationmembers staff will serve on the group • Team-building activities in the initial CAG meetings • Seek timely, informed advice from the community advisory committeeon such issues and developments initiate a biennial review of the community advisory group

Tools	Standard Operating procedure will be developed
Training	One day advisory group establishing workshop
Supervision	Quarterly engagement
Evaluation	Number of meetings conducted
Gender mainstreaming	Equal gender opportunities for beneficiaries will be provided

Appendix 7: Data collection tool

No	Variables	Description	**Coding**		Note
001	EClaydate	Ethiopian calendar Interview date (E.C.)	**[ ] [ ] / [ ] [ ]/ [ ] [ ] [ ] [ ]**		
002	GClaydate	European Calendar Interview date (G.C.)	**[ ] [ ] / [ ] [ ]/ [ ] [ ] [ ] [ ]**		
003	Cname	Health center name	**Gusha**		
004	cid	Health center code	**1-Gusha health center**		
005	gend	Sex (by observation)	Male	0	
			Female	1	

Section 1 : Eligibility criteria					
006	eligres	Is the respondent a resident of Guagusa Shikudad district? (Resident at least in the past 6 months)	No	0	
			Yes	1	
007	eligage	Is the respondent above 18 years old?	No	0	
			Yes	1	
008	eligcom	Is the respondent able to hear sufficiently, i.e. the respondent does not have difficulty communicating because she/he is deaf?	No	0	
			Yes	1	
009	Elignonc	Is the respondent able to communicate sufficiently in Amharic?	No	0	
			Yes	1	
010	eligill	Is the respondent healthy enough to take part, i.e. the respondent is not acutely ill or in pain?	No	0	
			Yes	1	

011	Consent	Has the respondent consented to participate in the study?	No	0	
			Yes	1	
012	Non consent	If the respondent is not willing to participate in the study, what is his/her reason? Write reason briefly in the next column. (Ask in a non-coercive way about reason. If person does not want to respond, thank them and end interview)			

013	PNA	Participant Name		
014	PID	Participant ID		
015	Kebele	Kebele		
016	Got	Gott		
017	Tele	Telephone number		
018	Tele2	Additional telephone number		
019	Nhead	Name of the head of the household		

SECTION 2: General Information				
101	PCNO			Participant's card No (complete this by looking at the participant's card)
102	SEX	Male	0	Sex (by observation)
		Female	1	
103	age	_____Years		Age
104	EDU	Illiterate[→go to Q 106]	1	Educational background (What is the
		Can read and write but didn't attend formal education (e.g learned at church or mosque or got	2	

		non formal basic education) [→go to Q 106]		highest level of education you have completed?)
		Attended formal education [→go to Q 105]	3	
105	EDUYR E.g Grade 6	_____		If you attended formal education, up to what grade/level did you attend?
106	MARIT	Never Married	1	Marital status (What is your current marital status)?
		Married	2	
		Divorced	3	
		Widowed	4	
		Married but not living together	5	
		Cohabitating	6	
107	RELIG	Christian	1	Religion (what is your religion?)
		Muslim	2	
		If other [specify]_____	77	
108	PLRES	Urban	0	Living place (where do you live, in urban or rural kebele?)
		Rural	1	
109	EMP	Paid work	1	How do you primarily spend your time in a typical day?
		Private work (shopkeeper, own business, etc)	2	
		Private work (farming)	3	
		Housewife (work in the home and child care)	4	
		Study	5	

		Unemployed	6	
		Other (specify)	77	
10	REINC	Very low	1	When you compare yourself with other people in your neighborhood, how would you express your family's current income?
		Low	2	
		Middle	3	
		High	4	
		Very high	5	
111	Do you have children?	No [Skip to next section (Section 2)]	0	KIDS
		Yes	1	
112	How many children do you have?	[ ][ ]		KIDSNO
113	How old is your youngest child?	[ ][ ] year		KIDYR

