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## A 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-056620
Article Type:	Protocol
Date Submitted by the Author:	20-Aug-2021
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Keywords:	Infectious diseases & infestations < DERMATOLOGY, EDUCATION & TRAINING (see Medical Education & Training), INFECTIOUS DISEASES, PREVENTIVE MEDICINE, PUBLIC HEALTH, WOUND MANAGEMENT

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# A 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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**Word count** (excluding title page, abstract, references, figures, tables and acknowledgments): 3,275

## 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-, LF- 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 is to assess the effectiveness of a family-based intervention for prevention and self-management of disabilities due to leprosy, podoconiosis and LF compared to 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. A total of 630 participants will be included in the study, consisting of 420 persons affected (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) and 210 family members (in the intervention group). The family-based intervention comprises 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. Participants in the control areas will receive usual practice and care.

### Ethics and dissemination

Ethical approval has been obtained from the Debre Markos University Health Sciences Institutional

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2  
3 Research Ethics Review Committee. Results will be disseminated through peer-reviewed  
4 publications, conference presentations and workshops.  
5

### 6 **Registration details**

7 This study has been registered at the Pan African Clinical Trial Registry (PACTR202108907851342).  
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## 10 **Article Summary**

### 11 **Strengths and limitations of this study**

- 12 • This family-based intervention cluster-randomised controlled trial was preceded by a proof-  
13 of-concept study, in which the intervention was found feasible.
- 14 • While self-management of disabilities is the main component of the family-based  
15 intervention, the essential care package goes beyond self-care and also includes economic  
16 empowerment and a psychosocial care component.
- 17 • This study is led by and partly carried out by the Ethiopian National Association of Persons  
18 Affected by Leprosy (ENAPAL), a large Ethiopian leprosy disabled persons' organisation.
- 19 • Inclusion of family members in self-care activities ensures sustainability of the intervention.
- 20 • It is difficult to select study districts with a similar prevalence of persons with disease-related  
21 disabilities, that have geographical similarities and in which no previous or ongoing leprosy,  
22 podoconiosis or LF-related work of other organisations is or has been conducted.  
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### 30 **Introduction**

31 Leprosy, podoconiosis and lymphatic filariasis (LF) are Neglected Tropical Diseases (NTDs) [1]. NTDs  
32 are a group of communicable diseases that are among the most common conditions, particularly  
33 among the world's poorest populations [2,3]. These diseases predominate in rural and impoverished  
34 urban areas of low and middle-income countries [4]. Worldwide, over one billion people have one or  
35 more NTDs [5]. NTDs are "poverty promoting" conditions, they cause suffering through acute illness,  
36 pain, long-term disability, early death and through mental and social consequences [2,4].  
37  
38

39 Leprosy, podoconiosis and LF are three skin-related NTDs [1]. All three conditions have skin  
40 manifestations such as patches, ulcers, wounds, nodules or localized swelling [6–9]. They are caused  
41 by bacteria (leprosy), chronic exposure to red clay volcanic soil (podoconiosis) and nematode worms  
42 that are transmitted by mosquitoes (LF) [7,8,10]. Leprosy, podoconiosis and LF can lead to temporary  
43 and permanent impairments if not diagnosed and treated early [1,6,11]. These impairments  
44 progressively worsen and are major determinants of stigma and participation restrictions [12–14].  
45  
46

47 Social consequences of all three conditions may include reduced work and education opportunities,  
48 social isolation, exclusion and problems in interpersonal relationships, including marital problems  
49 [15–18]. Psychological consequences may include feelings of shame, low self-esteem, mental  
50 distress, depression, anxiety, and decreased individual and family quality of life [15–18]. In addition,  
51 these conditions may impose a social and economic burden on families [16,19]. Family members may  
52 also experience stigma [16,20–23]. Furthermore, costs for treatment and reduced ability to work  
53 may cause a financial burden for the entire family [16,19].  
54  
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56 Most impairments, such as wounds, swelling and contractures, are largely preventable [1]. The most  
57 effective strategy for prevention of disabilities is early diagnosis and prompt treatment [24]. Self-care  
58 is also an essential component of prevention of disabilities, and for prevention of chronic disease  
59 complications [24–27]. Relatively simple methods exist for self-management of impairments, such as  
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3 daily washing of affected limbs, skin care, bandaging, exercises and the use of shoes [27]. Most of  
4 these methods can be practiced at home and are suitable for use across different skin-related NTDs  
5 [27–29]. These self-care interventions have been found effective in for example reducing the  
6 incidence of acute dermatolymphangioadenitis (ADLA) in persons affected by podoconiosis and LF  
7 [30,31] and in reducing ulcers among persons affected by leprosy [32]. Because physical impairments  
8 are an important determinant of stigma, disease management is also an indirect intervention to  
9 reduce stigma [33].  
10

11  
12 Many persons with leprosy-, podoconiosis- and LF-related disabilities need to practice self-  
13 management routines their entire life. This is difficult without support and encouragement of others.  
14 Family members can provide such support and encouragement. We recently conducted a proof-of-  
15 concept study in which we piloted a family-based intervention for prevention and self-management  
16 of disabilities due to leprosy, podoconiosis and LF in Ethiopia [34]. This family-based intervention  
17 consisted of self-management of disabilities, awareness raising and economic empowerment, and  
18 was delivered during several monthly group meetings. We found that the intervention had a positive  
19 effect on impairments and self-management of disabilities, family quality of life and stigma.  
20 However, sampling was not randomised, which means we couldn't determine the effectiveness of  
21 the intervention. To collect credible evidence for this new, previously piloted intervention, we aim to  
22 conduct a similar study using a randomised controlled design.  
23  
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### 25 **Objectives**

26 The primary objective of this study is to assess the effectiveness of a family-based intervention for  
27 prevention and self-management of disabilities due to leprosy, podoconiosis or LF compared to usual  
28 practice and care. In addition to demonstrating the effectiveness of the family-based intervention in  
29 terms of management of disabilities, we also aim to assess the impact of the intervention on family  
30 quality of life, mental wellbeing, stigma, participation and economic empowerment of person  
31 affected and their families.  
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### 34 **Methods and analysis**

35 The protocol for this study is outlined below. This study protocol adheres to the SPIRIT statement  
36 [35].  
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#### 39 **Study design**

40 The intervention consists of a cluster-randomised controlled trial, with two study arms. The two  
41 study arms consist of (1) the family-based intervention and (2) usual practice and care (control  
42 group).  
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#### 45 **Study setting**

46 The project is carried out in endemic districts in East and West Gojjam zones in the Amhara region in  
47 Ethiopia (the proof-of-concept study was conducted in a different zone, the Awi zone). The Amhara  
48 region is the second largest state in population and is divided in 11 zones. All three conditions are  
49 endemic in the Amhara region. In 2019, Ethiopia had 3,201 new leprosy patients, 13% of the new  
50 patients had Grade 2 disabilities [36]. The prevalence of leprosy is highest in the Amhara, Afar and  
51 Oromiya regions [37,38]. LF is endemic in the Amhara, Beneshangul-Gumuz, SNNPR and Oromia  
52 regions. Thirty million people have been estimated to be at risk of LF in Ethiopia [37]. In addition,  
53 Ethiopia is estimated to have 25% (1 million cases) of the global burden of podoconiosis.  
54 Podoconiosis is spread out over one-fifth of the surface of Ethiopia, especially the Western part  
55 [37,39,40]. The regions with the high prevalence of podoconiosis are Amhara, SNNPR, Oromiya and  
56 Beneshangul-Gumuz [39,40].  
57  
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59 West Gojjam zone and East Gojjam zone are subdivided into 16 and 20 districts (woredas)  
60 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.

**Table 1. Characteristics of the selected study areas. Data has been collected from field census, health office reports and [41,42].**

	<b>Dega Damot district</b>	<b>Dembecha district</b>	<b>Enarge Enawga district</b>
Total population, <i>n</i> (%)	181,325 (100%)	218,257 (100%)	172,939 (100%)
Men, <i>n</i> (%)	89,756 (49.5%)	105,809 (48.48%)	86,297 (49.9%)
Women, <i>n</i> (%)	91,156 (50.5%)	112,448 (51.52%)	86,642 (49.1%)
Number of kebeles, <i>n</i> (%)			
Rural, <i>n</i> (%)	36 (100%)	31 (100%)	35 (100%)
Urban, <i>n</i> (%)	34 (94%) 2 (6%)	27 (87%) 4 (13%)	31 (89%) 4 (11%)
Number of health facilities			
Hospital, <i>n</i>	1	1	1
Health centre, <i>n</i>	7	7	7
Health post, <i>n</i>	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 leprosy-, podoconiosis- or LF-related disabilities living in the area	Leprosy=132 Podoconiosis =352	Leprosy=135 Podoconiosis=1,042	Leprosy=213 Podoconiosis or LF=797
Geographic and background information	<ul style="list-style-type: none"> <li>• Climate zones: 75% dega (cool temperate), 20% woina dega (subtropical) and 5% kolla (hot lowland).</li> <li>• Annual rainfall between 900-1,200 mm.</li> <li>• The district consists of 35% mountain, 30% hills, 20% valleys and 15% plains.</li> </ul>	<ul style="list-style-type: none"> <li>• Climate zones: 11% dega (cool temperature), 83% woina dega (subtropical) and 6% kolla (hot lowland)</li> <li>• Annual rainfall is between 1,221-1,602 mm.</li> <li>• The district consists of 60% plains, 30% mountain and 10% hills.</li> <li>• Elevation is between 1500-2995 meters above sea level.</li> </ul>	<ul style="list-style-type: none"> <li>• Climate zones: 30% dega (cool temperate), 50% woina dega (subtropical) and 20% kolla (hot lowland).</li> <li>• Annual rainfall is between 1,200-1,400 mm.</li> <li>• The district consists of 50% plains, 30% mountain and 20% hills.</li> <li>• Elevation is 1100-3200</li> </ul>

		• Other: bordered by the Nile river.	meters 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

### Participants

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 (e.g. people who have a family member such as sibling, child, parent or grandparent affected by leprosy, LF or podoconiosis living in the same household).

