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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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ASSESSING THE EFFECTIVENESS OF FAMILY-BASED APPROACHES AIMED AT PREVENTION AND SUSTAINABLE SELF-MANAGEMENT OF DISABILITIES, IMPACTING THE QUALITY OF LIFE, MENTAL WELLBEING AND PARTICIPATION OF PEOPLE WITH LEPROSY, PODOCONIOSIS AND OR LYMPHATIC FILARIASIS AND THEIR FAMILIES IN EAST AND WEST GOJJAM, ETHIOPIA.

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MEGA RESEARCH PROJECT PROPOSAL

OCTOBER, 2020

DEBRE MARKOS, ETHIOPIA

van 't Noordende AT, *et al. BMJ Open* 2022; 12:e056620. doi: 10.1136/bmjopen-2021-056620

Mega Research Project proposal

<table>
<tr><td colspan="4">Title: Assessing the effectiveness of family-based approaches aimed at prevention and sustainable self-management of disabilities, impacting the quality of life, mental wellbeing and participation of people with leprosy, podoconiosis and or lymphatic filariasis and their families in East and West Gojjam, Ethiopia.</td></tr>
<tr><td colspan="4">Person(s) undertaking the project in order of contribution</td></tr>
<tr><td>Name</td><td>Qualification
(Area of study & Degree)</td><td>Institution/Company</td><td>Country</td></tr>
<tr><td>Moges Wubie</td><td>MSc, Assistant professor</td><td>Debre Markos University</td><td>Ethiopia</td></tr>
<tr><td>Alice Schippers</td><td>PhD</td><td>Disability Studies in Netherlands</td><td>Netherlands</td></tr>
<tr><td>Anna van ’t Noordende</td><td>PhD</td><td>NLR; and
Disability Studies in Netherlands</td><td>Netherlands</td></tr>
<tr><td>Tesfaye Tadesse</td><td>MA</td><td>Ethiopian National People Affected by Leprosy (ENAPAL)</td><td>Ethiopia</td></tr>
<tr><td colspan="2">Source of budget: Leprosy Research Initiative</td><td colspan="2">Total budget required: 203,209.00 €</td></tr>
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<tr><td>Study period: 36 months</td><td colspan="2">Date of commencement: September 2020 –August 2023</td><td>Date of completion: August 31/2023</td></tr>
<tr><td colspan="4">Institution at which study to be conducted and address: (Debre Markos University, Debre Markos, Ethiopia)</td></tr>
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2. TABLE OF CONTENTS

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3. ABBREVIATIONS AND ACCRONYMS

DMU – Debre Markos University

DPO - Disability of People Organization

ENAPAL - Ethiopian National People Affected by Leprosy

FQoL - Family quality of life

ILEP - International Federation of Anti-Leprosy Associations

LF – Lymphatic Filariasis

LRI - Leprosy Research Initiative

NLR – Netherlands Leprosy Relief.

NTDs - Neglected Tropical Diseases

PHQ-9- Patient Health Questionnaire

P-scale - Participation levels

RCT – Randomized Control Trials

SARI- Stigma Assessment and Reduction of Impact

TLMI - The Leprosy Mission International

4. LIST OF APPENDICES

SUMMARY

Background: The family-based intervention had a positive impact on impairments and self-management of disabilities, family quality of life and on stigma. However, the short term outputs and impact of the approaches in a non-random sample of persons affected by leprosy, lymphatic filariasis and podoconiosis not shown the long term effectiveness of the approach. Effectiveness of the family-based approach cannot be studied in such a non-random sample and with a relatively short follow-up time. To date most prevention of disability effectiveness studies have been flawed by failing to use a randomized controlled design. This has resulted in a lack of evidence about the effectiveness of these interventions. To collect credible evidence for a new, family-based approach, the current study will use a randomized controlled design. A randomized controlled design is the most rigorous way of determining whether a cause-effect relation exists between intervention and outcome(s).

In this study a unique thing is participating the family throughout avoiding misunderstanding of the diseases, help to disability management as well as for socioeconomic empowerment. It is necessary to get the diseases affected person recover from their disability and performed activities without difficulty.

In this three-year study, we aim to assess the effectiveness, longer-term outcomes and sustainability of the family-based approach aimed at prevention and sustainable self-management of disabilities due to leprosy, lymphatic filariasis and podoconiosis, impacting the quality of life, mental wellbeing and participation of affected persons and their families in Ethiopia. The research question of this project is "how effective is the family-based approach aimed at prevention and sustainable self-management of disabilities due to leprosy, podoconiosis and lymphatic filariasis compared to usual practice and care?"

Objective of the project: The primary objective of this study is 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 wellbeing compared to usual practice and care. Secondary objectives include: (1) to reduce the number of people who have an episode of depression, as measured with the Patient Health Questionnaire (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; (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 Materials: This project will be conducted in East and West Gojjam Zone Amhara region, with randomized control Trial on 516 leprosy, podoconiosis and lymphatic filariasis affected persons and their family members. The project is interventional on disability management, awareness creation and socioeconomic empowerment. We used both qualitative and quantitative data. For qualitative data using open code, inductive coding and content analysis. Similar phrases with recurring themes will be coded in the software program MAXQDA and clustered together in tables, to identify connections. For quantitative data four tools used to collect data from the study population before and after intervention. Along with these

continuous follow up data of disability management also other intervention data. Quantitative data will be entered in a database created using Epi Info and exported to SPSS Verssion 25. Simple descriptive methods will be used to generate a demographic profile of the study sample. In addition, mean total scores of the measures used will be calculated per participant group. Stepwise multivariate regression with backward elimination will be done to examine what factors will have an independent effect on the outcomes. In addition, by using difference in difference (*Diff-in-diff)* model - used to compare before and after the family-based approach is implemented will be calculated using one sample and two sample independent t-test.

Outcome measures include:

- Physical impairment outcomes (for persons affected by leprosy: Eyes, Hands, Feet (EHF) score, total number of wounds present (wound count), and registration of infection; for persons affected by podoconiosis and LF: lymphedema grading, measuring the largest point of swelling below the knee circumference, registering the frequency of acute attacks, wound count, and registration of infection).

- Perceived, experienced and self-stigma among affected persons (SARI stigma scale)

- Family quality of life score (Beach Centre FQoL and in-depth interviews)

- Participation levels (P-scale)

- Mental wellbeing/depression levels (PHQ-9)

- Attitudes, disability management practices and acceptability of the family-based approach (observations and in-depth interviews).

- Economic empowerment (Monthly household income, monthly financial contribution to the self-help group, use of credit; in-depth interviews)

- Most significant change in the community (in-depth interviews and focus group discussions)

This research project has three phases, starting from the first phase fulfill the family-based intervention component, validating measuring tool, training workshop will accomplish, study participants will be identify and randomized and baseline data will be collected. During the implementation phase addressing the three intervention areas like awareness creation, disability management and socioeconomic empowerment accompanied with taking recording of the activities. Lastly, follow up and evaluation phase, the effectiveness, feasibility and acceptability of the approaches will be evaluated.

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. The Ethiopian applicant of the project will responsible to carry out the research aspect of this study.

Work plan and Budget: The study will be conducted from October 2020 to September 2023 (36 months) with 203, 209 Euro. The first group meeting is anticipated to be held on February 2022 (meetings will be held until September/October 2022).

6. BACKGROUND AND JUSTIFICATION

Background: Most impairments of persons affected by leprosy, lymphatic filariasis (LF) and podoconiosis, particularly secondary impairments such as wounds, swelling and contractures, are largely preventable. Relatively simple methods exist for self-management of impairments that can be practiced at home, without the need for a lot of medical supplies. Too often, however, these methods are not taught to patients with neuropathic limbs or lymphedema, or if taught, they are not consistently practiced. Many practices for prevention and self-management of disabilities are suitable for use across different skin-related Neglected Tropical Diseases (NTDs) such as leprosy, LF and podoconiosis (1). Leprosy, LF and podoconiosis-related impairments are major determinants of stigma and participation restrictions. Negative attitudes towards affected persons and community and internalized stigma negatively impacts on the mental wellbeing of affected persons (2).

An important tool to assess general well-being is quality of life (3-6). Several studies showed leprosy, LF and podoconiosis to have an impact on quality of life (7-12). In contrast, family quality of life has not received much attention, despite the crucial role of the family in most societies around the world. In addition, several studies have indicated that family support is a highly significant factor that affects adherence to self-care (13, 14).

Persons affected often experience pain and visible impairments due to their condition. Some participants are ashamed of their disease and/or feel inferior to those who are not affected. Persons affected and their family members are sometimes insulted by their community members. Divorce and difficulties in finding a spouse, also for family members, was not uncommon. Especially persons with younger children seem to lack social support. Many participants reported participation restrictions. Half of the study participants were unable to work because of the physical or social limitations they face. Financial problems and loss of livelihood were reported by almost all participants, this sometimes led to begging. Financial problems and stigma also prevented affected persons and their family members from attending school (15). Many of the reported problems relate to stigma and a lack of finances. Family-based approaches that emphasize social and economic aspects could improve individual and family quality of life.
Based on the result, persons affected had significantly higher family quality of life than family members. The family quality of life dimensions that were affected were the same for persons affected and family members, with the physical / material wellbeing and emotional wellbeing domains being affected most. The persons affected by leprosy, podoconiosis and LF included in this study experienced stigma. Persons affected by podoconiosis and LF experienced significantly more stigma. In addition, persons affected experienced activity limitations, mostly related to walking. Result not indicated association between family quality of life and stigma, or between family quality of life and activity limitations (already accepted finding for publication on Transactions of The Royal Society of Tropical Medicine and Hygiene journal), [Unpublished] and;

The result of the family-based intervention had a positive impact on impairments and self-management of disabilities, family quality of life and stigma (submitted article for PLOS Neglected Tropical Disease) [Unpublished].

These findings are supported by a recent literature review by van Heuvel (16), who reported that the economic impact of leprosy is significant. According to van Heuvel (2018), many families of persons affected suffer from a loss of income. In addition, both stigma and visible impairments contribute to high levels of unemployment among persons affected by leprosy (16). Van Heuvel (16) recommends socio-economic

rehabilitation, vocational education, self-care groups and stigma reduction to further reduce leprosy-related disability. Stigma reduction and socio-economic empowerment are also key factors identified (15). The short-term impact of the family-based approaches that are being implemented on a small scale in the project areas from March 2019 to September 2019 was assessed.

The previous LRI-funded project only studied the short term outputs and impact of the approaches in a non-random sample of persons affected by leprosy, LF and podoconiosis. Effectiveness of the family-based approach cannot be studied in a non-random sample and with a relatively short follow-up time. A non-random sample and repeat measurements, conducted over an adequate time span, are needed to understand the effectiveness of the intervention and the longer-term impact on quality of life, mental wellbeing and participation. This also allow, for studying the underlying processes involved in the success or failure of the intervention (17). The current project, therefore, use a randomized controlled design to study the effectiveness of the family-based approach, as this is the most rigorous way of determining whether a cause-effect relation exists between intervention and outcome(s). The ultimate aim of the proposed study is to gather solid evidence of the effectiveness of family-based approaches for prevention and self-management of disabilities due to leprosy, LF and podoconiosis.