SECTION 3: MMDP assessment (fill it by examining the participant)					
301	Case	LF/podo		1	CAS
		Leprosy		2	
302	Sign of bacterial/Fungal infection	Right leg	No	0	INF
			Yes	1	
		Left leg	No	0	
			Yes	1	
303	Wounds	Right leg	No	0	WOU
			Yes	1	
		Left leg	No	0	

			Yes		1	
304	Nodules	Right leg	No		0	NOD
			Yes		1	
		Left leg	No		0	
			Yes		1	
305	Swelling size	Longitudinal Circumference at the biggest swelling site measurement	Right lower leg	Long@		SWS
				Size		
			Left lower leg	Long@		
				Size		
		Latitudinal circumference at the biggest swelling site measurement	Right foot	Lat@		
				Size		
			Left foot	Lat@		
				Size		
306	Lymphoedema Stage (Use podoconiosis lymphoedema scale)	Right leg				LES
		Left leg				
307	Leprosy disability grade					LEG
308	Has your leg ever suddenly become hot, red and painful?	No			0	AAH
		Yes			1	
309	How often does your leg become hot, red and painful? (acute attack)	Every week			1	HOA
		Every two weeks			2	
		Every month			3	
		Every 3 months			4	
		Every 6 months			5	
		Every year			6	
		Less often than every year			7	
310	Acute attack/reaction in the last month (Number of episodes)					AAT

311	Have you ever received treatment for your leg lymphoedema	No [→go to section 4]	0	LTH
		Yes [→go to Q 312]	1	
312	Are you currently receiving treatment for, or self-treating your leg(s)?	No	0	ACT
		Yes	1	
313	From where are you receiving treatment?	Government clinic	1	LTD
		Non-government clinic	2	
		Pharmacy	3	
		Traditional healer	4	
		Friend or family	5	
		Self-treatment	6	
		Other(Specify)	7	
314	Can you describe the treatment you are using?			CDT

SECTION 4: Patient Health Questionnaire (PHQ-9)				
401	Over the last 2 weeks, how often have you been bothered by any of the following problems?			
401A	Little interest or pleasure in doing things	Not at all	0	BPDT
		Several days	1	
		More than half the days	2	
		Nearly every day	3	
401B	Feeling down, depressed, or hopeless	Not at all	0	BFDH
		Several days	1	

		More than half the days	2	
		Nearly every day	3	
401C	Trouble falling or staying asleep, or sleeping too much	Not at all	0	BFTS
		Several days	1	
		More than half the days	2	
		Nearly every day	3	
401D	Feeling tired or having little energy	Not at all	0	BFTE
		Several days	1	
		More than half the days	2	
		Nearly every day	3	
401E	Poor appetite or overeating	Not at all	0	BPAO
		Several days	1	
		More than half the days	2	
		Nearly every day	3	
401F	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	Not at all	0	BFBY
		Several days	1	
		More than half the days	2	
		Nearly every day	3	
		Not at all	0	BTCT

401G	Trouble concentrating on things, such as reading the newspaper or watching television	Several days	1	
		More than half the days	2	
		Nearly every day	3	
401H	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	Not at all	0	BMSS
		Several days	1	
		More than half the days	2	
		Nearly every day	3	
401I	Thoughts that you would be better off dead or of hurting yourself in some way	Not at all	0	BTDH
		Several days	1	
		More than half the days	2	
		Nearly every day	3	
402	If you checked off any problems, ask how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	0	HDPY
		Somewhat difficult	1	
		Very difficult	2	
		Extremely difficult	3	

SECTION 5: Suicidal Ideation and Action (CIDI)				
601	Have you experienced any accident (including injury and an assault) in the past one month?	No	0	Accident
		Yes	1	
602	In the past one month, did you think a lot about death?	No	0	Deaththou
		Yes	1	
603	Have you thought of taking your life in the past one month?	No	0	SUITHINK
		Yes	1	
604	Did you ever make a plan for taking your own life at any time in the past one month?	No	0	SUIPLAN
		Yes	1	
605	Have you attempted to take your own life in the past one month?	No	0	SUIATT
		Yes[→ Go to Q606]	1	
If the response for questions 603, 604 and 605 is 'no' , skip to the next section (Q701)				
606	If you have attempted to take your own life in the past one month, how many times have you attempted?	[ ] [ ] times		SUIATF
607	Did you receive any treatment for thinking about or attempting to take your own life? Note: If the response is no and the interviewee still has thought of suicide, refer him/her to THE PROJECT COORDINATO	No [→go to 701]	0	SUITX
		Yes	1	

