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Transforming the treatment and prevention of leprosy and Buruli ulcers in LMICs

PROTOCOL

REductioN of disABility in Leprosy through Enhanced self care in Janjgir-Champ district, Chhattisgarh, India (ENABLE India)

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1 Summary

1.1 Background

The nerve damage in leprosy increases the risk of repeated injuries and ulcers in the feet and hands leading to disfigurement of limbs leading to stigma, restriction in social participation and loss of work.

1.2 Objectives

To evaluate an enhanced self-care program in collaboration with stakeholders, which will be embedded within a larger care and prevention program called the Replicable Model.

1.3 Design

This will be a prospective interventional cohort study. The intervention (enhanced self-care program) will be delivered by the Replicability model project team through the national leprosy program. The research (RIGHT research project) team will evaluate the program using a mixed methods approach.

1.4 Participants

Patients with neuropathy in their eyes, hands and feet from the three blocks (sub-unit of district) of Janjgir-Champa district.

1.5 Intervention

Enhanced self-care program implemented through front-line health worker of the public health system in Janjgir-Champa district, Chhattisgarh state, India.

1.6 Follow-up

Twelve months from the implementation of enhanced self-care program.

1.7 Outcomes

The main outcomes will be prevalence of ulcers among those at risk of an ulcer; the total surface area of ulcers (cm^2) among those with ulcers and disability severity level as measured using Eye, Hand and Foot score (EHF score). We will also make qualitative observations of the implementation of the progress.

2 Introduction

2.1 Background

Leprosy, also called Hansen's disease, is a chronic bacterial infectious disease caused by Mycobacterium leprae affecting the skin, peripheral nerves, lining of the nose, mucosa of the upper respiratory tract and the eyes of people. If not detected and treated early, it can damage the peripheral nerves leading to loss of sensation and muscle function, resulting in impairments, deformities and disabilities, with serious health, social and economic consequences. Despite treatment with Multidrug Therapy (MDT), nerve damage continues to occur.(1, 2)

Nerve involvement is the hallmark of leprosy. Upto 47% of patients present with established nerve damage at the time of diagnosis, and a further 8% to 12% develop nerve damage after the start of treatment and during the follow-up.(1) Shetty *et al,* from their survey of those who completed treatment, showed that up to 18% of patients develop events that require medical attention.(2) Early identification of nerve damage and initiation of corticosteroids is critical for recovery of nerve function.(3) Nevertheless, 11-51% of patients who received corticosteroids did not recover or their impairments worsen. In addition, 16-56% of patients present with impairments at diagnosis, often not responsive to drug treatment.(4) Therefore, patient education on how to protect their limb (self-care practice) and prompt medical care where required at acute phase of an impairment is essential for preventing further worsening of existing impairments. Each year about 30-50% of newly diagnosed leprosy patients develop disabilities during and/or after treatment. However, there is a paucity of cumulative data on those patients with disability-including ulcers for planning evidence informed interventions.(5)

2.2 Self-care to prevent disabilities and ulcers in leprosy

WHO defines self-care as "the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a healthcare provider".(6) Self-care interventions improve health, both from a health systems perspective and for people who might use these interventions. Self-care has been acknowledged in global initiatives, especially in advancing primary health care

with the new Declaration of Astana(7) coming 40 years after the 1978 Declaration of Alma-Ata(8) advance the health and well-being of people most effectively, equitably, efficiently and sustainably through primary health care. The primary unit of self-care implementation is the individual; however, its impact is realized at the population level. Self-care in leprosy is a set of practices by persons affected by leprosy which equips them with the knowledge and motivation that they need to take care of themselves and to prevent impairments. Self-care can be practiced individually at home or in group with the peer-support. Self-care will continue to be an essential component of any leprosy program where prevention of impairment cannot be completely realised.

In a recent scoping review on self-care programs for leprosy affected persons in low-middle income countries, only 15 studies were identified. Majority of the self-care programs aimed to reduce the secondary changes to an anaesthetic foot such as cracks, callus and wounds. Almost all self-care programs were developed and implemented in the form of a project by organizing authorities external to the affected community, some which included government and non-governmental organizations. This results in non-ownership by the community (9) which can lead to non-adherence to self-care practices. Non adherence can also happen to lack of supervision once the organising authorities involved in the initial set-up cease their activities.(10) Given the chronic nature of the impairments, compliance to self-care is essential to minimize the resulting disabilities. Only one study from the scoping review looked at the adherence to self-care one year after cessation of formal supervision. This study found that 87% of people who lived in leprosy settlements and only 50% of people who lived in the general community adhered to self-care. Consequently, the prevalence of ulcer was higher among those who did not practice (38%) self-care than those who did (25%). However, the reasons behind non-adherence to self-care were not explored. Overall, self-care interventions reduced disability and ulcers but the findings are to be interpreted with caution due to methodological flaws in these studies.

Protective footwear is an essential component of self-care practice. Footwear with a Micro-cellular rubber (MCR) insole is the current standard of protective footwear in leprosy across many countries. However, the stigma associated with the footwear has led to poor

acceptance of its use, increasing risk of damage to foot.(11, 12) The interim analysis of ongoing data collection, as part of our RIGHT project study, on prevalence of disability in the Champa district has shown that less than 10% of patients actually use protective footwear and less than half of all those with neuropathy are currently practicing self-care, highlighting the low adherence to self-care practices. Despite all the supporting literature on the benefits of self-care practices, it is clear that there is a need for an enhanced self-care program to improve self-care practice among people affected by leprosy. Interventions should be evaluated for effectiveness.(13)

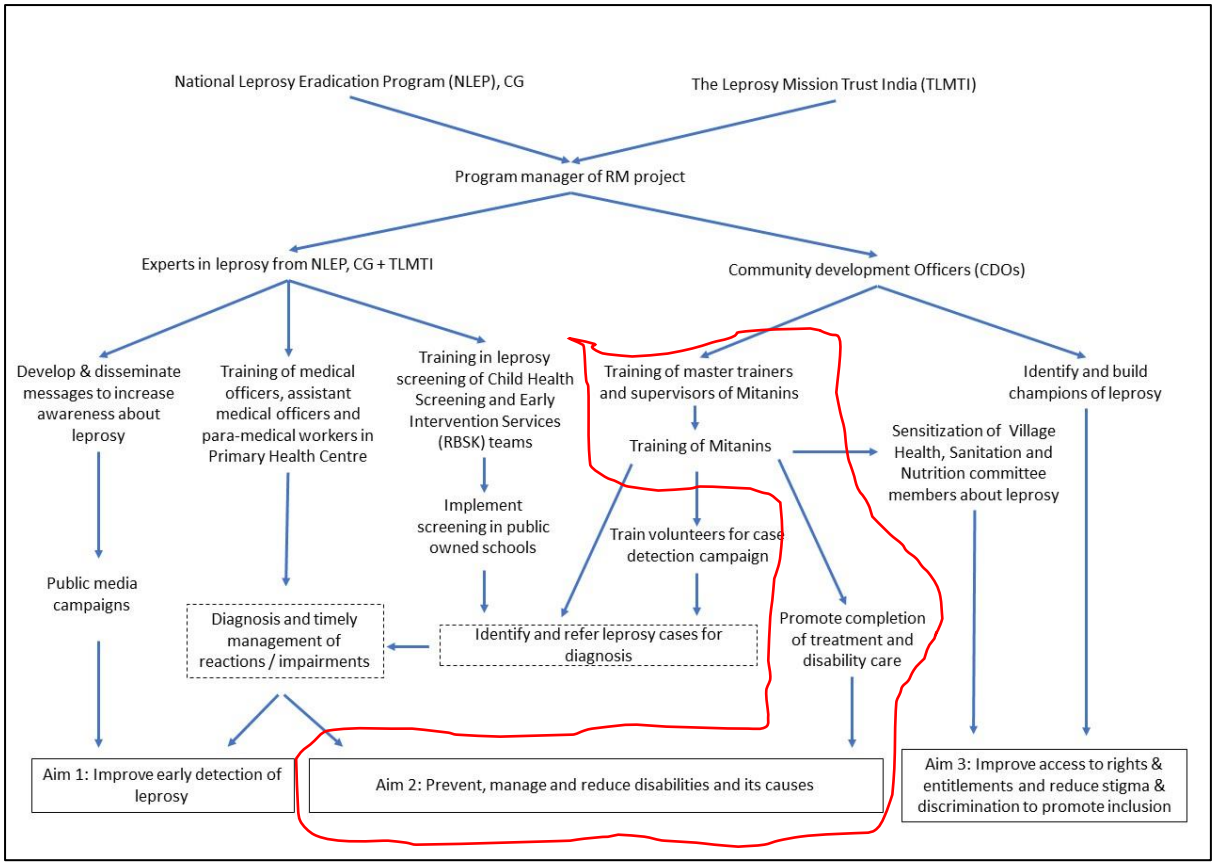
2.3 Guidelines documents for self-care

The NIHR RIGHT team have developed a set of international guidelines documents for self-care, with the intention that these are a resource for organisations implementing self-care programmes rather than as a manual for individual communities. The guidelines aimed to set out general principles and frameworks and to provide examples, and thus aim to produce a 'state-of-the-art' summary of best evidence and opinion currently available to implement self-care in the field of leprosy(14).

