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Family-based intervention for prevention and self-management of disabilities due to leprosy, podoconiosis and lymphatic filariasis versus usual care in Ethiopia: study protocol for a cluster-randomised controlled trial

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ABSTRACT

Introduction Leprosy, podoconiosis and lymphatic filariasis (LF) are three skin-related neglected tropical diseases. All three conditions can lead to temporary and permanent impairments. These impairments progressively worsen and are major determinants of stigma, discrimination and participation restrictions. Self-care is essential to prevent disabilities and chronic disease complications. Many persons with leprosy-related, LF-related and podoconiosis-related disabilities need to practice self-management routines their entire life. This is difficult without support and encouragement of others. The objective of this study was to assess the effectiveness of a family-based intervention in terms of physical outcomes related to prevention and self-management of disabilities due to leprosy, podoconiosis and LF and family quality of life and well-being compared with usual practice and care.

Methods and analysis The study will use a cluster-randomised controlled trial design with two study arms. The project will be carried out in endemic districts in East and West Gojjam zones in the Amhara region in Ethiopia. Clusters consist of kebeles (lower administrative structures in the district) that have been merged, based on their geographical proximity and the number of cases in each kebele. A total of 630 participants will be included in the study. The intervention group will consist of 105 persons affected by leprosy, 105 persons affected by LF or podoconiosis, and 210 family members. The control group will consist of 105 persons affected by leprosy and 105 persons affected by LF or podoconiosis. The family-based intervention comprises an essential care package that consists of the following three main components: (1) self-management of disabilities, (2) economic empowerment and (3) psychosocial support. Participants in the control areas will receive usual practice and care. Data analysis includes, but is not limited to, calculating the percentage of change and corresponding 95% CI of physical impairment outcomes in each group, before and after the intervention is implemented, effect sizes, intention to treat and difference in difference analysis.

Ethics and dissemination Ethical approval has been obtained from the Debre Markos University Health Sciences Institutional Research Ethics Review Committee. Results will be disseminated through peer-reviewed publications, conference presentations and workshops.

Trial registration number PACTR202108907851342.

Strengths and limitations of this study

- This family-based intervention cluster-randomised controlled trial was preceded by a proof-of-concept study, in which the intervention was found feasible.
- While self-management of disabilities is the main component of the family-based intervention, the essential care package goes beyond self-care and also includes economic empowerment and a psychosocial care component.
- This study is led by and partly carried out by the Ethiopian National Association of Persons Affected by Leprosy, a large Ethiopian leprosy disabled persons' organisation.
- Inclusion of family members in self-care activities ensures sustainability of the intervention.
- Because randomisation will be done at the level of kebeles, it will not be possible to conduct a blinded outcome assessment because research staff will be aware of the area they are in. It is not considered feasible to find people from outside the study areas to conduct the outcome assessment.

INTRODUCTION

Leprosy, podoconiosis and lymphatic filariasis (LF) are neglected tropical diseases (NTDs).[1] NTDs are a group of communicable diseases that are among the most common conditions, particularly among the world's poorest populations.[2 3] These diseases predominate in rural and impoverished urban areas of low-income and middle-income countries.[4] Worldwide,

over one billion people have one or more NTDs.[5] NTDs are 'poverty promoting' conditions; they cause suffering through acute illness, pain, long-term disability, early death and through mental and social consequences.[2 4]

Leprosy, podoconiosis and LF are three skin-related NTDs.[1] All three conditions have skin manifestations such as patches, ulcers, wounds, nodules or localised swelling.[6–9] They are caused by bacteria (leprosy), chronic exposure to red clay volcanic soil (podoconiosis) and nematode worms that are transmitted by mosquitoes (LF).[7 8 10] Leprosy, podoconiosis and LF can lead to temporary and permanent impairments if not diagnosed and treated early.[1 6 11] These impairments progressively worsen and are major determinants of stigma and participation restrictions.[12–14]