Scientific justification/rationale of the study:

"The family based approach is new approach in Ethiopia except the exploratory study conducted in Awi zone previously." Thus, the approach developed in the exploratory LRI-funded project consists of the following main components:

1. Awareness raising of leprosy, LF and podoconiosis among persons affected, their families and community members
2. Disability management: prevention and self-management of disabilities
3. Socio-economic empowerment

To collect credible evidence for such a new, family-based approach, a randomized controlled design will be used. To date most prevention of disability effectiveness studies have been flawed by failing to use a randomized controlled design. This has resulted in a lack of evidence about the effectiveness of for example self-care groups, nerve decompression surgery, treatment of ulcers with antibiotics and use of certain footwear. Van Veen and colleagues (18), who conducted a systematic literature review into the cost-effectiveness of prevention of disability interventions concluded that evidence for cost-effectiveness of interventions aimed at prevention of disabilities for leprosy is scarce. They are calling researchers to develop strategies aimed at affordable and sustainable prevention of disability interventions in developing countries. Demonstrating the effectiveness of prevention of disability interventions is a recommendation of several systematic literature reviews (1, 16, 18)

In addition to solid evidence about effectiveness, we recognize the importance of psychosocial outcomes such as quality of life outcomes as ultimate focus of services, supports and policy development (19). We will therefore also study the inputs, throughputs, outputs and outcomes of the family-based approach. The following descriptions have been adapted from Schippers, Zuna and Brown (19):

- **Inputs:** the ideas, resources, and capacities within systems, organizations, and families that are readily available to be worked with and used, for example resources;
- **Throughputs:** are practices or actions, what you do, for example certain choices made and followed;
- **Outputs:** are the results of action taken in throughputs. Because throughputs are dynamic, changing life situations, outputs are also subject to change over time. For example money earned from working;
- **Outcomes:** are the longer term impact on a person's or a family's life, they influence the person and family involved, their social networks and the broader society. For example life satisfaction.

In this study, we aimed to assess the effectiveness, longer-term outcomes and sustainability of the family-based approach aimed at prevention and sustainable self-management of disabilities, impacting the quality of life, mental wellbeing and participation of affected persons and their families in Ethiopia. This way, we will be able to report on (a) the effectiveness, including acceptability and feasibility, of the family-based approach; (b) the longer term impacts of the family-based approach on the person affected and their families on (family) quality of life, stigma, mental wellbeing and participation and (c) provide a summary of their quality of life and perceptions as well as a description of how they arrived at that summary.

We will use a randomized controlled design as this is considered to provide the most reliable evidence on the effectiveness of interventions. The randomly assigned control group will help reduce the likelihood that any benefits or risks during the study occur due to factors outside of the intervention.

This research project planned to implement in East and West Gojjam, Amhara region, Ethiopia. Thus the prevalence of the diseases with in these two zones varies based on the type of diseases. The distribution of disability even though not specifically supported by the study figure there are more than seven leprosy affected people registered associations with a member of 30 – 400 according to Ethiopian national association of people affected by leprosy (ENAPAL) (20), evidence got from International Orthodox Christian Charity (IOCC), non- governmental organization working on podoconiosis and based on their report in these two zones the prevalence of podoconiosis reaches 0 – 10 % (21). Whereas, the prevalence of lymphatic filariasis occurred in one Woreda based on Biruk K. et al, 2018 in East Gojjam, Enarg Enawga the prevalence of lymphedema caused by lymphatic filariasis and podoconiosis 72.1 in 10, 000 population and 2.6 hydrocele (22).

Main research question

How effective is the family-based approach aimed at prevention and sustainable self-management of disabilities due to leprosy, podoconiosis and lymphatic filariasis compared to usual practice and care?

7. OBJECTIVE OF THE RESEARCH PROJECT

7.1. General Objective

The general objective of this study is to assess the effectiveness of a family-based intervention for 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 wellbeing compared to usual practice and care in East and West Gojjam, Ethiopia, 2021 -2023.

7.2.1. Primary Specific objectives (To determine the effectiveness of the family-based approach)

(1) to reduce the number of people who have an episode of depression, as measured with the Patient Health Questionnaire (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; (5) to empower people economically as measured by monthly household income, monthly financial contribution to the self-help group and in-depth interviews. **7.2.2. Secondary Specific objectives (To contribute to mutual learning and local capacity building)**

1. To train persons affected as research assistants and optimize capacity by combining experiential, practical and scientific knowledge

2. Support Ethiopian leprosy-related research by having an Ethiopian researcher.

3. To identify key elements or factors that increased the success of the approach.

8. MATERIALS AND METHODS

(1) Study design

The quantitative study will use a randomized controlled trial design. The randomization units will be endemic districts (woredas), in the East and West Gojjam zone, Ethiopia. The woredas will be determined at the beginning of the project.

Intervention

The family-based approach developed in the exploratory LRI-funded project consists of the following four main components that will be implemented as family-based approach:

- Awareness raising of leprosy, LF and podoconiosis among persons affected, their family members and community members (= improving knowledge, reducing stigma).
- Disability management, prevention and self-management of disabilities (= prevention of disabilities, improving participation, reducing stigma). This will be done based on lymphedema management guideline (23) and
- Socio-economic empowerment (= improving the socio-economic situation) – encourage to establish association of disabled persons this may solve social concern besides the improvement of health status outcome. Giving hygiene materials including shoes and energy saving stoves during the implementation of intervention has economic importance.
- A psychosocial care component, that will be developed in the first few months of the project based on a literature review, will additionally be included (= improving participation, quality of life and mental wellbeing).

(2) Study population and participant characteristics

The following groups of people will be included in the study:

- People affected by leprosy, LF and podoconiosis

- Family members of people affected by leprosy, LF and podoconiosis

People with leprosy-related impairments and people with LF or podoconiosis-related lymphedema will be included in this study. Of each person affected, at least one adult family member will be included as well.

Operational Definition

Effectiveness in disability measured by physical impairment outcomes (for persons affected by leprosy: Eyes, Hands, Feet (EHF) score, total number of wounds present (wound count), and registration of infection; for persons affected by podoconiosis and LF: lymphedema grading, measuring the largest point of swelling below the knee circumference, registering the frequency of acute attacks, wound count, and registration of infection).

Effectiveness in related to mental wellbeing/depression levels measured by Patient health questionnaire (PHS-9) which contains 9 question with the maximum score of 27 and this described severe depression while low score no depression.

Effectiveness in related to family quality of life measured and indicated by tool based 25 items of questions and has five subscales and maximum score of 125 can be obtained, with higher scores denoting better family quality of life.

Effectiveness in related to participation levels measured by participation scale the tools contains 13 questions with the maximum score of 90 can be obtained with the higher score indicated as extreme restriction.

Effectiveness in related to perceived, experienced and self-stigma among affected persons measured by SARI stigma scale tool. The tool contains 21 questions, its sum score ranges from 0 to 63 – with higher scores denoting higher levels of stigma.

Community members are person at the heart of healthy communities. They include all who live, learn, work, play, and pray in communities with in local area.

Family members of people affected by leprosy, LF and podoconiosis mean people who have lived in the same household such as blood related sibling, child, parent or grandparent of affected person by leprosy, LF or podoconiosis living in the same household). Belong with this if a person not related by blood but living together with the affected person considered as also family members if not fulfill the first blood related criteria.

Eligibility criteria

Inclusion criteria:

Both men and women affected by the three diseases affected persons have equal chance of selection or over the age of 15 will be included in the study. All men and women have leprosy, LF or podoconiosis-related

impairments and have to be eligible to participate in self-care activities. Besides these, one – one family member selected for the intervention group of the diseases affected persons whose age greater than or equal to 15 years. The focus is on skin and wound care of the lower limbs. All persons have to be residents of project areas of the study equal or more than six months.

(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 doesn't 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. A total of 420 persons affected will be included: 210 persons affected by leprosy and 210 persons affected by LF or podoconiosis; for each disease there will be one intervention and one control group. In the intervention group, a total of 210 family members will also be included. 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, 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.In addition, at least 15 persons affected by leprosy, 15 persons affected by LF or podoconiosis and 15 family members (half of them of persons affected by leprosy) will be interviewed in-depth for the most significant change, acceptability and impact assessment interviews. Data will be collected until data saturation has been reached.

(4) Primary and secondary endpoints.

Qualitative outcomes of the intervention are

- Family quality of life
- Attitudes towards having a family member with leprosy, LF and podoconiosis-related disabilities
- Practices for prevention and self-management of disabilities
- Acceptability of family-based approach
- Practicability of the approach

Outcome measures

- Physical impairment outcomes: impairment scores, wound count, wound condition, the stage or grade of affected limb, and frequency of acute attacks in people affected – this will be collected using the Eyes, Hands, Feet (EHF) score, lymphedema grading, by measuring the largest point of swelling below the knee circumference in cm using measuring tape, by (self-) registering the frequency of acute attacks in a notebook, and by observation.
- Perceived, experienced and self-stigma among affected persons, using the SARI Stigma Scale (SSS).
- Family quality of life score, using the Beach Centre Family Quality of Life scale (FQoL scale).
- Participation levels, using the Participation Scale (P-scale).
- Mental wellbeing/depression levels, using the Patient Health Questionnaire (PHQ-9)
- Economic empowerment (Monthly household income, monthly financial contribution to the self-help group, use of credit; in-depth interviews)
- Most significant change in the community (in-depth interviews and focus group discussions)

(5) Data collection

The following data collection methods will be used: assessment of physical impairment outcomes,

standardized questionnaires and in-depth interviews. In addition, demographic data will be collected from each participant.

To assess the effectiveness of the intervention, the following evaluation methods will be used:

- **Outcome evaluation**

(1) A baseline and follow-up study will be done before, a few months after and one year after the approaches have been implemented. This will consist of administration of instruments (SARI, Beach Centre FQoL, P-scale, PHQ-9 and KAP). We will assess the outcomes by comparing the results of the baseline and follow-up studies.

(2) By comparing the changes to the physical impairment outcomes (impairment scores, wound count, wound condition, the stage or grade of affected limb, and frequency of acute attacks in people affected) that will be assessed using the EHF score, lymphedema grading, swelling measurement, frequency of acute attacks and observation. Physical outcomes will be registered every month. The changes over time will be compared to see if there are any (significant) differences.

- **Impact assessment.** An impact assessment will be carried out to evaluate the change in the target population, persons affected, and their family members and, also their community members, which has been brought about by the interventions. This will be done by conducting in-depth interviews with people from the target population, including influential people in the communities.
- The Most Significant Change Technique (MSC): in-depth interviews will be conducted with various stakeholders (persons affected, their family members and their community members) to collect 'significant change stories' - stories of significant changes caused by the family-based approaches.

• Acceptability study. In-depth interviews will be held with persons who participated in the intervention, to explore their acceptability of the intervention.

The PHQ-9 has already been validated for use in Ethiopia (24-26). The SARI stigma scale, Beach Centre FQoL and P-scale have not yet been validated. This will be done in the first months of the project by Master students from the VU University in Amsterdam or Ethiopian Master Students or Master holder professionals depending on the situation of the current COVID 19 pandemic and other factors, aiming at inclusion of 120 people per scale. The interview guide and questionnaires will all be pilot testing among a small sample of participants before use.