2.4 The RM project in which the enhanced self-care module will be developed

The RM project has multiple interventions to improve early detection of leprosy, prevention of disability during and after MDT and creating champions who will advocate for their community to reduce stigma and discrimination. In order to prevent and reduce disability by self-care in the community is facilitated using existing public health systems and Mitanins (front-line health worker) (shown on the right side of Figure 1). RM project covers entire district of Janjgir-Champa, Chhattisgarh, India. The self-care intervention will be staggered across the blocks and their constituent Primary Health Centres (PHCs).

Figure 1: Overall framework of Replicability Model project



2.5 The self-care program itself

In this project our focus is on rural areas in Janjgir-District in Chhattisgarh state. It is an accepted tenet of implementation science that interventions must be adapted for local conditions (15), and the variegated context in which people suffering from the effects of leprosy means that a one-size-fits-all solution is particularly inappropriate. Therefore, we will adapt the NIHR RIGHT team developed international guidelines documents for self-care (14) and contextualize them, which will be called an enhanced self-care intervention, for implementation and dissemination in Chhattisgarh, in collaboration with colleagues responsible for implementing and supporting self-care in the community (Figure 2). The key difference between the current practice of self-care and our enhanced self-care intervention is highlighted in the Table 1 and other details are given in Appendix 9. More description on enhanced self-care intervention will be provided after contextualization of international guideline document and process evaluation (see Section 3.6). All patients with neuropathy due to leprosy, at risk for developing ulcers (had an ulcer in the past) and currently having an ulcer will be included in the self-care program. We plan to embed our enhanced self-care

intervention in the operational program of the Replicable Model (RM) project described below. Our proposal is based on the MRC framework for development and evaluation of complex interventions (16). This research project will be an independent assessment of the effectiveness of an enhanced self-care intervention embedded within the RM project.

Table 1: Difference between current and enhanced self-care program

Current practice of self-care (RM project)	**Enhanced self-care program (by the RIGHT project)**
Common information materials for care of eyes, hands and feet	Individual booklet for care of eyes, hands and feet with both written and illustrations using images
Self-care was taught when patients was taking Multi-drug therapy (MDT) or at completion of MDT	Taught by Mitanins – frontline workers from the village where the patient is from
No structured follow-up	Monthly follow-up by Mitanins
No documentation of progress of impairments	Documentation of progress of impairments using simple form by Mitanins
Institution based self-care teaching	Community based self-care teaching
Fixed model of Micro-cellular Rubber (MCR) footwear	Footwear with different models for female and male which is at par with the market
No specific involvement of family members	Involvement of family members during the training / demonstration of patients
No provision of assistive devices	Provision of assistive devices such as walking stick, crutches.

The delivery of the self-care intervention to patient will be through Mitanins facilitated by community development officers (CDO) of RM team. Mitanins are the pillars of the National Health Mission in implementation activities of various health programs and are familiar with and accepted in their own communities, as the first person to be called for health-related problems. There are about 20 Mitanins supervised by one Mitanin trainer (MTs) in each block of the district. All MTs from will receive training on the enhanced self-care intervention by CDOs of the RM team in a one-off training session. The MTs in turn will train their respective existing Mitanins, in a phased manner. The Mitanins will deliver the self-care intervention in the form of training and demonstration to the patients from their respective villages and follow them up. The follow-up will be done monthly documenting the conditions of the limbs in a register. The CDO's of the RM team will support Mitanins in provision of footwear, self-care kits and assistive devices. If there is deterioration in the impairments / ulcers they will refer to the primary health centre.

Figure 2: International self-care guideline and contextualization in Chhattisgarh

Stages	What	By whom	Supported by
1 International guideline	Development of set of "high-level" principles to support self-care in community	Scientific Guidelines and Advisory Committee (SGAC)	Academic team, clinicians, experts in leprosy & community of people affected by leprosy
2 Local co-production	Co-production of guideline by adaption of above guideline in Chhattisgarh state	Community of people affected by leprosy, community health workers, Community leaders & clinicians	Members who overlap SGAC
3 Implementation	Implementation in the community	Community health workers & clinicians	Chhattisgarh site project administrators

3 Research plan

3.1 Evaluation study design

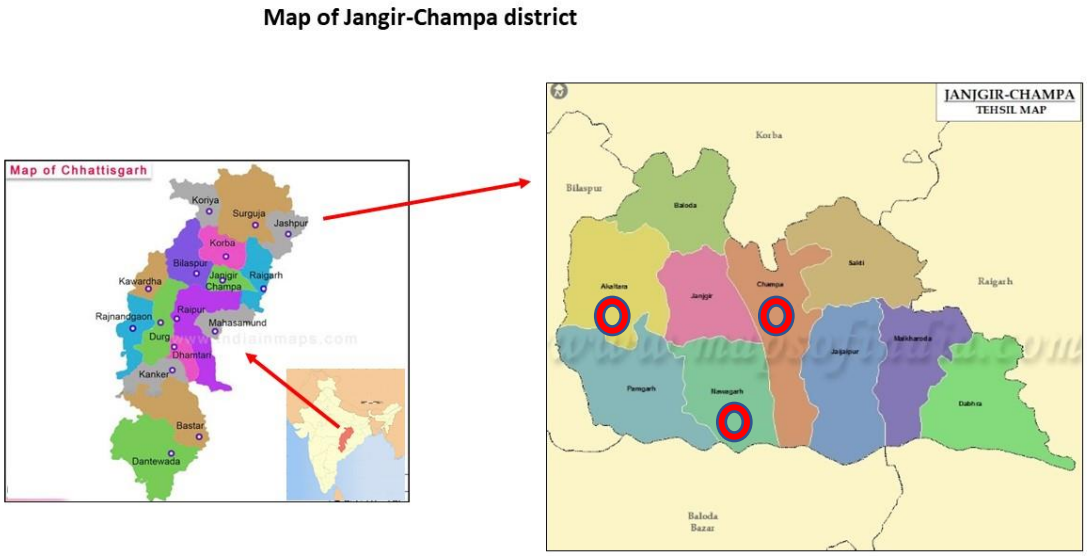
This will be a prospective interventional cohort study design. The enhanced self-care intervention embedded within the National Leprosy Eradication Program of Champa district, Chhattisgarh through Replicability model project intervention will be evaluated.

3.2 Evaluation site selection

The evaluation of enhanced self-care intervention will happen in three blocks of the Champa-Janjgir district, namely Nawagarh, Champa and Akaltara (Figure). The blocks have been chosen by purposive sampling . Based on number of cases registered for treatment during the last 5 years, these three blocks' accounts for 40% (1878/4813) of all cases from the district. During the same period the proportion of patients presenting with disability at the time of diagnosis was 21%, 13.5% and 7.5%, in Nawagarh, Champa and Akaltara block, respectively. As part of the larger project, we are conducting a survey on prevalence of patients with disability among those who were diagnosed during the last 5 years from the Janjgir-Champa district. Interim analysis revealed that, of the 728 patients screened from two (Nawagarh and Champa) of nine blocks in the district, 185 (25%) were found with neuropathy.

With respect to ulcers, 58 (31%) patients were at risk (history) of ulcer and 49 (25%) patients were with ulcer at the time of assessment. The data collection is ongoing. These findings highlight the burden of disability due to leprosy in these blocks, hence selected for evaluation.

Figure 3: Map showing the study area



The research team will work in close collaboration with RM project implementation team for planning data collection. The phasing of intervention and outcome assessment time points are shown in Figure 4. Research team will conduct the outcome assessment at baseline 3 months, 6 months and 12 months relative to the intervention's delivery in each PHC as shown in Figure 5.