Social consequences of all three conditions may include reduced work and education opportunities, social isolation, exclusion and problems in interpersonal relationships, including marital problems.[15–18] Psychological consequences may include feelings of shame, low self-esteem, mental distress, depression, anxiety, and decreased individual and family quality of life.[15–18] In addition, these conditions may impose a social and economic burden on families.[16 19] Family members may also experience stigma.[16 20–23] Furthermore, costs for treatment and reduced ability to work may cause a financial burden for the entire family.[16 19]

Most impairments, such as wounds, swelling and contractures, are largely preventable.[1] The most effective strategy for prevention of disabilities is early diagnosis and prompt treatment.[24] Self-care is also an essential component of prevention of disabilities and for prevention of chronic disease complications.[24–27] Relatively simple methods exist for self-management of impairments, such as daily washing of affected limbs, skin care, bandaging, exercises and the use of shoes.[27] Most of these methods can be practised at home and are suitable for use across different skin-related NTDs.[27–29] These self-care interventions have been found effective in, for example, reducing the incidence of acute dermatolymphangioadenitis in persons affected by podoconiosis and LF[30 31] and in reducing ulcers among persons affected by leprosy.[32] Because physical impairments are an important determinant of stigma, disease management is also an indirect intervention to reduce stigma.[33]

Many persons with leprosy-related, podoconiosis-related and LF-related disabilities need to practise self-management routines their entire life. This is difficult without support and encouragement of others. Family members can provide such support and encouragement. We recently conducted a proof-of-concept study in which we piloted a family-based intervention for prevention and self-management of disabilities due to leprosy, podoconiosis and LF in Ethiopia.[34] This family-based intervention consisted of self-management of disabilities, awareness raising and economic empowerment, and was delivered during several monthly group meetings. Economic empowerment was an important component of the intervention, as income generation is essential for sustainable self-management and prevention of disabilities: without income, self-care items such as Vaseline and shoes cannot be bought. We found that the intervention had a positive effect on impairments and self-management of disabilities, family quality of life and stigma. However, sampling was not randomised, which means we could not determine the effectiveness of the intervention. To collect credible evidence for this new, previously piloted intervention, we aimed to conduct a similar study using a randomised controlled design.

Objectives

The primary objective of this study was to assess the effectiveness of a family-based intervention in terms of physical outcomes related to prevention and self-management of disabilities due to leprosy, podoconiosis or LF, and family quality of life and well-being compared with usual practice and care. Secondary objectives included the following: (1) to reduce the number of people who have an episode of depression, as measured with the Patient Health Questionnaire-9 (PHQ-9); (2) to reduce the level of stigma as measured with the SARI Stigma Scale (SSS), in-depth interviews and focus group discussions; (3) to improve social participation as measured with the Participation Scale (P-Scale); (4) to increase the number of people who have adequate knowledge of leprosy, LF and podoconiosis as measures with disease-specific Knowledge, Attitudes and Practices (KAP) measures; and (5) to empower people economically as measured by monthly household income, monthly financial contribution to the self-help group and in-depth interviews.

METHODS AND ANALYSIS

The protocol for this study is outlined further. This study protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement.[35]

Study design

The intervention consists of a cluster-randomised controlled trial (RCT), with two study arms. The two study arms consist of (1) the family-based intervention and (2) usual practice and care (control group).

Study setting

The project is carried out in endemic districts in East and West Gojjam zones in the Amhara region in Ethiopia (the proof-of-concept study was conducted in a different zone, the Awi zone). The Amhara region is the second largest state in population and is divided in 11 zones. All three conditions are endemic in the Amhara region. In 2019, Ethiopia had 3201 new patients with leprosy, 13% of the new patients had grade 2 disabilities.[36] The prevalence of leprosy is highest in the Amhara, Afar and Oromiya regions.[37 38] LF is endemic in the Amhara, Beneshangul-Gumuz, Southern Nations, Nationalities, and Peoples'

