INTERSHIP REPORT

# Cross-Cultural validation of two scales to assess stigma and social participation in leprosy-affected persons in Kathmandu Valley, Nepal

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## Colophon

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## Summary

**Introduction**: Leprosy is one of the oldest diseases known to humankind and causes severe disabilities and disfigurements in many countries worldwide. It is connected to many social problems, such as stigma and restrictions in social participation. Many factors drive leprosy-related stigma, and its impact can include social, psychological, health and economic consequences, which decreases the quality of life of leprosy-affected people.

Measuring stigma and the level of restriction in social participation is crucial for the development, implementation and evaluation of stigma reduction, rehabilitation and other interventions for persons affected by leprosy in Nepal. Two instruments that aim to measure these concepts have been recently developed in the English language. The 5-Question Stigma Indicator-Affected People (5-QSI-AP) is a five-item tool aimed to measure experienced stigma. The Participation Scale Short Simplified (PSSS), is a 13-item tool based on the commonly endorsed Participation Scale. The conceptualization of stigma and social participation differs across culture, making it challenging to generalize tools from one country to another. In order to validate these tools for use in Nepal and potential inclusion in the, by van 't Noordende et al. developed, neglected tropical disease (NTD) morbidity and disability toolkit (NMD – toolkit), this study aimed to perform a cross-cultural validation using the "cultural equivalence" framework to answer the following research question: *"How valid are the 5-QSI-AP and PSSS among people affected by leprosy in Nepal?".*

**Methodology:** This study took place at several places in the Kathmandu Valley, Nepal. The 5-QSI-AP and PSSS were translated following WHO guidelines. Next, cultural validity was examined by assessing the conceptual, semantic, item, operational (qualitative) and measurement validity (quantitative). A qualitative pilot study with eight semi-structured interviews was performed to 1) increase our understanding of the concept of stigma and 2) ensure that people in Nepal understand the meaning of the items on the questionnaires (semantic), that they consider them as relevant and appropriate (item), and that they know how to use it (operational). This was an iterative process of translation, discussions with experts and adaptions, which resulted in final versions of both instruments. Finally, a total of 110 people affected by leprosy were selected through convenience sampling, followed by purposive sampling, and 50 repeated measures were obtained. In addition, parallel measures with the Participation Scale Short were performed, and a normative sample of 50 people without any disability was included. Measurement validity was assessed by testing the following psychometric properties: Criterion validity, construct validity, internal consistency, floor and ceiling effects, reproducibility and interpretability

**Results and discussion:** For the 5-QSI-AP, conceptual exploration of stigma led to the identification of the three themes - social exclusion, avoidance and concealment - that are covered by the items of the questionnaire. The true meaning and words of all five items of the 5-QSI-AP and 13 items of the PSSS were clearly understood, confirming semantic validity. None of the questions caused any discomfort among the respondents, and the importance of the items of the 5-QSI-AP and PSSS was confirmed during the pilot study. However, item non-validity, in the form of irrelevance, was present in one question of the PSSS, which was then adapted to better represent the female population. Neither the interviewer nor the respondents reported any difficulties in the administration format of the 5-QSI-AP and PSSS.

Regarding measurement validity, using a ROC-curve, the normal cut-of value of the PSSS was defined at 12. The sensitivity and specificity of the PSSS versus the P-Scale Short are 0.86 and 0.92, respectively. For assessment of construct validity, three of the four a priori hypotheses for the PSSS and two of the three hypotheses for the 5-QSI-AP were confirmed. Internal consistency was tested using Cronbach's alpha. A score of 0.87 for the PSSS is considered optimal, and indicates that items measure the same underlying construct. For the 5-QSI-AP, removal of Q4, which concerns "difficulties in marriage/in getting married," would increase the Cronbach's alpha from 0.66 to 0.71. This is consistent with another study that used the 5-QSI community version and reported a higher alpha when deleting Q4. The test-retest reliability was measured using the Intraclass Correlation and was 0.79 for the PSSS and 0.72 for the 5-QSI-AP. The results show that both the 5-QSI-AP and PSSS are capable of effectively discriminating between groups, for example in age, gender, and disability status, supporting their reliability. These findings support the notion that gender, and visible signs of leprosy are factors closely related with stigma and, consequently, restrictions in social participation. Finally, floor and ceiling effects were not present for either scale.

**Conclusion:** For the PSSS, we can conclude that it has acceptable cultural validity in the Nepali culture and that it can be included in the NTD morbidity and disability toolkit. However, for the 5-QSI-AP we recommend identifying alternative constructs that better reflect stigma in people affected by leprosy. The performance of an alternative item should be examined in the target population to determine whether it can replace the current item 4.

## List of abbreviations

| | |
|---|---|
| 5-QSI-AP | 5- Question Stigma Indicator- Affected People |
| 95% CI | 95% Confidence Interval |
| DALY | Disability-Adjusted Life Year |
| EHF score | Eye Hand Feet score |
| EMIC- Stigma Scale | Explanatory Model Interview Catalogue Stigma Scale |
| HRQoL | Health-Related Quality of Life |
| ICC | Intraclass Correlation |
| ICF | International Classification of Functioning, Disability and Health |
| IQR | Interquartile Range |
| M.leprae | Mycobacterium leprae |
| MIC | Minimal Important Change |
| MDT | Multidrug therapy |
| NMD-Toolkit | Neglected Tropical Disease Morbidity and Disability - Toolkit |
| NPV | Negative Predictive Value |
| NTD | Neglected Tropical Disease |
| PS; P-Scale | Participation Scale |
| PPV | Positive Predictive Value |
| PSS; P-Scale Short | Participation Scale Short |
| PSSS | Participation Scale Short Simplified |
| SDC | Smallest Detectable Change |
| SEM | Standard Error of the Mean |
| SSI | Semi-Structured Interview |
| TLM | The Leprosy Mission Nepal |
| WHO | World Health Organization |

# Table of Contents

# 1 Introduction

Neglected tropical diseases (NTDs) consist of a range of diseases, caused by a variety of pathogens, that may lead to progressive and chronic disabling and disfiguring conditions. They are strongly associated with poverty and poor hygiene, occurring mainly in poor rural and urban areas of low and middle-income countries. Unfortunately, little attention has been paid to NTDs by the general health community (e.g. major donors, etc.), which has generally focused on three major diseases: HIV, tuberculosis and malaria. One of the NTDs, leprosy, remains endemic in many countries despite the availability of effective treatment, and continues to be a major public health problem. Caused by infection with the bacterium *Mycobacterium Leprae,* Leprosy may lead to chronic disease accompanied by permanent impairments. Leprosy is associated with stigma and discrimination, leading to social exclusion of affected people by their families and communities.

Nepal has a long history of leprosy, but by 2009 it achieved the leprosy elimination threshold of less than 1 case per 10.000 inhabitants. Nevertheless, on a local level leprosy is still endemic in some districts, which are striving for elimination (Engelbrektsson, 2012). Leprosy is feared in most countries due to risk of infection, concerns about disfigurement, beliefs that the disease is inherited, and the potential of negative social consequences. In addition, in the worldview of Nepal's leading religion, Hinduism, leprosy is thought to be the result of bad karma or a punishment for a sin or for breaking a cultural taboo (van Brakel and Miranda-Galarza, 2013). These misconceptions cause problems related to social gatherings, friendship, marriage, educational and employment opportunities, among other things (Tsutsumi et al., 2007, Molyneux et al., 2005). Consequently, these determinants of leprosy may lead to huge economic and mental health problems (Hotez et al., 2006, Barrett, 2005).

It is important to measure the aspects of disability so that the resulting data can be used for advocacy, policy formulation, implementation, monitoring and evaluation of leprosy elimination strategies. There are many tools available that measure disabilities, however, they use several different concepts of disability or are aimed at and developed in different cultural settings (Stevelink and van Brakel, 2013). Disability-related concepts, such as stigma, may vary in different cultures, stressing the importance of cultural validity of instruments that measure NTD-related disability, stigma and restriction in social participation (Stevelink and van Brakel, 2013). Two of these tools, the 5-Question Stigma Indicator for Affected people (5-QSI-AP) and the Participation Scale Short Simplified (PSSS), aimed to measure stigma and restriction in social participation, respectively. Before this research project, these tools had not yet been validated in the Nepali language and culture.

Therefore, the *aim* of this study was to contribute to the body of knowledge that enables development of suitable interventions for persons affected by leprosy, and so to reduce leprosy-related stigma and its consequences in Nepal. In addition, this study aimed to enhance data collection regarding stigma related to leprosy and other NTDs, which will in turn support advocacy and funding for interventions. The *objective* of this study was to provide evidence for the cultural validity of the 5-QSI-AP and PSSS to assess leprosy-related stigma and restrictions in social participation in Kathmandu valley, Nepal.

# 2 Background

## 2.1 Leprosy

Leprosy, also known as Hansen's disease, is a NTD. NTDs occur primarily in poor and rural areas of developing countries, and are called *neglected* because they afflict the world's poorest people and do not receive (enough) national and international attention (Hotez et al., 2014). Leprosy is a chronic infectious disease caused by the *Mycobacterium leprae* (World Health Organization, 2019b). *M.leprae* is a slowly multiplying bacillus that has an average incubation period of five years. Symptoms may occur within one year, but it may also take as long as 20 years before the onset of any clinical manifestations. Though not highly infectious, the assumed mode of transmission is through droplets during close and frequent contact with infectious, untreated people (World Health Organization, 2019b). *M.leprae* affects the peripheral nerves, skin, mucosa of the upper respiratory tract and eyes. Leprosy is a curable disease, and early treatment with multidrug therapy (MDT) greatly reduces the risk of further disability. Nevertheless, immunological reactions still occur during and after MDT and cause additional impairments in a proportion of people, despite adequate treatment. If left untreated, the progressive disease leads to permanent damage of the skin, limbs and eyes.

In 2000, leprosy was eliminated as a global public health problem, defined as less than 1 case per 10.000 population (Molyneux, 2008). The World Health Organization (WHO) targeted leprosy for elimination as public health problem through active case-finding, treatment of all new cases with MDT, and preventive community treatment (World Health Organization, 2010). However, despite the availability of treatment and case-finding strategies, leprosy remains endemic in many countries, such as Nepal, still constituting a major public health burden (Hotez et al., 2014).