People 15 years and above will be included in the study. All participants need to have leprosy-, LF- or podoconiosis-related impairments and have to be eligible to participate in self-care activities. The focus is on skin and wound care of affected persons. All persons have to be residents of project areas of the study. People who are unable to coherently express themselves verbally (i.e. are unable to understand and participate in an interview) will be excluded. In addition, persons affected who live alone will be 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 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 group will collect a small contribution fee from its

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3 participants, these fees are used to provide loans for the participants of the self-help groups  
4 (micro-finance). Self-help groups will also lobby for 'benefits', e.g. the use of land, from the  
5 government. In addition, each self-help group participant and at least one of their family  
6 members will receive (one) vocational training. Income generation is essential for sustainable  
7 self-management and prevention of disabilities: without income, self-care items such as  
8 Vaseline and shoes cannot be bought. Income generation will benefit the whole family.

- 9 • Psychosocial support will be part of the training sessions/group meetings for self-  
10 management and prevention of disabilities. Persons affected and their family members will  
11 be trained in using and giving psychosocial support.  
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14 The control group will receive treatment as usual. Participants in the control areas will receive the  
15 same basic training (one session) as the participants in the intervention group, but will have no family  
16 members present during the training. When the intervention group has their additional four  
17 meetings (at least five meetings will be held), the participants in the control group will receive usual  
18 practice and care. In addition, they will receive information about existing mechanisms for economic  
19 empowerment (such as "funeral saving groups" and other existing credit saving initiatives).  
20  
21

## 22 **Procedures**

23 This study has two main phases. Each phase is briefly described below.

24 Phase 1: Preparatory phase. In this phase, a literature review will be conducted to guide the  
25 development of the psychosocial support component that will be added to the family-based  
26 intervention. In addition, the Sari Stigma Scale (SSS), Beach Centre Family Quality of Life (FQoL) scale  
27 and Participation scale (P-scale) will be cross-culturally validated (the Patient Health Questionnaire  
28 (PHQ-9) has already been validated in Amharic [43–45]). We will assess conceptual, item, semantic,  
29 operational and measurement equivalence using a framework for cross-cultural equivalence testing  
30 based on the work of Herdman et al. [46], Terwee et al. [47] and Stevelink & van Brakel [48]. The  
31 Knowledge Attitudes and Practices (KAP) measure will be translated, and pilot tested. A training  
32 workshop will be organized to train community health extension workers, local area health workers  
33 and the research team in research methods and family-based intervention. A list of persons affected  
34 registered in the community level census that are eligible to participate in self-care activities will be  
35 prepared. Persons affected by leprosy, podoconiosis or LF and their family members will be  
36 recruited. A database will be established to monitor the routine intervention activities. Baseline data  
37 will be collected, and the results analysed.  
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40  
41 Phase 2: Implementation and evaluation of the family-based intervention. In this phase, the  
42 intervention will be implemented: at least five training sessions and family meetings will be held. This  
43 training is done by the local researcher, with the research assistants and with at least one community  
44 health extension worker present at the meeting. Participants in the intervention and control area will  
45 receive basic tools to practice self-care (Vaseline, a bucket, shoes, and soda). In this phase, the  
46 effectiveness and acceptability of the intervention will be evaluated (feasibility has already been  
47 established [34]). This will be done by collecting the same information as in the baseline study (Table  
48 2), a few weeks and one year after implementation of the intervention. In addition, interviews will be  
49 conducted to collect most significant change stories and to assess the impact qualitatively. All  
50 components of the study will be conducted in Amharic, the official language of Ethiopia and language  
51 spoken in the study areas.  
52  
53

## 54 **Outcomes**

55 Table 2 details the outcomes measured during this study, including the methods that will be used to  
56 measure the outcomes. Physical impairment outcomes are the primary outcome measures.  
57 Acceptability, family quality of life, stigma, social participation, mental wellbeing, disease knowledge,  
58 attitudes and economic empowerment are secondary outcomes.  
59  
60



Table 2. Outcomes measures

Type of outcome	Specific outcome	Outcome measures <sup>a</sup>
Implementation outcomes	Acceptability	Qualitative (IDI and FGD)
	Disability management practices	Observations (field notes), Qualitative (IDI and FGD)
Effectiveness (persons affected level)	Physical impairment outcomes	For persons affected by leprosy: <ul style="list-style-type: none"> <li>Eyes, Hands, Feet (EHF) score, wound count, registration of infection, observation</li> </ul> For persons affected by podocniosis and LF: <ul style="list-style-type: none"> <li>Lymphedema grading, measuring the largest point of swelling below the knee circumference, registering the frequency of acute attacks, wound count, registration of infection, observation.</li> </ul>
	Family quality of life	Beach Centre Family Quality of Life scale (FQoL scale), IDI
	Perceived, experienced and self-stigma	SARI Stigma Scale (SSS)
	Social participation	Participation Scale (P-scale)
	Mental wellbeing [43–45]	Patient Health Questionnaire (PHQ-9)
	Disease knowledge [49,50]	Disease specific Knowledge Attitudes and Practices (KAP) measure
	Attitudes towards the disease and persons affected by the disease	Qualitative (IDI, FGD)
	Economic empowerment	Registration of attendance of persons affected organisation group meetings, monthly contribution, use of credit, qualitative (IDI)
Effectiveness (family member level)	Family quality of life	Beach Centre Family Quality of Life scale (FQoL scale), qualitative (IDI)
	Perceived, experienced and self-stigma	IDI
	Mental wellbeing [43–45]	Patient Health Questionnaire (PHQ-9)
	Disease knowledge [49,50]	Disease specific Knowledge Attitudes and Practices (KAP) measure
	Attitudes towards (persons affected by) the disease	Qualitative (IDI, FGD)
	Economic empowerment	Registration of attendance of persons affected organisation group meetings, monthly contribution, use of credit 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)

<sup>a</sup> IDI = in-depth interview, FGD = focus group discussion.

### Participant timeline

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

**Table 3. Participant timeline**

Time point	Study period <sup>a</sup>					
	Enrolment	Pre-allocation	Allocation	Post allocation		
		T0		Tx	T1	T2
<b>ENROLMENT:</b>						
Eligibility screen	X					
Informed consent	X					
Allocation			X			
<b>INTERVENTION:</b>						
Group meetings				X		
<b>ASSESSMENTS:</b>						
Questionnaires <sup>b</sup> :						
SSS		X			X	X
FQoL		X			X	X
P-scale		X			X	X
PHQ-9		X			X	X
KAP		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

<sup>a</sup> T0= before the intervention / baseline. Tx = monthly monitoring during the intervention (routine data collection). T1 = One-month post-intervention. T2 = One-year post-intervention.

<sup>b</sup> SSS = SARI Stigma Scale, FQoL = Beach Centre Family Quality of Life scale, P-scale = Participation Scale, PHQ-9 = Patient Health Questionnaire, KAP = Disease specific Knowledge Attitudes and Practices measure.

### Sample size

A total of 630 participants will be included in the study. 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 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 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.