Region (SNNPR) and Oromia regions. Three million people are estimated to be at risk of LF in the Amhara region.[39] In addition, Ethiopia is estimated to have 25% (1 million cases) of the global burden of podoconiosis. Podoconiosis is spread out over one-fifth of the surface of Ethiopia, especially the Western part.[37 40 41] The regions with the high prevalence of podoconiosis are Amhara, SNNPR, Oromiya and Beneshangul-Gumuz.[40 41]

East and West Gojjam zones are subdivided into 16 and 20 districts (woredas), respectively. The three districts selected for this study are Dega Damot and Dembecha districts (West Gojjam zone) and Enarge Enawga (East Gojjam zone). These districts have been selected based on their similarity in total population, sex ratio, number of urban/rural neighbourhoods (kebeles), number of hospitals, health centres and health posts, disease prevalence and lack of previous or ongoing leprosy, podoconiosis or LF-related work of other organisations (table 1). The latter to avoid possible contamination of the study results. The study is being conducted in real-world settings and populations.

Participants

People with leprosy-related impairments and people with LF-related or podoconiosis-related lymphoedema ('persons affected') will be included in this study. In

Table 1 Characteristics of the selected study areas

	Dega Damot district	Dembecha district	Enarge Enawga district
Total population, n (%)	181 325 (100)	218 257 (100)	172 939 (100)
Men	89 756 (49.5)	105 809 (48.5)	86 297 (49.9)
Women	91 156 (50.5)	112 448 (51.5)	86 642 (49.1)
Number of kebeles, n (%)	36 (100)	31 (100)	35 (100)
Rural	34 (94)	27 (87)	31 (89)
Urban	2 (6)	4 (13)	4 (11)
Health facilities, n			
Hospital	1	1	1
Health centre	7	7	7
Health post	34	28	34
Number of health extension workers working in the area	88	60	76
Percentage of total population that has podoconiosis (%)	>10	1–5	>10
Estimated number of persons with leprosy-related, podoconiosis-related or LF-related disabilities living in the area	Leprosy=132 Podoconiosis=352	Leprosy=135 Podoconiosis=1042	Leprosy=213 Podoconiosis or LF=797
Geographical and background information	► Climate zones: 75% Dega (cool temperate), 20% Woina Dega (subtropical) and 5% Kolla (hot lowland). ► Annual rainfall between 900 m and 1200 mm. ► The district consists of 35% mountain, 30% hills, 20% valleys and 15% plains.	► Climate zones: 11% Dega (cool temperature), 83% Woina Dega (subtropical) and 6% Kolla (hot lowland). ► Annual rainfall is between 1221 mm and 1602 mm. ► The district consists of 60% plains, 30% mountain and 10% hills. ► Elevation is 1500–2995 m above sea level. ► Other: bordered by the Nile River.	► Climate zones: 30% Dega (cool temperate), 50% Woina Dega (subtropical) and 20% Kolla (hot lowland). ► Annual rainfall is between 1200 mm–1400 mm. ► The district consists of 50% plains, 30% mountain and 20% hills. ► Elevation is 1100–3200 m above sea level.
Previous or ongoing work with the target group in the area?	No	Yes, with persons affected by podoconiosis (no persons affected by podoconiosis will be included from this district).	No

Data were collected from field census, health office reports and Molla *et al* and Berhe *et al*.[50 51]
LF, lymphatic filariasis.

addition, of each person affected, at least one adult family member will be included (eg, sibling, child, parent or grandparent of a person affected by leprosy, LF or podoconiosis).

People 15 years and above will be included in the study. All persons have to be residents of project areas of the study. All persons affected need to have leprosy-related, LF-related or podoconiosis-related impairments and have to be eligible to participate in self-care activities, as the focus is on skin and wound care of affected persons. Family members need to live in the same household as persons affected. People who are unable to coherently express themselves verbally (ie, are unable to understand and participate in an interview) will be excluded. In addition, persons affected who live alone will excluded.