## 2.2 Stigma and social participation

Visible disfigurements, together with lack of knowledge about leprosy and cultural and religious beliefs, are the primarily reason that, throughout history, affected people have been stigmatized by their families and communities (Raju and Kopparty, 1995). Visible impairments reinforce the general perception that leprosy is linked to disfigurements, as people without conspicuous signs can successfully conceal their disease (Rensen et al., 2011, Sermrittirong and van Brakel, 2014). These stigma-facilitating factors may, in turn, cause social, psychological, health and economic consequences. Affected people experience problems in finding employment, being accepted for education and using public facilities (van Brakel et al., 2012, Stevelink et al., 2011, Barrett, 2005). In addition, having someone with leprosy in the family jeopardizes the chances of one's (other) children finding a marriage partner. The determinants of stigma cause people to avoid being close to or associated with leprosy-affected persons, making it hard for them to fully engage in society. These determinants also act as reasons for affected people to isolate themselves, to avoid being hurt or discriminated against (Stevelink et al., 2011). These social consequences cause fear of discrimination and social stigma, which itself is a facilitator for stigma, making it a self-perpetuating process (van Brakel and Miranda-Galarza, 2013). The diagnosis with leprosy has a tremendous impact as well, and people affected often have psychological stress and struggle with depression and anxiety (Tsutsumi et al., 2007). They may internalize negative societal attitudes, and this internalised stigma, or self-stigma, is characterized by negative feelings about themselves, shame and maladaptive behaviour. Internalised-stigma impacts on social participation and the quality of life of affected people in a similar way to discrimination (Rensen et al., 2011, Stevelink et al., 2012b).

Another major problem with leprosy-related stigma is that people use concealment as a coping strategy, which may result in delayed diagnosis and poor adherence to treatment (Peters et al., 2014, Engelbrektsson and Subedi, 2018). In addition, other stigma-related consequences, such as shame and guilt experienced by patients, make them reluctant to use health services. In conclusion, stigmatization causes people to become 'invisible,' making it difficult for current leprosy control strategies to eliminate leprosy without first breaking the taboos (Hofstraat and van Brakel, 2016). In 2016, to reinforce efforts for leprosy control, the WHO launched the *"Global Leprosy Strategy 2016–2020: Accelerating Towards a Leprosy-free World"*, in which the fight against stigma therefore has an important place (World Health Organization, 2019a).

## 2.3 Measuring disability

Globally, NTDs occur in more than 149 countries, affecting more than a billion people. They are responsible for 500,000 to 1,000,000 deaths annually, which is considerably less than mortality rates associated with HIV, respiratory infections or diarrheal diseases (Hotez et al., 2007, World Health Organization, 2018). However, when using disability-adjusted life years (DALYs), the number of healthy life-years lost from disability, as a metric, NTDs account for approximately the same global disease burden as diarrheal diseases and malaria (Hotez et al., 2006). In addition to disability and morbidity, the stigma attached to these conditions often causes even more suffering. Together, these have a major impact on mental wellbeing and social participation, as well as reduced ability to work. For these reasons, NTDs not only typically occur among people who are poor, but they also aggravate poverty (Kindhauser and WHO, 2003). The true burden of disease and its global health impact is therefore better reflected by life-long disabilities, disfigurement, social stigma, lost educational potential and reduced economic capacity (Hotez et al., 2006, Molyneux et al., 2005).

Unfortunately, this impact is difficult to translate into a universally understood value and is not taken into account when DALYs are calculated, so the actual burden is likely to be a multiple of what is currently known.

Current strategies for fighting NTDs are primarily focused on treatment and prevention, but almost none address the lifelong consequences that come with (permanent) disability and which continue after treatment has ended (Hotez et al., 2014). In the case of leprosy, socio-economic rehabilitation and stigma reduction programmes are very important to reduce social participation restrictions experienced by people affected (Lesshafft et al., 2010). Suitable tools that are able to measure the severity of different types of disability are crucial for the advocacy and policy formulation, implementation, monitoring and evaluation of appropriate strategies aimed at reducing disability, and disability-related consequences among people affected in low and middle income countries (van Brakel and Officer, 2008, Hotez et al., 2007). Although there are several potentially suitable instruments available, the challenge with measuring disability is that many tools differ in how they conceptualize construct such as stigma and social participation. In addition, the way disability is understood varies in different cultures, so it cannot be assumed that these tools are valid in each culture (Stevelink and van Brakel, 2013). This makes it difficult to compare outcomes, demanding a more universal approach for measuring disability.

### NTD Morbidity and Disability Toolkit

Answering to this demand, van 't Noordende et al. (2016), together with an expert panel, developed a toolkit to assess, monitor and evaluate disability and morbidity caused by NTDs. This cross-NTD Morbidity and Disability (NMD) toolkit is based on the assumption that the majority of NTDs share similarities with regard to their disabling and stigmatizing aspects. The selection of instruments for inclusion in the NMD toolkit is based on the WHO's International Classification of Functioning, Disability and Health (ICF) framework. This framework classifies problems in six health and health-related domains and can be used to describe, compare and measure health and disability at different levels (World Health Organization, 2002). The instruments included in the NMD toolkit cover all the domains of the ICF framework, except for the health conditions themselves.

The acceptability and relevance of the toolkit for several NTDs was assessed in Northern Brazil and was considered good (van 't Noordende et al., 2016). To date, several studies have translated some of the tools included into a range of languages and cross-culturally validated their use in several cultures, but much work is still to be done. Two tools, the 5-Question Stigma Indicator for Affected

Persons and the Participation Scale Short Simplified, are recent additions, and have not been translated and validated in Nepal yet.

### The 5-Question Stigma Indicator

The 5-QSI-AP was developed by Van Brakel as a short and easy tool to assess and monitor the level of stigma perceived by leprosy-affected people. The WHO referred to it as an easy to use questionnaire for stigma assessment in the suggested actions section of the *"Global Leprosy Strategy 2016–2020: Accelerating Towards a Leprosy-free World."* (World Health Organization, 2019a). The 5-QSI-AP relates to the "environmental factors domain" of the ICF framework, and covers life areas commonly affected by stigma, including work, pity and shame, disclosure concerns, avoidance, and impact on marriage or marital prospects (Rensen et al., 2011). It was initially developed in English, and is comprised of five questions from other instruments that are most commonly endorsed, notably the Explanatory Model Interview Catalogue (EMIC) stigma scale (Weiss, 1997). When the respondents provided a "never" or "do not know" answer, zero points are given. For the answer "sometimes" one point is awarded, and for "often," two points. The answers are combined for a total response score ranging from 0-10. The higher the score, the higher the level of stigma experienced by people affected. The English version of the 5-QSI-AP and its Nepali translation used in this study are presented in *Appendix 1* and *Appendix 2*.

### The Participation Scale Short Simplified

The original Participation Scale (P-Scale) was developed in the study by Van Brakel et al. (2006), and is a generic tool that measures (social) participation for use in rehabilitation, stigma reduction and social integration programmes. It is based on the "participation domain" of the ICF framework, which classifies "problems an individual may experience in involvement in life situations" as 'participation restrictions' (World Health Organization, 2002). The items cover different aspects of social participation, aimed at comparing the degree of social participation of individuals to the perceived degree of social participation of 'their peer'. In 2012, the Participation Scale was abbreviated to a 13-item version called the "Participation Scale Short" (PSS; P-Scale Short) and structurally validated in several languages (Stevelink et al., 2012a). Last year, the generic P-Scale Short was successfully modified to the "Participation Scale Short Simplified" (PSSS) and validated in Indonesia (Coltof, 2019). This included a switch from the concept of 'peer', for which many languages have no word, to the concept 'others' to facilitate a more generic comparison, and to simplify the two-level question structure. All questions are closed, with six different answer options: "Easy," "A bit difficult," "Difficult," "Very difficult," "Irrelevant" and "Not specified/answered." To each answer a value of, respectively, 4, 2, 1 or 0 is assigned. This provides a maximum sum score of 52; the higher the sum score, the higher the severity of social participation restrictions experienced by people suffering from a disability such as leprosy. The English version of the PSSS and its Nepali translation used in this study are presented in *Appendix 3* and *Appendix 4*.

## 2.4 Socio-demographic data of the research area

Nepal is one of the least developed and poorest countries in the world, with approximately half of its population living near or below the poverty threshold. In 2011, the population counted 26.6 million people of many various ethnic and caste groups. The leading religion in Nepal is Hinduism (80%), followed by Buddhism, Islam and a growing number of Christians. According to the 2011 national consensus, approximately 123 local languages are spoken. The official language "Nepali" is clearly leading (44.6%) and followed by Maithili (11.7%) (Central Bureau of Statistics, 2011). Although the caste system has been legally irrelevant since the 60's, it still forms the foundation for understanding one's own basic identity and greatly determines your opportunities in live. In addition, gender also plays an important role in the Hindu society, and women are traditionally seen as inferior (Engelbrektsson, 2012).

Nepal is a naturally hilly country that is ecologically divided into three regions: the Terai, Hill and Mountain region. Anandaban Hospital, were the research was performed, is located in the Hill region, around 16km north of Kathmandu city. It is the main referral leprosy hospital in Nepal and also serves some of the Indian population. Apart from its leprosy care, it also provides basic medical care to the surrounding communities. It is highly specialized, and the only places that provides reconstructive surgeries, rehabilitation and disability-prevention support. The hospital also runs a weekly outpatient clinic in the city, which provides diagnosis and treatment as well as community-based rehabilitation programmes.

### Leprosy in Nepal

The most important factors in leprosy-related stigma in Nepal are the fear of infection, the belief that people affected are unclean, and the belief that it is a curse from the gods or bad karma due to misconduct in a previous life (Engelbrektsson and Subedi, 2018, Sermrittirong and van Brakel, 2014). Community members may not allow leprosy-affected people to wash in communal water, even when they have been treated and are not infectious anymore (Rafferty, 2005). Leprosy-related stigmatization and social exclusion do not only impact the quality of life of persons affected by the disease, but they may also result in tremendous economics and socials costs for their families and for the Nepali society as a whole (Gyapong et al., 2016, Hotez et al., 2014, Mieras et al., 2016, Molyneux et al., 2005, Tsutsumi et al., 2007). In Nepal, there are more registered leprosy cases among men compared to females. Possible explanations for this are the greater mobility of men, which increases the risk of exposure, and their higher literacy rates, making them more easy informed (Engelbrektsson, 2012).

# 3 Conceptual framework

## 3.1 Theoretical framework for cultural equivalence

This study aimed to perform a cross-cultural validation of the 5-QSI-AP and PSSS in the Kathmandu valley, Nepal. The majority of the Health-Related Quality of Life (HRQoL) instruments are developed in only one culture and they need to be translated and adapted in order for them to be used in different cultures. This is important because the understanding of concepts such as stigma, disability, social participation and quality of life varies in different cultures (Stevelink and van Brakel, 2013). Herdman et al. (1998) recommended researchers to adopt a universalist approach to cross-cultural research of HRQoL instruments. This approach emphasizes the need to establish whether a certain concept actually exists, and whether it is interpreted similarly, in the two cultures. In order to reflect the universalist view, Herdman developed a "model of equivalence." This model highlights important types of equivalence and how to test them, in order to come up with a culturally valid instrument that has a comparable level of equivalence with the original version. This framework has been widely used as a guide for the cross-cultural translation and adaption of HRQoL and other measurement instruments. The framework consists of the following five types of equivalence: conceptual, item, semantic, operational and measurement. The extent to which these five types of equivalence are addressed determines the degree to which "functional or cultural equivalence" is achieved (see *Figure 1*.)