Study process

The study consists of the following phases:

(1) Phase 1: 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 approach. In addition, students from the VU University or Ethiopian Master Students or Master holder professionals will cross-culturally validate the SARI stigma scale, Beach Centre FQoL and P-scale. A training workshop will be organized to train the team in research methods and family-based approaches. People affected by leprosy, podoconiosis or LF and their family members will be recruited. Baseline data will be collected and the results analyzed. The study areas will be randomized. Protocol will be evaluated, revised, and approved /verified it.

(2) Phase 2: Implementation of the intervention.

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 is an integral part of the intervention. The essential care package is described in more detail below:

- 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 on course and treatment of disease, identifying barriers and facilitators to self-care and creating strategies to overcome these barriers. 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).

- 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. Each self-help groups will collect a small contribution fee from its participants, these fees are used to provide loans for the participants of the self-help groups (micro-finance). Self-help groups will also lobby for 'benefits', e.g. 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 is essential for sustainable self-management and prevention of disabilities: without income, self-care items such as Vaseline and shoes cannot be bought. 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 receive treatment as usual. Participants in the control areas will receive 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).

The intervention will take **eight months**.

(3) Phase 3: Follow-up and evaluation.

In this phase, the effectiveness of the approaches will be evaluated. This will be done by collecting information for the outcome evaluation (see 'outcome evaluation') above, this information will be collected routinely (e.g. each month during the meetings), at baseline and one year after the intervention has been completed. Effectiveness will be determined based on data from the baseline, data collected at the final group meeting, and data collected one year after the intervention. In addition, interviews will be conducted to collect most significant change stories and to assess the impact qualitatively.

Participant recruitment / sampling procedure and follow-up procedures

All participants will be asked for consent before they are enrolled in the study. The kebeles will be randomly divided to implement either the family-based approach or usual practice and care (control group).

A list will be prepared with all patients (leprosy, LF or podoconiosis) living in the project areas, that are registered at the health center 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 health care center. This is done by selecting the first person affected on the list at random (by lottery method), and then selecting every X th 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 affected by LF or podoconiosis (one intervention and one control). The two intervention and two control areas will be randomly selected from four project area lists, by putting the district names in a cup or box and randomly drawing two names (the two intervention areas).

Data quality assurance

The questionnaire used to assess the FQoL, stigma, participation restriction and Patient health Questionnaire prepared in English. From this only PHQ -9 already validated in Amharic. But the others three of the questionnaire not validated but written in English. So translated to Amharic and then back to English to maintain consistency. Then we have translated in to Amharic and validating that before use for the actual data. Rigorous training will be given for research assistants on the basic techniques of the data collection procedures.

Data management and data analysis

Quantitative data will be coded and entered in a database created using Epi data version 3.0 and exported to SPSS Verssion 25.

Simple descriptive methods will be used to generate a demographic profile of the study sample. In addition, mean total scores of the measures used will be calculated per participant group. Stepwise multivariate regression with backward elimination will be done to examine what factors will have an independent effect on the outcomes. In addition, by using difference in difference (*Diff-in-diff)* model - used to compare before and after the family-based approach is implemented will be calculated using one sample and two sample independent t-test. Data analysis will be done in the software packages Epi Info and SPSS Statistics.

The recordings of the in-depth interviews and focus group discussions will transcribed, translated to English and analyzed using open code, inductive coding and content analysis. Similar phrases with recurring themes will be coded in the software program MAXQDA and clustered together in tables, to identify connections.

Confidentiality and anonymity of data is of utmost important and 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. Only data that have been fully anonymised will be shared with the Dutch research team. The project leader (lead applicant) of this study will take full responsibility for ensuring the appropriate storage and security of data.

Data will be kept for five years and will be destroyed after this timeframe when no longer required.

9. STRENGTHS AND LIMITATION OF THE STUDY

STRENGTHS

- ✓ Strong research design
- ✓ Follow up time interval longer

LIMITATION

- ✓ **None for the time being**

10. COMMUNICATION AND DISSEMINATION OF STUDY FINDINGS

What is expected to be achieved (Concrete output/deliverables)?

1) An article on the validation of the SARI stigma scale in Ethiopia

2) An article on the validation of the Beach Centre FQoL scale in Ethiopia

3) An article on the validation of the P-scale in Ethiopia

4) An article on the baseline data collected (questionnaires)

5) An article about impact (qualitative data collected) and most significant change

6) An article on the effectiveness of the family-based approach

7) An article on the feasibility and acceptability of the family-based approach

8) Report on how to implement the family-based approach to be shared across the ILEP network.

Deliverables 1 to 7 will be published in peer-reviewed, open-access journals. Findings will also be presented at conferences (details of appropriate conferences will be explored later). A detailed report on how to implement the family-based approach that has been developed will be shared across the ILEP network. Updates on the project will be shared on Disability Studies in Nederland's website (https://disabilitystudies.nl/) and on the NLR website (https://www.leprastichting.nl/ and https://nlrinternational.org/). We will explore possibilities of giving updates about the project in the ILEP newsletter.

Additionally, the copy of reports delivered to the Health Science College, and accessible on DMU website.
The finding will be present in national conferences in Ethiopia.

11. ETHICAL CONSIDERATIONS AND REVIEW PROCESS

Ethical approval will be obtained from the Ethical review Committee of Health Science College, Debre Markos University. Supportive letter will be obtained from Amhara Public Health Institute before starting the research project. All participants will be fully informed about the nature and objective of the study and of confidentiality of the data prior to data collection. Signed written consent will be obtained from each participant prior to data collection. Assent will be obtained from their guardian if participants present between the ages of 15 – 17 years. Their data will be confidentially maintained throughout.

12. IMPLEMENTATION OF THE PROJECT

	YEAR 1 (April–Dec 2020)				YEAR 2 (Jan-Dec 2021)				YEAR 3 (Jan-Dec 2022)				YEAR 4 (Jan-March 2023)			
ACTIVITY	01 - 03	04 - 06	07 - 09	10 - 12	13 - 15	16 - 18	19 - 21	22 - 24	25 - 27	28 - 30	31 - 33	34 - 36	37 - 39	40 - 42	43 - 45	46 – 48
Finalize partnerships and identify suitable sites																
Finalize selection of districts																
Apply for ethical approval																
Validate scales																
Recruitment of program manager																
Prepare training materials and resources for the intervention, including literature review																
Recruitment and training research assistants																
Set up project management system and database																
Recruitment of participants																
Pilot and adjustment forms, procedures and interview guides																
Randomization																
Kick-off meeting																
Baseline measurements (mixed methods)																
Implementation of intervention (eight months)																
International meeting and monitoring																
Follow-up measurements (mixed methods) and acceptability study																
One-year follow-up																
Visit of Ethiopian Researcher to the Netherlands to write his thesis (2-3 months per visit)																
Analyze results, write reports / articles, disseminate findings																

13. COST OF THE PROJECT WITH COMPLETE BUDGET BREAKDOWN

	Year 1	Year 2	Year 3	Year 4	Total
Personnel National	€ 30,170.00	€ 49,824.00	€ 50,748.00	€ 10,098.00	€ 140,840.00
Personnel International	€ 2,520.00	€ 3,360.00	€ 3,360.00	€ 840.00	€ 10,080.00
Travel	€ 7,050.00	€ 9,550.00	€ 9,550.00	€ 3,450.00	€ 29,600.00
Equipment	€ 1,440.00	€ -	€ -	€ -	€ 1,440.00
Running costs	€ 603.00	€ 1,200.00	€ 870.00	€ 156.00	€ 2,829.00
Other costs	€ 2,500.00	€ 7,170.00	€ 7,050.00	€ 1,700.00	€ 18,420.00
Total	€ 44,283.00	€ 71,104.00	€ 71,578.00	€ 16,244.00	€ 203,209.00

14. BENEFITS OF THE STUDY RESULTS

Target group(s)

We expect that the study will have the following benefit on the target groups:

- Improved knowledge and skills about practices for prevention and self-management of disabilities; sustainable self-management and prevention of disabilities (disability management) within the family.
- Improvements in activity levels and social participation, less wounds and a lower lymphedema grade
- Improved individual and family quality of life and mental wellbeing. Improved self-confidence.
- Improved knowledge and attitudes (reduction of stigma) towards having a family member with leprosy, LF or podoconiosis-related disabilities.
- Socio-economic empowerment.

Expected impact

As preliminary results indicate, by improving the health situation of the persons affected and including family members in self-care and the wider community in awareness raising, their quality of life and that of their family is positively impacted. This RCT is targeted at sustainable improvement of the lives of persons affected, aiming at sustainable outcomes from the family based approach that are replicable in other regions with NTDs. Implementation will be encouraged as well bottom-up as top-down. Via ENAPAL (lead applicant) other regional health care centers and NTD-groups will be informed. ENAPAL will also inform and lobby at national level and within their international connections.

The participation in the study of persons affected and their family members, involvement of research assistants that are familiar with leprosy, LF and podoconiosis, and the establishment of a Disability of People Organization (DPO) are essential ingredients for sustainable results, as we know from other studies with a participatory design.

The research community will profit from experience of the study in general and the validation of scales in Ethiopia specifically. This is moreover important because this project aims also at local capacity building by involvement of local research assistants and the researcher in DMU.

15. FACILITIES AVAILABLE FOR THE STUDY (MAJOR FACILITIES)

Main tasks and responsibilities of lead applicant, co-applicant and other partners

Ethiopian National Association of People Affected by Leprosy (ENAPAL):

- Lead research team
- Hire the program manager and research assistants
- Partake in selection of people affected by leprosy

- Follow-up monitoring
- Networking with co-applicants and government
- Responsible for the training of field staffs
- Organizes review meetings
- Oversees project implementation
- Responsible for budget

Debre Markos University / Researcher:

- Assist in training of field staff, administer the ethical issue and scientific aspect of the project.
- Data collection
- Responsible for data analysis
- Partake in selection of persons affected by podoconiosis and LF
- Support organizing and participate in review meetings
- Support project implementation
- Writes articles on the findings

The Leprosy Mission International (TLMI) Ethiopia:

- Technical support in implementation of project
- Assist in training of field staff
- Follow-up monitoring

Disability Studies in the Netherlands:

- Support on family-based approaches and family quality of life
- Supervise VU Master Students (but currently this changed to be Debre Markos university Master students if feasible unless those concerned professionals from the college with the decision of management of Health Science College).
- Support in working with research partners through training and monitoring
- Facilitate training of field staff
- Support in development of psychosocial component of family-based approach
- Support in data analysis

Leprosy Research initiative

- Funding and receiving report.

Study area local health institution

- ✓ It is site to give health education, demonstration of practical exercise for the patients and their family members.

16. AUTHORSHIP RIGHT

- ✓ Researchers, Advisors and co Advisors have mandate about the publication of the finding.

17. DECLARATION OF CONFLICT OF INTEREST

- ✓ Funder has no conflict of interest about the publication.