### Recruitment

Potential participants will be approached via community level enumeration, health care settings, persons affected organisations, community leaders, and by word of mouth. The recruitment period is six months, starting in October 2021. Once participants are enrolled, they will be followed up during

1  
2  
3 the study period up to 12 months in the nearby health centre or health posts. In the case of loss to  
4 follow up, participants will be visited in their home.  
5

### 6 **Allocation**

7 The three districts will be randomly divided into clusters to implement either the family-based  
8 intervention or usual practice and care (control group). A complete enumeration of persons with the  
9 three diseases has been conducted in each district, kebeles (a lower administrative structure in the  
10 district) have been merged into “clusters” based on their geographical proximity and the number of  
11 cases in each kebele. In the three study districts a total of four clusters for leprosy and six clusters for  
12 podoconiosis and LF have been identified. The intervention and control areas will be randomly  
13 selected, by putting the cluster names in a cup or box and randomly drawing names. We will ensure  
14 that the number of intervention and control areas (clusters) in each district is equal. A list will be  
15 prepared with all patients (leprosy, podoconiosis/LF) living in the project areas, that are registered at  
16 community level enumeration and that are eligible to participate in self-care activities. Persons  
17 affected to be included in the study will be selected by stratified systematic sampling with a random  
18 start from a list of persons affected registered at the primary health care centre. This is done by  
19 selecting the first person affected on the list at random (by throwing dice), and then selecting every  
20 X-th patient on the list, based on the total number needed. Four separate lists will be created: two  
21 for persons affected by leprosy (one intervention and one control) and two for persons affected by LF  
22 or podoconiosis (one intervention and one control).  
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25

### 26 **Blinding**

27 Due to the nature of the intervention, participants cannot be blinded.  
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### 30 **Data management**

31 Confidentiality and anonymity of data will be ensured in data collection, data storage, analysis and  
32 publication. Research assistants who will collect the data will be fully trained in proper data  
33 management, maintenance of confidentiality and ensuring privacy during data collection. All data will  
34 be collected in Ethiopia. Only data that have been fully anonymised will be shared with the  
35 international research team. The project leader of this study will take full responsibility for ensuring  
36 the appropriate storage and security of data. Data will be kept for five years and will be destroyed  
37 after this timeframe when no longer required.  
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39

### 40 **Data analysis**

41 Quantitative data will be entered in a database created using EpiData software. Analyses will start  
42 once baseline data has been collected. Simple descriptive methods will be used to generate a  
43 demographic profile of the study sample. Differences between participants in the intervention and  
44 control groups will be evaluated using the Mann-Whitney U test or t-test for continuous variables  
45 and the chi-square statistic for categorical variables. In addition, the mean with standard deviation  
46 (or median with interquartile range, depending on the distribution of the data) of the total scores of  
47 the measures used will be calculated per participant group and per study area. The percentage  
48 change and corresponding 95%CI before and after the interventions are implemented and the  
49 statistical significance of this difference using a Z-test for differences between proportions will be  
50 calculated. Effect sizes will also be calculated. Stepwise multivariate regression with backward  
51 elimination will be done to examine what factors will have an independent effect on the outcomes.  
52 Data analysis will be done in the software packages Epi Info and SPSS Statistics. We will also use  
53 intention to treat (ITT) and difference in difference (DID) analysis to evaluate the effectiveness of the  
54 intervention.  
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58 Qualitative data -the recordings of the in-depth interviews and focus group discussions- will be  
59 transcribed, translated to English and analysed using open, inductive coding and content analysis.  
60

1  
2  
3 Similar phrases with recurring themes will be coded in a qualitative software programme (MAXQDA)  
4 and clustered together in tables, to identify connections.  
5

### 6 **Patient and public involvement**

7 This research will be led by and partly carried out by the Ethiopian National Association of Persons  
8 Affected by Leprosy (ENAPAL), a large Ethiopian leprosy disabled persons' organisation. Persons  
9 affected by leprosy, LF and podoconiosis will assist the researchers in analysis of the data by helping  
10 to put issues in perspective and context. We will seek to employ and train persons affected as  
11 research assistants or at least those who have a family member affected by an NTD or with a  
12 disability.  
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### 15 **Ethics and dissemination**

#### 16 **Ethics**

17 Ethical approval has been obtained from the Debre Markos University Health Sciences Institutional  
18 Research Ethics Review Committee (approval number HSC/R/C/Ser/Co/11/13). All participants will be  
19 fully informed about the nature and objective of the study and of confidentiality of the data prior to  
20 data collection. Written informed consent will be obtained from each participant prior to data  
21 collection. All people who are participating in the research will be provided with a participant  
22 information sheet. No incentives will be paid to participants.  
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#### 25 **Dissemination**

26 A publication plan has been developed, which lists several planned articles for publication in scientific  
27 journals. All articles will be published in peer-reviewed, open access journals. The results of the study  
28 will also be shared through international conferences and at (working) meetings with international  
29 researchers and local policy makers and health care staff. A meeting will be organised at the end of  
30 the study to disseminate the results in the communities in the study areas. In addition, we aim to  
31 share updates of the study through the International Federation of Anti-Leprosy Associations (ILEP)  
32 newsletter and the Sasakawa Health Foundation newsletter.  
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#### 36 **Authors' contributions**

37 ATN, MWA, TT and APS designed the study and were responsible for funding acquisition. MWA is the  
38 principal investigator of the study. MWA, NAM and TT are responsible for the implementation of the  
39 study in Ethiopia. MWA will lead data analysis with support from ATN and NAM. ATN drafted the  
40 manuscript. All authors have read and approved the final version of the manuscript.  
41  
42

#### 43 **Funding statement**

44 This work is supported by the Leprosy Research Initiative (LRI), grant number 708.20.17. The funders  
45 had no role in study design, decision to publish, or preparation of the manuscript.  
46  
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#### 48 **Competing interests statement**

49 The authors declare that they have no competing interests.  
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For peer review only



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description
<b>Administrative information</b>		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym <i>The study design, population and intervention are mentioned in the title.</i>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry <i>Mentioned in the abstract.</i>
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier <i>N/a</i>
Funding	4	Sources and types of financial, material, and other support <i>This has been mentioned in the funding statement.</i>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors <i>Addressed under author contributions.</i>
	5b	Name and contact information for the trial sponsor <i>N/a</i>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities <i>This has been mentioned in the funding statement.</i>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) <i>N/a</i>

**Introduction**



1			
2	Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
3			<a href="#">Introduction</a>
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7		6b	Explanation for choice of comparators
8			<a href="#">Introduction, and methods &gt; intervention</a>
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10	Objectives	7	Specific objectives or hypotheses
11			<a href="#">Introduction &gt; objectives</a>
12			
13	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
14			<a href="#">Introduction, and methods &gt; study design</a>
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20	<b>Methods: Participants, interventions, and outcomes</b>		
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22	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
23			<a href="#">Methods &gt; study setting</a>
24			
25	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
26			<a href="#">Methods &gt; participants</a>
27			
28	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
29			<a href="#">Methods &gt; intervention, and methods &gt; procedures</a>
30		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
31			<a href="#">N/a</a>
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33		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
34			<a href="#">Methods &gt; intervention</a>
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36		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
37			<a href="#">Methods &gt; intervention</a>
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2	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
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9			<a href="#">Methods &gt; outcomes, and Table 2.</a>
10			
11	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
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15			<a href="#">Methods &gt; participant timeline and Table 3</a>
16			
17	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
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21			<a href="#">Methods &gt; sample size</a>
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23	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
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25			<a href="#">Methods &gt; recruitment</a>
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### Methods: Assignment of interventions (for controlled trials)

#### Allocation:

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31	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
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38			<a href="#">Methods &gt; allocation</a>
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40	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
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45			<a href="#">Methods &gt; allocation</a>
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47	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
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50			<a href="#">Methods &gt; allocation</a>
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52	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
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55			<a href="#">Methods &gt; blinding</a>
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- 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial

N/a

### Methods: Data collection, management, and analysis

Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol

Methods > outcomes, and methods > data analysis plan

- 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols

Methods > outcomes, and methods > sample size calculation

Data management 19 Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol

Methods > data management

Statistical methods 20a Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol

Methods > data analysis

- 20b Methods for any additional analyses (eg, subgroup and adjusted analyses)

Methods > data analysis

- 20c Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

Methods > data analysis

### Methods: Monitoring

Data monitoring 21a Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

N/a

1		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
2			N/a
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7	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
8			N/a
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13	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
14			N/a
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22	<b>Ethics and dissemination</b>		
23	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
24			Ethics and dissemination > ethics
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26	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
27			N/a
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32	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
33			Ethics and dissemination > ethics
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37		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
38			N/a
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41	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
42			Methods > data analysis plan
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47	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
48			Competing interests statement
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51	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
52			Methods > data analysis plan
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2	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for
3	post-trial care		compensation to those who suffer harm from trial participation
4			N/a
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6	Dissemination	31a	Plans for investigators and sponsor to communicate trial results to
7	policy		participants, healthcare professionals, the public, and other relevant
8			groups (eg, via publication, reporting in results databases, or other
9			data sharing arrangements), including any publication restrictions
10			Ethics and dissemination > dissemination
11			
12		31b	Authorship eligibility guidelines and any intended use of professional
13			writers
14			Author's contributions
15			
16		31c	Plans, if any, for granting public access to the full protocol, participant-
17			level dataset, and statistical code
18			N/a
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23	<b>Appendices</b>		
24	Informed consent	32	Model consent form and other related documentation given to
25	materials		participants and authorised surrogates
26			
27	Biological	33	Plans for collection, laboratory evaluation, and storage of biological
28	specimens		specimens for genetic or molecular analysis in the current trial and for
29			future use in ancillary studies, if applicable
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\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

# BMJ Open

## A 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-056620.R1
Article Type:	Protocol
Date Submitted by the Author:	02-Dec-2021
Complete List of Authors:	van 't Noordende, Anna ; NLR, Technical Department; Erasmus MC, Public Health Aycheh, Moges; Debre Markos University, Department of Public Health Moges, Nurilign; Debre Markos University College of Health Science, Public health Tadesse, Tesfaye; 5. Ethiopian National Association of Persons Affected by Leprosy Schippers, Alice; AMC,
<b>Primary Subject Heading</b>:	Infectious diseases
Secondary Subject Heading:	Global health, Mental health, Public health, Evidence based practice
Keywords:	Infectious diseases & infestations < DERMATOLOGY, EDUCATION & TRAINING (see Medical Education & Training), INFECTIOUS DISEASES, PREVENTIVE MEDICINE, PUBLIC HEALTH, WOUND MANAGEMENT

SCHOLARONE™  
Manuscripts

# A 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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**Word count** (excluding title page, abstract, references, figures, tables and acknowledgments): 3,275

## 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-, LF- 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 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 and LF and family quality of life and wellbeing compared to 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 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. 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.