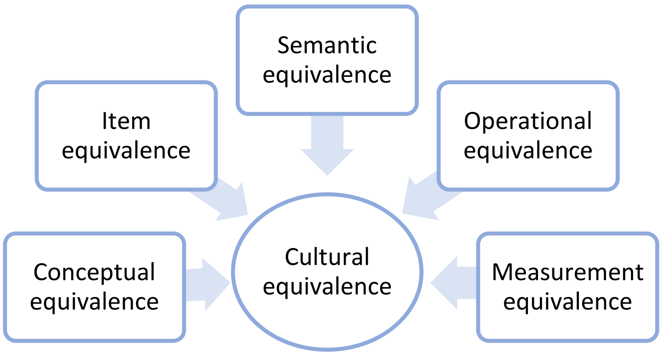

**Figure 1.** Herdman's model of equivalence for the cultural translation and adaptation of Health-Related Quality of Life instrument (Herdman et al., 1998).

Stevelink and van Brakel (2013) adapted Herdman's framework in a review describing the need for cultural equivalence of instruments across cultures. They defined "cultural equivalence" as "the extent to which an instrument is equally suitable for use in two or more cultures." In this review, they combined cultural equivalence and measurement insights, and provided a guideline for achieving cultural validity of measurement instruments. The definition of the types of equivalence and the different ways to assess them are listed in *Table 1*.

**Table 1.** Herdman's framework for 'cultural equivalence', adapted by Stevelink & van Brakel (Herdman et al., 1998, Stevelink and van Brakel, 2013).

| Validity | Definition | Sub-categories (ways to assess) |
|---|---|---|
| Conceptual | *"The questionnaire has the same relationship to the underlying concept in both cultures"* | - Local population's conceptualization<br>- Appropriateness of the measure<br>- Theoretical arguments questioning or accepting conceptual validity |
| Semantic | *"The transfer of meaning across languages must be preserved and understanding of the items in the instrument"* | - Translation procedure<br>- Meaning of key words and phrases |
| Item | *"Equal relevance and acceptability of items in different cultures"* | - Assessment of the relevance and acceptability<br>- Discussions of the findings on relevance and acceptability<br>- Well-argued adaptations made of items |
| Operational | *"The possibility to use the similar format, response scales, instructions and mode of administration and measurement methods"* | - Assessment on missing data<br>- Administration format<br>- Pilot/Pre-testing |
| Measurement | *"The psychometric properties must be valid in the original and adapted instrument"* | - Content validity<br>- Construct validity<br>- Criterion validity<br>- Internal consistency<br>- Reproducibility<br>- Interpretability<br>- Floor and ceiling effects |

## 3.2 Translation and adaption of the health measures

For a questionnaire to be used in a different culture, it first needs to be properly translated. The cultural equivalence model of Stevelink and van Brakel acts as a guide that addresses all the important aspects that construct a 'good cross-cultural validation'. However, it says nothing about the method of translation and adaptation. There are many guidelines proposing strategies for a 'valid translation', such as those recommended by the WHO, which consists of the following four phases: 1) forward translation, 2) back translation, 3) expert review/ cognitive interviewing and 4) pre-final testing (World Health Organization, 2014).

## 3.3 Conceptual Model

This study combined the framework of Stevelink and van Brakel with the translation procedure recommend by the WHO. Since the 5-QSI-AP and PSSS are derived from EMIC Stigma Scale and generic P-scale, respectively, neither of the modified scales was ever validated in English. Hence, since this study does not compare to another validated version of the same instrument, we used the term 'validity' instead of 'equivalence'. The different types of validity and ways to assess them functioned as a guide for the translation and adaption of the two tools used in this study (*Table 1*).

This study consisted of three parts. In the first part, both the 5-QSI-AP and PSSS were translated into Nepali and then back again into English to ensure an adequate conceptual translation. The second part entailed interviews to assess the conceptual, item, semantic and operational validity of the two tools. In the third, quantitative, part, the final (revised) version of the tools were pilot-tested in the target population to evaluate the measurement validity. See methods for a detailed description of each part. *Figure 2* presents a schematic visualisation of the different parts of this study.

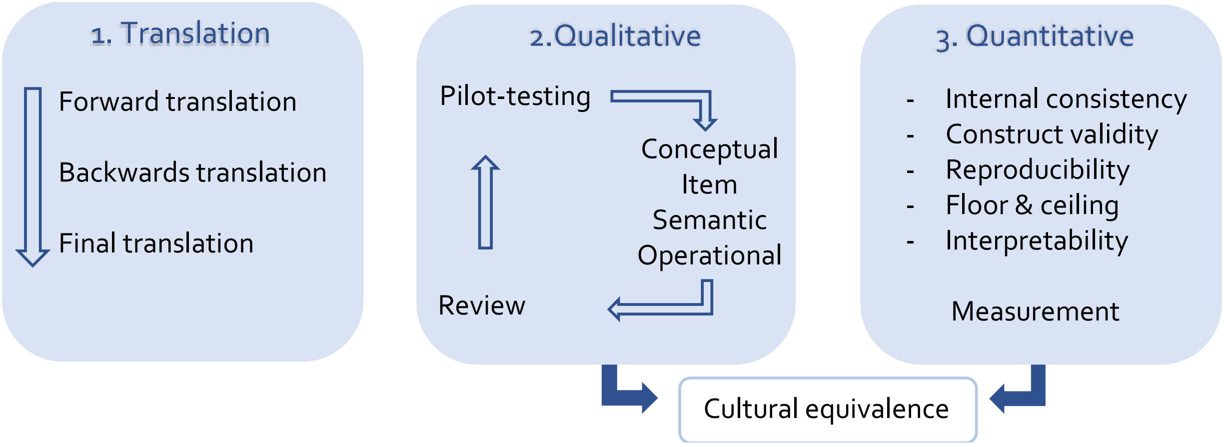

**Figure 2.** Conceptual model of this study based on the translation framework of the WHO and the model for cultural equivalence of Stevelink & van Brakel. The five types of equivalence are assessed in the qualitative and quantitative part of this study in order to achieve 'cultural equivalence'.

### Conceptual validity

Conceptual validity indicates whether an instrument is suitable for translation. This is essential, and should be assessed first in order to prevent potential operationalisation and measurement problems (Stevelink and van Brakel, 2013). In this study, the conceptual validity of the PSSS was not extensively tested. The concept of participation has already been widely examined in the Nepalese culture, as the P-scale was originally co-developed in Nepal (van Brakel et al., 2006). In addition, the P-scale, and thus the PSSS, was developed based on the participation component of the ICF, which encompasses almost all aspects of participation.

### Semantic validity

Semantic validity concerns "the transfer of meaning across languages" and the aim is to achieve a similar effect in different languages. It is important that the respondents understand the items on both the 5-QSI-AP and PSSS without rephrasing and/or use of additional examples. According to Herdman et al. (1998), a major challenge when translating HRQoL instruments is establishing the true meaning of words, phrases and items as they were initially intended. Problems may arise such as: confused respondents, insufficient reflection of the initial meaning behind the items and difficulties in administration of the scale. This study addressed both sub-categories of semantic validity (*Table 1*). First, an adequate and detailed translation and adaptation procedure can be ensured by following the recommendations of the World Health Organization (2014). Second, a common way to assess the initial meaning of keywords and phrases is to ask respondents to paraphrase each of the items on the questionnaires.

### Item validity

Item equivalence refers to the relevance and acceptability of items in the questionnaires with regard to the concepts of interest, social participation and stigma in this study, as this may vary across different cultures (World Health Organization, 2011). According to Herdman et al. (1998), item equivalence is achieved whenever "the items are equally relevant and acceptable in both cultures." The most common way to examine this is by asking the target population about their perception of the importance and acceptability of the items of the instruments. Since this is the first formal validation of the 5-QSI-AP it was not possible to make a comparison with other cultures. Therefore, this study uses the following definition: "The items are relevant and acceptable in the culture of interest."

### Operational validity

Operational validity concerns the administration format of the questionnaire, including the response scale instructions. Misunderstanding of the response-scale and/or framing of the items can lead to useless results as they do not reflect the real view of the participants (Stevelink and van Brakel, 2013). Pilot-testing of the questionnaire and asking the participants about the ease of understanding of the items and the response scales would ensure that the tool is tailored to the needs of the target population.

### Measurement validity

For the detailed assessment of measurement validity, Stevelink and van Brakel (2013) included a range of "quality criteria for measurement properties of health status questionnaires," as proposed by Terwee et al. (2007). It is important to assess these psychometrics, as they demonstrate whether the 5-QSI-AP and PSSS are able to accurately and reliably assess stigma and social participation, respectively. Which psychometric properties to test depends on the measurement aim of the tool of interest, and the ones used in this study are described in *Table 2*. Two psychometric properties are omitted in *Table 2*. First is construct validity: although it is assessed in this study, it cannot be considered a quantitative property, as it merely relates to the theoretical content of the concept under investigation. Second, responsiveness was excluded, as this is a measure of longitudinal validity, while this study has a cross-sectional design (Herdman et al., 1998).

***Table 2.*** Quality criteria for measurement properties of Health-Related Quality of Life questionnaires (Terwee et al., 2007)

| Property | Definition | Quality criteria |
|---|---|---|
| Internal consistency | *"The extent to which items in a scale are interrelated, thus measuring the same construct"* | - Factor analyses performed on adequate sample size (7 X (n) items and >100), and<br>- Cronbach's alpha(s) between 0.70 and 0.95. |
| Criterion validity | *"The extent to which scores on a particular questionnaire relate to a gold standard."* | - Convincing arguments that the gold standard is indeed ''gold''<br>- Correlation with gold standard >0.70<br>- Acceptable sensitivity and specificity |
| Construct validity | *"The extent to which scores on a particular questionnaire relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured"* | - Specific hypotheses were formulated, and<br>- At least 75% of the results are in accordance with these hypotheses. |
| Reproducibility | | |
| 1. Agreement | *"The extent to which the scores on repeated measures are close to each other"* | - MIC < SDC OR<br>- Convincing arguments that agreement is acceptable |
| 2. Reliability | *"The extent to which repeated measures provide similar answers"* | - ICC or weighted Kappa>0.70. |
| Floor and ceiling effects | *"The number of respondents who achieved the lowest or highest possible score"* | - <15% of the respondents achieved the highest or lowest possible scores. |
| Interpretability | *"The degree to which one can assign qualitative meaning to quantitative scores"* | - Mean, SD scores and 95% CI presented for at least four relevant subgroups of patients. |

CI = 95% Confidence Interval; ICC= Intraclass correlation; SEM = Standard Error of Measurement; SD= Standard deviation; SDC= Smallest detectable change.

# 4 Objective and research questions

### Overall objective

This study aims to contribute to the development, implementation and evaluation of appropriate stigma reduction, rehabilitation and other interventions for persons affected by leprosy and so reduce leprosy-related stigma in Nepal. In addition, we aim to enhance data collection to support advocacy and funding to reduce stigma related to leprosy and other NTDs.