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19. ASSUMPTIONS, RISKS AND MITIGATION ACTIONS

Risks	**Mitigation plan(s)**
Delays due to political unrest	Personnel used for the research are from the project areas (locals) so it is anticipated that the work can continue
Delays due to environmental problems e.g. severe drought, people may move to another place	May need to provide some food to sustain the participants
Unable to reach enough participants in time due to	May need to select another district

not meeting the selection criteria	
Delays due to administrative obstacles such as for example obtaining ethical approval	Expected duration for obtaining will be 2 months, so will start applying for it as soon as we get approval from the LRI (if we get approval from the LRI for this study).
COVID 19 illness	In Ethiopia ➢ Program manager if get illness roles of the person covered by program assistant. ➢ Program assistant if get illness vice versa roles covered by program manager. ➢ Country coordinator from ENAPAL roles covered a delegate from the same institution. ➢ Research assistants (Data collectors) at the beginning will recruit enough number of employee which plan to be six so if they face illness others covers the role of the ill person. In Netherlands ➢ Technical support: Director DSiN – delegate person in the organization handle the role Technical support: Researcher roles covered by technical supporter or director of DSiN.
COVID 19 related mortality	ENAPAL ✓ ENAPAL will substitute country coordinator DMU ✓ DMU, CHS will substitute country coordinator DSiN DSiN will substitute
If COVID 19 related problem challenges us to continue implementation	✓ By discussing with the funder we interrupt for certain period of time with budget free.

20. ASSURANCE OF THE PRINCIPAL INVESTIGATOR:

I the undersigned agree to accept responsibilities for:

• The scientific, ethical and technical conduct of the research project,

- Requesting amendment for ANY change on the protocol that might need to happen during execution of the project, and obtain written approval for the request from concerned ethical review committee, of DMU, HSC.
- Submitting progress report every year and technical report within six months during the implementation of the project, for DMU, HSC.
- Reporting any adverse event that might happen to the study participants, data collectors, supervisors and coordinators during investigation,
- Submitting scientific publications that emanate from the project within two months of publication, and

Name _____ Signature _____

Date_____

21. COMMITMENT FOR AND SIGNATURE OF CO-INVESTIGATORS.

Name	Specific Roles and Responsibilities	Signature
1. Alice Schippers	_____	_____
2. Anna van 't Noordende	_____	_____
3. Tesfaye Tadesse	_____	_____

22. COMMENT AND CONCURRENCE OF THE RESPONSIBLE HEAD FOR PRINCIPAL INVESTIGATOR

_____

_____

_____

_____

Name_____Signature_____Date_____

23. APPENDICES (Cite all appendices in the body of the proposal; attach all appendices under this section).

Informed Consent Form

Title of the study: Assessing the effectiveness of family-based approaches aimed at prevention and sustainable self-management of disabilities, impacting the quality of life, mental wellbeing and participation

of people with leprosy, podoconiosis and lymphatic filariasis and their families in the East and West Gojjam, Ethiopia.

Investigator(s): Moges Wubie, Alice Schippers, Anna van't Noordende, Tesfaye Tadesse

Organization: Debre Markos University

Sponsor: Leprosy Research Initiative (LRI)

You are being invited to take part in this research because you **are person(s) affected by leprosy/podoconiosis/ lymphatic filariaisis/ family member(s) of these individual(s).**

There will be **a total of 630** individuals taking part in this research.

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please read **by yourself/ anybody can read for you** through the following information carefully and feel free to ask if it is not clear or to discuss it with anyone you wish.

Please take time to decide whether or not you want to take part in this research. We would like to stress that taking part in this study is entirely voluntary (Box 1). If you decide not to participate in the study, you will receive treatment going to the nearby health institution or course(s) of treatment] (Box 2).

Box 1. Taking part in this research is voluntary

- ✓ You can refuse to take part in this study.
- ✓ You can with draw your participation from the study at any time.

Box 2. Alternative procedure(s) or course(s) of treatment)	
- As any unhealthy person you have the right to access treatment from the health institution.	The advantage of taking treatment from the health institution is that you will get every time. Disadvantage of that may be the level of expertise in that health institution may not take especial training on the case. Payment for the treatment may be required.
- Get advice from the research groups what alternatives have to solve the problem	Not call every time for follow up by researcher as well manage the case by themselves. Disadvantage not get consecutive advice from the researcher.

Information related to the study

Most impairments of persons affected by leprosy, lymphatic filariasis (LF) and podoconiosis, particularly secondary impairments such as wounds, swelling and contractures, are largely preventable. Relatively simple methods exist for self-management of impairments that can be practiced at home, without the need for a lot of medical supplies. Too often, however, these methods are not taught to patients with neuropathic limbs or lymphedema, or if taught, they are not consistently practiced. But on the contrary, related to impairment many challenges faced persons affected by the diseases like stigma, activity restriction, encountered with economic deficit and the like. This negatively impacts on the mental wellbeing of affected persons. In fact, not only persons affected impacted by presence of disability but also the family members.

We found that many of the reported problems relate to stigma and a lack of finances. Family-based approaches that emphasize social and economic aspects could improve individual and family quality of life. The approach focuses on beyond the three pillars of the problem like; awareness raising of leprosy, LF and podoconiosis among persons affected, their families and community members. Disability management: prevention and self-management of disabilities and; Socio-economic empowerment of the affected persons as well the family members.

Box 3. The expected possible adverse effects of [the investigational drug/intervention]

- Based on the Ministry of Health and WHO and ILEP guideline the wound, contracture and lymphedema morbidity management there is no expected adverse effects.

The objective of this research is to assess the effectiveness of family-based approaches aimed at prevention and sustainable self-management of disabilities, impacting the quality of life, mental wellbeing and participation of people with leprosy, podoconiosis and lymphatic filariasis and their families in the East and West Gojjam, Ethiopia, 2021 -2023.

The current project will use a randomized controlled design to study the effectiveness of the family-based approach, as this is the most rigorous way of determining whether a cause-effect relation exists between intervention and outcome(s).

Box 4. Study design

The study will use a randomized controlled trial design.

The study will last around eight months in total. If you decide to take part in this study, you will be asked to follow the schedule shown in Box 5. You should ensure that you are

Available to comply with the schedule.

Box 5. Please see schedule of study above.

We have summarized the foreseeable risks and expected benefits arising from participation in the study in Box 6.

Box 6.Foreseeable risks and expected benefits arising from participation in the study	
Foreseeable risks	Expected benefits
- No any foreseeable risk	We expect that the study will have the following benefit on the target groups: ➢ Improved knowledge and skills about practices for prevention and self-management of disabilities; sustainable self-management and prevention of disabilities (disability management) within the family. ➢ Improvements in activity levels and social participation, less wounds and a lower lymphedema grade ➢ Improved individual and family quality of life and mental wellbeing. ➢ Improved knowledge and attitudes (reduction of stigma) towards having a family member with leprosy, LF or podoconiosis-related disabilities. ➢ Socio-economic empowerment.

Certain occurrences may take place during the course of the study. We have summarized these in

Box 7 and described how to manage them.

Box 7. Occurrences that may take place during the study period	
Occurrences	How to manage
Withdrawal of volunteers from the study	We consider and add 15% of the total sample for non-response rate at the beginning.
Availability of new information that may affect your decision	We (the research group) discussed about the issue as well share the idea with the concerned ethical committee and will decide about that.
[Criteria for the termination of participation, if any]	➢ The selected individual interrupt the intervention and two follow up visits. ➢ If the study participant has no interest to continue with the study. ➢ If they want to change their living place.

- At the end of the study, you will improved knowledge and skills about practices for prevention and self-management of disabilities; sustainable self-management and prevention of disabilities

(disability management) within the family. Improvements in activity levels and social participation, less wounds and a lower lymphedema grade. Improved individual and family quality of life and mental wellbeing. Improved knowledge and attitudes (reduction of stigma) towards having a family member with leprosy, LF or podoconiosis-related disabilities. Additionally, there is also socio-economic empowerment of the study participants. Lastly a psychosocial care component, that will be developed in the first few months of the project based on a literature review, will additionally be included (= improving participation, quality of life and mental wellbeing).

All data collected from the study will be kept confidential. The project leader (lead applicant) and principal investigator of this study will take full responsibility for ensuring the appropriate storage and security of data. Presentations of the study's results at meetings/ conferences or their publication in a scientific journal will not include your name. However, the national authority for drug use, ethics committees and sponsor's representatives will have access to the data for verification.

As you are a participant of the study there is no any payment given to you but the necessary hygiene materials and some other important kind of directly or indirectly disability prevention things (energy saving stoves) will be given to you. In case of any injury or illness resulting directly from participation in the study, will entertain according to the legal law rule.

If you have any questions related to the study or you experience any adverse event before/during participation in the study, you can consult the contact persons listed in Box 8.

Box 8. The contact persons

1. Moges Wubie

Tel. +251912076152 E-mail: mogeswub@gmail.com

2. Tesfaye Tadesse (Ethiopian National people affected by Leprosy (ENAPAL)).

Tel. +251911440367 E-mail: tadesse.tesfaye@ymail.com

If you have any questions related to your rights, you can contact [name of the ethics committee and contact number].

Regarding to publication the funder no involved or decided.

Certificate of Consent I have read or somebody I trusted with read the foregoing information. I have an opportunity to ask questions and all my quest have been answered to my satisfaction. I voluntary consent to participate in this research study. _____ Printed name of the participant _____ Signature of the participant Date _____	I confirm that the participant was given an opportunity to ask questions about the study and all questions have been answered correctly. I confirm that the consent has been given voluntarily. A copy of this ICF has been provided to the participant. _____ Printed name of the person taking the consent _____ Signature of the person taking the consent Date _____
If illiterate I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely. _____ Printed name of the witness _____ Signature of the witness Date _____	

Beach Center Family Quality of Life Scale:

Code Number

FAMILY QUALITY OF LIFE (cont.)

How satisfied am I that...	*Very Dissatisfied*	*Dissatisfied*	*Neither*	*Satisfied*	*Very Satisfied*
1. My family enjoys spending time together.	☐	☐	☐	☐	☐
2. My family members help the children learn to be independent.	☐	☐	☐	☐	☐
3. My family has the support we need to relieve stress.	☐	☐	☐	☐	☐
4. My family members have friends or others who provide support.	☐	☐	☐	☐	☐
5. My family members help the children with schoolwork and activities.	☐	☐	☐	☐	☐
6. My family members have transportation to get to the places they need to be.	☐	☐	☐	☐	☐
7. My family members talk openly with each other.	☐	☐	☐	☐	☐
8. My family members teach the children how to get along with others.	☐	☐	☐	☐	☐
9. My family members have some time to pursue our own interests.	☐	☐	☐	☐	☐
10. Our family solves problems together.	☐	☐	☐	☐	☐
11. My family members support each other to accomplish goals.	☐	☐	☐	☐	☐
12. My family members show that they love and care for each other.	☐	☐	☐	☐	☐
13. My family has outside help available to us to take care of special needs of all family members.	☐	☐	☐	☐	☐
14. Adults in our family teach the children to make good decisions.	☐	☐	☐	☐	☐

FAMILY QUALITY OF LIFE (cont.)