### **Registration details**

This study has been registered at the Pan African Clinical Trial Registry (PACTR202108907851342).

## **Article Summary**

### **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 (ENAPAL), 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 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 localized 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



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3 may cause a financial burden for the entire family [16,19].  
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5 Most impairments, such as wounds, swelling and contractures, are largely preventable [1]. The most  
6 effective strategy for prevention of disabilities is early diagnosis and prompt treatment [24]. Self-care  
7 is also an essential component of prevention of disabilities, and for prevention of chronic disease  
8 complications [24–27]. Relatively simple methods exist for self-management of impairments, such as  
9 daily washing of affected limbs, skin care, bandaging, exercises and the use of shoes [27]. Most of  
10 these methods can be practiced at home and are suitable for use across different skin-related NTDs  
11 [27–29]. These self-care interventions have been found effective in for example reducing the  
12 incidence of acute dermatolymphangioadenitis (ADLA) in persons affected by podoconiosis and LF  
13 [30,31] and in reducing ulcers among persons affected by leprosy [32]. Because physical impairments  
14 are an important determinant of stigma, disease management is also an indirect intervention to  
15 reduce stigma [33].  
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18 Many persons with leprosy-, podoconiosis- and LF-related disabilities need to practice self-  
19 management routines their entire life. This is difficult without support and encouragement of others.  
20 Family members can provide such support and encouragement. We recently conducted a proof-of-  
21 concept study in which we piloted a family-based intervention for prevention and self-management  
22 of disabilities due to leprosy, podoconiosis and LF in Ethiopia [34]. This family-based intervention  
23 consisted of self-management of disabilities, awareness raising and economic empowerment, and  
24 was delivered during several monthly group meetings. Economic empowerment was an important  
25 component of the intervention, as income generation is essential for sustainable self-management  
26 and prevention of disabilities: without income, self-care items such as Vaseline and shoes cannot be  
27 bought. We found that the intervention had a positive effect on impairments and self-management  
28 of disabilities, family quality of life and stigma. However, sampling was not randomised, which means  
29 we couldn't determine the effectiveness of the intervention. To collect credible evidence for this  
30 new, previously piloted intervention, we aim to conduct a similar study using a randomised  
31 controlled design.  
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### 35 **Objectives**

36 The primary objective of this study is to assess the effectiveness of a family-based intervention in  
37 terms of physical outcomes related to prevention and self-management of disabilities due to leprosy,  
38 podoconiosis or LF and family quality of life and wellbeing compared to usual practice and care.  
39 Secondary objectives include: (1) to reduce the number of people who have an episode of  
40 depression, as measured with the Patient Health Questionnaire (PHQ-9); (2) to reduce the level of  
41 stigma as measured with the SARI stigma scale (SSS), in-depth interviews and focus group  
42 discussions; (3) to improve social participation as measured with the Participation Scale (P-scale); (4)  
43 to increase the number of people who have adequate knowledge of leprosy, LF and podoconiosis as  
44 measures with disease specific Knowledge Attitudes and Practices (KAP) measures; (5) to empower  
45 people economically as measured by monthly household income, monthly financial contribution to  
46 the self-help group and in-depth interviews.  
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### 50 **Methods and analysis**

51 The protocol for this study is outlined below. This study protocol adheres to the SPIRIT statement  
52 [35].  
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### 55 **Study design**

56 The intervention consists of a cluster-randomised controlled trial, with two study arms. The two  
57 study arms consist of (1) the family-based intervention and (2) usual practice and care (control  
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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 3,201 new leprosy patients, 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, 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.

**Table 1. Characteristics of the selected study areas. Data has been collected from field census, health office reports and [42,43].**

	Dega Damot district	Dembecha district	Enarge Enawga district
Total population, <i>n</i> (%)	181,325 (100%)	218,257 (100%)	172,939 (100%)
Men, <i>n</i> (%)	89,756 (49.5%)	105,809 (48.48%)	86,297 (49.9%)
Women, <i>n</i> (%)	91,156 (50.5%)	112,448 (51.52%)	86,642 (49.1%)
Number of kebeles, <i>n</i> (%)	36 (100%)	31 (100%)	35 (100%)
Rural, <i>n</i> (%)	34 (94%)	27 (87%)	31 (89%)
Urban, <i>n</i> (%)	2 (6%)	4 (13%)	4 (11%)
Number of health facilities			
Hospital, <i>n</i>	1	1	1
Health centre, <i>n</i>	7	7	7
Health post, <i>n</i>	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 leprosy-, podoconiosis- or LF-related disabilities living in the area	Leprosy=132 Podoconiosis =352	Leprosy=135 Podoconiosis=1,042	Leprosy=213 Podoconiosis or LF=797
Geographic and background information	• Climate zones: 75% dega (cool temperate), 20% woina dega (subtropical) and	• Climate zones: 11% dega (cool temperature), 83% woina dega (subtropical) and	• Climate zones: 30% dega (cool temperate), 50% woina dega

	<p>5% kolla (hot lowland).</p> <ul style="list-style-type: none"> <li>• Annual rainfall between 900-1,200 mm.</li> <li>• The district consists of 35% mountain, 30% hills, 20% valleys and 15% plains.</li> </ul>	<p>6% kolla (hot lowland)</p> <ul style="list-style-type: none"> <li>• Annual rainfall is between 1,221-1,602 mm.</li> <li>• The district consists of 60% plains, 30% mountain and 10% hills.</li> <li>• Elevation is between 1500-2995 meters above sea level.</li> <li>• Other: bordered by the Nile river.</li> </ul>	<p>(subtropical) and 20% kolla (hot lowland).</p> <ul style="list-style-type: none"> <li>• Annual rainfall is between 1,200-1,400 mm.</li> <li>• The district consists of 50% plains, 30% mountain and 20% hills.</li> <li>• Elevation is 1100-3200 meters above sea level.</li> </ul>
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

### Participants

People with leprosy-related impairments and people with LF or podoconiosis-related lymphedema ('persons affected') will be included in this study. In addition, of each person affected, at least one adult family member will be included (e.g. 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-, LF- 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 (i.e. are unable to understand and participate in an interview) will be excluded. In addition, persons affected who live alone will be 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 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). We anticipate that the first group meeting will be held in January 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 (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 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).

### **Procedures**

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

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 intervention. In addition, the Sari Stigma Scale (SSS), Beach Centre Family Quality of Life (FQoL) scale and Participation scale (P-scale) will be cross-culturally validated (the Patient Health Questionnaire (PHQ-9) has already been validated in Amharic [44–46]). 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. [47], Terwee et al. [48] and Stevelink & van Brakel [49]. The Knowledge Attitudes and Practices (KAP) measure will be translated, and pilot tested. A training workshop will be organized 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 analysed by the researcher.

Phase 2: 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 four-day training on how to implement the intervention, this training is facilitated by the researcher and 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 [50], the Ethiopian Ministry of Health's LF and podoconiosis morbidity management and disability prevention guidelines and ILEP's guideline for prevention of disabilities in leprosy [51]. Participants in the intervention and control area will receive basic tools to practice 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 one 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 wellbeing, disease knowledge, attitudes and economic empowerment are secondary outcomes.

**Table 2. Outcomes measures**

Type of outcome	Specific outcome	Outcome measures <sup>a</sup>
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, total amount of money disbursed
Effectiveness (persons affected level)	Physical impairment outcomes	For persons affected by leprosy: <ul style="list-style-type: none"> <li>• Eyes, Hands, Feet (EHF) score, total number of wounds present (wound count), registration of infection, observation (field notes)</li> </ul> For persons affected by podoconiosis and LF: <ul style="list-style-type: none"> <li>• Lymphedema grading, measuring the largest point of swelling below the knee circumference, registering the frequency of acute attacks, wound count, registration of infection, observation (field notes).</li> </ul>

	Family quality of life	Beach Centre Family Quality of Life scale (FQoL scale), IDI
	Perceived, experienced and internalised stigma	(SSS)
	Social participation	(P-scale)
	Mental wellbeing [44–46]	(PHQ-9)
	Disease knowledge [52,53]	Disease specific KAP measure
	Attitudes towards the disease and persons affected by the disease	Qualitative (IDI, 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 wellbeing [44–46]	(PHQ-9)
	Disease knowledge [52,53]	Disease specific KAP measure
	Attitudes towards (persons affected by) the disease	Qualitative (IDI, 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)

<sup>a</sup> IDI = in-depth interview, FGD = focus group discussion.