### Specific objective(s)

The objective of this study is to assess to extent to which the 5-QSI-AP and the PSSS are culturally valid to assess leprosy-related stigma and the degree of participation restriction experienced by leprosy-affected people in the Kathmandu valley, Nepal.

### Research questions

The following main research question was formulated:

*"How valid are the 5-QSI-AP and PSSS among people affected by leprosy in Nepal?"*

Following the theoretical framework proposed by Stevelink and Brakel, several sub-questions, addressing the different types of equivalence, are formulated in order to answer the main question.

1. Conceptual – Do both cultures conceptualise stigma and social participation in similar ways?
2. Semantic – Has the true meaning of the items in the questionnaires been adequately translated and do respondents understand the items well?
3. Item – Are the items of the two tools relevant and acceptable to the respondents?
4. Operational – To what extent is the same format applicable in Nepal?
5. Measurement – Do the instruments have adequate psychometric properties compared to international standards?

# 5 Methods

## 5.1 Study design

The different types of validity described and the ways to assess them functioned as a guide for the translation and adaption of the two tools of this study (*Table 1*). They were investigated in the first qualitative phase, while adapting the instrument to the culture, and in the second quantitative phase of the cultural validation. We can therefore say that this study has a cross-sectional, within-person comparative, exploratory study design, with a mixed-methods approach.

## 5.2 Study population and sample

The study population of both the qualitative and quantitative part of this study were chosen based on the same inclusion and exclusion criteria.

Who is eligible?

- Persons (temporarily) residing in the Kathmandu Valley, Nepal
- Persons over the age of 18
- Persons affected by leprosy
- Persons who can answer the questions independently

Who is not eligible?

- Persons who refuse to provide (informed) consent
- Persons not able to communicate in Nepali

## 5.3 Sample size and method

Data collection took place in the Kathmandu valley, Nepal, from May until July 2019. Data was mainly collected at the Anandaban Hospital, the Patan outpatient clinic and the Kokhana leprosy colony. For the qualitative part, eight semi-structured interviews with persons affected by leprosy were conducted. All were recruited at the Anandaban Hospital. The sample size of the quantitative part was calculated following the rule proposed by Terwee et al. (2007): In order to determine the internal consistency, analysis should be performed on an adequate sample of 7 times [number of items on the scale of interest] participants, with a minimum of 100. The PSSS is the longest of the two scales and includes a total of 13 items, resulting in a required minimum of 100 participants. Persons with impairments across the range of severity were included, as the severity of the impairments was expected to correlate with experienced stigma and the extent of restriction in social participation (Rensen et al., 2011, Brouwers et al., 2011). The severity of impairment was determined according to the WHO's Eyes, Hand and Feet (EHF) score, which grades each individual eye, hand and foot on the visibility of impairments (van Brakel et al., 1999). Severity is scored as: 0: no visible impairment, no sensory impairment or vision loss; 1: no visible disfigurement or wounds, presence of anaesthesia and mild eye problems without loss of vision; and 2: presence of visible impairment and severe loss of vision. The total EHF score ranges between 0 – 12.

Within the hospital, clinic and leprosy colony, a convenience sampling approach was used to retrieve both participants and controls, followed by purposive sampling. By using a convenience sampling approach, this study aimed to locate controls with roughly similar demographic characteristics as the cases (Gray, 2013). The purposeful sampling approach aimed to reach an equal proportion of men and women, ensuring the study's representativeness for both populations. Inclusion of the control group (n=50) was necessary for interpretability and to calculate a cut-off for 'normal participation' for the PSSS (Terwee et al., 2007).

## 5.4 Interviews

Prior to all interviews, the purpose of the interview was explained, and informed consent was obtained (*Appendix 7*). Next, socio-demographic information was collected using the personal information form (*Appendix 8*). The whole procedure of the semi-structured interviews can be found in *Appendix 9*. The interviewer verbally explained the purpose of the interview, the two tools and their answer options to the respondents in a way similar to the English version. For the PSS and PSSS, people need to compare themselves to 'a peer' or to 'other people,' respectively. To ensure that both reflect the same meaning, the interviewer explained to all respondent that they should compare themselves with people who are similar to them in respect of age, socio-cultural, economic and demographic factors, except that they do not have leprosy.

The researcher, together with a Nepali interpreter trained in interviewing, and with experience and knowledge of working with people affected by leprosy, conducted the semi-structured interviews. The interviews were done in Nepali, and after each question the interpreter would repeat exactly what the respondent had answered in English. All interviews were voice recorded, and contemporaneous observation notes were taken by the researcher as well. A different interpreter was used for administration of the questionnaires. The data was handled anonymously through the assignment of a unique interview number.

## 5.5 Qualitative study

### Technical methods

#### *Translation and adaption of the 5-QSI-AP and PSSS*

The first step in this procedure was forward translation of the 5-QSI-AP and PSSS from English to Nepali. This translation was done by a professional with significant experience in the field of leprosy and leprosy-related stigma. To ensure a valid and accurate translation, the emphasis was on a conceptual rather than the literal translation of the questionnaires. The second step was the back translation, which was done by someone with little knowledge about leprosy-related stigma (World Health Organization, 2014). Both versions were compared, and any dissimilarities were discussed with the translators, interpreter and other hospital staff involved.

#### *Semi-structured interviews*

The qualitative part of this study addressed the conceptual, semantic, item and operational validity. Eight semi-structured interviews of approximately 30-60 minutes were conducted with people affected by leprosy to explore their perceptions and beliefs regarding their disease, stigma and restrictions in social participation. The obtained information was analysed and discussed with the interpreter and researchers, and revisions were made. With respect to the process of translation, and the assessment of the several types of validity, it is important to mention that the adaptations followed an iterative process, meaning that changes were continuously made whenever required.

### Outcome measures

The outcomes for the qualitative part were the conceptual, item, semantic and operational validity. Conceptual validity was assessed in the first part of the SSI1 (*Appendix 9*, SSI1) by gathering information about the participant's perception of and experiences with leprosy. The second part of the SSI1 (*Appendix 9*, SSI1) assessed item, semantic and operational validity. Here, the outcome was information gathered through the comments of the respondents on the individual items/questions and response scale of the 5-QSI-AP and PSSS.

### Data management and analysis

The conceptual content of the interviews was analysed with the help of ATLAS.ti software (version 8.4.3 (1077), ATLAS.ti Scientific Software Development GmbH). All responses were assessed for significance and coded if considered useful. The main findings were discussed with the interpreter to verify that the results had been placed in the correct context. For the item, semantic and operational analysis, data was managed using Excel (version 16.29, Microsoft). The data was divided into the five items of the 5-QSI-AP and the 13 items of the PSSS. A directed content analysis, using a coding tree based on the framework of cultural equivalence, objectively and systematically classified the content in sub-categories.

## 5.6 Quantitative study

### Technical methods

#### *Questionnaires*

The quantitative part of this study assessed the measurement validity of both questionnaires, by testing whether they comply with the quality criteria of good psychometric properties of health measurement tools (*Table 2*). The generic PSS was included to test criterion validity (*Appendix 5* and *Appendix 6*). Repeated measures in approximately half of all cases, a minimum of two weeks later, was needed to evaluate the reproducibility. The questionnaires were administered in an interview-based manner, and took 10-20 minutes [see *Appendix 9*: SSI2. Interview guide).

### Outcome measures

The following psychometric properties were measured: Criterion validity, construct validity, internal consistency, floor and ceiling effects, reproducibility and interpretability. For these measurements, we used the following quality criteria:

- The *criterion validity* of the PSSS was assessed by comparing it to the PSS (golden standard) using two methods. 1) A Spearman's test where $\rho$>0.70 is considered acceptable. 2) By calculating the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). The optimal cut-off score for 'normal participation' of both the PSS and the PSSS was calculated using the 95th percentile of the scores of the normative group. Another way used to determine the optimal cut-off of the PSSS was by a ROC-curve.
- *Construct validity* was determined by assessing the predefined hypotheses described below. The instruments were compared with each other as well as with the generic PSS for a positive correlation. As the response scale of both questionnaires is a rank order (ordinal scale), the appropriate test to use is the Spearman's Rank-Order Correlation test (rho ($\rho$)). The outcome of this test ranges between 0 and (-)1, where 1 indicates an excellent and 0 a poor correlation between the items of both instruments (Swank and Mullen, 2017). A significant coefficient means that the hypothesis is confirmed. Construct validity is achieved when, per instrument, more than 75% of the hypothesis are confirmed (Terwee et al., 2007).

***Hypotheses***

1) The PSSS median score is significantly higher among leprosy-affected people than among controls.
2) The PSSS and PSS have a positive correlation, $\rho$ = > 0.70
3) The 5-QSI-AP positively correlates with the PSSS, $\rho$ = 0.40 – 0.80.
4) The 5-QSI-AP positively correlates with the PSS, $\rho$ = 0.40 – 0.80.
5) People with a higher EHF score have a significantly higher sum scores of both the 5-QSI-AP and PSSS, $\rho$ = 0.40 – 0.80.

- The *internal consistency* was explored by calculating the Cronbach's alpha. An alpha between 0.70 and 0.95 is considered optimal.
- *Floor and ceiling effects* were assessed by measuring the prevalence of the lowest and highest score possible among the respondents. It is considered present when more than 15% of the respondents achieve either the lowest or highest possible score.
- *Reproducibility* of the questionnaires was investigated by measuring the reliability and agreement.
  - *Reliability* was determined using an intra-class correlation coefficient ($ICC_{agreement}$). A coefficient >0.7 can be considered as good reliable.
  - *Agreement* is tested by calculating 1) the Standard Error of Measurement (SEM) using the formula $SEM_{agreement} = \sqrt{\sigma^2_{errors}}$, 2) the Smallest Detectable Change in one individual ($SDC_{individual}$) using the formula $1.96*\sqrt{2}*SEM$, 3) the SDC in the group ($SDC_{group}$) by dividing the $SDC_{individual}$ by $\sqrt{n}$, and 4) the Bland and Altman limits of agreement, which equals the $mean_{difference} \pm 1.96*SD_{difference}$.
- For the *interpretability* of the PSSS and 5-QSI-AP, the median and the Interquartile Range (IQR) of the score for the following five subgroups were calculated: Age, gender, marital status, education and EHF score. For the PSSS, the scores of the control group were calculated as well.

### Data management and analysis

All personal information and data were entered and managed in Excel (version 16.29, Microsoft). Statistical analyses were carried out using STATA (version 16.0, StataCorp). Missing data was handled as followed: a questionnaire would be excluded when more than 10% of the items on the scale was identified as missing.

## 5.7 Ethical considerations

Before initiation of research activities, ethical approval was obtained from the Ethics Research Board of the Nepal Health Research Council (Proposal ID: 346 - 2019). Prior to all interviews, participants were orally informed about the objective of the research and methods used. The participants were made aware of their rights and asked to provide written informed consent. The management of data was done anonymously by assigning a code to the participant’s questionnaire and interview transcripts.

# 6 Qualitative results

This chapter will first describe the socio-demographic characteristics of the participants. Thereafter, the results of the interviews are reported, following the framework of cultural equivalence.