How satisfied am I that...	*Very Dissatisfied*	*Dissatisfied*	*Neither*	*Satisfied*	*Very Satisfied*
15. My family gets medical care when needed.	☐	☐	☐	☐	☐
16. My family has a way to take care of our expenses.	☐	☐	☐	☐	☐
17. Adults in my family know other people in the children's lives (friends, teachers, etc.).	☐	☐	☐	☐	☐
18. My family is able to handle life's ups and downs.	☐	☐	☐	☐	☐
19. Adults in my family have time to take care of the individual needs of every child.	☐	☐	☐	☐	☐
20. My family gets dental care when needed.	☐	☐	☐	☐	☐
21. My family feels safe at home, work, school, and in our neighborhood.	☐	☐	☐	☐	☐
22. My family member with a disability has support to accomplish goals at school or at workplace.	☐	☐	☐	☐	☐
23. My family member with a disability has support to accomplish goals at home.	☐	☐	☐	☐	☐
24. My family member with a disability has support to make friends.	☐	☐	☐	☐	☐
25. My family has good relationships with the service providers who provide services and support to our family member with a disability.	☐	☐	☐	☐	☐

Thank you! You have finished completing this survey. Please make sure you erase any extra marks and have answered all the questions.

Reference: Beach Center on Disability (2005), The Beach Center Family Quality of Life Scale. Beach Center, The University of Kansas, Lawrence, KS, in partnership with families, service providers and researchers.

The Stigma Assessment and Reduction of Impact (SARI) Stigma Scale: Code Number

	SARI Stigma Scale v.1.1 (*based on the Berger HIV stigma scale*)	No	Yes	Don't	Not Relev	Always/Of	Sometime	Rarely/on	Score
Experienced stigma									
1a	Do some people who know you have	0		0	0				
b	*(If yes) How often has this happened?*					3	2	1	
2a	Do people you care about stop	0		0	0				
b	*(If yes) How often has this happened?*					3	2	1	
3a	Did you lose friends by telling them you	0		0	0				
b	*(If yes) How often has this happened?*					3	2	1	
4a	Do people avoid touching you once they	0		0	0				
b	*(If yes) How often has this happened?*					3	2	1	
5a	Have people physically backed away from	0		0	0				
b	*(If yes) How often has this happened?*					3	2	1	
6a	Do people seem afraid of you once they	0		0	0				
b	*(If yes) How often has this happened?*					3	2	1	
7a	Do you feel set apart and isolated from the community since learning	0		0	0				
b	*(If yes) How often has this happened?*					3	2	1	
		Subtotal							
Disclosure concerns									
8a	Are you careful who you tell that you have	0		0	0				
b	*(If yes) How often are you careful?*					3	2	1	
9a	Do you feel the need to hide your leprosy	0		0	0				
b	*(If yes) How often do you feel the need to*					3	2	1	
10a	Do you believe telling someone you have	0		0	0				
b	*(If yes) How often do you believe it is risky?*					3	2	1	
11a	Do you worry that people may judge you	0		0	0				
b	*(If yes) How often do you worry about this?*					3	2	1	
		Subtotal							

Reference: Dadun, Peters, M.H, van Brakel, W.H., Lusli, M., Zweekhorst, M.B.M., Damayanti, R.,Bunders, J.F.G., Irwanto (in preparation). Cultural validation of a new instrument to measure leprosy-related stigma: the SARI Stigma Scale.

	SARI Stigma Scale v.1.1 (*based on the Berger HIV stigma scale*)	No	Yes	Don't	Not	Always/Of	Sometime	Rarely/on	Score
Internalised stigma									
12a	Do you feel guilty because you	0		0	0				
b	*(If yes) How often has this*					3	2	1	
13a	Do you feel you are not as	0		0	0				
b	*(If yes) How often has this*					3	2	1	
14a	Are you embarrassed that	0		0	0				
b	*(If yes) How often has this*					3	2	1	
15a	Does having (had) leprosy	0		0	0				
b	*(If yes) How often has this*					3	2	1	
16a	Do you regret having told some	0		0	0				
b	*(If yes) How often has this*					3	2	1	
17a	Does having (had) leprosy make	0		0	0				
b	*(If yes) How often has this*					3	2	1	
		Subtotal							
Anticipated stigma									
18a	Do people affected by leprosy	0		0	0				
b	*(If yes) How often does this*					3	2	1	
19a	Are people affected by leprosy	0		0	0				
b	*(If yes) How often does this*					3	2	1	
20a	Do most people think that a	0		0	0				
b	*(If yes) How often does this*					3	2	1	
21a	Do most people feel	0		0	0				
b	*(If yes) How often does this*					3	2	1	
		Subtotal							
		Total score							

Code Number

No	Participation Scale Short 1.0	Not specified, not	Yes	Sometimes	No	Irrelevant, I don't want to, don't	NO problem	Small	Medium	Large	SCORE
1	Do you have equal opportunity as your peers to find work?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
2	Do you work as hard as your peers do? (same hours, type of		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
3	Do you contribute to the household economically in a similar		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
4	Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars,		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
5	Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
6	Do you take part in social activities as much your peers do? (e.g. in sports, chat, meetings, religious or community		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
7	Do you have the same respect in the community as your		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
8	Do you visit other people in the community as often as other		0			0					
	[if sometimes or no] How big a problem is it for you?						1	2	3	5	
9	Do you move around inside and outside the house and around the village / neighbourhood just as other people do?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
10	In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices,		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
11	In your home, do you do household work?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	

No	Participation Scale Short 1.0	Not specified,	Yes	Sometimes	No	Irrelevant, I don't	NO problem	Small	Medium	Large	SCORE
1	In family discussions, does your opinion count?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
1	Are you comfortable meeting new people?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	

Comment:

TOTAL

Name: _____

Age:_____ Gender: _____

Interviewer:_____ Date of interview:_____/____/ _____

Grades of participation restriction

No significant restriction	Mild restriction	Moderate restriction	Severe restriction	Extreme restriction
0 – 12	13 – 22	23 – 32	33 – 52	53 – 90

Disclaimer: The Participation Scale is the intellectual property of the Participation Scale Development Team. Neither the Team
or its sponsors can be held responsible for any consequences of the use of the Participation Scale.

Code Number

PATIENT HEALTH QUESTIONNAIRE- 9(PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use " ✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. 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	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
	FOR OFFICE CODING	*0*_____+_____+_____+		

=Total Score: _____If you checked off any problems, 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	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute. https://patient.info/do or/patient-health-questionnaire-phq-9

በደብረ ሚርቆስ ዩኒቨርሲቲና በኢትዮጵያ የቆዳ በሽታ ተ/ሚህበር በዚገ ምወረዳ በእግር እብጠትና የቆዳ በሽታ ተጠቂዎችን ለማጥናት የጥናት ተሳታፊዎች ማከታተያ ቅፅ

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ሚጃየተነገረበት ስምምነት ቅጽ

የጥናቱርዕስ-የአካልጉዳትን ለማላከል እና ዘላቂየራስ-አያያዝን ለመቆጣጠር ያተኮሩ በቤተሰብላይ የተመሰረቱአቀራረቦችን ውጤታማነት መመርመር፣ የኦሮሞ ጥራት ላይ ተጽዕኖ ማሳደር ፣ የአእምሮ ጤንነት እና የሥጋ ደዌ በሽታ፣ ፖዶኮኒስስ እና ሊምፍቲክ ፊላሪያስ ያሉ ሰዎች እና ቤተሰቦቻቸውበምስራቅ እና ምዕራብጎጃም፣ ኢትዮጵያ ፡ ፡

ሚመሪ (ዎቹ) ሞስ ውቢ፣ አሊስ ስቺፐር ፣ እና ቫንትኑርደንድ፣ ተስፋዬ ታደሰ

አደረጃጀት -ደብረ ሚቆስ ዩኒቨርሲቲ

የገንዘብድጋፍየሚያደርግ -የሥጋ ደዌ ምርምር ኢኒሸቲቭ(ኤል አር አይ)

የዚህ ጥናት ተካፋይ እንዲሆኑ ተጋብዘዋል ምክንያቱምእርሰዎ የሥጋ ደዌ / ፖዶኮኒስስ / የሊምፍቲክ ፊሊያሪያሲስ ተጎጂ / የቤተሰብአባል / በመሆነ ዎት ፡ ፡

በዚህ ጥናት ውስጥ በአጠቃላይ 516 ግለሰቦች ይሳተፋሉ::

ከመወሰንዎ በፊት ጥናቱ ለምን እየተካሄደ እንደሆነ እና ምን እንደሚካትት መገንዘቡለእርስዎ አስፈላጊ ነው ፡ እባክዎን እራስዎ ያንብቡ/ማንኛውምሰውየ ሚከተሉትን ሚጃዎች በጥንቃቄ ሊያነብልዎ ይችላል እና ግልፅ ካልሆነ ለማከየቅ ወይምከምትፈልጉት ጋር ለመወያየት ነፃነት ይሰማው፡ ፡

እባክዎን በዚህ ምርምር ውስጥ መሳተፍ ይፈልጉ ወይምአይፈልጉምየ ሚለውን ለመወሰን ጊዜ ይውሰዱ፡ ፡

በዚህ ጥናት ውስጥ መሳተፍ ሙሉ በሙሉ በፈቃደኝነት ሚሆኑን ለማሳሰብእንፈልጋለን (ሣጥን 1)፡ ፡

በጥናቱ ውስጥ ላለመሳተፍ ከወሰኑ በአቅራቢያዎ ወደሚ ኘውየ ጤፍ ተቋምወይምወደ ሕክምና (አካሄድ) ሕክምና የ ሚፈረግ ሕክምና ያገኛሉ (ሣጥን 2)::

ሣጥን 1. በዚህ ምርምር መሳተፍ በፈቃደኝነት ነው

- ✓ በዚህ ጥናት ውስጥአለመሳተፍ ይችላሉ፡ ፡
- ✓ በማንኛውምጊዜ ከጥናቱ መውጣት/ማቋረጥ ይችላሉ፡ ፡

ሣጥን 2. ተለዋጭየ አሠራር ሂደት (ቶች) ወይምየ ሕክምና ውአካሄድ)	
- እንደ ማንኛውምጤፍ ማያልሆነ ሰው ከጤፍ ተቋመህክምና የ ማግኘት መብት አለዎት፡ ፡	ህክምና ን ከጤፍ ተቋመመውሰድ ጥቅመብ ማንኛውምጊዜ ህክምና ያገኛሉ ማለት ነው፡ ፡ በዚያ ያለ ጉድለት ምን አልባት በጤፍ ተቋምውስጥ ያለዉ ባለሞያ የ ሞያ ደረጃ ሊሆን ይችላል በጉዳዩ ላይ ልዩ ሥልጠና ያልዎሰደ ሊሆን ይችላል ፡ ፡ ለህክምና ውክፍያ ሊያስፈልግዎ ይችላል ፡ ፡
- ችግሩን ለመፍታት ምን አማራጮች እንዳሉ ከምርምር ቡድኖቹ ምክር ያግኙ	በተመራማሪ በየጊዜዉለክትትል አይደውልበዎትምእንዲሁም ጉዳዩን በራሳቸውመገድ ይዎጡልል ፡ ፡ ጉዳቱ ከተመራማሪ ውተከታታይ ምክር አያገኝም፡ ፡