Figure 1: The phasing of intervention rollout in blocks and PHCs within the block

			Time (in weeks)																														
Block	PHC		2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32	34	36	38	40	42	44	46	48	50	52	54	56	58	60	6
Nawagarh	1A	0	1-4					1						2															3				
	1B		0	5-8					1						2															3			
	1C			0	9-11					1						2														3		
	1D				0	12-15					1						2														3	
	1E					0	16-18					1						2															3
	1F						0	19-21					1						2														
Champa	2A							0	1-4					1						2													
	2B								0	5-8					1						2												
	2C									0	9-12					1						2											
	2D & 2E										0	13-15					1						2										
Akaltara	3A											0	1-4					1						2									
	3B												0	5-8					1						2								

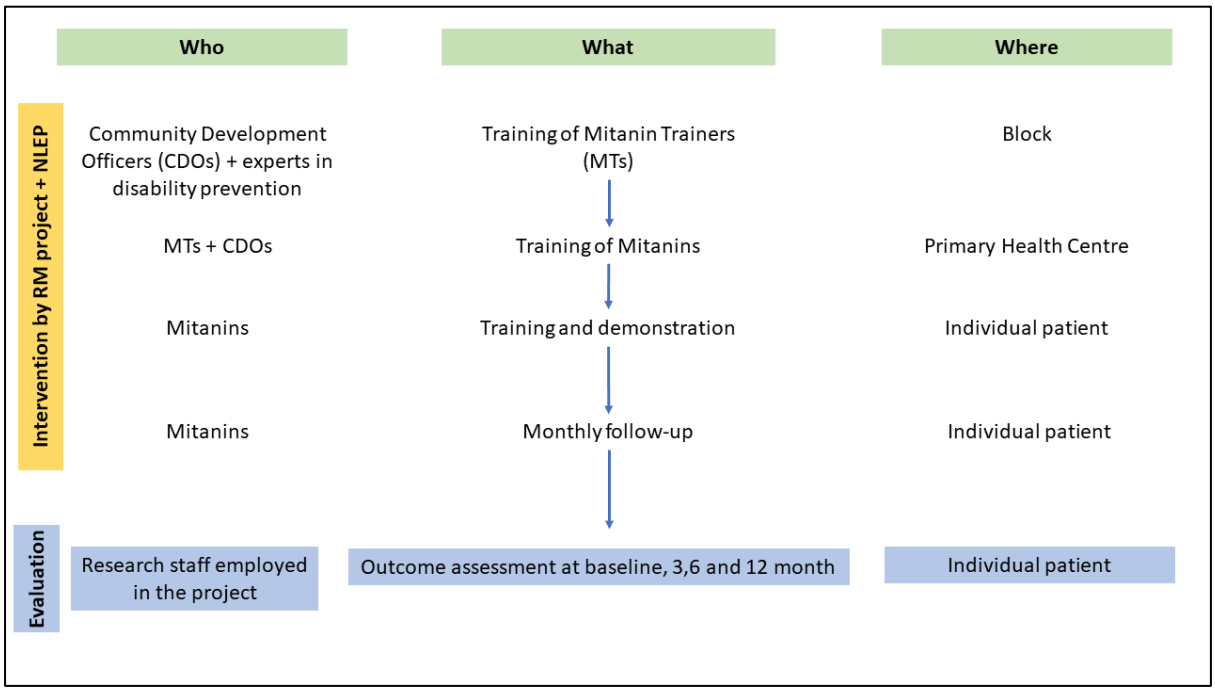
	3C													0	9-12					1						2							
	3D & 3E														0	13-16					1						2						

0	Baseline assessment
	Training of Mitanin Trainers (MTs)
subgroup of villages	Training of Mitanins by MTs
	Delivery of self-care Intervention (Mitanins to patients)
	Follow-up (Mitanin follows up with patients)
1	Post-intervention assessment 1 at 3 months
2	Post-intervention assessment 2 at 6 months
3	Final assessment at 12 months

3.3 Implementation of enhanced self-care program and evaluation

The flow diagram of overall process of implementation of enhanced self-care program and evaluation are shown in the Figure 2.

Figure 2: Implementation of enhanced self-care program and evaluation of outcomes



3.4 Quantitative study

The aim of the quantitative study is to evaluate the embedded self-care intervention by estimating the prevalence of ulcers and any difference in total ulcer area and severity. We will also examine disability-related outcomes. We hypothesise that following the enhanced self-care program will result in:

- reduced ulcer prevalence
- reduction in the ulcer 'burden' as measured by the total ulcer area and severity
- there will be an overall reduction in the disability
- improved quality of life and wellbeing among all people who received enhanced self-care intervention.

We will measure the prevalence among all those at risk and the total ulcer area among those who have one or more ulcer. It is possible for the prevalence to decrease while the average area increases, for example, if those with less severe or smaller ulcers benefit from the intervention while those with larger ulcers do not. We will allow for this in the analysis.

3.4.1 Clinical outcomes

The two clinical ulcer-related outcomes for the study are:

- The prevalence of ulcers among those at risk of an ulcer;
- The total surface area of ulcers (cm^2) among those with ulcers.
- Disability severity level – Eye, Hand and Foot score (EHF score) (17)

The limbs will be inspected and their condition described using a standard clinical case record form (Appendix 1) with information on anaesthesia, ulcers and any deformities using the World Health Organisation (WHO) disability grading system (18). Any ulcers will be noted and described on a form, resident on the electronic tablet. The clinical appearance of the wound (e.g. any residual exudate) will be recorded. All the ulcers will be photographed in a standard manner for independent analysis blind to 'treatment' status (see below). In addition, photographs of the plantar surfaces of the two feet together will also be taken from all participants to study the overall foot and pre-ulcerative conditions. Ulcer metrics will be based on photographs taken, during dressing changes if dressing is applied, in a standardised manner, as recommended in the literature (19). The photographs will be obtained by the research assistant using the camera in the data collection tablet and metrics obtained using the Electronic Pressure Ulcer Scale for Healing (PUSH) tool version 3.0. The PUSH tool enables measurement of the surface area (cm^2) of the lesion calibrated from a 3cm size clean paper ruler, placed in the photograph frame at the level of the ulcer. The ruler will have the date and participant's study identification number in the photograph frame above or below the ulcer but at the level of the skin. Tongue depressors will be used to stick the paper ruler and hold it above or below the ulcer. The photographs will be assessed completely independently of assessor by two local research staff in India. This will ensure that the main outcomes are assessed blind to intervention status. Two assessors will be trained to take ulcer measurements. Both observers will be 'blinded' to the treatment allocated to the participant. All photographs from a given participant will be assigned to the observers at random. A proportion (20%) of all ulcer photographs will be measured by both assessors to estimate inter-rater reliability. These photographs will be selected at random. None of the photographs will include patient identification information apart from the patient's study number, which will be produced under software control when the patient is entered in the study. The total

area of all ulcers present in the foot and hands will be calculated and used as the 'ulcer area' metric in the analysis.

3.5 Psychological and social outcomes

Three questionnaires (Appendix 2 - 4) will be administered to all participants as follows:

1. A general health related Quality of Life questionnaire in the form of the EQ-5D-3L (20-22) Validated version: Country: India, Language: Hindi, Platform: REDCap (Appendix 2). It comprises two parts:
    I. EQ-5D descriptive system: assesses five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression, across three levels: no problems, some problems, and extreme problems.
    II. EQ VAS (visual analogue scale): this records the patient's self-rated health on a vertical scale from 'Best imaginable health state' to 'Worst imaginable health state'.

We shall not use a disease specific questionnaire because the majority of patients will not have an ulcer at any one time, because ulcer state is measured directly, and because we need to reduce the time requirement for participants.

2. A life satisfaction (subjective wellbeing) questionnaire (Appendix 3) (23, 24). This instrument comprises five questions to:
    I. capture a cognitive evaluation of the participant's level of life satisfaction (Q1);
    II. capture an eudemonic concept of whether the things the participant does in their life are worthwhile (Q2); and
    III. Characterise the participant's affective state on the previous day (Q3, Q4, Q5).
3. Social inclusion. We propose using the P-Scale [Participation scale (P-scale). (Appendix 4). We selected the P-scale (25) over, say, the Explanatory Model Interview Catalogue (EMIC) stigma scale for the following reasons:
    a. Translated versions are available for Hindi.
    b. It has strong correlation with the EMIC scale.(26)
    c. It has been used successfully in the past in the context of leprosy in India.

3.5.1 Analysis plan of quantitative data

We describe the analysis plan for the two main outcomes: ulcer prevalence and ulcer area. Analysis for the other outcomes will follow the same model-based approach, with appropriate change to the distribution and link function if required. We will use a Bayesian generalised linear mixed model methodology for analysis to account for within-person correlation over time and correlation of outcomes within villages. Specifically, our baseline specification for person i in village j at time t the mean function is:

$$\mu_{ijt} = \beta_0 + \beta_1 x_{ijt} + \gamma D_{jt} + \alpha_i + \alpha_j + f(t)$$

where x_{ijt} is a vector of individual level covariates (age, gender, duration of impairments and level of disability (EHF)). D_{jt} is an indicator for whether the village has received the intervention at time t, $\alpha_i \sim N(0, \sigma_1^2)$ and $\alpha_j \sim N(0, \sigma_2^2)$ are individual and village level random effects, respectively, and $f(t)$ is a function of time. We will compare different models with different specifications for time and also allow for more complex random effects structures, such as temporal decay in correlation at individual level and village-time period effects. Models will be compared using posterior predictive model checks and the leave-one-out cross-validation criterion.