## 6.1 Socio-demographic characteristics

The socio-demographic characteristics of the participants can be found in *Appendix 9*. In total, eight participants were interviewed with the PSSS and 5-QSI-AP. The population was unequally divided between men (n=6) and women (n=2). They were aged between 19 and 51 years of age and the majority were Hindu. Of the participants, half were married, and the rest were either unmarried (n=2) or widowed (n=2). Two participants were uneducated, five finished primary school and only one participant attended secondary school. Finally, there was an equal distribution between participants with and without visible signs of the disease.

## 6.2 Conceptual validity

The conceptual validity was briefly explored by asking the participants about their perceptions, beliefs and experiences regarding their disease, leprosy-related stigma and leprosy-related restrictions in social participation.

### Effects of having Leprosy

Open questions led to a conversation about the effects of having leprosy and we started with asking what the first things was that came into their mind when they heard they had been diagnosed with leprosy. Four people mentioned that they never heard of leprosy before:

> *"I never heard of leprosy before and all of the sudden I was diagnosed with leprosy."* (female, 32)

The main thing mentioned was that they were worried and scared after the diagnosis because of stigmatization, physical changes and not being able to continue life as before. They saw leprosy as a socially unacceptable disease, and one respondent referred to it as "*a disease of hate*" (male, 50). Three participants reported that they concealed their disease from their family and/or community because of fear of misunderstanding and hate:

> *"I still have not told my elder daughter that I am affected. She was getting married I did not want to tell her because I was afraid, she would get rejected by the parents of her husband. Now they are already married but I still have not told her." (*male, 41)

All respondent experienced social exclusion and discrimination because of misunderstandings of the cause and mode of transmission. They experienced this within their families, communities or both and this has an impact on how the respondents feel about themselves:

> *"I feel bad about how other people feel towards me, I sleep badly and sometimes I cry."* (male, 50)

> *"I have a lot of anxiety because of leprosy and the reactions."* (female, 32)

Another factor that has a big impact on the respondent's state of mind is the loss of ability to participate in life. Not only due to stigmatization, but also because of physical barriers and hospitalizations:

> *"How will my life go just sitting here all day without being able to work, how do I continue my life in this situation. I am the only person to earn money for the family and because of the leprosy I cannot work and earn money and it feels like a burden to me."* (male, 35)

> *"I cannot go outside as freely as I could before I had leprosy. I cannot participate as freely in social events as before. This made and still makes me emotionally feel down and makes me feel frustrated."* (male, 41)

> *"From the inside I am afraid that I am not able to work."* (female, 41)

**Stigma and discrimination**

All people mentioned that leprosy is very stigmatized, and one woman said:

> *"I do not like the word 'leprosy', it scares me hearing the word. It is a negative word, stigmatized word."* (female, 32)

The general consensus is that a lack of education and knowledge facilitates stigmatization. However, one respondent mentioned the following:

> *"Even educated people are involved in stigmatization and isolate infected people. I have problems with my friends, they hide me, isolate me and do not come near me. Even though the majority studied they will not talk to me and come near me. They are afraid to get infected." (male, 19)*

The main underlying concepts of stigma reported in the interviews were: exclusion, avoidance and concealment. Within the life area of avoidance, four respondents reported that they experience stigma as not being able to use the same plates, water etc. as the rest of the family does:

> *"I feel like my maternal family discriminates me, I feel this when we have food at festivals or something like that. I am hurt by my maternal relatives. My brother and my sister in law washed my plate and cup in different water." (female, 41)*

In addition, all respondent experienced some type of avoidance and exclusion, mainly because of fear of infection and the sight of the disability:

> *"When I walk in the village area other people will not use that road for some period because they think it is contaminated."* (male, 50)

*"People are scared to come to hospital and see the patients."* (male, 41)

Acceptance of having leprosy by their environment was reported as using the same things, being taken care of, experiencing no restrictions in social participation etc.:

> *"In my community everybody eats what I cook."* (female, 41)

> *"My landlord let me live in my [her] house and also the person I work for wants me to come back."* (female, 32)

As explained earlier, stigmatization occurs is different ways and does not always have to be obvious as in the examples described above:

> *"People behave differently, not in their words but from the inside. I feel it within my family and community."* (female, 32)

## 6.3 Translation process

Before the questionnaires were pilot tested, several steps were taken with the involvement of multiple leprosy professionals to ensure an adequate translation of good quality. First, the English version of the 5-QSI-AP and PSSS was translated into Nepali by a senior researcher of the Mycobacterium Research Laboratory of the Anandaban Hospital. In addition, the PSS was not yet available in the Nepali language and was developed using the original P-Scale, as these two scales use the same wording. In the translation process, emphasis was put on the use of simple language and the conceptual translation of words rather than the literal. The back translation was done by someone with little experience in leprosy research. The original version and back-translated English version were compared for differences by the researcher and a random outsider. A new version was created which was tested and optimized in eight qualitative interviews.

The original English version of the PSSS uses "compared to other people" in almost each of the questions. However, the back-translated version showed that the questions were translated in Nepali to "compared to friends." It was decided to use "compared to other people." Furthermore, Q10 of the PSSS asks how easy it for people is to visit public places in their village/neighbourhood. For "visit" the Nepali word "*brahaman*" was used, which means to travel, traveling somewhere, and implies a far distance. Therefore, it was decided to use the word "*jana,*" which means to go, and better reflects the concept of a visit. For the 5-QSI-AP no adjustments were necessary.

## 6.4 Semantic Validity

To ensure semantic validity, we asked the respondents to rephrase the items of the questionnaire and if any words were unclear to them. None of the respondents experienced difficulties in understanding the questions of the 5-QSI-AP. For the PSSS, Q8, Q9 and Q10 ask whether it is easy for people to visit other places or roam around in the community, which caused for some confusion. Restrictions in this area can be caused by social discomfort or physical impairments and for some participants it was unclear how to answer these questions. Furthermore, one respondent (male, 52) did not understand the word "*salhas*" ("easy") used in Q10; "*compared to other people, how easy is it for you to visit public places in your village/neighbourhood? (e.g. schools, shops, offices, market and tea/coffee shops)*". "*Salhas*" is a more formal word and when using the casual variant "*Sajilo*" the question became clear. However, "*salhas*" was used in other questions before as well where the respondent had no problems with understanding. Because other respondents had no problems with this word it was decided not to change it.

## 6.5 Item validity

The item validity of the questions of the 5-QSI-AP and PSSS was assessed by asking the respondents whether they felt uncomfortable answering any of the questions, and whether they considered them as relevant/important to their personal situation.

*5-QSI-AP*

All respondents considered the items on the 5-QSI-AP important and in this context one respondent said: "*These questions touch my life,"* (male, 35). All questions were considered relevant except for one question for one respondent. One female (41) reported that Q4, "*Have you had problems getting married / in your marriage because of having (had) leprosy?,"* was not relevant for her as she was widowed.

*PSSS*

All respondents considered the items relevant and important with the exception of Q6, "*Compared to other people, how easy is it for you to take part in social activities? (e.g. in sports, chat, meetings, religious or community activities)".* Both female respondents answered with irrelevant because they consider this more an activity for men. We consulted a few more women and asked them what they consider as an important and relevant activity, on which they answered with singing or dancing. Therefore, we added the word "*nachaan*" (meaning both dancing and singing) to the question.

## 6.6 Operational validity

Testing the format and design of the 5-QSI-AP and PSSS is crucial to ensure operational validity. In general, all interviewees understood the questionnaires and they reported no difficulties or remarks when asked at the end of the interview. The only aspect that led to some confusion was the two-level questions structure of the PSS (included as golden standard). Furthermore, none of the respondents had difficulties comparing themselves to other people and used different people for different questions. The duration of an interview, including both scales and additional validity questions, varied from 18 to 45 minutes with an average of 30 minutes. Some respondents felt that the interview was a bit long. This was mainly because the respondents felt like they needed to answer each question on the PSSS and 5-QSI-AP with a personal story. We decided to explicitly mention to the respondents that they did not have to explain their answers to the question. This showed some improvement in the administration time, although some respondents still had the tendency tell their story.

# 7 Quantitative results

## 7.1 Socio-demographic characteristics

After revision of the tools, a total of 110 people affected by leprosy, and 50 people without leprosy or any other disability were interviewed in May and June 2019. See *Appendix 11* for the socio-demographic data. The cases and controls showed similar characteristics except for the level of education. The control population was significantly higher educated (secondary education or higher) compared to the people affected by leprosy, 50% vs. 22%, respectively. The average interview time was 3.5 minutes for the PSSS and 4.1 for the PSS.

## 7.2 Measurement equivalence

### PSSS

***Criterion validity***

First, a Spearman's correlation was run to assess the relationship between the PSS and the PSSS in a sample of 110 people affected by leprosy. The PSS and PSSS showed a strong positive correlation, which was statistically significant, rho = .817, $p$ = .0000. Second, the sensitivity and specificity were calculated. The 95th percentile of the normative group represents a score of 16 for the PSSS and 14 for the PSS. This means that a score of 14 for the PSS and 16 for the PSSS can be used as cut-off score to differentiate between 'restriction' and 'no restriction'. Two-by-two table analyses using the cut-off score 14 for the PSS and 16 for the PSSS resulted in a sensitivity and specificity of 0.71 and 0.98, respectively. The PPV was 0.98 and the NPV 0.72 (*Table 3*). The normative scores of the PSSS are not normally distributed and have a high standard deviation (4.88). Therefore, an additional analysis, using a ROC-curve, calculated that the sensitivity and specificity of the PSSS were found optimal at the cut-off value 12. The sensitivity was 0.86 and the specificity 0.92. PPV and NPV were 0.93 and 0.81, respectively (T*able 3*).

**Table 3.** The sensitivity and specificity of the PSSS against the PSS.

| PSS cut-off value 14 | | | | |
|---|---|---|---|---|
| Cut-off score 12 | | + | - | Total |
| PSSS | + | 45 | 1 | 46 |
| | - | 18 | 46 | 64 |
| | Total | 63 | 47 | |
| Cut-off score 16 | | | | |
| PSSS | | + | - | Total |
| | + | 53 | 4 | 57 |
| | - | 10 | 43 | 53 |
| | Total | 63 | 47 | |

***Construct validity***

For the PSSS, four pre-defined hypotheses were tested. The first hypothesis, that the PSS and PSSS show a strong positive correlation, has already been confirmed in the previous paragraph. Second, the median score of the PSSS for the case group (14) was indeed significantly higher than that of the control group (5), $p$ = .0000. Third, a Spearman's correlation showed a positive and statistically significant correlation (rho = .524, $p$ = .0000) between the 5-QSI-AP and the PSSS. Finally, a Spearman's correlation was run in a sample of 104 people affected by leprosy between the EHF and PSSS scores. This showed a weak correlation, which was not statistically significant, rho = .1704, $p$ = .0837

### *Floor and ceiling effects*

No floor or ceiling effects were detected. None of the respondents scored the highest score (65), and only 1.8% (n=2) scored 0.