ከጥናቱጋር የተዛመደ ሚጃ

በሥጋ ደዌ ፣ በሊንፋቲክ ፊሊሪያሲስ (ኤል.ኤፍ.ኤ) እና በፖዶኮኒዮስ የተጎዱ ሰዎች አብዛኛዎቹ የአካል ጉዳቶች፣ በተለይም ሁለተኛ ደረጃ እንደ ቁስሎች ፣ እብጠቶች እና ሞርሞት ያሉት በአብዛኛው ልንከላከላቸዉየ ምንችላቸዉናቸዉ፡ ፡ ብዙ የሕክምና አቅርቦቶች ሳያስፈልጋቸውበቤት ውስጥ ሊተገበሩ የሚችሉ የአካል ጉዳቶችን በራስ-የ ሚመከሙአንፃራዊነት ቀላል ዘዴዎች አሉ፡ ፡ ብዙውን ጊዜ ግን እነዚህ ዘዴዎች ከነርቭ ጋር የተያያዙ የአካል ጉዳት ወይምበሰዉ ታችን የዉሃ ሞላል ፈሳሽ ሞሚር በሞዛጋት የሜፈጠር እብጠት ያለባቸውታካሚዎች አልተሞሙመወይምቢሞሙምያለሜቋረጥ አይተገበሩም፡ ፡ ነገር ግን በተቃራኒውበሽታዎች የተጠቁ ሰዎች የአካል ጉዳተኝነት ጋር የተዛመዱከብዙ ችግሮች ያጋጥሞቸዋል እንደ ማለል ፣ የእንቅስቃሴ ማደብ ፣ በኢኮኖሚጉድለት እና የሞሰሉት ናቸው፡ ይህ በተጎዱ ሰዎች የአእምሮ ጤንነት ላይ አሉታዊ ተጽዕኖ ያሳድራል ፡ ፡ በእርግጥ በህመሙየተጎዱ ሰዎች ብቻ ሳይሆኑ የአካል ጉዳተኝነት በሞኖሩ ተፅእኖዉለቤተሰብአባላትምጭምር ነዉ፡ ፡

ሪፖርት የተደረጉት ብዙ ችግሮች ከማለል እና የገንዘብእጥረት ጋር የሚዛመዱሆነ ውአግኝተናል ፡ ፡ ማህበራዊ እና ኢኮኖሚያዊ ገጽታዎችን የሚያጎሉ በቤተሰብ ላይ የተሞከረቱ አቀራረቦች የግለሰቦችን እና የቤተሰብን የኑሮ ደረጃ ሊያሻሽሉ ይችላሉ ፡ ፡ አካሄዱ የሚያተኩረውከችግሩ ሶስቱ ምክሶዎች ባሻገር ነው፡ ፡ በበሽታውበተጠቁ ሰዎች ፣ በቤተሰቦቻቸውእና በማህበረሰቡ አባላት ሞካከል ስለ የሥጋ ደዌ በሽታ ፣ ኤል ኤፍ እና ፖዶኮኒዮሲስ ግንዛቤ ማስደግ ፡ ፡ የአካል ጉዳት አያያዝና -የአካል ጉዳቶችን ሞከላከል እና ራስን ማከምእና; የተጎዱ ሰዎችን እንዲሁምየቤተሰብ አባላትን ማህበራዊ-ኢኮኖሚያዊ አቅምማጎልበት፡ ፡

ሣጥን 3. በምርምሩ/በሜደረገዉጤጣልቃገብነት የሚከበቁ ሊሆኑ የሚቻሉ አሉታዊ ውጤቶች

በጠፍ ጥበቃ ሚስቴር በአለምየጤፍ ድርጅት እና ዓለምአቀፍ የፀረ-የሥጋ ደዌ ማህበራት ፌዴሬሽን መሞሪያ ላይ በመሞከዝ ቁስሉ ፣ ኮንትራቱ እና የሊምፍ ኢዴማ/እብጠት/ህመሞአያያዝ ምንምየሚከበቁ አሉታዊ ውጤቶች የሉም ፡

የዚህ ጥናት ዓላማየአካል ጉዳትን ለሞከላከል እና በዘላቂነት ለሞቆጣጠር የራስ-ህክምና በቤተሰብላይ የተሞከረቱ እና ያተኮሩ አቀራረቦችን ሞተግበር በሜሳድረዉየኑሮ ጥራት ደረጃ ፣ የአእምሮ ጤንነት እና የሥጋ ደዌ ፣ ፖዶኮኒስስ እና የሊንፋቲክ ፊላሪያሲስ የተጎዱ ሰዎች እና የቤተሰባቸዉተሳታፊነት በምዕራብእና ምስራቅጎጃም፣ ኢትዮጵያ ፣ ከ2021 -2023 ውጤታማነት ለመገሰስነው፡ ፡

የአሁኑ ፕሮጀክት በቤተሰብ ላይ የተመሠረተ አቀራረብን ውጤታማነት ለማጥናት በዘፈቀደ ቁጥጥር የተደረገበት ዲዛይንን ይጠቀሜል ፣ ምክንያቱምበችግሮች እና በውጤቶች (ቶች) ሞካከል የምክንያት እና ውጤት ግንኙነት ሞኖር አለሞኖሩን ለሜወቅ ይህ በጣምጠንከር ያለ ማገድነው፡ ፡

ሣጥን 4. የጥናት ንድፍ

ጥናቱ በዘፈቀደ ቁጥጥር የተደረገበት የሞከራንድፍን ይጠቀሜል ፡ ፡

ጥናቱ በጠቅላላውወደ ስምንት ወር ያህል ይወስዳል ፡ ፡ በዚህ ጥናት ውስጥ ለሞሳተፍ ከወሰኑ በቦክስ 5. ላይ የሜሙየውን የጊዜ ሰሌዳ እንዲከተሉ ይጠየቃሉ

የጊዜ ሰሌዳን ለማክበር ይገኛል።

በሳጥን 6 ውስጥ በጥናቱ ውስጥ በማሳተፍ የሚማኩትን ወደፊት ሊታዩ የሚቻሉ አደጋዎችን እና የሚከበቁ ጥቅሞችን ጠቅለል አድርገናል ፡ ፡

ሣጥን 6. በጥናቱ ውስጥ በማተፍየሚማኩሊታዩ የሚችሉ አደጋዎች እና የሚከበቁ ጥቅሞች	
ሊጠበቁ የሚችሉ አደጋዎች	የሚከበቁ ጥቅሞች
- ምን ምሊጠበቅ የሚል አደጋ የለም	ጥናቱ በታለማላቸውቡድኖች ላይ የሚከተለውጥቅምይኖረዋል ብለን እንጠብቃለን፡፡ ➢ የአካል ጉዳትን ለማከላከል እና ራስን በራስ ስለመሙራት ልምዶች የተሻሻለ ዕውቀት እና ክህሎቶች; በቤተሰብ ውስጥ ዘላቂ የራስ አስተዳደር እና የአካል ጉዳትን ማከላከል (የአካል ጉዳት አስተዳደር)፡፡ ➢ በእንቅስቃሴ ደረጃዎች እና በማህበራዊ ተሳትፎ ማሻሻል ፣ አነስተኛ ቁስሎች እና ዝቅተኛ የእብጠት ደረጃ ➢ የተሻሻለ የግለሰብእና የቤተሰብየሂወት ጥራት ደረጃ እና የአእምሮ ጤንነት። ➢ የሥጋ ደዌ ፣ የኤል.ኤፍ. ወይምከፖዶኮኒዝስ ጋር የተያያዙ የአካል ጉዳተኞች ያሉበት የቤተሰብአባል የተሻሻለ እንዲኖር የእውቀት እና አመለካከቶች ማዳበር (ማለል ማቀነስ)፡፡ ➢ ማህበራዊ-ኢኮኖሚያዊ ማህል በት.

በጥናቱ ወቅት የተወሰኑ ክስተቶች ሊከናወኑ ይችላሉ፡፡ እነዚህን በሳጥን 7 ላይ ጠቅለል አድርገን እነሱን እንዴት ማስተዳደር እንደምንችል ገልፀናል፡፡

ሣጥን 7. በጥናቱ ወቅት ሊከሰቱ የሚችሉ ክስተቶች	
የሚከሰቱ ክስተቶች	እንዴት ማስተካከል እንደሚቻል
የበጎ ፈቃደኞች መጨጡት/ማቆረዝ ከ ጥናቱ	መጀመሪያ ላይ ይህን ከግምት በማገባት የጠቅላላውና ሞኛ 15% ጨምረናል፡፡

የአዳዲስ ሚጃዎች ተገኝነት በእርስዎ ውሳኔ ላይ ተጽዕኖ ሊያሳድር ይችላል	እኛ (ተሟጋሚ ቡድኑ) በጉዳዩ ላይ ተወያይተን ሀሳቡን ለሚመለከተውየስነ ምግባር ኮሜቴ አካፍለን በዚያ ላይ እንወስናለን፡፡
[የ መቋረጡማክፈርት ተሳትፎ፣ ድንገት ካለ]	➢ የተሟጋውግለሰብየሚደረግለትን ክትትል ጣልቃ ሁለት ተከታይ ጉብኝቶች ካቋረጠ፡፡ ➢ የጥናቱተሳታፊ በጥናቱለመቀጠል ፍላጎት ከሌለው፡፡ ➢ የሞሪያ ቦታቸውን ማላወጥ ከፈለጉ፡፡

• በጥናቱ ሜጩፈሻ የአካል ጉዳትን ለመከላከል እና ራስን በራስ ስለማከም ልምዶች ዕውቀቶችን እና ክህሎቶችን ያሻሽላሉ ፤ በቤተሰብ ውስጥ ዘላቂ የራስ አስተዳደር እና የአካል ጉዳትን መከላከል (የአካል ጉዳት ማከም)፡፡ በእንቅስቃሴ ደረጃዎች እና በማህበራዊ ተሳትፎ መሻሻል ፣ አነስተኛ ቁስሎች እና ዝቅተኛ የሊምፍዴማ/እብጠት/ ደረጃ ሜድረስ። የተሻሻለ የግለሰብ እና የቤተሰብ የህይወት ጥራት ደረጃ እና የአእምሮ ጤንነት። የተሻሻለ ዕውቀት እና አመለካከቶች (መላለልን መቀነስ) የሥጋ ደዌ ፣ የኤል.ኤፍ. ወይምከፖዶኮኒዝስ ጋር የተዛመደ የአካል ጉዳት ላለበት የቤተሰብአባል እንዲኖር ሜድረግ ፡፡ በተጨሜምየጥናቱን ተሳታፊዎች ማህበራዊና ኢኮኖሚያዊ አቅምማጠልበት ይኖራል፡፡ በሜጩፈሻም በስነ -ጽሁፍ ግምግማላይ በመሚኮዝ በፕሮጀክቱ የመጀሚያ ወራቶች ውስጥ የሜበረውየስነ -ልቦና እንክብካቤ ክፍል በተጨሜ (= ተሳትፎን ማሻሻል ፣ የሕይወት ጥራት ደረጃ እና የአእምሮ ጤንነት) ይካትታል፡፡