We will specify weakly-informative prior distributions for the model parameters. There is little available strong evidence to support informative priors in this setting; weakly informative priors limit the plausible range of the model parameters to facilitate computation, but provide little information within this range. In particular, we will use $\beta_0, \beta_1 \sim N(0, 5^2)$ and $\gamma \sim N(0,1)$; this latter choice limits the effect of the intervention to an odds ratio or relative effect in the range of approximately 0.2 to 7.0 with 95% probability. We also set half-t_2 priors on the standard deviation terms which allow for relatively large values, which may be possible for the cohort terms.

To complete the models specifications, for the prevalence outcome, where y_{ijt} is equal to one if the patient has an ulcer at that time and zero otherwise:

$$y_{ijt} \sim Bernoulli\left(\Lambda(\mu_{ijt})\right)$$

where Λ is the inverse logit function. For ulcer area, we condition on having an ulcer an exclude those who do not so the outcome, y_{2ijt} is strictly positive:

$$y_{2ijt} \sim N(\mu_{ijt}, \tau^2)$$

3.5.2 Sample size

We will include all Primary Health Centres (PHCs) from three selected blocks for intervention (Nawagarh, Champa and Akaltara). Each block comprises 4 to 6 intervention areas defined as "health posts - PHCs" and each of these areas has between 5 and 10 people affected by leprosy who are at risk of an ulcer and another 5 to 8 patients with impairments in eye, hands with or without impairment in the foot who will require self-care. Based on our preliminary survey of two of the three blocks we anticipate there will be approximately 150 people in our cohort across 15 intervention areas. Each member of the cohort will have observations taken at four times at the time points defined in the schedule above as described in the section 3.2 and Figure 1.

3.5.3 Estimated precision

We propose to investigate several models for our analysis and select the best fitting alternative. However, we give an approximate estimate of the expected posterior variance based on the priors stated in the previous section. The average posterior variance is:

$$E\big(Var(\gamma|Y)\big)$$

where Y is the study data and the expectation is taken with respect to the prior distributions. For this analysis we assume no covariates and a linear function of time. Based on the priors stated above the expected posterior variance for the intervention effect in the prevalence model is 0.090. For the ulcer area model the value is 0.059. These values imply 95% credible interval widths of approximately +/- 0.59 and +/- 0.46, respectively. The smallest effects of the intervention for which these values would provide a 95% credible interval excluding zero would be odds ratios greater than 1.80 or less than 0.55 for prevalence, and greater than 1.58 and less than 0.63 for ulcer area.

3.6 Process Evaluation

3.6.1 Process Evaluation

Process evaluation design is based on the UK MRC process evaluation framework (27). The intervention at the focus of this evaluation is the Mitanin training which Mitanins then put into practice in their communities. The purpose of the qualitative work is to understand how the intervention is delivered and received, including the level of elasticity of the context to

allow the intervention to fit (or not) and the plasticity of the intervention allowing it to be moulded to the context (28).

Our mixed methods approach (qualitative and quantitative) will:

1. Assess enhanced self-care intervention fidelity
2. Identify whether and how the intervention is delivered by Mitanins in the community, facilitators, and challenges to delivery, how the challenges are managed, and delivery adapted
3. Explore how community members experience the intervention and how this experience results in impact on any ulcer they have, their wellbeing and community participation.

Except where indicated, we will collect data from two randomly selected PHCs from each of the 3 study blocks (total 6 PHCs)

3.3.1 Fidelity

a) **Evaluation of Mitanin Trainers Training**: Mitanins will be trained in a cascade approach. In the first training stage, Mitanin trainers will receive a single day training. To assess impact of the training, all Mitanins receiving the training will complete pre and post knowledge test as part of the training process. We expect that the training will cover multiple aspect of the Mitanins work, however, we shall focus on assessing the aspects of the training related to leprosy related disability prevention and management which included self-care.

b) **Evaluation of cascaded training** in the second training stage, Mitanin trainers will be expected to cascade the training to the Mitanins within their PHC. To assess fidelity of the cascaded training, we will observe a training session. Using a pre-piloted checklist based on the first stage training, we will record delivery of leprosy related issues.

3.3.2 Delivery of intervention

a) Home Visit Records: Mitanins are expected to keep records of homes visited and services provided. Leprosy self-care documentation is currently not included in their routine recording. However, during Mitanins training, they will be encouraged to record when leprosy related advice/services are delivered including self-care education. The research team will examine the records from all Mitanins from each of the six PHCs. Records will be examined in the

i. 4 weeks after post-intervention assessment 1

ii. 4 weeks after post-intervention assessment 2

iii. 4 weeks before final intervention assessment (see figure 4).

Data will be extracted from records kept over the 4-week period prior to data extraction. The data will be extracted into a pre-piloted checklist.

b) **Observations of a home visits**: We will randomly select two PHCs per block for observing Mitanins. Members of the research team will observe 3 Mitanins per PHC (n=18) on pragmatically selected home visits at least 12 weeks after completion of cascaded training. Visits will be organised and agreed upon beforehand by Mitanins and the research team. This is to avoid the disruption to Mitanins schedules and ensure that observations are conducted on days when they visit people affected by leprosy. Mitanins are responsible for scheduling their home visits as required and their responsibilities include populations other than people affected by leprosy making unscheduled observations impossible. Using a pre-piloted checklist based on the training manual, researchers will observe which activities Mitanins perform, and the accuracy of information delivered. A limitation of the observations is that because the Mitanins will be pre-informed we are likely to observe best practices. We will take this into account when reporting results.

c) **Interviews with Mitanins:** Since the intervention is delivered through Mitanins, it is likely that they will be the best informants on facilitators, challenges and how they manage these challenges including any adaptations made. At least 12 weeks post completion of cascaded training, we will randomly select two PHCs per block and we will conduct interviews with three Mitanins per PHC (n=18) exploring these issues and we will ask how they would improve the intervention.

3.3.3 Community member experience of intervention and its impact

We aim to undertake interviews between post intervention assessment 2 and 3 (see fig.5)

a) Interviews with community members receiving leprosy related self-care education or support from Mitanins We will identify from Mitanin records community members who have received leprosy related advice and support from a Mitanin (data extraction i. and ii. in section 3.3.2a). We will first randomly select two PHCs per block and we

will then randomly select from this list individuals to be invited for interview. We will continue to invite individuals until we have recruited and undertaken three interviews in each PHC (n=18). We will explore with interviewees what they recall of the Mitanin advice and support, how they have used this input and how this has impacted on any ulcer they have, their wellbeing and community participation. The intervention provides self-care materials such as footwear and crutches. The researcher will ask the interviewee about utilisation of self-care materials and with the interviewee, visually inspection the footwear for wear and discuss the findings. We will ask about their experience of other aspects of the Replicability model. We will ask each interviewee to nominate for interview someone in their household (or village) who is involved with or knows about their leprosy care such as a family member. We will see an interview with this nominated person to explore their perceptions of the intervention and its impact.

b) **Interviews with community representatives**: To explore community experiences of the self-care intervention, both the Mitanin delivered advice/support and the wider Replicability model, at least 12 weeks post cascade training, we will interview 1-3 community representatives from the localities serviced by each PHC (total n=6-18). These are likely to include community leaders and leaders of local initiatives such as women's groups or community businesses.

3.6.2 Analysis plan of qualitative data

Quantitative data collected using educational test or checklists will be analysed using descriptive statistics.

For qualitative data we will use framework analysis (29) guided by the MRC Framework (27, 30).

We will code and analyse interview data for:

- Context - factors that influence or are affected by the intervention and its outcomes, and that prevent or enable change prompted by the intervention
- Intervention - how intervention is delivered and adapted.
- Mechanisms of impact: how do participants respond, what mediates this, and any unanticipated pathways and consequences.

- Impact of the intervention on the participants lived experience and that of the community.

Within our framework we will comparing data across sites and between data sources.
All interviews will be audio recorded and transcribed and translated into English. Observation notes will similarly be translated. Coding will be applied to all interview data whilst alert to new emerging themes and need for sub-themes.

4 Governance, Ethics, data collection and security

4.1 Ethics

4.1.1 When will obtain consent?

A local researcher will approach all people recently allocated to a self-care intervention by the facilitator (CDO) who implements the intervention. Except those under 18 years of age, all those with neuropathy will be included in the study – for instance if a person has difficulty in communicating, they will still be offered entry in the data collection. People who are willing to receive it will be given a Patient Information Leaflet (Appendix 5) to read but consent will be sought after the day when this is provided. If a person cannot read, then they will be assisted in understanding the information in the leaflet. The Patient Information Leaflet (Appendix 5) and Consent Form (Appendix 6) will be translated into Hindi and back translated according to the WHO methodology (31). Separate participant information leaflet (Appendix 7) and consent form (Appendix 8) will be used for health care workers, such as Mitanins, who will take part in the study.