### *Internal consistency*

A Cronbach's alpha of 0.87 was measured which can be considered optimal. The corrected item to total correlation ranged between 0.472 and 0.748, and none of the items of the PSSS raised the total Cronbach's alpha when deleted. Results for the PSSS are displayed in *Table 4*.

**Table 4.** Cronbach's alpha per item of the PSSS.

| Item | Item-test correlation | Item-rest correlation | Average inter-item correlation | Alpha |
|---|---|---|---|---|
| Q1 | 0.6495 | 0.5706 | 0.3509 | 0.8664 |
| Q2 | 0.6807 | 0.6070 | 0.3470 | 0.8644 |
| Q3 | 0.6889 | 0.6166 | 0.3459 | 0.8639 |
| Q4 | 0.6398 | 0.5593 | 0.3521 | 0.8670 |
| Q5 | 0.5486 | 0.4551 | 0.3635 | 0.8727 |
| Q6 | 0.6218 | 0.5385 | 0.3543 | 0.8682 |
| Q7 | 0.7401 | 0.6771 | 0.3396 | 0.8605 |
| Q8 | 0.7304 | 0.6657 | 0.3408 | 0.8612 |
| Q9 | 0.7480 | 0.6866 | 0.3386 | 0.8600 |
| Q10 | 0.6731 | 0.5980 | 0.3479 | 0.8649 |
| Q11 | 0.5782 | 0.4887 | 0.3598 | 0.8709 |
| Q12 | 0.4723 | 0.3701 | 0.3730 | 0.8771 |
| Q13 | 0.4765 | 0.3747 | 0.3725 | 0.8769 |
| Test scale | | | 0.3528 | 0.8763 |

### *Reproducibility*

To determine the reproducibility of both scales, 51 respondents were re-interviewed after a minimum of two weeks, under similar circumstances and with the same interviewer. The respondents had a PSSS median score of 15 and 14 when interviewed the first and second time, respectively. The $\text{ICC}_{\text{agreement}}$ was calculated to be 0.72 (95%CI: 0.50 – 0.84), which means that there is a high agreement between the measures and that the scale can be considered as reliable.

The $\text{mean}_{\text{difference}}$ between the interviews is 0.078 (SD 9.85), which led to a $\text{SEM}_{\text{agreement}}$ of 6.97. The limits of agreement are -19.23 and 19.39 (see *Appendix 12, figure 1)*. The $\text{SCD}_{\text{individual}}$ is 19.31 and $\text{SDC}_{\text{group}}$ 2.70, which represent 37.1% and 5.2% of the total score range, respectively.

### *Interpretability*

The median PSSS score and IQR were calculated for both the case and control group. The score of the control group acted as a reference to determine the cut-off value for 'normal participation restriction'. When stratified by gender, it was observed that the females scored higher in both the case and control group, compared to men (19 vs 11, respectively, $p = 0.01$) and 6 vs 3, respectively, $p = 0.2$). Among the cases, lower educated people scored significantly higher than higher educated individuals, although this difference was not observed in the control group. People with mild (EHF ≤3) disability had significantly lower PSSS total score compared to people with moderate/severe (EHF >3) disability, $p = 0.03$. However, when divided in three groups it was observed that people with moderate disability, and not those with severe disability had the highest median PSSS score. The median total PSSS score for the control as well as the different subgroups is illustrated in *Table 5*.

**Table 5.** Median PSSS scores and IQRs for the cases and control and per subgroup (gender, marital status, EHF) (score 0 – 65) (n=110).

| **Characteristics** | | **Cases** | | | | **Controls** | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | *n* | *Median* | *IQR* | $p^{\#}$ | *n* | *Median* | *IQR* | $p^{\#}$ |
| **PSSS** | Score (0 – 90) | 110 | 14 | 6 – 21 | | 50 | 5 | 2 – 8 | |
| Gender | Male | 61 | 11 | 4 – 19 | 0.01 | 26 | 3 | 1 – 9 | 0.16 |
| | Female | 49 | 19 | 11 – 22 | | 24 | 6 | 3 – 8 | |
| Age | ≤45 | 53 | 16 | 7 – 21 | 0.4 | 29 | 5 | 1 – 8 | 0.71 |
| | >45 | 57 | 12 | 6 – 21 | | 21 | 6 | 2 – 8 | |
| Marital status [a] | Married | 78 | 12.5 | 6 – 21 | 0.9 | 39 | 6 | 2 – 10 | 0.08 |
| | Unmarried | 32 | 15 | 5 -22.5 | | 11 | 2 | 1 – 7 | |
| Level of education [b] | Lower educated | 90 | 15 | 9 – 22 | 0.01 | 25 | 6 | 2 – 8 | 0.4 |
| | Higher educated | 20 | 6 | 3 -16.5 | | 25 | 4 | 1 – 7 | |
| EHF* | ≤3 | 40 | 11 | 3 – 18 | 0.03 | | | | |
| | >3 | 64 | 16 | 7- 23 | | | | | |
| EHF* | Mild (≤3) | 40 | 11 | 3 – 18 | | | | | |
| | Moderate (4-5) | 23 | 20 | 11 – 32 | 0.03 | | | | |
| | Severe (≥6) | 41 | 14 | 6 – 22 | | | | | |

[a] Unmarried is defined as; unmarried, widow or divorced.

[b] Lower educated: no education and primary school; Higher educated: Secondary school, High school and University.

[#] Calculated using a nonparametric equality-of-medians test.

[*] n=104, 6 people were excluded due to missing EHF scores.

### 5-QSI-AP

#### *Construct validity*

For the 5-QSI-AP only three hypotheses could be formulated. The first and second hypothesis concern a positive correlation between the 5-QSI-AP and both the PSSS and PSS. A Spearman's correlation was run to assess this relation, and showed a positive and statistically significant correlation for the PSSS (rho = .524, *p* = .0000) and PSS (rho = .439, *p* = .0000). A Spearman's correlation was then run in a sample of 104 people affected by leprosy, and showed a weak correlation with the EHF scores (rho= 0.255, *p* = .0089).

#### *Internal consistency*

The Cronbach's alpha was found to be 0.655. The corrected item to total correlation ranged between 0.463 and 0.761. The lowest item-rest correlation was found in item 4 (0.320), which concerns "difficulties in marriage/ in getting married". Removing this item from the questionnaire would increase the total Cronbach's alpha to 0.706. Results are displayed in *Table 6*.

**Table 6**. Cronbach's alpha per item of the 5-QSI-AP.

| Item | Item-test correlation | Item-rest correlation | Average inter-item correlation | Alpha |
|---|---|---|---|---|
| Q1 | 0.5832 | 0.3202 | 0.3101 | 0.6425 |
| Q2 | 0.7612 | 0.5722 | 0.2139 | 0.5212 |
| Q3 | 0.7207 | 0.5110 | 0.2358 | 0.5524 |
| Q4 | 0.4630 | 0.1716 | 0.3750 | 0.7059 |
| Q5 | 0.7124 | 0.4987 | 0.2403 | 0.5585 |
| Test scale | | | 0.2750 | 0.6548 |

#### *Floor and ceiling effects*

No floor or ceiling effects were detected. Of the respondents, 3.6% (n=4) had the lowest score of 0 and 11.8% (n=13) the highest (score of 10).

#### *Reproducibility*

The median score for both the first and second interview was 6. The test-retest reliability was good with an $\text{ICC}_{\text{agreement}}$ of 0.79 (95%CI: 0.63 – 0.89). The difference in mean between the interviews is 0.020 (SD 2.45), which corresponds to a $\text{SEM}_{\text{agreement}}$ of 1.73. The $\text{SCD}_{\text{individual}}$ (4.81) and $\text{SDC}_{\text{group}}$ (0.67) represent 48.1% and 6.7% of the total score range, respectively. The limits of agreement are -4.79 and 4.83 (see *Appendix 12, figure 2)*.

#### *Interpretability*

The 5-QSI-AP median score and IQR for the different subgroups is illustrated in *Table 7*. The female population reported a significantly higher level of experienced stigma than the male (8 vs. 5, respectively, *p*=0.04). Respondents who were married scored significantly lower compared to those unmarried (6 vs. 8, respectively, p=0.05). As expected, and in line with our pre-defined hypothesis, the more severe the disability, the higher the level of restrictions in social participation that people experienced (EHF ≤3; 5 vs. EHF >3; 8, *p*=0.01). In addition, when divided into three groups we see that people with a higher EHF score have higher 5-QSI-AP scores, although the difference in median is not significant, *p*=0.01.

**Table 7.** Median 5-QSI-AP scores and IQR for the different subgroups (Gender, Marital status, EHF) (score 0 – 10) (n=110).

| **Characteristics** | | **Cases** | | | |
|---|---|---|---|---|---|
| | | *n* | *Median* | *IQR* | *p*[#] |
| **5-QSI-AP** | Score (0 – 10) | 110 | 6 | 3 – 8 | |
| Gender | Male | 61 | 5 | 3 – 8 | 0.04 |
| | Female | 49 | 8 | 4 – 8 | |
| Age | ≤45 | 53 | 7 | 3 – 8 | 0.6 |
| | >45 | 57 | 6 | 3 – 8 | |
| Marital status[a] | Married | 78 | 6 | 3 – 8 | 0.05 |
| | Unmarried | 32 | 8 | 4.5 – 6.5 | |
| Level of education [b] | Lower educated | 25 | 6.5 | 3 – 8 | 0.4 |
| | Higher educated | 25 | 6 | 3 – 8 | |
| EHF* | ≤3 | 40 | 5 | 2 – 8 | 0.04 |
| | >3 | 64 | 8 | 4 – 8 | |
| EHF* | Mild (≤3) | 40 | 5 | 2 – 8 | 0.1 |
| | Moderate (4-5) | 23 | 6 | 3 – 8 | |
| | Severe (≥6) | 41 | 8 | 4 – 8 | |

[a] Unmarried is defined as; unmarried, widow or divorced.

[b] Lower educated: no education and primary education; Higher educated: Secondary education, High school and University.

* n=104, 6 people were excluded due to missing EHF scores.

[#] Calculated using a nonparametric equality-of-medians test.

# 8 Discussion

## 8.1 General

The purpose of this study was to conduct a cross-cultural validation of the 5-QSI-AP and the PSSS, two instruments that can be used to assess stigma and restrictions in social participation, respectively, among people affected by leprosy. To establish cultural validity, this study used the World Health Organization (2014) guidelines for translation and the cultural equivalence framework of Herdman et al. (1998), adapted by Stevelink and van Brakel (2013). Following this framework, the current study examined the conceptual, item, semantic, operational and measurement validity of the PSSS and 5-QSI-AP among people affected by leprosy in Nepal. Very minor changes were necessary to translate and adapt the 5-QSI-AP and PSSS to the Nepali culture. The current study showed that the translated and adapted version of the PSSS can be considered culturally valid among the study population in the Kathmandu Valley, Nepal. However, the 5-QSI-AP requires some re-evaluation.