**Participant timeline**

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

**Table 3. Participant timeline**

	Study period <sup>a</sup>					
	Enrolment	Pre-allocation	Allocation	Post allocation		
Time point		T0		Tx	T1	T2
<b>ENROLMENT:</b>						
Eligibility screen	X					
Informed consent	X					
Allocation			X			
<b>INTERVENTION:</b>						
Group meetings				X		
<b>ASSESSMENTS:</b>						

Questionnaires <sup>b</sup> :						
SSS		X			X	X
FQoL		X			X	X
P-scale		X			X	X
PHQ-9		X			X	X
KAP		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

<sup>a</sup> T0= before the intervention / baseline. Tx = monthly monitoring during the intervention (routine data collection). T1 = One-month post-intervention. T2 = One-year post-intervention.

<sup>b</sup> SSS = SARI Stigma Scale, FQoL = Beach Centre Family Quality of Life scale, P-scale = Participation Scale, PHQ-9 = Patient Health Questionnaire, KAP = Disease specific Knowledge Attitudes and Practices measure.

### 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. 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.

### Recruitment

Potential participants will be approached via community level enumeration, health care settings, persons affected organisations, community leaders, and by word of mouth. The recruitment period is six 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 geographical proximity and the number of cases in each kebele. In the three study districts a total of four clusters for leprosy and six clusters for podoconiosis and LF have been identified. 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

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3 that the number of intervention and control areas (clusters) in each district is equal. A list will be  
4 prepared with all patients (leprosy, podoconiosis/LF) living in the project areas, that are registered at  
5 community level enumeration and that are eligible to participate in self-care activities. Persons  
6 affected to be included in the study will be selected by stratified systematic sampling with a random  
7 start from a list of persons affected registered at the primary health care centre. This is done by  
8 selecting the first person affected on the list at random (by throwing dice), and then selecting every  
9 X-th patient on the list, based on the total number needed. Four separate lists will be created: two  
10 for persons affected by leprosy (one intervention and one control) and two for persons affected by LF  
11 or podoconiosis (one intervention and one control).  
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### 14 **Blinding**

15 Due to the nature of the intervention, participants cannot be blinded.  
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### 18 **Data management**

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

29 Quantitative data will be entered in a database created using EpiData software. Analyses will start  
30 once baseline data has been collected. Simple descriptive methods will be used to generate a  
31 demographic profile of the study sample. Differences between participants in the intervention and  
32 control groups, including demographic information and physical impairment outcomes, will be  
33 evaluated using the Mann-Whitney U test or t-test for continuous variables and the chi-square  
34 statistic for categorical variables. In addition, the mean with standard deviation (or median with  
35 interquartile range, depending on the distribution of the data) of the total scores of the measures  
36 used will be calculated per participant group and per study area. The percentage change and  
37 corresponding 95%CI of physical impairment outcomes in each group, before and after the  
38 intervention is implemented and the statistical significance of this difference using a Z-test for  
39 differences between proportions will be calculated. Effect sizes will also be calculated. Stepwise  
40 multivariate regression with backward elimination will be done to examine what factors will have an  
41 independent effect on the outcomes. Data analysis will be done in the software packages Epi Info  
42 and SPSS Statistics. We will also use intention to treat (ITT) for categorical/nominal variables and  
43 difference in difference (DID) analysis for continues variables to evaluate the effectiveness of the  
44 intervention.  
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48 Qualitative data -the recordings of the in-depth interviews and focus group discussions- will be  
49 transcribed, translated to English and analysed using open, inductive coding and content analysis.  
50 Similar phrases with recurring themes will be coded in a qualitative software programme (MAXQDA)  
51 and clustered together in tables, to identify connections.  
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### 54 **Patient and public involvement**

55 This research will be led by and partly carried out by ENAPAL (a leprosy disabled persons'  
56 organisation). Persons affected by leprosy, LF and podoconiosis will assist the researchers in analysis  
57 of the data by helping to put issues in perspective and context. We will seek to employ and train  
58 persons affected as research assistants or at least those who have a family member affected by an  
59 NTD or with a disability.  
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## 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. S/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 health care 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 aim to share updates of the study through the International Federation of Anti-Leprosy Associations (ILEP) newsletter and the Sasakawa Health Foundation newsletter.

### Authors' contributions

ATN, MWA, TT and APS 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 ATN and NAM. ATN drafted the manuscript. All authors have read and approved the final version of the manuscript.

### Funding statement

This work is supported by the Leprosy Research Initiative (LRI), grant number 708.20.17. The funders had no role in study design, decision to publish, or preparation of the manuscript.

### Competing interests statement

The authors declare that they have no competing interests.

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For peer review only



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description
<b>Administrative information</b>		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym <i>The study design, population and intervention are mentioned in the title.</i>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry <i>Mentioned in the abstract.</i>
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier <i>N/a</i>
Funding	4	Sources and types of financial, material, and other support <i>This has been mentioned in the funding statement.</i>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors <i>Addressed under author contributions.</i>
	5b	Name and contact information for the trial sponsor <i>N/a</i>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities <i>This has been mentioned in the funding statement.</i>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) <i>N/a</i>

**Introduction**

1			
2	Background and	6a	Description of research question and justification for undertaking the
3	rationale		trial, including summary of relevant studies (published and
4			unpublished) examining benefits and harms for each intervention
5			<b>Introduction</b>
6			
7		6b	Explanation for choice of comparators
8			<b>Introduction, and methods &gt; intervention</b>
9			
10	Objectives	7	Specific objectives or hypotheses
11			<b>Introduction &gt; objectives</b>
12			
13	Trial design	8	Description of trial design including type of trial (eg, parallel group,
14			crossover, factorial, single group), allocation ratio, and framework (eg,
15			superiority, equivalence, noninferiority, exploratory)
16			<b>Introduction, and methods &gt; study design</b>
17			
18			
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20	<b>Methods: Participants, interventions, and outcomes</b>		
21			
22	Study setting	9	Description of study settings (eg, community clinic, academic hospital)
23			and list of countries where data will be collected. Reference to where
24			list of study sites can be obtained
25			<b>Methods &gt; study setting</b>
26			
27	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility
28			criteria for study centres and individuals who will perform the
29			interventions (eg, surgeons, psychotherapists)
30			<b>Methods &gt; participants</b>
31			
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33	Interventions	11a	Interventions for each group with sufficient detail to allow replication,
34			including how and when they will be administered
35			<b>Methods &gt; intervention, and methods &gt; procedures</b>
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38		11b	Criteria for discontinuing or modifying allocated interventions for a
39			given trial participant (eg, drug dose change in response to harms,
40			participant request, or improving/worsening disease)
41			<b>N/a</b>
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44		11c	Strategies to improve adherence to intervention protocols, and any
45			procedures for monitoring adherence (eg, drug tablet return,
46			laboratory tests)
47			<b>Methods &gt; intervention</b>
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49		11d	Relevant concomitant care and interventions that are permitted or
50			prohibited during the trial
51			<b>Methods &gt; intervention</b>
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2	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
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9			<a href="#">Methods &gt; outcomes, and Table 2.</a>
10			
11	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
12			
13			
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15			<a href="#">Methods &gt; participant timeline and Table 3</a>
16			
17	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
18			
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21			<a href="#">Methods &gt; sample size</a>
22			
23	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
24			
25			<a href="#">Methods &gt; recruitment</a>
26			

### Methods: Assignment of interventions (for controlled trials)

#### Allocation:

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31	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
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38			<a href="#">Methods &gt; allocation</a>
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40	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
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45			<a href="#">Methods &gt; allocation</a>
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47	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
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50			<a href="#">Methods &gt; allocation</a>
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52	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
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55			<a href="#">Methods &gt; blinding</a>
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- 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
- N/a

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### Methods: Data collection, management, and analysis

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- Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol  
**Methods > outcomes, and methods > data analysis plan**
- 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols  
**Methods > outcomes, and methods > sample size calculation**
- Data management 19 Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol  
**Methods > data management**
- Statistical methods 20a Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol  
**Methods > data analysis**
- 20b Methods for any additional analyses (eg, subgroup and adjusted analyses)  
**Methods > data analysis**
- 20c Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)  
**Methods > data analysis**

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### Methods: Monitoring

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- Data monitoring 21a Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed  
**N/a**