ከጥናቱ የተሰበሰቡ ሚጃዎች በማሉ በሚስጥር ይቀመጣሉ፡፡ የፕሮጀክቱ ሚ (ሚ አመልካች) እና የዚህ ጥናት ዋና ሚ ሚ ተገቢውን የ ሚጃ ማከማቸት እና ደህንነት ለሚጋገጥ ማሉ ሃላፊነቱን ይወስዳሉ፡፡ የጥናቶቹ ውጤቶች አቀራረቦች በስብሰባዎች / ስብሰባዎች ላይ ወይምበሳይንሳዊ ሙጽሔት ውስጥ መታተማቸውስምሞን አያካትቱም፡፡ ሆኖምለሜድሃኒት አጠቃቀምእና ቁጥጥር ፣ ለሥነ ምግባር ኮሜቴዎች እና ለስፖንሰር ተወካዮች ብሔራዊ ባለሥልጣን ለማካራት ሚጃውን ያገኛል፡፡

የጥናቱ ተካፋይ እንደሚሆንዎ ለእርስዎ ምንምክፍያ አይሰጥምነገር ግን አስፈላጊ የሆኑ የንፅህና ማከበቂያ ቁሳቁሶች እና ሌሎች በቀጥታምሆነ በተዘዋዋሪ የአካል ጉዳት ማከላከያ ነገሮችን (የኃይል ቆጣቢ ምድጃዎችን) ሌሎች አስፈላጊ ዓይነቶችን ይሰጥዎታል፡፡ በጥናቱ ውስጥ በቀጥታ በማሳተፍ የሚማማኝ ውምጉዳት ወይምህመምቢኖር በሕጋዊው ደንብይስተናገዳል፡፡

ከጥናቱ ጋር የሜዝ መዱ ማሻቸውምጥያቄዎች ካሉዎት ወይምበጥናቱ ውስጥ ከማሳተፍዎ በፊት / ወቅት ማንኛውንምመጥፎ ክስተት ካጋጡመዎት በሳጥን 8 ውስጥየተዘረዘሩትን የእውቂያ ሰዎች ማማከር ይችላሉ ፡፡

ከጥናቱ ጋር የሜዝ መዱ ማሻቸውምጥያቄዎች ካሉዎት ወይምበጥናቱ ውስጥ ከማሳተፍዎ በፊት / ወቅት ማንኛውንምመጥፎ ክስተት ካጋጡመዎት በቦክስ 8 ውስጥየተዘረዘሩትን ሰዎች ማማከር ይችላሉ፡፡

ሣጥን 8. የግንኙነት ሰዎች

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2. ተስፋዬ ታደሰ (የኢትዮጵያ ብሔራዊ በሥጋ ደዌ በሽታየተጠቁት ሰዎች ማህበር (ኢናፓል))፡፡

ስልክ +251911440367 ኢሜል tadesse.tesfaye@ymail.com

ከጣብቶችዎ ጋር የተያያዙ ማናቸውምጥያቄዎች ካሉዎት [የስነ ምግባር ኮሜቴውስምእና የእውቂያ ቁጥር] ማግኘት ይችላሉ፡፡

የገንዘብድጋፍ አድራጊዉሀትሞትን በተመለከተ ምንምተሳትፎ ወይምውሳኔ አይኖረዉም፡፡

ስምምነት ሚጋገጫ	
ከላይየተጠቀሱትን ሚጃዎች አንብቤአለሁ ወይምእኔ የማማ ዉሰውአንብቦልኛል፡፡ ጥያቄዎችን የማከየቅ እድል አለኝ እናምለሁሉም ጥያቄዬ ፍላጎቴ ሜልስ እስኪያረካኝ ድረስ አግኝቻለሀ፡፡ በዚህ የምርምር ጥናት ውስጥ በፈቃደኝነት ለማተፍ እፈቅዳለሁ፡፡ _____ የተሳታፊውስም _____ የተሳታፊውፊርማ ቀን _____	ተሳታፊውስለ ጥናቱ ጥያቄዎችን የማከየቅ እድል እንደተሰጠእና ሁሉምጥያቄዎች በትክክል እንደተመለሱአረጋግጣለሁ፡፡ ስምምነቱ በፈቃደኝነት ማሳጡቱን አረጋግጣለሁ፡፡ _____ ፈቃዱን የሚወስደውሰውፊርማ ቀን _____

የቤተሰብየኑሮ ሁኔታ (Family Quality of Life)

ተ.ቁ	የእርካታ/ደስተኛነት ደረጃዎ ከሚከተሉትነጥቦች አኳያ ሲታይ	በጣም አልስማማም	አልስማማም	ሀሳብየለኝም	እስማማለሁ	በጣም እስማማለሁ
1	ቤተሰቦች በጋራ በሚሰልፉት ጊዜ ደስተኛ ናቸው					
2	የቤተሰቡአባላት ልጆች እራሳቸውን እንዲችሉ ያግዛሉ					
3	ቤተሰቡን ከጭንቀት የሚያድን ድጋፍ አለው					
4	ለቤተሰቡአባላት ድጋፍ የሚያደርጉ ጎረቤት/ጓደኛ አለ					
5	የቤተሰቡአባላት ልጆች ትምህርታቸውን እንዲሙና በሌሎች					

	ስራዎች እንዲሳተፉ ያደርጋሉ					
6	የቤተሰቡ አባላት ወደ ሜፈልጉበት ቦታ ለሜድየ ትንስፖርት ችግር የለም					
7	የቤተሰቡ አባላት በማ ኛውምነ ገር ላይ በግልፅ ይወያያሉ					
8	የቤተሰቡ አባላት ልጆችን ከሌላ ሰዎች ጋር እንዴት እንደሞ ሩ ያስተምራሉ					
9	የቤተሰቡ አባላት የቤተሰቡ ፍላጎ ት ለሞሟላ ት ጊዜ ይሰጣሉ					
10	የቤተሰቡ አባላት የ ሚያ ጋጥሞቹውን ችግር በጋራ ይፈታሉ					
11	የቤተሰቡ አባላት በሞባበር ኑሯቸውን ያሽንፋሉ					
12	የቤተሰቡ አባላት በፍቅርና በ ሚዳዳት ይኖራሉ					
13	ቤተሰቡን በ ሞሉ በችግር ጊዜ የ ሚ ግዝ ሌላ አ ካል/ሰ ውአ ለ					
14	በቤተሰቡ ውስ ጥህፃ ና ት የ ራሳ ቸውን ጥሩ ውሳኔ እንዲወስኑ ይሚራሉ					
15	ቤተሰቡ የ ሚ ያስ ፈልጋ ቸውን ህክ ምና ያገ ኛሉ					
16	ቤተሰቡ ለ ወጪአ ይቸገ ር ም					
17	በቤተሰቡ ውስ ጥ ያሉ አ ዋቂ ዎች የ ህፃ ና ትን ህ ይዎት እንደ ጓ ደኛ ሁነ ውይ ረዳ ሉ					
18	ቤተሰቡ የ ህ ይዎትን ውጣ ውረ ድ መቋቋ ምይች ላ ሉ					
19	በቤተሰቡ ውስ ጥ ያሉ አ ዋቂ ዎች የ እ ያንዳንዱን ህፃ ና ት ፍላጎ ት ለ ሞሟላ ት ይሰ ራሉ					
20	ቤተሰቡ የ ጥር ስ ህክ ምና ሲ ያስ ፈልግ ማ ገኘ ት ይች ላ ል					
21	ቤተሰቡ በስ ራ ቦ ታ፤ በ ት/ቤትምሆነ በጎ ረቤት ም ቾት/ደህንነ ት ይሰ ማ ቸዋ ል					
22	የ አ ካል ጉዳ ት ያ ለበ ት የ ቤተሰቡ አ ባ ል በስ ራ ቦ ታ ምሆነ በ ት/ቤት አ ላ ሟ ሟ ን ለ ማ ከ ካ ት ተ ገ ቢ ድ ጋ ፍ ያ ገ ኛ ል					

23	የ አ ካ ል ጉ ዳ ት ያ ለ በ ት የ ቤ ተ ሰ ቡ አ ባ ል በ ቤ ት ው ስ ጥ አ ላ ማ ው ን ለ ማ ህ ካ ት ተ ገ ቢ ድ ጋ ፍ ያ ገ ኛ ል					
24	የ አ ካ ል ጉ ዳ ት ያ ለ በ ት የ ቤ ተ ሰ ቡ አ ባ ል ጓ ደ ኛ እ ን ዲ ኖ ረ ው ድ ጋ ፍ ያ ገ ኛ ል					
25	የ ቤ ተ ሰ ቡ አ ባ ላ ት ከ ማ ህ ኛ ው ም አ ገ ል ግ ሎ ት ሰ ጭ አ ካ ላ ት ጋ ር ጥ ሩ ግ ን ኙ ነ ት አ ላ ቸ ው					

ለ ሰ ጡ ኝ ቃ ለ ማ ኪ ይ ቅ አ ማ ህ ግ ና ለ ሁ!

የ ማ ለ ል ዳ ሰ ሳ ና ማ ቀ ነ ስ (the stigma assessment and reduction of impact –SARI scale)

ተ.ቁ	ዝር ዝር	ምላሽ	በ አ ብዛ ኛ ው	አ ል ፎ አ ል ፎ	አ ን ዳ ን ዴ/አ ን ድ ጊ ዜ	አ ላ ው ቅ ም
	በ ግ ለ ሰ ቡ ላ ይ የ ደ ረ ሰ ማ ለ ል		4	3	2	1
የ ገ ጡ መ ማ ለ ል						
1U	የ ስ ጋ ደ ቄ በ ሽ ታ/የ ዝ ሆ ኔ ተ ጡ ቂ በ ሚ ሆ ን ዎ ሰ ዎ ች ር ቀ ዎ ታ ል	1 አ ዎ 2 የ ለ ም 3 አ ላ ው ቅ ም				
ለ	ም ላ ሽ ዎ አ ዎ ከ ሆ ነ ም ን ያ ህ ል ያ ጋ ጥ ሜ ል					
2U	በ ጣ ም የ ሚ ቅ ር ቡ ት ሰ ው የ ስ ጋ ደ ቄ በ ሽ ታ/የ ዝ ሆ ኔ ተ ጡ ቂ በ ሚ ሆ ን ዎ ር ቆ ዎ ታ ል	1 አ ዎ 2 የ ለ ም 3 አ ላ ው ቅ ም				
ለ	ም ን ያ ህ ል ነ ው					
3U	የ ስ ጋ ደ ቄ በ ሽ ታ/የ ዝ ሆ ኔ እ ን ዳ ለ ብ ዎ ለ ሰ ዎ ች በ ጣ ን ር ዎ ጓ ደ ኛ አ ጡ ዋ ል	1 አ ዎ 2 የ ለ ም 3 አ ላ ው ቅ ም				
ለ	ም ን ያ ህ ል ነ ው					
4U	የ ስ ጋ ደ ቄ በ ሽ ታ/የ ዝ ሆ ኔ ተ ጡ ቂ በ ሚ ሆ ን ዎ ሰ ዎ ች አ ይ ነ ኩ ዎ ት ም	1 አ ዎ 2 የ ለ ም 3 አ ላ ው ቅ ም				
ለ	ም ን ያ ህ ል ነ ው					
5U	የ ስ ጋ ደ ቄ በ ሽ ታ/የ ዝ ሆ ኔ ተ ጡ ቂ በ ሚ ሆ ን ዎ ሰ ዎ ች በ አ ካ ል ይ ር ቃ ሉ	1 አ ዎ 2 የ ለ ም 3 አ ላ ው ቅ ም				
ለ	ም ን ያ ህ ል ነ ው					
6U	ሰ ዎ ች የ ስ ጋ ደ ቄ በ ሽ ታ/የ ዝ ሆ ኔ ተ ጡ ቂ ሚ ሆ ን ዎ ን ሲ ያ ው ቁ ሚ ፈ ሩ ይ ማ ከ ል ዎ ታ ል	1 አ ዎ 2 የ ለ ም 3 አ ላ ው ቅ ም				
ለ	ም ን ያ ህ ል ነ ው					
7U	ከ ሚ ህ በ ረ ሰ ቡ የ ማ ለ ል ስ ሜ ት ይ ሰ ማ ዎ ታ ል	1 አ ዎ 2 የ ለ ም 3 አ ላ ው ቅ ም				
ለ	ም ን ያ ህ ል ነ ው					