## 8.2 Conceptual validity

This study supports the notion that the way stigma and social participation are conceptualized in the instruments is appropriate in the Nepali culture. The questions of the PSSS reflect a similar content to that of the original P-scale, of which the conceptual validity was already established in Nepal, and many other countries (Coltof, 2019, van Brakel et al., 2006, Akkerman, 2016, Kelders et al., 2012, Rolink, 2016). The 5-QSI-AP is relatively new, and its conceptual validity, or that of the 5-QSI community version, have not been assessed so far (Hanoeman, 2017).

The main conceptualizations of stigma reported by leprosy-affected people in Nepali in this study were exclusion, avoidance and concealment. These concepts overlap with areas reflected in the questions of the 5-QSI-AP, supporting its conceptual validity. This was not unexpected, as the 5-QSI-AP was derived from the EMIC Stigma Scale, a widely used tool for assessing stigma that has already been validated in Nepal, among many other countries (Peters et al., 2014).

Furthermore, this study substantiates that stigmatization occurs in different, not always obvious, ways and that the feeling of being stigmatized is also associated with an individual's perceptions and anticipations (Rensen et al., 2011, van Brakel et al., 2006). It is also context-specific: for example, one of the respondents mentioned stigmatization and social exclusion by his educated friends. This supports the notion that stigmatization is a multifaceted problem, and that education and public awareness interventions may not be effective on their own (Sermrittirong and van Brakel, 2014, Sermrittirong and Wim, 2014). It is important to explore public health interventions based on group communications that aim to understand attitudes towards people affected and promote behavioural changes (Castro et al., 2018). In the development of these programmes it is also crucial to consider that different groups (e.g. age, race, educational status) may require a different approach (National Academies of Sciences et al., 2016).

## 8.3 Translational process and semantic validity

In general, all questions of both the 5-QSI-AP and PSSS were well and correctly understood by the respondents, which was as expected, as the thorough translation procedure resulted in an excellent conceptual translation. This is in agreement with other studies using the P-scale (original and shortened version) that reported no difficulties in understanding the items of the tool (Rolink, 2016, van Brakel et al., 2006, Kelders et al., 2012). Only minor adaptions were made after the first translation. During the translation, the phrase "compared to other people," which is used in almost each of the PSSS, was translated in Nepali to "compared to friends." It was decided to use "compared to other people," as this matches the original questionnaire and it might be easier for people to compare themselves. Some leprosy-affected people might only have friends that are also leprosy-affected, and "other people" are more than only friends. The respondents had no problem comparing themselves to other people without disability but of the same age and socio-economic status. This supports previous studies that "other people" is a suitable replacement for the peer concept used in the original P-scale (Coltof, 2019, Kelders et al., 2012).

## 8.4 Item validity

In general, the respondents considered the items of the PSSS and 5-QSI-AP as relevant and important to their situation and felt comfortable answering the questions. Exception was one item in both questionnaires. Q6 of the PSSS concerns participation in community chats, sports or meeting and some females reported this as irrelevant to their lives. Therefore, the word "*nachaan*," which means dancing and singing, was added to the question to ensure the tools' content validity. For the 5-QSI-AP, Q4, which is about difficulties in marriage or in getting married, was considered irrelevant by one widow who had no interest in getting re-married. For the others, this question was considered as highly relevant, so it was decided to retain this question.

## 8.5 Operational validity

Concerning the administration format of the 5-QSI-AP and PSSS, all respondents had a positive experience. Both the questions and the answering options were well understood, which is supported by the absence of any missing data. The difficulties in understanding the PSS were expected as the two-level question structure of this questionnaire is known to cause for confusion. Moreover, this was, together with the administration time, one of the rationales that led to the development of a simplified version of the P-Scale (Coltof, 2019, Kelders et al., 2012). As no problems were detected with the PSSS, we substantiate the hypothesis that the single-question structure of the simplified scale is better understood. In addition, although the difference was small, this study indeed reported a shorter administration time for the PSSS. Operational validity was confirmed, as neither the instructions, the items, nor the answering format had to be changed.

## 8.6 Measurement validity

### PSSS

This study showed that the PSSS strongly relates to the "golden standard" PSS, and the correlation found (rho = .817) is better than the one reported in the development study, rho = .688 (Coltof, 2019). We used two ways to determine the PSSS optimal cut-off score. First, using the 95th percentile of the normative group the cut-off values were calculated at 16 for the PSSS and 14 for the PSS. Second, as the data was not normally distributed, a ROC-curve was used that determined an optimal cut-off value for the PSSS of 12 and showed a sensitivity and specificity of 0.86 and 0.92, respectively. This is slightly higher than the sensitivity and specificity of the PSSS by Coltof (2019) (0.82; 0.75), the PSSS by Kelders et al. (2012) (0.88; 0.80) and the PSS by Jansen (2012) (0.85; 0.88). A lower cut-off score will increase the number of persons classified as having "participation restrictions," whilst a higher cut-off value will only classify people with more severe restrictions as "restricted." In this study, the lower cut-off score of 12 is most suited for two reasons. First, a lower cut-off score ensures that persons with less severe restrictions will not be missed, and second, selecting people that might not need interventions will, in this context, not be of any harm. The benefit of the ROC-curve is that it enables a comparison with the "golden standard," which in this study was the PSS with a cut-off value of 14 (Habibzadeh et al., 2016). The PSS cut-off value of 14 is slightly higher than the international standard of 12. However, as described in the Participation Scale Users' Manual, this may differ geographically and culturally differ (The Participation Scale Development Team, 2010). Furthermore, using a ROC-curve with a PSS cut-off of 14 as well as 12 both resulted in an optimal cut-off score of the PSSS of 12.

A few characteristics impact the median score of the PSSS. In the case as well as the control group, females scored higher compared to men, which is similar to the PSSS development study (Coltof, 2019). This can be explained by the traditional picture that the life of Nepali women consists of hard work and service to others, and that their life consists of disproportional amount of 'suffering' compared to men (Engelbrektsson, 2012). As expected, people with visible signs of leprosy experienced more restrictions in participation than those without any visible disability. However, this did not hold for those with the most severe impairment, as people with moderate disability (EHF score = 4-5) had the highest median PSSS score (Rolink, 2016, van Brakel et al., 2006). Reason for this finding is not clear. Possible explanation is that people feel comfortable in their living environment and experience few social restrictions despite their physical limitations (Kelders et al., 2012). Another explanation could be that, although the most severe group remains stigmatized and restricted, they no longer find this objectionable because they have accepted living with leprosy. The process of self-acceptance and progression away from feelings such as shame and disbelief, and towards acceptance and survivorship have been reported as coping strategies in other stigmatized disease, such as HIV/AIDS (Psaros et al., 2015, Sayles et al., 2007). However, there is no evidence to support this.

The responsiveness of the PSSS was good in this study. Although the test-rest reproducibility of the PSSS was sufficient, the value of the $SDC_{individual}$ was high. This means that a change of at least 19 points is required, which is just over one third of the 0 -52-point scale, to detect any change on the individual level beyond the measurement error. The $SDC_{group}$ was small, meaning that at group level small score differences are already sufficient enough to demonstrate change. Furthermore, the construct validity was established as 75% of the hypothesis were confirmed. The internal consistency of the PSSS was very good and similar to that reported in the development (Coltof, 2019) and other P-scale validation studies (Jansen, 2012, Kelders et al., 2012). Finally, no floor or ceiling effects were detected proving the discriminative ability of the PSSS.

### 5-QSI-AP

Formally, the construct validity is not supported as only 66% of the hypothesis has been confirmed. However, as only three hypotheses could be formulated it can still be considered as sufficient. The hypothesis that was not confirmed concerns the relation between the severity of impairment and the score of the 5-QSI-AP. A Spearman's rho of 0.255 is too weak to support this relation.

With regard to the internal consistency, a Cronbach's alpha of 0.66 is just under the pre-defined 0.70 threshold. Nevertheless, it can be considered sufficient enough due to the social feature of this study and the five-item format (Samuel and Okey, 2015). Second, the limited number of questions in the 5-QSI-AP makes it challenging to demonstrate a strong correlation. Q4 of the 5-QSI-AP, which concerns "difficulties in marriage/ in getting married," showed a low item-rest correlation and removal would increase the total Cronbach's alpha to 0.71. This is consistent with the results of item validity were one respondent, a widow, considered this question irrelevant. Furthermore, a previous study in Nepal using the community version of the 5-QSI also reported a higher alpha when deleting Q4. There, many respondents were widowed and considered the question about marriage opportunities as irrelevant (van Dorst, 2018). We would recommend looking for alternatives.

The responsiveness of the 5-QSI-AP in this study is acceptable. The $\text{ICC}_{\text{agreement}}$ was 0.79, indicating a good test-retest reliability. The SDC was high at individual (48%) but small at group level (0.67 out of score range of 10). This results in similar implications as described for the PSSS. Regarding the interpretability, this study substantiates that gender and visible signs of leprosy are enforcers of stigma in leprosy endemic countries (Van Elteren, 2017). Furthermore, the absence of any floor or ceiling effects demonstrates the discriminative ability of the 5-QSI-AP. Finally, the criterion validity was omitted for the 5-QSI-AP, while it is possible for people not affected by leprosy to be stigmatized for other reasons, conceptually, there is not a 'normal level' of stigma.

## 8.7 Strengths and limitations

This is the first study to ever culturally validate the 5-QSI-AP and the second validation of the PSSS, thereby contributing to the body of knowledge regarding the measurement of stigma and restrictions in social participation. The thorough and extensive translation phase ensured that only eight interviews were needed, after which only minor adaptions were deemed necessary. This study had an almost equal distribution men and females which enhances the representativeness.

This study has several limitations. First, it might be possible that essential information was lost since the interpreter translated the answers of the respondents directly into English, after which it was voice recorded, because of the limited available time. This resulted in a detailed summary of the answers instead of a literal translation. Second, the interpreter was an experienced councillor with excellent skills in showing empathy. However, although explicitly instructed not to, the interpreter sometimes kept explaining the questions to the respondents. This might have influenced the item or semantic results. We experienced the same problem with the interpreter used in the quantitative measurements, but this resolved after continuous feedback was given. Third, the data was collected and analysed by one researcher, which could potentially lead to information bias. Therefore, several researchers were consulted to ensure neutrality. Fourth, a review by Stewart and Napoles-Springer (2000) suggests that for an item to be cross-culturally valid, an additional criterion needs to be achieved, namely a similar distance between response choices across cultures. This exact picture can be gained through more complex psychometric testing methods such as the Rasch item analysis

(Herdman et al., 1998, Stewart and Napoles-Springer, 2000). However, this was omitted due to the complexity of this method. Finally, for the interpretability of change scores over time in the target population, it should be ideal to compare both scales with the score differences representing Minimal Important Change (MIC). However, this was not possible as the MIC is not yet available for the PSSS and 5-QSI-AP.