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2		21b	Description of any interim analyses and stopping guidelines, including
3			who will have access to these interim results and make the final
4			decision to terminate the trial
5			N/a
6			
7	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and
8			spontaneously reported adverse events and other unintended effects
9			of trial interventions or trial conduct
10			N/a
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12			
13	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and
14			whether the process will be independent from investigators and the
15			sponsor
16			N/a
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19	<b>Ethics and dissemination</b>		
20			
21	Research ethics	24	Plans for seeking research ethics committee/institutional review board
22	approval		(REC/IRB) approval
23			Ethics and dissemination > ethics
24			
25	Protocol	25	Plans for communicating important protocol modifications (eg,
26	amendments		changes to eligibility criteria, outcomes, analyses) to relevant parties
27			(eg, investigators, REC/IRBs, trial participants, trial registries, journals,
28			regulators)
29			N/a
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32	Consent or assent	26a	Who will obtain informed consent or assent from potential trial
33			participants or authorised surrogates, and how (see Item 32)
34			Ethics and dissemination > ethics
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37		26b	Additional consent provisions for collection and use of participant data
38			and biological specimens in ancillary studies, if applicable
39			N/a
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41	Confidentiality	27	How personal information about potential and enrolled participants will
42			be collected, shared, and maintained in order to protect confidentiality
43			before, during, and after the trial
44			Methods > data analysis plan
45			
46			
47	Declaration of	28	Financial and other competing interests for principal investigators for
48	interests		the overall trial and each study site
49			Competing interests statement
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51	Access to data	29	Statement of who will have access to the final trial dataset, and
52			disclosure of contractual agreements that limit such access for
53			investigators
54			Methods > data analysis plan
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2	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for
3	post-trial care		compensation to those who suffer harm from trial participation
4			N/a
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6	Dissemination	31a	Plans for investigators and sponsor to communicate trial results to
7	policy		participants, healthcare professionals, the public, and other relevant
8			groups (eg, via publication, reporting in results databases, or other
9			data sharing arrangements), including any publication restrictions
10			Ethics and dissemination > dissemination
11			
12		31b	Authorship eligibility guidelines and any intended use of professional
13			writers
14			Author's contributions
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16		31c	Plans, if any, for granting public access to the full protocol, participant-
17			level dataset, and statistical code
18			N/a
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23	<b>Appendices</b>		
24	Informed consent	32	Model consent form and other related documentation given to
25	materials		participants and authorised surrogates
26			
27	Biological	33	Plans for collection, laboratory evaluation, and storage of biological
28	specimens		specimens for genetic or molecular analysis in the current trial and for
29			future use in ancillary studies, if applicable
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\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

# BMJ Open

## A 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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-056620.R2
Article Type:	Protocol
Date Submitted by the Author:	21-Jan-2022
Complete List of Authors:	van 't Noordende, Anna ; NLR, Technical Department; Erasmus MC, Public Health Aycheh, Moges; Debre Markos University, Department of Public Health Moges, Nurilign; Debre Markos University College of Health Science, Public health Tadesse, Tesfaye; 5. Ethiopian National Association of Persons Affected by Leprosy Schippers, Alice; AMC,
<b>Primary Subject Heading</b>:	Infectious diseases
Secondary Subject Heading:	Global health, Mental health, Public health, Evidence based practice
Keywords:	Infectious diseases & infestations < DERMATOLOGY, EDUCATION & TRAINING (see Medical Education & Training), INFECTIOUS DISEASES, PREVENTIVE MEDICINE, PUBLIC HEALTH, WOUND MANAGEMENT

SCHOLARONE™  
Manuscripts

# A 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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**Word count** (excluding title page, abstract, references, figures, tables and acknowledgments): 3,275

## 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-, LF- 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 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 and LF and family quality of life and wellbeing compared to 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

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3 family-based intervention comprises of an essential care package that consists of the following three  
4 main components: (1) self-management of disabilities; (2) economic empowerment; and (3)  
5 psychosocial support. Participants in the control areas will receive usual practice and care. Data  
6 analysis includes, but is not limited to, calculating the percentage of change and corresponding  
7 95%CI of physical impairment outcomes in each group, before and after the intervention is  
8 implemented, effect sizes, intention to treat and difference in difference analysis.  
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### 11 **Ethics and dissemination**

12 Ethical approval has been obtained from the Debre Markos University Health Sciences Institutional  
13 Research Ethics Review Committee. Results will be disseminated through peer-reviewed  
14 publications, conference presentations and workshops.  
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### 17 **Registration details**

18 This study has been registered at the Pan African Clinical Trial Registry (PACTR202108907851342).  
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## 22 **Article Summary**

### 23 **Strengths and limitations of this study**

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

43 Leprosy, podoconiosis and lymphatic filariasis (LF) are Neglected Tropical Diseases (NTDs) [1]. NTDs  
44 are a group of communicable diseases that are among the most common conditions, particularly  
45 among the world's poorest populations [2,3]. These diseases predominate in rural and impoverished  
46 urban areas of low and middle-income countries [4]. Worldwide, over one billion people have one or  
47 more NTDs [5]. NTDs are "poverty promoting" conditions, they cause suffering through acute illness,  
48 pain, long-term disability, early death and through mental and social consequences [2,4].  
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51 Leprosy, podoconiosis and LF are three skin-related NTDs [1]. All three conditions have skin  
52 manifestations such as patches, ulcers, wounds, nodules or localized swelling [6–9]. They are caused  
53 by bacteria (leprosy), chronic exposure to red clay volcanic soil (podoconiosis) and nematode worms  
54 that are transmitted by mosquitoes (LF) [7,8,10]. Leprosy, podoconiosis and LF can lead to temporary  
55 and permanent impairments if not diagnosed and treated early [1,6,11]. These impairments  
56 progressively worsen and are major determinants of stigma and participation restrictions [12–14].  
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59 Social consequences of all three conditions may include reduced work and education opportunities,  
60 social isolation, exclusion and problems in interpersonal relationships, including marital problems

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3 [15–18]. Psychological consequences may include feelings of shame, low self-esteem, mental  
4 distress, depression, anxiety, and decreased individual and family quality of life [15–18]. In addition,  
5 these conditions may impose a social and economic burden on families [16,19]. Family members may  
6 also experience stigma [16,20–23]. Furthermore, costs for treatment and reduced ability to work  
7 may cause a financial burden for the entire family [16,19].  
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10 Most impairments, such as wounds, swelling and contractures, are largely preventable [1]. The most  
11 effective strategy for prevention of disabilities is early diagnosis and prompt treatment [24]. Self-care  
12 is also an essential component of prevention of disabilities, and for prevention of chronic disease  
13 complications [24–27]. Relatively simple methods exist for self-management of impairments, such as  
14 daily washing of affected limbs, skin care, bandaging, exercises and the use of shoes [27]. Most of  
15 these methods can be practiced at home and are suitable for use across different skin-related NTDs  
16 [27–29]. These self-care interventions have been found effective in for example reducing the  
17 incidence of acute dermatolymphangioadenitis (ADLA) in persons affected by podoconiosis and LF  
18 [30,31] and in reducing ulcers among persons affected by leprosy [32]. Because physical impairments  
19 are an important determinant of stigma, disease management is also an indirect intervention to  
20 reduce stigma [33].  
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23 Many persons with leprosy-, podoconiosis- and LF-related disabilities need to practice self-  
24 management routines their entire life. This is difficult without support and encouragement of others.  
25 Family members can provide such support and encouragement. We recently conducted a proof-of-  
26 concept study in which we piloted a family-based intervention for prevention and self-management  
27 of disabilities due to leprosy, podoconiosis and LF in Ethiopia [34]. This family-based intervention  
28 consisted of self-management of disabilities, awareness raising and economic empowerment, and  
29 was delivered during several monthly group meetings. Economic empowerment was an important  
30 component of the intervention, as income generation is essential for sustainable self-management  
31 and prevention of disabilities: without income, self-care items such as Vaseline and shoes cannot be  
32 bought. We found that the intervention had a positive effect on impairments and self-management  
33 of disabilities, family quality of life and stigma. However, sampling was not randomised, which means  
34 we couldn't determine the effectiveness of the intervention. To collect credible evidence for this  
35 new, previously piloted intervention, we aim to conduct a similar study using a randomised  
36 controlled design.  
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### 40 **Objectives**

41 The primary objective of this study is to assess the effectiveness of a family-based intervention in  
42 terms of physical outcomes related to prevention and self-management of disabilities due to leprosy,  
43 podoconiosis or LF and family quality of life and wellbeing compared to usual practice and care.  
44 Secondary objectives include: (1) to reduce the number of people who have an episode of  
45 depression, as measured with the Patient Health Questionnaire (PHQ-9); (2) to reduce the level of  
46 stigma as measured with the SARI stigma scale (SSS), in-depth interviews and focus group  
47 discussions; (3) to improve social participation as measured with the Participation Scale (P-scale); (4)  
48 to increase the number of people who have adequate knowledge of leprosy, LF and podoconiosis as  
49 measures with disease specific Knowledge Attitudes and Practices (KAP) measures; (5) to empower  
50 people economically as measured by monthly household income, monthly financial contribution to  
51 the self-help group and in-depth interviews.  
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### 55 **Methods and analysis**

56 The protocol for this study is outlined below. This study protocol adheres to the SPIRIT statement  
57 [35].  
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### Study design

The intervention consists of a cluster-randomised controlled trial, 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 3,201 new leprosy patients, 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, 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.