Intervention

This RCT was preceded by a proof-of-concept study in which a family-based intervention was developed and found feasible.[34] The family-based intervention consists of an essential care package that consists of the following three main components: (1) self-management of disabilities, (2) economic empowerment and (3) psychosocial support. All components of the intervention are family-based and family focused. Although not mentioned as a separate component, awareness raising of leprosy, LF and podoconiosis in the family and the community is an integral part of the intervention. The essential care package is described in more detail as follows:

- Training sessions/group meetings for self-management and prevention of disabilities. Based on the proof-of-concept study, at least five group meetings will be held in a location that is most convenient for the participants. These sessions will be delivered in group format (several families participate with one person affected and one family member present per family) to introduce the family-based methods for self-management and prevention of disabilities. In the first session, basic training will be given to persons affected and their family members in using and giving psychosocial support, increasing prevention and self-management of disabilities skills, information about the disease, creating strategies to overcome barriers and facilitators to self-care. In the following training sessions, the research assistants support and guide all participating families (repeating the basic training given in the first session) and are available to clarify questions. During these meetings, physical impairment outcomes will routinely (monthly) be collected. Family members are encouraged to help their affected family member with self-care at home. (Each group will have approximately 20 participants; therefore, training for participants in the intervention group will not all be given at the same day/time.) We anticipate that the first group meeting will be held in February 2022. Group meetings will be conducted until September 2022.
- Formation of self-help groups for economic empowerment. The project will facilitate the formation of self-help groups of affected persons; their family members are encouraged to join group meetings. The Ethiopian National Association of Persons Affected by Leprosy (ENAPAL), a large Ethiopian leprosy disabled persons' organisation with a successful track record in establishing self-help groups, will coordinate and guide this part of the intervention. The facilitators of the project, trained by ENAPAL, will help to establish the self-help groups and will be present during the meetings but will not give guidance on the management of the groups. Management of the groups will be done by persons affected themselves; participants of the group will be asked to elect a 'committee' of persons affected. Each self-help group will collect a small contribution fee from its participants; these fees are used to provide loans for the participants of the self-help groups (microfinance). Self-help groups will also lobby for 'benefits', for example, the use of land, from the government. In addition, each self-help group participant and at least one of their family members will receive (one) vocational training. Income generation will benefit the whole family.
- Psychosocial support will be part of the training sessions/group meetings for self-management and prevention of disabilities. Persons affected and their family members will be trained in using and giving psychosocial support.

The control group will undergo treatment as usual. Participants in the control areas will undergo the same basic training (one session) as the participants in the intervention group but will have no family members present during the training. When the intervention group has their additional four meetings (at least five meetings will be held), the participants in the control group will receive usual practice and care. In addition, they will receive information about existing mechanisms for economic empowerment (such as 'funeral saving groups' and other existing credit-saving initiatives).

Procedures

This study has two main phases. Each phase is briefly described as follows.

Phase I: preparatory phase. In this phase, a literature review will be conducted to guide the development of the psychosocial support component that will be added to the family-based intervention. In addition, the SSS, FQoL scale and P-Scale will be cross-culturally validated (the PHQ-9 has already been validated in Amharic[42–44]). We will assess conceptual, item, semantic, operational and measurement equivalence using a framework for cross-cultural equivalence testing based on the work of Herdman *et al*,[45] Terwee *et al*[46] and Stevelink and van Brakel.[47] The KAP measure will be translated and pilot tested. A training workshop will be organised to train community health extension workers, local area health workers and the research team

in research methods and family-based intervention. A list of persons affected registered in the community-level census that are eligible to participate in self-care activities will be prepared. Persons affected by leprosy, podoconiosis or LF and their family members will be recruited. A database will be established to monitor the routine intervention activities. Baseline data will be collected by the research assistants, and the results will be analysed by the researcher.