4.1.2 Who will take consent?

One of the local clinically-trained researchers deployed on the grant will offer the person participation in the data collection for the trial. The researchers will all complete GCP training online and will be included in the delegation log. They will be trained to obtain consent as follows:

1. They will attend a 30 minute talk given by the project manager covering the essence of the Helsinki recommendations (1964 and revisions) (32) and the right to withdraw at any stage (Dr Joydeepa, local or Sopna Choudhury, international).

2. They will then discuss the issues concerned with the chief investigators and also at least two representatives drawn from the leprosy community.
3. They will then simulate the consent process at least twice where public representatives will act as patient 'surrogates'.

4.1.3 How will we obtain consent?

The forms will be read aloud to people who are illiterate. If they are unable to sign their name using a writing instrument then they will sign consent by thumb print (or finger print if the thumb has been damaged by leprosy). See data management regarding bio-metric data. Screening and the obtaining of informed consent will be evidenced by the completion of an electronic case report form (e-CRF) within the REDCap closed data capture system by staff named and on the delegation log. If any person declines to contribute data, then it will be noted that a person has declined but no data will be retained on them. However, reasons for not taking part will be recorded in a place provided on the computer.

4.1.4 Withdrawal

Participants are free to withdraw at any time as explained to people in the information provided. The participant may withdraw in two ways:

1. Does not wish to continue in self-care intervention, but happy to contribute follow-up data
2. Does not wish to continue to contribute follow-up data

There will be a notice of withdrawal form on the data collection tablet for people in the second group above but people who are in the first group will continue to contribute data but their withdrawal from participation in group activity will be noted.

As this is not a clinical trial there will be no data monitoring committee and no interim analysis. Rather the study statistician will monitor accruing data as a check on quality and so that action may be taken if data are incomplete. We do not think that policy trials should be required to comply with procedures that are necessary for patient protection when people are exposed to novel or potentially high risk treatments in clinical trials (33).

4.1.5 Protocol amendment

Any protocol amendment will be reported to the Leprosy Mission Trust India ethics committee to approve the change.

4.1.6 Sponsorship

The University of Birmingham will be the sponsor.

4.2 Data collection, use and storage

We will adhere to international standards on conducting health research (34). We will ensure that the communities taking part in this research are also those who will see the benefits, and that the privacy of participants are protected. All data (save consent forms) will be collected using tablets (which will also be used to take photographs). Patient facing materials (Information/consent forms and QoL forms) will be translated and back translated according to WHO criteria (e.g. back translation carried out independently of forward translation and results checked independently). Data will be captured and encrypted using the REDCap database. We will comply with local regulations governing research: https://intranet.birmingham.ac.uk/it/documents/public/Information-Security-Policy.pdf and the Indian Health Research Council.

All data generated from this study will be classified according to the University of Birmingham Information Security Framework. All data will be collected and stored electronically to eliminate data collection errors, such as contradicting answers, building on our experience under our current NIHR Global Health Research Unit on Improving Health in Slums. Data will be reported on an electronic Case Report Form (eCRF), and all local and University of

Birmingham research staff will be trained to collect data directly onto electronic tablets. Data will be acquired and stored on the REDCap platform with access restricted by passwords at both the University of Birmingham and the local site in India. Each participant will be allocated a unique study number when they agree to participate which will be used on all documents. In summary, we will collect data as outlined in Figure 4. REDCap is capable of storing and transferring photographic images.

Range limits and logic checks (e.g. for conflicting responses) will be built into the REDCap form to prevent erroneous data entry. Base-line data from the first ten patients will be cross-checked by the local lead investigator to assure that full and accurate data are collected.
All data will be stored only in backed-up shared network spaces. “Restricted” and “reserved” data files will be encrypted using PGP encryption. The study site in India will create their own unique set of PGP keys to access data locally. For data transmission between study sites and the University of Birmingham the files will be encrypted using the relevant study site public key. Only authorised individuals at each institution will have access to the data. The information collected on REDCap is encrypted on the tablet and sent through a secure link to the server hosted at the University of Birmingham.

Once the project has ended, the anonymised trial data will be made available for sharing with all requests being approved by the Chief Investigator. Those accessing the data will abide by the same rules as are applicable throughout the project. Data will be stored for a minimum period of ten years and then reassessed rather than destroyed, as per the University’s research data management policy. During the 10 year post-project period paper data, such as consent forms, will be archived locally in India in a locked cabinet. Electronic data including

photos will be stored in an encrypted archive at the University of Birmingham. All electronic data held locally at the investigator site in India will be archived for ten years and then deleted. Should the investigator site wish to access the electronic data, this will be done through the Birmingham secure file transfer portal.

4.3 Study organization and management

4.3.1 Study management group

The Study Management Group (SMG) includes individuals at the University of Birmingham and The Leprosy Mission India who are responsible for the day-to-day management of the trial. This will include the Chief Investigator for the whole study (Prof Richard Lilford), Principal Investigator in India (Dr Joydeepa Darlong) and Co-Principal Investigator (Mr Karthikeyan Govindasamy), Project Manager for overall study and local Project Manager in India, lead methodologists and patient representatives. The Study Management Group will meet monthly by teleconference, but this may be more frequent if deemed necessary by the members.

The role of the Study Management Group is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself.

4.3.2 Summary of staff training

All current site staff in India have undertaken Good Clinical Practice Training and new appointees to the trial will be required to complete online training. Staff will be trained to seek patient consent (as outlined in 4.1).

We will create a data management manual for use to guide online data collection and entry systems and data security.

5 Dissemination and Publication

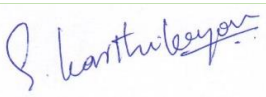
The results of the study will be reported to collaborators of this study. The success of the study depends on researchers across India and the UK. Equal credit will be given to those who have collaborated in the trial.

The findings will be shared with the patients and communities through the networks of The Leprosy Mission Trust India, who have extensive experience in working with the patient communities.

We shall also present our work at conferences of Indian Association of Leprologists (IAL), Indian Association of Dermatologists, Venereologists and Leprologists (IADVL), the Annual Neglected Tropical Disease NGO (NNN) conference, International Leprosy Congress in 2022 and Diabetes disease related conferences.

Tools we will use to disseminate our research output include: bite-sized research reports in lay format; publication in peer reviewed international journals; public announcements in LMICs; policy briefings; print and online media; the director's news blog (680+ subscribers); institutional and social media accounts and websites.

The context (Chhattisgarh) specific principles and guidelines to promote self-care practice in the community with an emphasis on prevention of recurrent leprosy ulcers will be disseminated across different networks of The Leprosy Mission Trust India.

SIGNATURES		
Date (DD/MM/YYYY): 25/02/2022		
	Name	**Signature**
Principal investigator for India	**Dr Joydeepa Darlong**	
Co-PI for India	**Mr Karthikeyan G**	

6 Appendix

6.1 Appendix – 1: Case record form

1. Study number ……
10. Ethnicity: -…….
11. Religion: - …….
12. Language spoken Chhattisgarhi / Hindi / Both

13. **Education:**

Never Joined Formal School ☐ Primary Level ☐ Secondary Level ☐

Higher Secondary Level ☐ University Level ☐

14. **Employment/Occupation**

Employed Fulltime ☐ Farming ☐

Unemployed ☐ Self Employed/ Business (Own) ☐ Unable to Work ☐

Student ☐ Housewife ☐ Daily Wage Labourer ☐

15. Did you ever change occupation due to disability? Y / N, If yes, why? ……

16. **Income per month in IRs (Self + households)**

Below 10,000 ☐ 10000 to 20000 ☐ 20000- to 30000 ☐

30000 to 40000 ☐ Above 40000 ☐

17. **Marital Status**

Single (Never Married) ☐ Married ☐

Divorced ☐ Widowed ☐

18. **Residence**

Urban ☐ Rural ☐

19. Do you live with someone or alone? Living alone ☐

Living with family / someone ☐

20. If with family / someone **Number of people:** …….

Clinical details (Leprosy related):

21. Date of diagnosis: ……. (approx. years).
22. Leprosy Treatment (MDT or Dapsone monotherapy) Completed:- Y / N
23. If completed (RFT), when? - …… (Approx. years)

24. **Disability assessment details and EHF score**

	Hand		**Foot**	
	Right	**Left**	**Right**	**Left**
Sensory impairment	Normal / Impaired	Normal / Impaired	Normal / Impaired	Normal / Impaired