**Table 1. Characteristics of the selected study areas. Data has been collected from field census, health office reports and [42,43].**

	Dega Damot district	Dembecha district	Enarge Enawga district
Total population, <i>n</i> (%)	181,325 (100%)	218,257 (100%)	172,939 (100%)
Men, <i>n</i> (%)	89,756 (49.5%)	105,809 (48.48%)	86,297 (49.9%)
Women, <i>n</i> (%)	91,156 (50.5%)	112,448 (51.52%)	86,642 (49.1%)
Number of kebeles, <i>n</i> (%)	36 (100%)	31 (100%)	35 (100%)
Rural, <i>n</i> (%)	34 (94%)	27 (87%)	31 (89%)
Urban, <i>n</i> (%)	2 (6%)	4 (13%)	4 (11%)
Number of health facilities			
Hospital, <i>n</i>	1	1	1
Health centre, <i>n</i>	7	7	7
Health post, <i>n</i>	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 leprosy-, podoconiosis- or LF-related disabilities living in the area	Leprosy=132 Podoconiosis =352	Leprosy=135 Podoconiosis=1,042	Leprosy=213 Podoconiosis or LF=797

<p>Geographic and background information</p>	<ul style="list-style-type: none"> <li>• Climate zones: 75% dega (cool temperate), 20% woina dega (subtropical) and 5% kolla (hot lowland).</li> <li>• Annual rainfall between 900-1,200 mm.</li> <li>• The district consists of 35% mountain, 30% hills, 20% valleys and 15% plains.</li> </ul>	<ul style="list-style-type: none"> <li>• Climate zones: 11% dega (cool temperature), 83% woina dega (subtropical) and 6% kolla (hot lowland)</li> <li>• Annual rainfall is between 1,221-1,602 mm.</li> <li>• The district consists of 60% plains, 30% mountain and 10% hills.</li> <li>• Elevation is between 1500-2995 meters above sea level.</li> <li>• Other: bordered by the Nile river.</li> </ul>	<ul style="list-style-type: none"> <li>• Climate zones: 30% dega (cool temperate), 50% woina dega (subtropical) and 20% kolla (hot lowland).</li> <li>• Annual rainfall is between 1,200-1,400 mm.</li> <li>• The district consists of 50% plains, 30% mountain and 20% hills.</li> <li>• Elevation is 1100-3200 meters above sea level.</li> </ul>
<p>Previous or ongoing work with the target group in the area?</p>	<p>No</p>	<p>Yes, with persons affected by podoconiosis (no persons affected by podoconiosis will be included from this district)</p>	<p>No</p>

### Participants

People with leprosy-related impairments and people with LF or podoconiosis-related lymphedema ('persons affected') will be included in this study. In addition, of each person affected, at least one adult family member will be included (e.g. 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-, LF- 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 (i.e. are unable to understand and participate in an interview) will be excluded. In addition, persons affected who live alone will be 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



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3 family-based and family focused. Although not mentioned as a separate component, awareness  
4 raising of leprosy, LF and podoconiosis in the family and the community is an integral part of the  
5 intervention. The essential care package is described in more detail below:

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

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

## 51 52 53 **Procedures**

54 This study has two main phases. Each phase is briefly described below.

55 Phase 1: Preparatory phase. In this phase, a literature review will be conducted to guide the  
56 development of the psychosocial support component that will be added to the family-based  
57 intervention. In addition, the Sari Stigma Scale (SSS), FQoL scale and Participation scale (P-scale) will  
58 be cross-culturally validated (the Patient Health Questionnaire (PHQ-9) has already been validated in  
59 Amharic [44–46]). We will assess conceptual, item, semantic, operational and measurement  
60 equivalence using a framework for cross-cultural equivalence testing based on the work of Herdman

et al. [47], Terwee et al. [48] and Stevelink & van Brakel [49]. The Knowledge Attitudes and Practices (KAP) measure will be translated, and pilot tested. A training workshop will be organized 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 analysed by the researcher.

Phase 2: 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 four-day training on how to implement the intervention, this training is facilitated by the researcher and 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 [50], the Ethiopian Ministry of Health's LF and podoconiosis morbidity management and disability prevention guidelines and ILEP's guideline for prevention of disabilities in leprosy [51]. As has been described in detail previously [34], participants in the intervention and control area will receive basic tools to practice 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 one 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 wellbeing, disease knowledge, attitudes and economic empowerment are secondary outcomes.

**Table 2. Outcomes measures**

Type of outcome	Specific outcome	Outcome measures <sup>a</sup>
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, total amount of money disbursed
Effectiveness (persons affected level)	Physical impairment outcomes	For persons affected by leprosy: <ul style="list-style-type: none"> <li>Eyes, Hands, Feet (EHF) score [52], total number of wounds present (wound count),</li> </ul>

		<p>registration of infection, observation (field notes)</p> <p>For persons affected by podoconiosis and LF:</p> <ul style="list-style-type: none"> <li>• Lymphedema grading, measuring the largest point of swelling below the knee circumference, registering the frequency of acute attacks, wound count, registration of infection, observation (field notes).</li> </ul>
	Physical wellbeing	IDI
	Family quality of life	Beach Centre Family Quality of Life scale (FQoL scale), IDI
	Perceived, experienced and internalised stigma	SSS
	Social participation	P-scale
	Mental wellbeing [44–46]	PHQ-9
	Disease knowledge [53,54]	Disease specific KAP measure
	Attitudes towards the disease and persons affected by the disease	Qualitative (IDI, 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 wellbeing [44–46]	PHQ-9
	Disease knowledge [53,54]	Disease specific KAP measure
	Attitudes towards (persons affected by) the disease	Qualitative (IDI, 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)

<sup>a</sup> IDI = in-depth interview, FGD = focus group discussion.

**Participant timeline**

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

**Table 3. Participant timeline**

	Study period <sup>a</sup>			
	Enrolment	Pre-allocation	Allocation	Post allocation

Time point		T0		Tx	T1	T2
<b>ENROLMENT:</b>						
Eligibility screen	X					
Informed consent	X					
Allocation			X			
<b>INTERVENTION:</b>						
Group meetings				X		
<b>ASSESSMENTS:</b>						
Questionnaires <sup>b</sup> :						
SSS		X			X	X
FQoL		X			X	X
P-scale		X			X	X
PHQ-9		X			X	X
KAP		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

<sup>a</sup> T0= before the intervention / baseline. Tx = monthly monitoring during the intervention (routine data collection). T1 = One-month post-intervention. T2 = One-year post-intervention.

<sup>b</sup> SSS = SARI Stigma Scale, FQoL = Beach Centre Family Quality of Life scale, P-scale = Participation Scale, PHQ-9 = Patient Health Questionnaire, KAP = Disease specific Knowledge Attitudes and Practices measure.

### 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. 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.

### Recruitment

Potential participants will be approached via community level enumeration, health care settings, persons affected organisations, community leaders, and by word of mouth. The recruitment period is six 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

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3 follow up, participants will be visited in their home.  
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### 5 **Allocation**

6 The three districts will be randomly divided into clusters to implement either the family-based  
7 intervention or usual practice and care (control group). A complete enumeration of persons with the  
8 three diseases has been conducted in each district, kebeles (a lower administrative structure in the  
9 district) have been merged into "clusters" based on their similarity, including their population  
10 characteristics, geographical proximity, the presence of a health centre and the number of cases in  
11 each kebele. Each cluster consists of 3-5 kebeles on average (ranging from 2-7) and all clusters have  
12 at least one health centre in the area. Sixteen clusters have been identified in the three study  
13 districts: Feresbet, Taeme, Dama Markos, Arefa, Damot Tsion, Sekela, Chat Warka (in Dega Damot  
14 district), Debre Work, Felege, Tenguma, Gedeb, Shifere, Metiya, Wonfit (in Enarge Enawga district),  
15 Dembecha town and Wad (in Dembecha district). Out of these sixteen clusters, a total of four  
16 clusters for leprosy and six clusters for podoconiosis and LF will be randomly selected. The  
17 intervention and control areas will be randomly selected, by putting the cluster names in a cup or  
18 box and randomly drawing names. We will ensure that the number of intervention and control areas  
19 (clusters) in each district is equal. A list will be prepared with all patients (leprosy, podoconiosis/LF)  
20 living in the project areas, that are registered at community level enumeration and that are eligible  
21 to participate in self-care activities. Persons affected to be included in the study will be selected by  
22 stratified systematic sampling with a random start from a list of persons affected registered at the  
23 primary health care centre. This is done by selecting the first person affected on the list at random  
24 (by throwing dice), and then selecting every X-th patient on the list, based on the total number  
25 needed. Four separate lists will be created: two for persons affected by leprosy (one intervention and  
26 one control) and two for persons affected by LF or podoconiosis (one intervention and one control).  
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### 31 **Blinding**

32 Due to the nature of the intervention, participants cannot be blinded.  
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### 35 **Data management**