Phase II: implementation and evaluation of the family-based intervention. In this phase, the intervention will be implemented: at least five training sessions and family meetings will be held. This training is done by the researcher (who has extensive experience in providing training, self-care practices and the three conditions included in this study), with support from the research assistants and with at least one community health extension worker present at the meeting. Research assistants will receive a 4-day training on how to implement the intervention; this training is facilitated by the researcher and the project manager. In addition, each training session is carried out using standard operating procedures that have been developed using the WHO's integrated morbidity management for LF and podoconiosis,[48] the Ethiopian Ministry of Health's LF and podoconiosis morbidity management and disability prevention guidelines and International Federation of Anti-Leprosy Associations (ILEP)'s guideline for prevention of disabilities in leprosy.[49] As has been described in detail previously,[34] participants in the intervention and control areas will receive basic tools to practise self-care (Vaseline, a bucket, shoes and soda). In this phase, the effectiveness and acceptability of the intervention will be evaluated (feasibility has already been established in the proof-of-concept study that was recently conducted[34]). This will be done by collecting the same information as in the baseline study (table 2), a few weeks and 1 year after implementation of the intervention. In addition, interviews will be conducted to collect most significant change stories and to assess the impact qualitatively. Because randomisation will be done at the level of kebeles, it will not be possible to conduct a blinded outcome assessment because research staff will be aware of the area they are in. It is not considered feasible to find people from outside the study areas to conduct the outcome assessment. All components of the study will be conducted in Amharic, the official language of Ethiopia and language spoken in the study areas.

Outcomes

Table 2 details the outcomes measured during this study, including the methods that will be used to measure the outcomes. Physical impairment outcomes are the primary outcome measures. Acceptability, family quality of life, stigma, social participation, mental well-being, disease knowledge, attitudes and economic empowerment are secondary outcomes.

Participant timeline

The participant timeline, in line with SPIRIT recommendations, can be found in table 3.

Sample size

A total of 630 participants, consisting of 420 persons affected and 210 family members, will be included in the study. It is difficult to distinguish LF and podoconiosis based on clinical features under field conditions, and the distinction between these conditions does not matter with regard to the outcomes of this study; therefore, persons affected by both these conditions are treated as one group. There will be one intervention and one control group for persons affected by leprosy, and one for persons affected by LF or podoconiosis. Family members are only included in the intervention group. The intervention group will consist of 105 persons affected by leprosy, 105 persons affected by LF or podoconiosis, and 210 family members. The control group will consist of 105 persons affected by leprosy and 105 persons affected by LF or podoconiosis. The sample size calculation is based on data from the proof-of-concept study.[34] In the proof-of-concept study, 43% of the participants had leg impairments (wounds, nodules and/or infections) at intake. During the final assessment, the last session participants attended, and the number of participants with leg impairments had dropped to 21%. A sample size calculation for two proportions (proportion 1: 43%, proportion 2: 21%) with a significance of 0.05 and a power of 90% would give a total sample size of 92 participants in each group. We expect that the loss to follow-up will be no more than 15% (we do not expect a higher loss to follow-up, as participants will be followed up at home). Our sample size will therefore be 105 persons affected in each group. The kebeles have been selected in such a way that they are similar to each other; we therefore do not anticipate a cluster effect in the current outcomes.

Recruitment

Potential participants will be approached via community-level enumeration, healthcare settings, persons affected organisations, community leaders and by word of mouth. The recruitment period is 6 months, starting in October 2021. Once participants are enrolled, they will be followed up during the study period up to 12 months in the nearby health centre or health posts. In the case of loss to follow-up, participants will be visited in their home.