Motor assessment

Right		**Left**
Normal / Low vision / Unable to count finger	Vision	Normal / Low vision / Unable to count finger
	Lid gap (in mm)	
Present / Absent	Blink	Present / Absent
Strong / Weak / Paralysed	Little finger out (ulnar)	Strong / Weak / Paralysed
Strong / Weak / Paralysed	Thumb up (median)	Strong / Weak / Paralysed
Strong / Weak / Paralysed	Wrist up (radial)	Strong / Weak / Paralysed
Strong / Weak / Paralysed	Foot up (CPN)	Strong / Weak / Paralysed
0 / 1 / 2	Disability grade eyes	0 / 1 / 2
0 / 1 / 2	Disability grade hands	0 / 1 / 2
0 / 1 / 2	Disability grade feet	0 / 1 / 2
EHF score		

25. **Photograph**

Left palm ☐ Right palm ☐

Left plantar surface foot ☐ Right plantar surface of foot ☐

26. **Duration of impairment ……** (give the duration of impairment with maximum duration)

27. **Eye impairment details**

	Lagophthalmos	Corneal ulcers /abrasions	Blindness	Remarks
Rt eye	Present/ Absent	Present/ Absent	Present/ Absent	
Lt eye	Present/ Absent	Present/ Absent	Present/ Absent	

28. **Hand impairment details**

	Claw hands	Ape thumb	Wrist drop	Finger shortening	Remarks
Rt hand	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	
Lt hand	Present/ Absent	Present/ Absent	Present/ Absent	Present/ Absent	

29. **Foot impairment details**

	Foot drop	Claw toes	Toe / foot shortening	Rocker bottom foot	Remarks
Rt foot	Present/ Absent	Present/ Absent	Present / Absent	Present / Absent	
Lt foot	Present/ Absent	Present/ Absent	Present / Absent	Present / Absent	

Ulcer Related Information:

31. Have you ever had an ulcer? Yes / No
32. Presence of ulcers in hand and/or foot? Yes / No (if Yes, proceed to question number 34)
33. If No, did you have ulcer during the last 12 months? Yes / No
34. If Yes

Location of Ulcer:- Hand: Rt Palm Dorsum
Lt Palm Dorsum

Foot: Rt Plantar Dorsum
Lt Plantar Dorsum

35. Number of Ulcers- in hands …….. in feet ……
36. Duration of the largest ulcer in the foot unhealed (in months): - ……

37. Size of current ulcer: - Length …….cm width ……cm Depth …… cm

38. Cause of present ulcer in the foot Due to:

Direct injury ☐

Due to friction / developed while walking ☐

Due to footwear ☐

Don't know ☐

39. **Exudate Volume***

None (dry) Scant ☐ Small ☐ Moderate ☐ Copious ☐

40. Have you ever been admitted in hospital for ulcer care before: Yes / No

Self-Care related Information:-

41. Do you examine your foot regularly? Yes/No

If yes, how often? Daily Weekly Monthly Once in a while

42. Do you soak your foot regularly? Yes/No

If yes, how often? Daily Weekly Monthly Once in a while

43. Do you have adequate tools / materials to practice self-care? Yes / No

44. Current footwear type:

a. No footwear (bare foot walking)
b. MCR sandal,
c. Canvas / regular shoe with MCR insole
d. Moulded boot
e. Canvas / regular shoe without MCR insole
f. Normal slipper / sandal
g. Other: specify: _____

45. Do you use assistive devices to protect the anaesthetic limbs while cooking, farming, using tools? Yes/ No

46. If Yes, what tool do you use?.....

47. Have you ever been/attended a Self Help Group / Self-care group in past? Y/N

48. If Yes, are you currently attending the group: Yes / No

Physical parameters

49. Height in cms _____

50. Weight in Kilograms: _____

51. Blood Pressure: Systolic _____, Diastolic: _____

Past and medication history

51. Have you ever smoked (history of smoking cigarette / bidi): Yes / No?

52. Have you ever consumed alcohol (history of consuming alcohol): Yes / No?

53. Are you under medication for diabetes: Yes / No / Not aware?

54.

Exudate volume definitions (see 39): None (Wound dry), Scant (tissues moist), small (wound wet, moisture evenly distributed, drainage involves 25% or dressing), moderate (wound

tissues saturated, draining may or may not be evenly distributed, drainage involves 25-75% of dressing), copious (wound tissues bathed in fluid, drainage freely expressed).

6.2 Appendix - 2: Euro Quality of life – 5 Dimensions – 3 Level scale

EQ-5D-3L

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

SELF-CARE

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

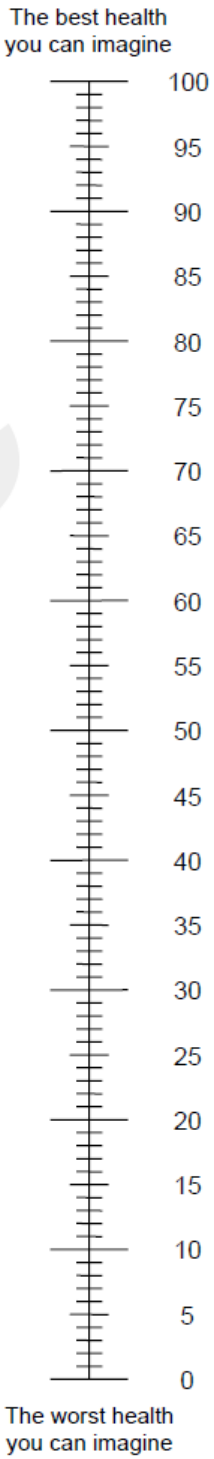
I am not anxious or depressed ❑

I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Please mark an X on the scale to indicate how your health is TODAY.
- Now, write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



6.3 Appendix – 3: Subjective wellbeing scale

The following question asks how satisfied you feel, on a scale from 0 to 10. Zero means you feel 'not at all satisfied', and 10 means you feel 'completely satisfied'.

Q1	Overall, how satisfied are you with life as a whole these days? [0-10]	

The following question asks how worthwhile you feel the things you do in your life are, on a scale from 0 to 10. Zero means you feel the things you do in your life are 'not at all worthwhile', and 10 means 'completely worthwhile'.

Q2	Overall, to what extent do you feel the things you do in your life are worthwhile? [0-10]	

The following questions ask about how you felt yesterday on a scale from 0 to 10. Zero means you did not experience the feeling 'at all' yesterday, while 10 means you experienced the feeling 'all of the time' yesterday. I will now read out a list of ways you might have felt yesterday.

Q3	How about happy? [0-10]	
Q4	How about worried? [0-10]	
Q5	How about depressed? [0-10]	

6.4 Appendix – 4: Participation scale

No	Participation Scale	Not specified, not answered	Yes	Sometimes	No	Irrelevant, I don't want to, don't have to	NO problem	Small	Medium	Large	SCORE
1	Do you have equal opportunity as your peers to find work?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
2	Do you work as hard as your peers do? (same hours, type of work etc)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
3	Do you contribute to the household economically in a similar way to your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
4	Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
5	Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
6	Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
7	Are you as socially active as your peers are? (e.g. in religious/community affairs)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
8	Do you have the same respect in the community as your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
9	Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
10	Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
11	Do you visit other people in the community as often as other people do?		0			0					
	[if sometimes or no] How big a problem is it for you?						1	2	3	5	

No	Participation Scale	Not specified, not answered	Yes	Sometimes	No	Irrelevant, I don't want to, don't have to	NO problem	Small	Medium	Large	SCORE
12	Do you move around inside and outside the house and around the village / neighbourhood just as other people do?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
13	In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
14	In your home, do you do household work?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
15	In family discussions, does your opinion count?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
16	Do you help other people (e.g. neighbours, friends or relatives)?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
17	Are you comfortable meeting new people?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
18	Do you feel confident to try to learn new things?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	

Comment:

TOTAL

Name: _____

Age: ____ Gender: _____

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

Grades of participation restriction

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

6.5 Appendix – 5: Patient Information sheet

Study title: Reduction of disability in Leprosy through enhanced self care in Janjgir-Champ district, Chhattisgarh, India

Introduction

We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. One member of our team will go through this information sheet with you and answer any questions you may have. Ask questions if anything you read or hear is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

Who is organising and funding the study?

The study is being organised by The Leprosy Mission Trust India in collaboration with the University of Birmingham, UK. The study is funded by the UK National Institute for Health Research.

What is the purpose of the study?

Leprosy ulcers are not caused by the leprosy germ but by loss of sensation leading to repetitive injury. As a result, patients (and their families) face stigma, social isolation as well as a lot of economic burden.

The purpose of our research study is to the improve the self-care practice of patients in the community, which will help reduce the ulcer and its associated complications. If required, we will observe while performing self-care to understand how people affected by leprosy undertake self-care practice.

Why have I been asked to take part?