	R FOR CLINICAL REVIEW			
608	What treatment did you receive?	_____ _		SUITXO

SECTION 6: Social support scale (OSLO 3)				
701	How easy is it to get practical help from neighbors if you should need it?	Very difficult	1	OSAS
		Difficult	2	
		Possible	3	
		Easy	4	
		Very easy	5	
702	How many people are so close to you that you can count on them if you have serious personal problems (choose one option)?	None	1	OSCRS
		1 or 2	2	
		3-5	3	
		More than 5	4	
703	How much concern do people show in what you are doing (choose one option)?	Little concern and interest	1	OSNPS
		Uncertain	2	
		Some concern and interest	3	
		A lot of concern and interest	4	
		Very much	5	

SECTION 7: Discrimination (DISC)				
In this section, I would like to ask about times in the last 6 months when you have been treated unfairly because of your lymphoedema and co-morbid mental health. In this section, there are 19 questions. Please give a response for each.				
801	Have you been treated unfairly in making or keeping friends?	Not at all	0	DIFUR6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
802	Have you been treated unfairly by the people in your neighborhoods?	Not at all	0	DNAU6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
803	Have you been treated unfairly in dating or intimate relationships? (excluding treatment by spouse or co-habiting partner as covered by Q806)	Not at all	0	DLFUA6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
804	Have you been treated unfairly in housing? (including becoming homeless)	Not at all	0	DHRUM6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
805	Have you been treated unfairly in your education? (ask about school, college, university, on the job training, vocational courses)	Not at all	0	DECUT6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
806		Not at all	0	DMRD6

	Have you been treated unfairly in marriage or divorce? (including co-habiting or civil partnership. Ask about ability to find a partner or spouse, problems during the relationship, divorce settlements)	A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
807	Have you been treated unfairly by your family? (ask about family of origin – parents, brothers, sisters and other relations as well as any children. Exclude treatment by spouse or co-habiting partner as covered by Q806)	Not at all	0	DFBSR6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
808	Have you been treated unfairly in finding a job? (this means finding full or part-time paid work)	Not at all	0	DGWU6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
809	Have you been treated unfairly in keeping a job?	Not at all	0	DWEU6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
810	Have you been treated unfairly when using public transport? (ask about using free travel pass, passengers, drivers, etc)	Not at all	0	DPRTU6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
811	Have you been treated unfairly in your religious practices? (ask about attending church, other church members, church leaders)	Not at all	0	DUDBO6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
812		Not at all	0	DSLPT6

	Have you been treated unfairly in your social life? (ask about socializing, hobbies, attending events, leisure activities)	A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
813	Have you been treated unfairly when getting help for physical health problems? (ask about GP, dentist, nurses, health officers, health extension workers, and emergency treatment)	Not at all	0	DPBHP6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
814	Have you been treated unfairly in your personal safety and security? (ask about verbal abuse, physical abuse, assault)	Not at all	0	DPSRT6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
815	Have you been treated unfairly in starting a family or having children? (ask about the behavior of health professionals, friends and family, as well as how they or their partner were treated during pregnancy or childbirth)	Not at all	0	DFCPD6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
816	Have you been treated unfairly in your role as a parent to your children? (ask about behavior of other parents, teachers, family or health staff)	Not at all	0	DFRT6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	
817	Have you been treated unfairly in your levels of privacy? (ask about privacy in hospital and in community settings, eg private letters or phone calls, medical records)	Not at all	0	dpriv6
		A little	1	
		Moderately	2	
		A lot	3	
		Not applicable	99	