Allocation

The three districts will be randomly divided into clusters to implement either the family-based intervention or usual practice and care (control group). A complete enumeration of persons with the three diseases has been conducted in each district; kebeles (a lower administrative structure in the district) have been merged into 'clusters' based on their similarity, including their population characteristics, geographical proximity, the presence of a health centre and the number of cases in each kebele. Each cluster consists of three to five kebeles on average (ranging from two to seven), and all clusters have at least one health centre in the area. Sixteen clusters have been identified in the three study districts:

Table 2 Outcome measures

Type of outcome	Specific outcome	Outcome measures
Implementation outcomes	Acceptability	Qualitative (IDI and FGD)
	Disability management practices	Observations (field notes), qualitative (IDI and FGD)
	Economic empowerment	Registration of attendance of persons affected organisation group meetings, number of loans disbursed and total amount of money disbursed
Effectiveness (persons affected level)	Physical impairment outcomes	For persons affected by leprosy: ► Eyes, Hands, Feet Score,[52] total number of wounds present (wound count), registration of infection and observation (field notes). For persons affected by podoconiosis and LF: ► Lymphoedema grading, measuring the largest point of swelling below the knee circumference, registering the frequency of acute attacks, wound count, registration of infection and observation (field notes).
	Physical well-being	IDI
	Family quality of life	FQoL Scale, IDI
	Perceived, experienced and internalised stigma	SARI Stigma Scale
	Social participation	Participation Scale
	Mental well-being[42–44]	Patient Health Questionnaire-9
	Disease knowledge[53 54]	Disease-specific KAP measure
	Attitudes towards the disease and persons affected by the disease	Qualitative (IDI and FGD)
	Economic empowerment	Monthly household income, monthly financial contribution to the self-help group, qualitative (IDI)
Effectiveness (family member level)	Family quality of life	FQoL Scale, qualitative (IDI)
	Perceived, experienced and internalised stigma	IDI
	Mental well-being[42–44]	Patient Health Questionnaire-9
	Disease knowledge[53 54]	Disease specific KAP measure
	Attitudes towards (persons affected by) the disease	Qualitative (IDI and FGD)
	Economic empowerment	Monthly household income, monthly contribution to the self-help group, qualitative (IDI)
Impact at community level	Most significant changes	Qualitative (IDI and FGD)
	Impact assessment (to evaluate the change in the target population and communities)	Qualitative (IDI and FGD)

FGD, focus group discussion; FQoL, Beach Centre Family Quality of Life; IDI, in-depth interview; KAP, Knowledge, Attitudes and Practices.

Feresbet, Taeme, Dama Markos, Arefa, Damot Tsion, Sekela, Chat Warka (in Dega Damot district), Debre Work, Felege, Tenguma, Gedeb, Shifere, Metiya, Wonfit (in Enarge Enawga district), Dembecha town and Wad (in Dembecha district). Out of these 16 clusters, a total of 4 clusters for leprosy and 6 clusters for podoconiosis and LF will be randomly selected. The intervention and control areas will be randomly selected by putting the cluster names in a cup or box and randomly drawing names. We will ensure that the number of intervention and control areas (clusters) in each district is equal. A list will be prepared with all patients (leprosy, podoconiosis/LF) living in the project areas that are registered at community-level enumeration and that are eligible to participate in self-care activities. Persons affected to be included in the study will be selected by stratified systematic sampling with a random start from a list of persons affected registered at the primary healthcare centre. This is done by selecting the first person affected on the list at random (by throwing dice), and then selecting every Xth patient on the list, based on the total number needed. Four separate lists will be created: two for persons affected by leprosy (one intervention and one control) and two for persons

Table 3 Participant timeline

	Study period*					
	Enrolment	Preallocation	Allocation	Postallocation		
Time point		T0		Tx	T1	T2
Enrolment						
Eligibility screen	X					
Informed consent	X					
Allocation			X			
Intervention						
Group meetings				X		
Assessments						
Questionnaires						
SARI Stigma Scale		X			X	X
Beach Centre Family Quality of Life scale		X			X	X
Participation Scale		X			X	X
Patient Health Questionnaire-9		X			X	X
Disease-specific Knowledge, Attitudes and Practices measure		X			X	X
Routine data						
Physical impairment outcomes		X		X	X	X
Group meeting attendance		X		X	X	X
In-depth interviews		X			X	X
Focus group discussions		X			X	X

*T0 denotes before the intervention/baseline. Tx denotes monthly monitoring during the intervention (routine data collection). T1 indicates 1-month postintervention. T2 indicates 1-year postintervention.

affected by LF or podoconiosis (one intervention and one control).