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

46 Quantitative data will be entered in a database created using EpiData software. Analyses will start  
47 once baseline data has been collected. Simple descriptive methods will be used to generate a  
48 demographic profile of the study sample. Differences between participants in the intervention and  
49 control groups, including demographic information and physical impairment outcomes, will be  
50 evaluated using the Mann-Whitney U test or t-test for continuous variables and the chi-square  
51 statistic for categorical variables. In addition, the mean with standard deviation (or median with  
52 interquartile range, depending on the distribution of the data) of the total scores of the measures  
53 used will be calculated per participant group and per study area. The percentage change and  
54 corresponding 95%CI of physical impairment outcomes in each group, before and after the  
55 intervention is implemented and the statistical significance of this difference using a Z-test for  
56 differences between proportions will be calculated. Effect sizes will also be calculated. Stepwise  
57 multivariate regression with backward elimination will be done to examine what factors will have an  
58 independent effect on the outcomes. Data analysis will be done in the software packages Epi Info  
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3 and SPSS Statistics. We will also use intention to treat (ITT) for categorical/nominal variables and  
4 difference in difference (DID) analysis for continues variables to evaluate the effectiveness of the  
5 intervention.  
6

7 Qualitative data -the recordings of the in-depth interviews and focus group discussions- will be  
8 transcribed, translated to English and analysed using open, inductive coding and content analysis.  
9 Similar phrases with recurring themes will be coded in a qualitative software programme (MAXQDA)  
10 and clustered together in tables, to identify connections.  
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### 13 **Patient and public involvement**

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

#### 22 **Ethics**

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

34 A publication plan has been developed, which lists several planned articles for publication in scientific  
35 journals. All articles will be published in peer-reviewed, open access journals. The results of the study  
36 will also be shared through international conferences and at (working) meetings with international  
37 researchers and national policy makers and health care staff. A meeting will be organised at the end  
38 of the study to disseminate the results in the communities in the study areas. In addition, we aim to  
39 share updates of the study through the International Federation of Anti-Leprosy Associations (ILEP)  
40 newsletter and the Sasakawa Health Foundation newsletter.  
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### 45 **Contributorship statement**

46 ATN, MWA, TT and APS designed the study and were responsible for funding acquisition. MWA is the  
47 principal investigator of the study. MWA, NAM and TT are responsible for the implementation of the  
48 study in Ethiopia. MWA will lead data analysis with support from ATN and NAM. ATN drafted the  
49 manuscript. All authors have read an approved the final version of the manuscript.  
50  
51

### 52 **Funding statement**

53 This work is supported by the Leprosy Research Initiative (LRI), grant number 708.20.17. The funders  
54 had no role in study design, decision to publish, or preparation of the manuscript.  
55

### 56 **Competing interests statement**

57 The authors declare that they have no competing interests.  
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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description
<b>Administrative information</b>		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym <i>The study design, population and intervention are mentioned in the title.</i>
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry <i>Mentioned in the abstract.</i>
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier <i>N/a</i>
Funding	4	Sources and types of financial, material, and other support <i>This has been mentioned in the funding statement.</i>
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors <i>Addressed under author contributions.</i>
	5b	Name and contact information for the trial sponsor <i>N/a</i>
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities <i>This has been mentioned in the funding statement.</i>
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) <i>N/a</i>

**Introduction**

1			
2	Background and	6a	Description of research question and justification for undertaking the
3	rationale		trial, including summary of relevant studies (published and
4			unpublished) examining benefits and harms for each intervention
5			<b>Introduction</b>
6			
7		6b	Explanation for choice of comparators
8			<b>Introduction, and methods &gt; intervention</b>
9			
10	Objectives	7	Specific objectives or hypotheses
11			<b>Introduction &gt; objectives</b>
12			
13	Trial design	8	Description of trial design including type of trial (eg, parallel group,
14			crossover, factorial, single group), allocation ratio, and framework (eg,
15			superiority, equivalence, noninferiority, exploratory)
16			<b>Introduction, and methods &gt; study design</b>
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### Methods: Participants, interventions, and outcomes

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22	Study setting	9	Description of study settings (eg, community clinic, academic hospital)
23			and list of countries where data will be collected. Reference to where
24			list of study sites can be obtained
25			<b>Methods &gt; study setting</b>
26			
27	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility
28			criteria for study centres and individuals who will perform the
29			interventions (eg, surgeons, psychotherapists)
30			<b>Methods &gt; participants</b>
31			
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33	Interventions	11a	Interventions for each group with sufficient detail to allow replication,
34			including how and when they will be administered
35			<b>Methods &gt; intervention, and methods &gt; procedures</b>
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38		11b	Criteria for discontinuing or modifying allocated interventions for a
39			given trial participant (eg, drug dose change in response to harms,
40			participant request, or improving/worsening disease)
41			<b>N/a</b>
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44		11c	Strategies to improve adherence to intervention protocols, and any
45			procedures for monitoring adherence (eg, drug tablet return,
46			laboratory tests)
47			<b>Methods &gt; intervention</b>
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49		11d	Relevant concomitant care and interventions that are permitted or
50			prohibited during the trial
51			<b>Methods &gt; intervention</b>
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2	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
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9			<a href="#">Methods &gt; outcomes, and Table 2.</a>
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11	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
12			
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15			<a href="#">Methods &gt; participant timeline and Table 3</a>
16			
17	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
18			
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21			<a href="#">Methods &gt; sample size</a>
22			
23	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
24			
25			<a href="#">Methods &gt; recruitment</a>
26			

### Methods: Assignment of interventions (for controlled trials)

#### Allocation:

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31	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
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38			<a href="#">Methods &gt; allocation</a>
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40	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
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45			<a href="#">Methods &gt; allocation</a>
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47	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
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50			<a href="#">Methods &gt; allocation</a>
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52	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
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56			<a href="#">Methods &gt; blinding</a>
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- 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
- N/a

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### Methods: Data collection, management, and analysis

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- Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol  
**Methods > outcomes, and methods > data analysis plan**
- 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols  
**Methods > outcomes, and methods > sample size calculation**
- Data management 19 Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol  
**Methods > data management**
- Statistical methods 20a Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol  
**Methods > data analysis**
- 20b Methods for any additional analyses (eg, subgroup and adjusted analyses)  
**Methods > data analysis**
- 20c Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)  
**Methods > data analysis**

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### Methods: Monitoring

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- Data monitoring 21a Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed  
**N/a**

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2		21b	Description of any interim analyses and stopping guidelines, including
3			who will have access to these interim results and make the final
4			decision to terminate the trial
5			N/a
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7	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and
8			spontaneously reported adverse events and other unintended effects
9			of trial interventions or trial conduct
10			N/a
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12			
13	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and
14			whether the process will be independent from investigators and the
15			sponsor
16			N/a
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19	<b>Ethics and dissemination</b>		
20			
21	Research ethics	24	Plans for seeking research ethics committee/institutional review board
22	approval		(REC/IRB) approval
23			Ethics and dissemination > ethics
24			
25	Protocol	25	Plans for communicating important protocol modifications (eg,
26	amendments		changes to eligibility criteria, outcomes, analyses) to relevant parties
27			(eg, investigators, REC/IRBs, trial participants, trial registries, journals,
28			regulators)
29			N/a
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32	Consent or assent	26a	Who will obtain informed consent or assent from potential trial
33			participants or authorised surrogates, and how (see Item 32)
34			Ethics and dissemination > ethics
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37		26b	Additional consent provisions for collection and use of participant data
38			and biological specimens in ancillary studies, if applicable
39			N/a
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41	Confidentiality	27	How personal information about potential and enrolled participants will
42			be collected, shared, and maintained in order to protect confidentiality
43			before, during, and after the trial
44			Methods > data analysis plan
45			
46			
47	Declaration of	28	Financial and other competing interests for principal investigators for
48	interests		the overall trial and each study site
49			Competing interests statement
50			
51	Access to data	29	Statement of who will have access to the final trial dataset, and
52			disclosure of contractual agreements that limit such access for
53			investigators
54			Methods > data analysis plan
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2	Ancillary and	30	Provisions, if any, for ancillary and post-trial care, and for
3	post-trial care		compensation to those who suffer harm from trial participation
4			N/a
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6	Dissemination	31a	Plans for investigators and sponsor to communicate trial results to
7	policy		participants, healthcare professionals, the public, and other relevant
8			groups (eg, via publication, reporting in results databases, or other
9			data sharing arrangements), including any publication restrictions
10			Ethics and dissemination > dissemination
11			
12		31b	Authorship eligibility guidelines and any intended use of professional
13			writers
14			Author's contributions
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16		31c	Plans, if any, for granting public access to the full protocol, participant-
17			level dataset, and statistical code
18			N/a
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23	<b>Appendices</b>		
24	Informed consent	32	Model consent form and other related documentation given to
25	materials		participants and authorised surrogates
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27	Biological	33	Plans for collection, laboratory evaluation, and storage of biological
28	specimens		specimens for genetic or molecular analysis in the current trial and for
29			future use in ancillary studies, if applicable
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\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.