You have been invited to take part because you have impairments due to leprosy in your limbs. Those who have had ulcers in their foot are invited take part in this study.

Do I have to take part?

No. It is up to you to decide to take part or no. If you do not want to take part, that is ok.

We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What will happen to me if I take part?

If you are willing to take part in this study, we will first ask you to sign a consent form which is your indication that you understand the study and agree to take part.

We will then issue you with a unique study identification number to ensure that any details we collect remain secure.

If you agree to take part in this study, you will be trained on self-care practice by Mitanins of your village and you will be asked questions about your hand and foot impairments and take photo of the foot. We may ask you in more detail about how you self-care and to show us how you self-care.

What will I have to do?

You will be expected to take part in self-care teaching by Mitanins, individual interviews, and to answer questions about the impairments and foot ulcers. We may ask you to show us how you self-care.

What information will be collected?

Only your name will be collected. However, the information you give will be anonymised and only ever be viewed by your unique identification number. We will keep this information separate from other information.
During the interview, you are expected to share information about your disability details, foot impairments in particular and ulcer details if present. We will take the picture of your both feet. The picture will not have any personal identification details except the unique identification number.

What will happen to information collected about me?

All information collected about you will be kept private. Only the study staff and authorities who check that the study is being carried out properly will be allowed to look at information about you. Data may be sent to other study staff at University of Birmingham but this will be anonymised. This means that any information that includes your name and address will be removed so that you cannot be recognized.
Anything you say during the interview will have names of people and places removed. We may use direct quotations in the reports or publications from the study, but they will not be linked to you. All the data will be securely stored in safe place.
The collected data may also be used for future research following approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project. For further information, please refer to the University of Birmingham Research Privacy Notice which is available here: https://www.birmingham.ac.uk/privacy/index.aspx or by contacting the Information and Data Compliance Team at dataprotection@contacts.bham.ac.uk.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. You can also contact Dr. Joydeepa Darlong, joydeepa.darlong@leprosymission.in, the investigator of this study for any queries. If you remain unhappy and wish to complain formally, you can do this by contacting Professor Richard Lilford, University of Birmingham UK, r.j.lilford@bham.ac.uk

Can I change my mind about taking part?

Yes. You can withdraw from the study at any time. You just need to tell your research fellow that you do not want to be in the study anymore. Information collected may still be used.

What will happen to the results of this study?

The study results will be published in a medical journal so that other people can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it.

Who has reviewed the study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the [insert name of ethics committee here]

Who should I contact if I want further information?

Dr Joydeepa Darlong, The Leprosy Mission Trust India E-mail: joydeepa.darlong@leprosymission.in
Professor Richard Lilford, University of Birmingham, r.j.lilford@bham.ac.uk

****Thank you for taking time to read this information leaflet. If you think you will take part in the study please read and sign the consent form. ****

6.6 Appendix – 6: Patient consent form

Study title: Reduction of disability in Leprosy through enhanced self care in Janjgir-Champ district, Chhattisgarh, India

Name of Investigator (s): Dr. Joydeepa Darlong, The Leprosy Mission Trust India, and Professor Richard Lilford, University of Birmingham, UK

A. I _____ understand that researchers from The Leprosy Mission Trust India and representatives at University of Birmingham are involved in a study regarding evaluation of self-care intervention and measurement of impairments including ulcers. Part of this study involves talking to people who had had or having ulcers. You are being invited to take part in an individual interview, disability assessment and consent to take picture of your feet.
B. I consent to be approached for more detailed interview and taking photographs of hands and feet with impairments.
C. I consent to be asked to be observed undertaking self-care.
D. The study has been explained to me and I understand what is expected of me.
E. I confirm that I am 18 years old or above.
F. I understand that once my data has been incorporated with others, it might not be possible for it to be withdrawn, though every attempt will be made to extract my data, up to the point of publication.
G. I understand that my name will not be revealed in any published material concerning this study.
H. I agree that my data can be used in reports, publications, conferences, and training events,
I. I agree that my data can be used for further research in future. YES/NO*
J. Please delete as appropriate. Please note that participants may say 'NO' to this question and still take part in the study. I understand that I can leave the study at any time for any reason and I will still receive support and care for my condition.
K. I have received enough information about the study in a language I understand. I have had the opportunity to discuss it and ask questions, and those questions have been answered to my satisfaction.

L. I agree to take part in the study.

Printed Name & Signature (or fingerprint) Date
Name of Patient _____
Signature/Fingerprint _____ _____/_____/20____
Name of Witness _____
Signature/ Fingerprint _____ _____/_____/20____
Name of Researcher_____

6.7 Appendix – 7: Study participants Information sheet

Study title: Reduction of disability in Leprosy through enhanced self care in Janjgir-Champ district, Chhattisgarh, India

Introduction

We would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. One member of our team will go through this information sheet with you and answer any questions you may have. Ask questions if anything you read or hear is not clear or you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

Who is organising and funding the study?

The study is being organised by The Leprosy Mission Trust India in collaboration with the University of Birmingham, UK. The study is funded by the UK National Institute for Health Research.

What is the purpose of the study?

People affected by leprosy with impairments are at risk of developing ulcers and further worsening of limbs due to lack of self-care practice.

The purpose of part of this study is to understand your role in identifying and managing people affected by leprosy with impairments who needs self-care.

Why have I been asked to take part?

Part of this study involves talking to and observing people who are in position to potentially identify and/or help manage people affected by leprosy with impairments. We believe you have important knowledge and experiences that can help to improve the care of patients with impairments in the community.

Do I have to take part?

No. It is up to you to decide to take part or no. If you do not want to take part, that is ok.

We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

What will happen to me if I take part?

If you are willing to take part in this study, we will first ask you to sign a consent form which is your indication that you understand the study and agree to take part.

We will then issue you with a unique study identification number to ensure that any details we collect remain secure.

If you agree to take part in this study, you may be observed undertaking your normal job and/or interviewed about your role.

What will I have to do?

You may; be asked to carry out your normal role while a researcher observes you; ; you will be asked questions about your usual role.

What information will be collected?

The information you give will be anonymised and only ever be viewed by your unique identification number. We will keep details of your name separately and destroy it once the data analysis is complete.

During interviews or observations, you will be asked about how you undertake your role in relation to people affected by leprosy and what helps or hinders you in this role. Notes may

be made, or the discussions audio-recorded so that we can listen to it afterwards and write it down.

What will happen to information collected about me?

All information collected about you will be kept private. Only the study staff and authorities who check that the study is being carried out properly will be allowed to look at information about you. Data may be sent to other study staff at University of Birmingham but this will be anonymised. This means that any information that includes your name and address will be removed so that you cannot be recognized.

Anything you say during the interview will have names of people and places removed. We may use direct quotations in the reports or publications from the study, but they will not be linked to you. All the data will be securely stored in safe place.

The collected data may also be used for future research following approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project. For further information, please refer to the University of Birmingham Research Privacy Notice which is available here: https://www.birmingham.ac.uk/privacy/index.aspx or by contacting the Information and Data Compliance Team at dataprotection@contacts.bham.ac.uk.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. You can also contact Dr. Joydeepa Darlong, joydeepa.darlong@leprosymission.in, the investigator of this study for any queries. If you remain unhappy and wish to complain formally, you can do this by contacting Professor Richard Lilford, University of Birmingham UK, r.j.lilford@bham.ac.uk

Can I change my mind about taking part?

Yes. You can withdraw from the study at any time. You just need to tell your research fellow that you do not want to be in the study anymore. Information collected may still be used.

What will happen to the results of this study?

The study results will be published in a medical journal so that other people can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it.

Who has reviewed the study?

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the [insert name of ethics committee here]

Who should I contact if I want further information?