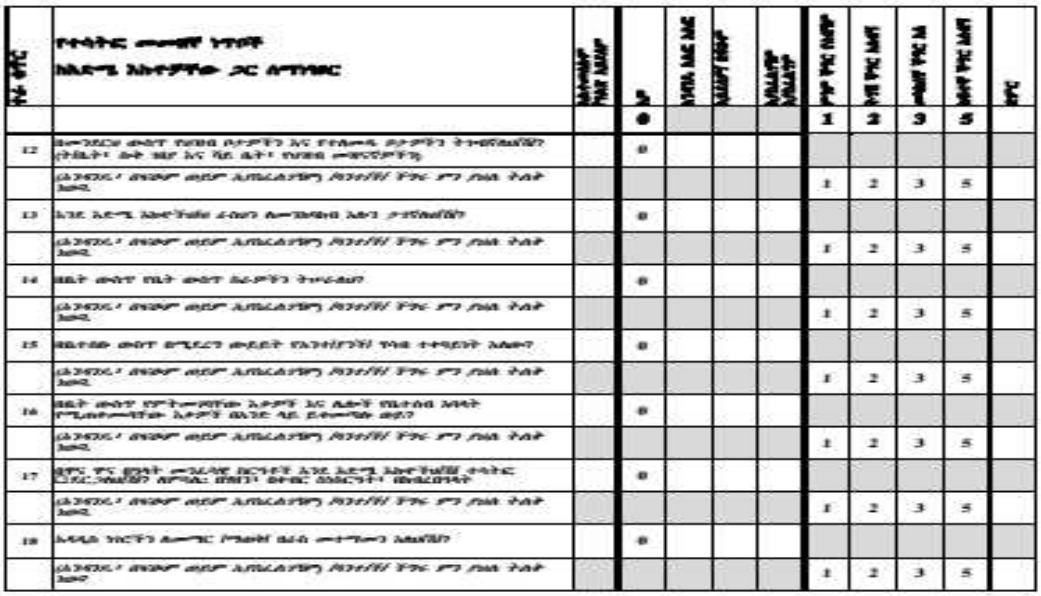
ራስን ማግለል						
8U	ሰዎች የስጋ ደዌ በሽታ/የ ዝሆኔ ተጠቂ ሚሆንዎን እንዳያውቁ ይጠነ ቀቃሉ	1 አዎ 2 የለም 3 አላውቅም				
ለ	ምን ያህል ነው					
9U	የስጋ ደዌ በሽታ/የ ዝሆኔ ተጠቂ ሚሆንዎን ሚደበቅ ያስፈልጋል ብለውያምናሉ	1 አዎ 2 የለም 3 አላውቅም				
ለ	ምን ያህል ነው					
10U	የስጋ ደዌ በሽታ/የ ዝሆኔ ተጠቂ ሚሆንዎን ለሌላ ሰውማገር አደጋ አለውብለውያምናሉ	1 አዎ 2 የለም 3 አላውቅም				
ለ	ምን ያህል ነው					
11U	ሰዎች የስጋ ደዌ በሽታ/የ ዝሆኔ አለበት ይሉኛል ብለውይጨነቃሉ	1 አዎ 2 የለም 3 አላውቅም				
ጪስጣዊ የማለል ስሜት						
ለ	ምን ያህል ነው					
12U	የስጋ ደዌ በሽታ/የ ዝሆኔ በሚሆንዎ ጥፋተኛነት ይሰማዎታል	1 አዎ 2 የለም3 አላውቅም				
ለ	ምን ያህል ነው					
13U	የስጋ ደዌ በሽታ/የ ዝሆኔ ስለአለብዎ ከሌሎች ሰዎች አንሳለሁብለውያስባሉ	1 አዎ 2 የለም 3 አላውቅም				
ለ	ምን ያህል ነው					
14U	የስጋ ደዌ በሽታ/የ ዝሆኔ ስለአለብዎ ሀፍረት ይሰማዎታል	1 አዎ 2 የለም 3 አላውቅም				
ለ	ምን ያህል ነው					
15U	የስጋ ደዌ በሽታ/የ ዝሆኔ ስለአለብዎ ንፁህ አይደለሁምብለውያስባሉ	1 አዎ 2 የለም 3 አላውቅም				
ለ	ምን ያህል ነው					
16U	የስጋ ደዌ በሽታ/የ ዝሆኔ እንዳለብዎ ለሰዎች በማገርዎ የቆጩ	1 አዎ 2 የለም 3 አላውቅም				
ለ	ምን ያህል ነው					
17U	የስጋ ደዌ በሽታ/የ ዝሆኔ ስለአለብዎ ማጭፎ ሰውነኝ ብለውያስባሉ	1 አዎ 2 የለም 3 አላውቅም				
ለ	ምን ያህል ነው					
በጥርጣሬ ማለል						
18U	የስጋ ደዌ በሽታ/የ ዝሆኔ ያለባቸውሰዎች በአሰሪዎቻቸውከስራ ሊባረሩ ይችላሉ	1 አዎ 2 የለም 3 አላውቅም				
ለ	ምን ያህል ነው					
19U	የስጋ ደዌ በሽታ/የ ዝሆኔ ያለባቸውሰዎች በማህበረሰቡዘንድየህዝብሽክምናቸውብለው	1 አዎ 2 የለም 3 አላውቅም				

	ያምና ሉ					
ለ	ምን ያህል ነ ው					
20 U	ሰዎች የ ስ ጋ ደ ቄ በ ሽ ታ/የ ዝ ሆ ኔ ያ ለ ባ ቸ ውን አ ስ ጨ ይ ታ ና ቸ ው ብ ለ ው ያ ስ ባ ሉ	1 አ ዎ 2 የ ለ ም 3 አ ላ ው ቅ ም				
ለ	ምን ያህል ነ ው					
21 U	ሰዎች የ ስ ጋ ደ ቄ በ ሽ ታ/የ ዝ ሆ ኔ ካ ለ ባ ቸ ው ጋ ር ለ ሞ ር ም ቾ ት አ ይ ሰ ማ ቸ ውም	1 አ ዎ 2 የ ለ ም 3 አ ላ ው ቅ ም				
ለ	ምን ያህል ነ ው					

አ መ ሰ ግ ና ሁ!

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
			0				1	2	3	5	
1	[illegible]		0								
	[illegible]						1	2	3	5	
2	[illegible]		0								
	[illegible]						1	2	3	5	
3	[illegible]		0								
	[illegible]						1	2	3	5	
4	[illegible]		0								
	[illegible]						1	2	3	5	
5	[illegible]		0								
	[illegible]						1	2	3	5	
6	[illegible]		0								
	[illegible]						1	2	3	5	
7	[illegible]		0								
	[illegible]						1	2	3	5	
8	[illegible]		0								
	[illegible]						1	2	3	5	
9	[illegible]		0								
	[illegible]						1	2	3	5	
10	[illegible]		0								
	[illegible]						1	2	3	5	
11	[illegible]		0								
	[illegible]						1	2	3	5	

P Scale ve4.1 Amharic 1 25 December 2009



12			0								
							1	2	3	5	
13			0								
							1	2	3	5	
14			0								
							1	2	3	5	
15			0								
							1	2	3	5	
16			0								
							1	2	3	5	
17			0								
							1	2	3	5	
18			0								
							1	2	3	5	

ለሳ አስተያየት ካለ፡

ስም፡ _____

□ኮሚ፡ _____ ፆ□: _____

የጥናቱ ዓላማ: _____

ቃለመጠይቁን ያደረገው: _____ ቀን: ___/___/____

የተሳትፎ ገደብ መለኪያ

0 - 12	13 - 22	23 - 32	33 - 52	53 - 99

የህመምተኛ ጤና ጥያቄዎች-9 (PHQ-9)

ባለፉት ሁለት ምንታት ዉስጥ ምን ያህል ጊዜ በሚከተሉት ችግሮች ተቸግረሃል፡ ፡ የ "✔" *ምልክት ለማምልከት ተጠቀም*

ተ. ቁ	ጥያቄ	በጭራሽ	ብዙ ቀናት	ከግማሽ ቀናት በላይ	በየቀኑ ማለት ይቻላል
1	ትንሽ ፍላጎት ወይምደስታ ነገሮችን ለማድረግ አለ	0	1	2	3
2	የተስፋ መቁረጥ ስሜት ፣ የመንፈስ ጭንቀት ወይምተስፋ መቁረጥ አለ	0	1	2	3
3	መዉደቅ ወይምመተኛት ፣ ወይምከማጠን በላይ መተኛት ችግር አለ	0	1	2	3
4	የድካምስሜት ወይምአነስተኛ ኃይል አለው	0	1	2	3
5	ደካማየ ምግብ ፍላጎት ወይምከማጠን በላይ መብላት አለ	0	1	2	3
6	መጥፎ ስሜት ስለራስዎ ተሰምቶዎት - ወይምእርስዎ ዉድቀት እንደሆኑ ወይምራስዎን ወይምቤተሰብዎን አፍርሰዋል	0	1	2	3
7	በነገሮች ላይ የማተኮር ችግር አለ ማለትም ጋዜጣወይምቴሌቪዥን መመልከት ችግር አለ	0	1	2	3
8	ሌሎች ሰዎች ሊያስተዉሉት በሚችሉት ሁኔታ አለ በዝግታ ማንቀሳቀስ ወይምመናገር አለ? ወይምበተቃራኒ ው- በጣምታማኝነት የጎደለውወይምእረፍት የሌለው በመሆኑ ከወትሮውበበለጠ ብዙ እየተንቀሳቀሱ ነ ው?	0	1	2	3
9	መሞት የተሸለ ነ ዉብለዉያዉቃሉ ወይም ራስዎን በሆነ መንገድ መጉዳት የተሻለ ነ ዉይላሉ?	0	1	2	3

ለቢሮ ኮድ *0*___+________+________+ ________

= ጠቅላላ ድምር ______ ማንኛውንምችግር ካረጋገጡሥራዎትን ለማሥራት ፣ በቤት ውስጥነገሮችን ለመንከባከብ ወይምከሌሎች ሰዎች ጋር ለመግባባት እነ ዚህ ችግሮች ምን ያህል ከባድ አድርገ ውብዎታል? በጭራሽ አስቸጋሪ አይደለም ☐ በተወሰነ ደረጃ ከባድ ነ ዉ ☐ በጣም ከባድ ነ ዉ ☐ እጅግ በጣም ከባድ ☐