818	How much do you agree with the following statement: I feel that receiving treatment for my lymphoedema and co-morbid mental health problems has led to people tending to treat me more fairly	Strongly agree	1	dtreat6
		Agree	2	
		Neither agree / disagree	3	
		Disagree	4	
		Strongly disagree	5	
819	*Main source of information for DISC*	Patient	1	discinfo6
		Caregiver	2	
		Both	3	

SECTION 8: Internalized Stigma Related to Lymphoedema (ISRL)				
We are going to use the term "lymphoedema illness" in the rest of this questionnaire, but please think of it as whatever you feel is the best term for it. I will ask you some questions about these problems. Let me know if you agree or disagree with the following statements.				
901	I feel out of place in the world because of my illness	Strongly disagree	1	_ISMI01
		Disagree	2	
		Agree	3	
		Strongly agree	4	
902	I am embarrassed or ashamed of these problems	Strongly disagree	1	_ISMI05
		Disagree	2	
		Agree	3	
		Strongly agree	4	
903	I am disappointed in myself due to these problems	Strongly disagree	1	_ISMI16
		Disagree	2	
		Agree	3	
		Strongly agree	4	
904	These problems have spoiled my life	Strongly disagree	1	_ISMI17
		Disagree	2	
		Agree	3	

		Strongly agree	4	
905	Because of these problems, I need others to make most decisions for me	Strongly disagree	1	_ISMI19
		Disagree	2	
		Agree	3	
		Strongly agree	4	
906	I can't contribute anything to society because of these problems	Strongly disagree	1	_ISMI23
		Disagree	2	
		Agree	3	
		Strongly agree	4	
907	People discriminate against me due to these problems	Strongly disagree	1	_ISMI03
		Disagree	2	
		Agree	3	
		Strongly agree	4	
908	People often patronize me, or treat me like a child, just because of these problems	Strongly disagree	1	_ISMI15
		Disagree	2	
		Agree	3	
		Strongly agree	4	
909	People ignore me or take me less seriously just because of these problems	Strongly disagree	1	_ISMI22
		Disagree	2	
		Agree	3	
		Strongly agree	4	
910	Nobody would be interested in getting close to me because of these problems	Strongly disagree	1	_ISMI25
		Disagree	2	
		Agree	3	
		Strongly agree	4	
911	Others think that I can't achieve much in life because of these problems	Strongly disagree	1	_ISMI28
		Disagree	2	
		Agree	3	
		Strongly agree	4	

911	Others think that I can't achieve much in life because of these problems	Strongly disagree	1	_ISMI28
		Disagree	2	
		Agree	3	
		Strongly agree	4	

Section 9: DERMATOLOGY LIFE QUALITY INDEX (DLQI)				
1001	Over the last week, how itchy, sore, painful or stinging has your lymphoedema been?	Not at all	0	LISP
		A little	1	
		A lot	2	
		Very much	3	
1002	Over the last week, how embarrassed or self-conscious have you been because of your lymphoedema?	Not at all	0	LESC
		A little	1	
		A lot	2	
		Very much	3	
1003	Over the last week, how much has your lymphoedema interfered with you going shopping or looking after your home or garden?	Not at all	0	LISH
		A little	1	
		A lot	2	
		Very much	3	
		Not relevant	4	
1004	Over the last week, how much has your lymphoedema influenced the clothes you wear?	Not at all	0	LICW
		A little	1	
		A lot	2	
		Very much	3	
		Not relevant	4	
1005	Over the last week, how much has your lymphoedema affected any social or leisure activities?	Not at all	0	LSLA
		A little	1	
		A lot	2	
		Very much	3	
		Not relevant	4	
1006	Over the last week, how much has your lymphoedema made it difficult for you to do any sport?	Not at all	0	LDDS
		A little	1	
		A lot	2	
		Very much	3	
		Not relevant	4	