Blinding

Due to the nature of the intervention, participants cannot be blinded.

Data management

Confidentiality and anonymity of data will be ensured in data collection, data storage, analysis and publication. Research assistants who will collect the data will be fully trained in proper data management, maintenance of confidentiality and ensuring privacy during data collection. All data will be collected in Ethiopia. Only data that have been fully anonymised will be shared with the international research team. The project leader of this study will take full responsibility for ensuring the appropriate storage and security of data. Data will be kept for 5 years and will be destroyed after this time frame when no longer required.

Data analysis

Quantitative data will be entered in a database created using EpiData software. Analyses will start once baseline data have been collected. Simple descriptive methods will be used to generate a demographic profile of the study sample. Differences between participants in the intervention and control groups, including demographic information and physical impairment outcomes, will be evaluated using the Mann-Whitney U test or t-test for continuous variables and the χ^2 statistic for categorical variables. In addition, the mean with SD (or median with IQR, depending on the distribution of the data) of the total scores of the measures used will be calculated per participant group and per study area. The percentage change and corresponding 95% CI of physical impairment outcomes in each group, before and after the intervention is implemented and the statistical significance of this difference using a Z-test for differences between proportions will be calculated. Effect sizes will also be calculated. Stepwise multivariate regression with backward elimination will be done to examine what factors will have an independent effect on the outcomes. Data analysis will be done in the software packages Epi Info and SPSS Statistics version 27. We will also use intention to treat for categorical/nominal variables and difference in difference analysis for continues variables to evaluate the effectiveness of the intervention.

Qualitative data—the recordings of the in-depth interviews and focus group discussions—will be transcribed, translated to English and analysed using open, inductive

coding and content analysis. Similar phrases with recurring themes will be coded in a qualitative software programme (MAXQDA) and clustered together in tables to identify connections.

Patient and public involvement

This research will be led by and partly carried out by ENAPAL (a leprosy disabled persons' organisation). Persons affected by leprosy, LF and podoconiosis will assist the researchers in analysis of the data by helping to put issues in perspective and context. We will seek to employ and train persons affected as research assistants or at least those who have a family member affected by an NTD or with a disability.

ETHICS AND DISSEMINATION

Ethics

Ethical approval has been obtained from the Debre Markos University Health Sciences Institutional Research Ethics Review Committee (approval number HSC/R/C/Ser/Co/11/13). All participants will be fully informed about the nature and objective of the study and of confidentiality of the data prior to data collection. Written informed consent will be obtained from each participant prior to data collection. For participants who cannot read, an impartial witness will be present for the whole informed consent discussion. She or he will sign and date the consent form after the consent giver has done so. All people who are participating in the research will be provided with a participant information sheet. No incentives will be paid to participants.

Dissemination

A publication plan has been developed, which lists several planned articles for publication in scientific journals. All articles will be published in peer-reviewed, open access journals. The results of the study will also be shared through international conferences and at (working) meetings with international researchers and national policy makers and healthcare staff. A meeting will be organised at the end of the study to disseminate the results in the communities in the study areas. In addition, we aimed to share updates of the study through the ILEP newsletter and the Sasakawa Health Foundation newsletter.

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Contributors ATvN, MWA, TT and AS designed the study and were responsible for funding acquisition. MWA is the principal investigator of the study. MWA, NAM and TT are responsible for the implementation of the study in Ethiopia. MWA will lead data analysis with support from ATvN and NAM. ATvN drafted the manuscript. All authors read and approved the final version of the manuscript.

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