Dr Joydeepa Darlong, The Leprosy Mission Trust India E-mail: joydeepa.darlong@leprosymission.in

Professor Richard Lilford, University of Birmingham, r.j.lilford@bham.ac.uk

****Thank you for taking time to read this information leaflet. If you think you will take part in the study please read and sign the consent form. ****

6.8 **Appendix – 8: Participant consent form**

Study title: Reduction of disability in Leprosy through enhanced self care in Janjgir-Champ district, Chhattisgarh, India

Name of Investigator (s): Dr. Joydeepa Darlong, The Leprosy Mission Trust India, and Professor Richard Lilford, University of Birmingham, UK

1. I _____ understand that researchers from The Leprosy Mission Trust India and representatives at University of Birmingham are involved in a study regarding the evaluation of self-care program to reduce impairments. Part of this study involves talking to and observing people in the community who have an interest in preventative health projects, including health care leaders, health professionals, master trainers, Mitanins, and volunteers. Participating will allow you to share your knowledge, experiences and thoughts. Findings will help us understand how the self-care intervention reduce risk of ulcers and their associated complications
2. The study has been explained to me and I understand what is expected of me.
3. I confirm that I am 18 years old or above.
4. I understand that if I am being interviewed this will be audio recorded and then made into an anonymised written transcript.
5. I understand that if I am being observed doing my normal job, then the researcher may write comments (field-notes) about my practice, and these will be anonymised and pooled with data from others. Findings will only be used to improve the study and not be reported to your employer.
6. I understand that any audio recordings and field-notes will be destroyed at the end of the study but transcripts will be kept for ten years after the study has finished.
7. I understand that the things I say will have the names of people and places removed, may be pooled with other participants' responses, and may be published.
8. I understand that once my data has been incorporated with others, it might not be possible for it to be withdrawn, though every attempt will be made to extract my data, up to the point of publication.
9. I understand that my name will not be revealed in any published material concerning this study.
10. I agree that my data can be used in reports, publications, conferences, and training events, or for further research in future.
11. I understand that I can leave the study at any time for any reason and if I am a member of the group, I will still receive support and care for my condition.
12. I have received enough information about the study in a language I understand. I have had the opportunity to discuss it and ask questions, and those questions have been answered to my satisfaction.
13. I agree to take part in the study.

Printed Name & Signature (or fingerprint) Date

Name of Patient _____

Signature/Fingerprint _____ _____/_____/20____

Name of Witness _____

Signature/ Fingerprint _____ _____/_____/20____

Name of Researcher_____

6.9 Appendix – 9: Self-care intervention description

Aim of the intervention

The aim of the self-care intervention is to reduce the wound counts and promote healing of ulcers and overall reduction in the disability level.

Contextualization of self-care in Champa district

Please refer section 2.5 and Figure 2.

Information booklet for eye, hand and foot care

Soft copies of the booklets to be added.

Implementation of enhanced self-care program

Please refer section 2.5 and 3.3 and Figure 4 and 5.

Training of patients on self-care

The training will be a two-way conversation and the Mitanins will provide information relevant to the problems (impairments) the client experiences. Mitanins will verify that the client has understood the information. She will also demonstrate self-care techniques. As far as possible, patients will be encouraged to offer the solutions (self-care) themselves (for better compliance) adapting to their local conditions so that self-care is customized rather than standardized. The patients will be motivated to practise what has been agreed under supervision. As far as possible clients should be helped to see self-care incorporated as part of daily living and not a specialized activity. Mitanin also will assess and provide required footwear and assistive devices such as crutches.

The client's details of self-care activities will include frequency and location of the self-care practice. Alternative solutions when self-care is deferred for eg busyness will be sought. Support system in the family and community will be ascertained. The mitanins will also do a modified disability access check to observe where bowls, water, oil, scraping stones for skin care are kept and how easily they can be accessed, by asking for a demonstration of skin care. For specific impairments, availability of tools will be asked e.g., a mirror to inspect the eyes. The hands and feet will be inspected to correlate the status with the reported frequency of self-care activities. This will be done during home-visits, but interviews in the OPD (Outpatient

Department) are also possible to ensure that documentation and follow-up is completed. Reasonable, achievable, short-term targets will be set, and accomplishments commended. Repetition will be done to reinforce the principles and adherence of self-care practice.

Self-care methods

The main principles guiding practice of self-care will inspection, prevention, intervention and maintenance of the affected part. It includes inspection of the affected parts for any unknown injuries, prevent worsening, care for those body parts already injured and maintain the status quo of the impairment and do not allow further damage. These methods are described for eye , hand and foot impairments for the Mitanins to impart to the people affected.

Eye care

- Examine the eyes routinely once or twice daily.
- Use a mirror and inspect for any redness of the eye, corneal injury, foreign body, eyelashes touching, conjunctiva/cornea, injury to the eye.
- Ask friends/relative to check. If there is any redness see the doctor immediately.
- Test the vision, look at any fixed object from the same distance every day, cover each eye one at a time with the palm and look at the same object daily from the fixed distance.
- Report any change in vision to the nearest health worker immediately.

Care for the eyes

- If the eyes cannot be closed fully, it is important to keep eyes moist and clean. To clean your eyes daily, rinse your eyes gently with clean water using the cupped palms; do not splash water on eyes; do not rub eyes with any cloth or towel.
- Instill prescribed drops to keep eyes moistened; don’t rub the eye if it is sore or red.
- To protect eyes against dryness and dust, wear sunglasses with large lenses and side-pieces. Wear a hat/ use a head cloth to shield and avoid injury to the eye. Use a cloth around the head to keep the eyes closed at night.

Exercise for weak eyelids

Close the eyes tightly for 1 min, open and close again repeat 30 times doing this 3 times a day; pull eye lids from sideways to close eyelids. to maintain and improve strength of eyelids.

Hand care

Examine the hands

- Set aside a definite time each day for this hand-care routine.
- Inspect the hand for redness, swelling, hot-spots, blisters, cracks, or wounds.
- To soften the hard skin of hands, soak your hands in water for about 20 min.
- Scrape off hard skin around cracks and old wound sites with the help of a hard cloth, coconut coir or loofa. Rub in oil on the wet hands immediately after soaking and scraping.

Care for the hands

- Always cover wounds with a clean cloth or bandage to protect them against injury, dirt, and infection. Rest the hand as much as possible.
- Protect the hands, while cooking food, always hold hot items/utensils from the sides with the help of a thick cloth to protect against heat and fire.
- Always use a pair of tongs to poke the fire or for touching hot cooking dishes.
- For drinking tea or coffee, put the hot glass inside a cup or simply use a protective padding of cloth, to hold the hot glass, as hot food can burn your hands. Allow the food to cool and eat with a spoon.
- Cover the handles of a cycle/rickshaw that is used regularly with a soft cloth to prevent wounds and blisters on your hands. Pad or cushion with cloth all hard and rough objects of daily use like spade, axe etc.

Exercise for fingers

- For stiff fingers, apply oil. Rest the back of hand on the thigh. Use the other hand by gently pushing forward, to straighten the fingers as much as they will go. Hold and count to ten before you relax your hand. Do this at least 10 times.
- For weakness of fingers. Cup the bent knuckle joints of the affected hand into another palm. Then straighten the end two joints as firmly as you can. Do this at least 10 times.
- Use the other hand to straighten the end thumb-joint gently but firmly as much as it will go. Do this at least 10 times.

- While resting the little finger side of the hand on the thigh, use other hand to firmly support the back of the thumb. Straighten the end joint of thumb as strongly as it can. Do this at least 10 times.

Foot care

Examine the Feet

- Set aside a definite time each day for this foot-care routine. Inspect the feet for redness, swelling, hot-spots, blisters, cracks, or wounds.
- To soften the hard skin of feet, soak your feet in water for about 20 min.
- Scrape-off hard skin around cracks and old wound sites with the help of a soft stone, loofa, or coconut coir. Rub in oil on the wet feet immediately after soaking and scraping.

Care for the Feet

- Always cover wounds with a clean cloth or bandage, to protect them against injury, dirt, and infection. Always check wounds every day. If the wounds are getting bigger, or if the skin around the wound is red and swollen, or if there is any pus or bad smell, then report immediately to the nearest health care centre. If the wounds are smaller and clean, and if there is no pus, then continue with self-care activities.
- Give enough rest to your affected foot. Keep the affected foot raised up on a pillow.
- Avoid walking. If you need to walk, use crutches, or stick for support.
- Protect the feet; always sit away from heat and fire.
- Correct way of sitting—either sit on a stool or sit down with the legs extended, to avoid injury to the feet, do not squat, do not sit cross-legged.
- Check footwear daily to look for any damage, and to see if there are any stones or sharp things sticking to the soles. Do not wear tight strapped footwear or shoes.
- Never walk barefoot. Always wear shoes with protective padding.
- To cover long distances, always use a bicycle or other means of transport, instead of walking.

Exercise for the feet

Hold the two ends of a long cloth with the hands. Place the middle of the cloth under the forefoot and pull the cloth upwards firmly 10 times. Repeat this process about 3 times daily. Consult the doctor and wear a foot drop—splint or spring attached to the footwear.

Footwear and assistive devices

- Footwear should fit comfortably and adjust to accommodate the shape of the feet. No nails or hard objects like metal wire should be used for repair. MCR will be the preferable material for the insole of the foot.
- Assistive devices will be recommended for use to prevent disabilities by protecting the affected person from developing new impairments and by facilitating activities and participation. The use of such devices will improve the functionality of a person, thereby increasing their level of independence in daily living.

When to refer

All patients who require urgent medical care will be referred to PHCs.

Monitoring

Monitoring of the impairments and ulcers will be done monthly by the mitanins. They will look for and document 2 aspects of the condition I.e, Presence or absence of new ulcers and improvement or worsening of existing ulcers.

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