1007A	Over the last week, has your lymphoedema prevented you from working or studying?	No[→ Go to Q7B]	0	LPWS
		Yes[→ Go to Q8]	1	
1007B	If "No", over the last week how much has your lymphoedema been a problem at work or studying?	Not at all	0	LP LHWS
		A little	1	
		A lot	2	
		Not relevant	3	
1008	Over the last week, how much has your lymphoedema created problems with your partner or any of your close friends or relatives?	Not at all	0	LCPF
		A little	1	
		A lot	2	
		Very much	3	
		Not relevant	4	
1009	Over the last week, how much has your lymphoedema caused any sexual difficulties?	Not at all	0	LCSD
		A little	1	
		A lot	2	
		Very much	3	
		Not relevant	4	
1010	Over the last week, how much of a problem has the treatment for your lymphoedema been, for example by making your home messy, or by taking up time?	Not at all	0	LMHM
		A little	1	
		A lot	2	
		Very much	3	
		Not relevant	4	

SECTION 10: World Health Organization Disability Assessment Schedule 2.0				
1101	In the past 30 days, how much difficulty did you have in *(Show flashcard #2)*:			
1101A	Standing for long periods such as 30 minutes?	None	1	HSLT
		Mild	2	
		Moderate	3	
		Severe	4	
		Extreme or cannot do	5	
1101B	Taking care of your household responsibilities?	None	1	HTHR
		Mild	2	
		Moderate	3	
		Severe	4	
		Extreme or cannot do	5	
1101C	Learning a new task, for example, learning how to get to a new place?	None	1	HLNT
		Mild	2	
		Moderate	3	
		Severe	4	

		Extreme or cannot do	5	
1101D	How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	None	1	HPJC
		Mild	2	
		Moderate	3	
		Severe	4	
		Extreme or cannot do	5	
1101E	How much have you been emotionally affected by your health problems?	None	1	HEAH
		Mild	2	
		Moderate	3	
		Severe	4	
		Extreme or cannot do	5	
1101F	Concentrating on doing something for ten minutes?	None	1	HCDT
		Mild	2	
		Moderate	3	
		Severe	4	
		Extreme or cannot do	5	
1101G	Walking a long distance such as a kilometre [or equivalent]?	None	1	HWLD
		Mild	2	
		Moderate	3	
		Severe	4	
		Extreme or cannot do	5	
1101H	Washing your whole body?	None	1	HWWB
		Mild	2	
		Moderate	3	
		Severe	4	
		Extreme or cannot do	5	
1101I	Getting dressed?	None	1	HGD
		Mild	2	
		Moderate	3	
		Severe	4	
		Extreme or cannot do	5	
1101J	Dealing with people you do not know?	None	1	HDPK
		Mild	2	
		Moderate	3	
		Severe	4	
		Extreme or cannot do	5	
1101K	Maintaining a friendship?	None	1	HMF
		Mild	2	
		Moderate	3	
		Severe	4	

		Extreme or cannot do	5	
1101D	Your day-to-day work/school?	None	1	HDWS
		Mild	2	
		Moderate	3	
		Severe	4	
		Extreme or cannot do	5	
1102	Overall, in the past 30 days, how many days were these difficulties present?	Record number of days _____		HMDD
1103	In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	Record number of days _____		HDUA
1104	In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	Record number of days _____		HDCB

Appendix 8- Question guide for qualitative study
Topic guide questions English version

Greetings! Thank you for agreeing to speak to us. As we discussed previously, this interview is part of our effort to improve care for people affected by podoconiosis, LF and leprosy who have limb care and psycho social care needs.

Part of our plan is to :

a.Provide an integrated morbidity management and disability prevention services for people affected by LF, podoconiosis and leprosy

b.Provide a holistic care for these patiens (both physical and psych-social)

c.Support integration of the above services into the routine care, particularly the primary care system.

I would just like to learn from you about the need you see in this area and what integrated and holistic care should look like for these people. There are no right or wrong answers. I value your perspectives.

Do you have any questions that you want to ask me beforehand?

Thank you in advance for your assistance!

1. Let's start by you telling me a little bit about your experience regarding people affected by podoconiosis, LF and leprosy with limb care and psychosocial care needs and your involvement with them.
2. What do you understand by integrated care?
3. What do you think about the importance and potential impact of integrated care for patients with podoconiosis, LF, and leprosy? Probe for possible gains/disadvantages of integration.
4. • How important and acceptable do you think it is to integrate psychosocial care aspects into the care package?
5. What do you think are the views of policy makers (Health bureau, office and facility manager)? Do you think that they believe that developing an integrated care package as an important, good and acceptable idea?
6. What do you think are the views of providers? Do you think that they view it is an important and acceptable idea?
7. What do you think are the views of patients themselves? Do you think that they view it as an important and acceptable idea?

8. What do you think are the views of caregivers (individuals who care for people with podo, LF or leprosy) Do you think that they view it as an important and acceptable idea?

9. What are the possible barriers for implementing the proposed integrated care package? What would be the strategies to overcome these obstacles? Probe for possible challenges and solutions in relation to policy, human resources, supplies, physical infrastructure, budget, feasibility and sustainability issues (how much external support is needed to make it work e.g. EnDPoINT).

10. Do you think an integrated care package would improve the care of patients? Improve the skills of providers?

11. What do you think are the best ways of stigma mitigation?
12. Would you recommend the intervention to similar patients in other places?

13. Any additional information you would like to add.

Topic guides questions Amharic version

ሠላምታ! ከኛ ለመወያየት በመስማማቶ እናመሰግናለን፡፡ ይህ ውይይት የእግር ክብካቤ ለሚሹ የህብረተሰብ ክፍሎች ክብካቤን ለማሻሻል የምናደርገው ጥረት አካል ነው፡፡ የኛ ከፊል ዕቅድ የእግር ክብካቤ የመደበኛ ክብካቤ አገልግሎት ውሥጥ እንዲቀናጅ ማገዝ ነው በተለይ በመጀመሪ ደረጃ የጤና ክብካቤ አሀድ፡፡ በዚህ አካባቢ ስላለው ፍላጎት፣ የተቀናጀና አጠቃላይ ክብካቤ ለነዚህ ህዝቦች ምን መምሰል እንዳለበት ከእናንተ ለመማር እሞክራለሁ፡፡ልክ ወይም የተሳሳተ መልስ የለም፡፡ እይታዎን አከብራለሁ፡፡

ከመጀመሪ በፊት ልትጠይቁኝ የምትፈልጉት ጥያቄ አላችሁ?

ለትብብራችሁ በቅድሚያ አመሰግናለሁ!

1) የእግር እንክብካቤ ከሚሾ የህብረተሰብ ክፍሎች ጋር ያሎችን ልምድና ቀረቤታ ለኔ በመንገር እንጀምራለን

2) የተቀናጀ እንክብካቤ ሲባል ምን ይገነዘባሉ?

3) የተቀናጀ እንክብካቤ ለፖዶኮኒሲስ፤ ሊንፍ ፊላሪያሲስ እና ስጋደዊ ህሙማን ማዘጋጀት ያለውን አስፈላጊነትና የወደፊት ውጤት እንዴት ያዩታል?
4) የተቀናጀ psychosicial care ምን የህል አስፈለጊና ተቀባይነት ያለዉ ነዉ ብለዉ ያስባሉ

5) የውሳኔ ሰጪ አካላትን እይታ እንዲት ያዩታል? የተቀናጀ የእንክብካቤ ፓኬጅ ማዘጋጀትን አስፈላጊ፣ ጥሩና ተቀባይነት ያለው ሃሳብ አርገው የሚያስቡ ይመስሎታል?

6) አገልግሎት ሰጪ ተቋማትን እይታ እንዲት ያዩታል? የተቀናጀ የእንክብካቤ ፓኬጅ ማዘጋጀትን አስፈላጊ፣ ጥሩና ተቀባይነት ያለው ሃሳብ አርገው የሚያስቡ ይመስሎታል?

7) የህሙማንን እይታ እንዲት ያዩታል? የተቀናጀ የእንክብካቤ ፓኬጅ ማዘጋጀትን አስፈላጊ፣ ጥሩና ተቀባይነት ያለው ሃሳብ አርገው የሚያስቡ ይመስሎታል?

8) እንክብካቤ የሚሰጡ ሙያተኞችን እይታ እንዲት ያዩታል? የተቀናጀ የእንክብካቤ ፓኬጅ ማዘጋጀትን አስፈላጊ፣ ጥሩና ተቀባይነት ያለው ሃሳብ አርገው የሚያስቡ ይመስሎታል?

9) የተዘጋጀውን የተቀናጀ የእንክብካቤ ፓኬጅ ለመተግበር ምን እንቅፋት ይሆናል? እንቅፋቱን ለመቅረፍ ዘዴው ምን መሆን አለበት? ከህግ፤ ከሰው ሀይል፤ ከአቅርቦት፤ ከህንጻ፤ ከበጀት፤ ከቀጣይነት አንጻር (ለመተግበር ምን ያህል ውጫዊ ድጋፍ ያስፈልጋል ለምሳሌ ከኢንድፖይንት) ሊኖሩ የሚችሉ እንቅፋቶችንና መፍትሄዎቻቸውን መርምር

10) የተቀናጀ ክብካቤ ፓኬጅ የህሙማን ክብካቤን ያሻሽላል ብለህ ታስባለህ? የአግልግሎት ሰጪን ክህሎትን በማሻሻል ረገድ?

11) አድሎና መገለል በምን ይገለጻል፣ ይህን ለመቀነስ ምን መደረግ አለበት

12) ይህንን ህክምና በሌሎች ቦታዎች ላሉ ሌሎች ህሙማን ቢሰጥ ዉጤታማ ይሆናል ብለዉ ይገምታሉ? እንዲሰጥ ይመክራሉ/ቢሰጥ ይደግፋሉ

13) መጨመር የሚፈልጉት ማንኛውም ሃሳብ ካለ

Group Discussion Guide

Group Discussion Facilitation Protocol

I. Introduction /Warm-up

- Thank participants for their willingness to participate in this discussion.
- Explain the purpose of the group discussion
- Introduce yourself
- Explain the role of the facilitator and note takers
- Let participants introduce themselves
- Introduce the topic of discussion

II. Instruction

- Assure all participants that personal data will be kept confidential.
- Make clear what is expected of participants
- Make clear the time length of discussion. Make sure that the discussion lasts anywhere between 45 minutes and 1 hour.
- Make sure that each participant in the group fills out the group discussion Participant Profiling Form.
- Ask for permission to take notes.
- Keep eye contact with the participants, make sure you shift your attention among all participants and make sure you include everyone.
- Maintain eye contact with the individual with a disability even if they are blind or are using an interpreter.
- Do not make any assumptions about limitations.
- Set ground rules for the group with the participants: Consider the following rules:

- Respect for different views, no wrong answers, one person speak at a time, everyone has the right to speak without being interrupted, raise your hands and get a signal from the facilitator before you talk, keep your answers short and precise to allow others to participate, switch off/silence your cellphones
- Do NOT promise what you cannot deliver.

III. Closing and Post Discussion Activities

A. We have had a very good discussion. Summarize the ideas which emerged from the focus group, noting where there was consensus and where there was not consensus
B. Is there anything anyone would like to add before we close? Probe: go around the group, giving each participant a chance to respond
C. Thank everyone for their time and input
D. Make sure to write the group discussion report immediately after the discussion.

Appendix 9 - Paper one

Ali O, Mengiste A, Semrau M et al., (2021) The impact of podoconiosis, lymphatic filariasis, and leprosy on disability and mental well-being: A systematic review. PLoS Negl Trop Dis 15(7):

Appendix 10 - Paper two

Ali O, Deribe K, Semrau M et al., (2020). A cross-sectional study to evaluate depression and quality of life among patients with lymphoedema due to podoconiosis, lymphatic filariasis and leprosy. Trans R Soc Trop Med Hyg ; 0: 1–12

Appendix 11 - Paper three

Ali O, Kinfe M, Semrau M et al., (2021). A qualitative study on the implementation of a holistic care package for control and management of lymphoedema: experience from a pilot intervention in northern Ethiopia. BMC Health Services Research 21:1065

Appendix 12- Pictures from field work


ጉሻ ጤና
አጠባበቅ ማዕከል
GUSHA HEALTH CENTER


3