## 8.8 Recommendations

Further research is necessary to confirm the results of this study and to validate the PSSS and 5-QSI-AP for more affected populations and in more countries. For further cross-cultural validation studies, we would recommend to initially focus on the translation process. An adequate translation that emphasizes on simple language and good conceptual translations ensures a good-quality questionnaire, and can positively contribute to semantic equivalence. With regard to the tools, for the 5-QSI-AP it is recommended to revise Q4, *"Have you had problems getting married / in your marriage because of having (had) leprosy?"*, and replace it with an alternative question that better reflects stigma in people affected by leprosy. The performance of an alternative item should be examined in the target population to determine whether it can replace the current item 4. In addition, it is recommended to compare the 5-QSI-AP with a golden standard to assess and determine the reliability.

# 9 Conclusion

The main research question, *"To what extent are the Nepali versions of the 5-QSI-AP and PSSS culturally valid among people affected by leprosy?"*, has been answered in this study. The results demonstrate that the PSSS has adequate item, semantic and operational validity, as well as good psychometric properties. Conceptual validity was already assessed and found to be good. Furthermore, this study shows that the outcomes of the PSSS are almost equal to the golden standard, and thus it is a valid tool to measure participation. The findings of this study indicate that both tools have the ability to discriminate between groups effectively, supporting their reliability. Both tools substantiate that gender, and visible signs of leprosy are closely associated with stigma levels and, consequently, with restrictions in social participation. For the 5-QSI-AP, we can conclude that conceptual, semantic and operational validity have been confirmed, and that it demonstrates acceptable psychometric properties. However, we cannot conclude this about item validity, as Q4: *"Have you had problems getting married / in your marriage because of having (had) leprosy?"* could be considered as irrelevant. Alternative constructs that reflect stigma in people affected by leprosy should be examined in the target population to determine whether it is a suitable replacement.

# 10 Acknowledgements

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Current strategies for fighting NTDs are primarily focused on treatment and prevention, but almost none address the lifelong consequences that come with (permanent) disability and which continue after treatment has ended. The TLM Nepal and Anandaban hospital do a lot of work in addressing these social and physical consequences. Experienced counsellors interact with patients in the wards or those vising the outpatient clinics and help them with the mental difficulties that they face. But what intrigued me most was the self-care unit run by the Anandaban hospital staff and were they learn patients how to handle their (new) disability in daily life. After hospital discharge, people enter a two-week rehabilitation program where they are taught how to carry out household and farming activities without harming themselves. This facilitates integration in their family and community and empowers them in life.

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# 12 Appendix

## 12.1 The 5-QSI-AP in English

| No | 5-Question Stigma Indicator - Affected People<br>**In the past year:** | Never | Sometimes | Often/ usually | Do not know | SCORE |
|---|---|---|---|---|---|---|
| 1 | Have you experienced problems in finding or keeping work because you have (had) Leprosy? | 0 | 1 | 2 | 0 | |
| 2 | Have you been worried about others finding out you have (had) leprosy? | 0 | 1 | 2 | 0 | |
| 3 | Have you ever felt ashamed because you have (had) leprosy? | 0 | 1 | 2 | 0 | |
| 4 | Have you had problems getting married / in your marriage because of having (had) leprosy | 0 | 1 | 2 | 0 | |
| 5 | Have people tried to avoid you because you have (had) leprosy? | 0 | 1 | 2 | 0 | |
| | | Total | | | | |

Comment: ______________________________________________

Time:

______________________________________________

Respondent Name: ________________________________________

Respondent number: ______________________________________

Interviewer: ____________________________________________

Date of interview: ____ / ____ / ____

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Disclaimer: The 5 – Questions Stigma Indicator – Affected Persons is the intellectual property of the NTD-Toolkit development team. Neither the team nor its sponsors can be held responsible for any consequences of the use of the 5 – Questions Stigma Indicator – Affected Persons.

## 12.2 The 5-QSI-AP in Nepali

| | [illegible] ५ [illegible]<br>[illegible] | [illegible] | [illegible] | [illegible] | [illegible] | [illegible] |
|---|---|---|---|---|---|---|
| १ | [illegible] ? | ० | १ | २ | ० | |
| २ | [illegible] डर [illegible] ? | ० | १ | २ | ० | |
| ३ | [illegible] ([illegible]) [illegible] ? | ० | १ | २ | ० | |
| ४ | [illegible]? | ० | १ | २ | ० | |
| ५ | [illegible] ? | ० | १ | २ | ० | |
| | | [illegible] | | | | |

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[illegible] .......................................... [illegible] समय...................................................................... .

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[illegible] ...................................................................

Disclaimer:- [illegible] ५ [illegible] । [illegible] ।

## 12.3 The PSSS in English

| No | Participation Scale Short Simplified<br>Explain in introduction that we ask the respondent to compare him/herself with other people | Easy | A bit difficult | Difficult | Very difficult | Irrelevant, I don't want to, I don't have to | Not specified, Not answered | SCORE |
|---|---|---|---|---|---|---|---|---|
| 1 | Compared to other people, how easy is it for you to find work? | 0 | 1 | 2 | 4 | | | |
| 2 | Compared to other people, how easy is it for you to work hard? (same hours, type of work etc) | 0 | 1 | 2 | 4 | | | |
| 3 | Compared to other people, how easy is it for you to contribute to the household economically? | 0 | 1 | 2 | 4 | | | |
| 4 | Compared to other people, how easy is it for you to make visits outside your village/neighbourhood? (e.g., bazaars, nearby villages) | 0 | 1 | 2 | 4 | | | |
| 5 | Compared to other people, how easy is it for you to take part in major festivals and rituals? (e.g. weddings, funerals, religious festivals) | 0 | 1 | 2 | 4 | | | |
| 6 | Compared to other people, how easy is it for you to take part in social activities? (e.g. in sports, chat, meetings, religious or community activities) | 0 | 1 | 2 | 4 | | | |
| 7 | Compared to other people, how easy is it for you to gain respect in your community? | 0 | 1 | 2 | 4 | | | |
| 8 | Compared to other people, how easy is it for you to visit other people in the community? | 0 | 1 | 2 | 4 | | | |
| 9 | Compared to other people, how easy is it for you to move around inside and outside the house and around the village/neighbourhood? | 0 | 1 | 2 | 4 | | | |
| 10 | Compared to other people, how easy is it for you to visit public places in your village/neighbourhood? (e.g. schools, shops, offices, market and tea/coffee shops) | 0 | 1 | 2 | 4 | | | |
| 11 | In your home, how easy is it for you to do household work? | 0 | 1 | 2 | 4 | | | |
| 12 | How easy is it for you to get people to listen to you in family discussions? | 0 | 1 | 2 | 4 | | | |
| 13 | How easy is it for you to meet new people? | 0 | 1 | 2 | 4 | | | |

Comment: ____________________________________________

Total score:

Respondent Name: ______________________________________

Time:

Respondent number: _____________________________________

Interviewer: ___________________________________________

Date of interview: ____/ ____ /____

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## 12.4 The PSSS in Nepali

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[illegible] ……………………………………………………………

Disclaimer:- [illegible] र [illegible] । [illegible] ।

## 12.5 The PSS in English

| **No** | **P - scale Short v1.0** | 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 part in social activities as much your peers do? (e.g. in sports, chat, meetings, religious or community activities) |  | 0 |  |  | 0 |  |  |  |  |  |
|  | *[if sometimes or no]* How big a problem is it to you? |  |  |  |  |  | 1 | 2 | 3 | 5 |  |
| 7 | Do you have the same respect in the community as your peers? |  | 0 |  |  | 0 |  |  |  |  |  |
|  | *[if sometimes or no]* How big a problem is it to you? |  |  |  |  |  | 1 | 2 | 3 | 5 |  |
| 8 | Do you visit other people in the community as often as other people do? |  | 0 |  |  | 0 |  |  |  |  |  |
|  | *[if sometimes or no]* How big a problem is it for you? |  |  |  |  |  | 1 | 2 | 3 | 5 |  |
| 9 | Do you move around inside and outside the house and around the village / neighbourhood just as other people do? |  | 0 |  |  | 0 |  |  |  |  |  |
|  | *[if sometimes or no]* How big a problem is it to you? |  |  |  |  |  | 1 | 2 | 3 | 5 |  |

| No | P - scale Short v1.0 | Not specified, not answered | Yes | Sometimes | No | Irrelevant, I don't want to, don't have to | **NO problem** | **Small** | **Medium** | **Large** | **SCORE** |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 10 | 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 | |
| 11 | In your home, do you do household work? | | 0 | | | 0 | | | | | |
| | *[if sometimes or no]* How big a problem is it to you? | | | | | | 1 | 2 | 3 | 5 | |
| 12 | 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 | |
| 13 | Are you comfortable meeting new people? | | 0 | | | 0 | | | | | |
| | *[if sometimes or no]* How big a problem is it to you? | | | | | | 1 | 2 | 3 | 5 | |

Comment: ______________________________________________

______________________________________________________

**Time:**

Respondent Name: ______________________________________

Respondent number: ____________________________________

Interviewer: __________________________________________

Date of interview: ____/ ____ /____

**Grades of participation restriction**

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

Disclaimer: The Participation Scale Short Simplified is the intellectual property of the Participation scale development team. Neither the team nor its sponsors can be held responsible for any consequences of the use of the Participation Scale Short Simplified.

## 12.6 The PSS in Nepali

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## 12.7 Informed consent form

**Informed Consent Form**

**Mode of administration**: Verbal

**Principle investigator:**
**Assistant investigator:** Louise de Vos Klootwijk
**Organizations:** The Leprosy Mission (TLM) and VU University

**Title of study:** Cross-cultural validation of the Participation Scale Short Simplified (PSSS) and the 5-Question Stigma Indicator – Affected Persons (5-QSI-AP) to measure stigma and social participation restrictions among people affected by leprosy in Nepal.

**Introduction**

The aim of the study is to perform a cultural validation of the PSSS and 5-QSI-AP in Nepal and to measure the degree of stigma and social participation restriction among people affected by leprosy with the validated PSSS and 5-SQI-AP. The results will help health services in Nepal to support people infected by leprosy better.

We want to translate the words and the sentences in the questionnaire so that everyone can understand. If you feel that the questions are too personal, we can skip this question. Thank you very much for participating in this study.

**Voluntary participation**

Your participation in this research is voluntary, which means that you decide to stop at any time.

**Procedures**

To protect your privacy, we will not share your information with anyone outside the research team. The information will be stored in a safe place and all the collected data will be saved without personal identifying information. Do you have any questions?

**Consent of participants**

I have understood the information, and the researcher has answered my questions. I have the opportunity to refuse to participate in this study. I am a voluntarily participant in this study.

Name participant:
Signature:
Date: ___ / ___ / ______ (dd/mm/yyyy)

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Name researcher:
Signature:
Date: ___ / ___ / _____ (dd/mm/yyyy)

## 12.8 Personal information form participants

**Personal information form**

[TO BE FILLED IN BY INTERVIEWER}

*Respondent ID:*______________________________________________________

*Current district:*____________________________________________________

*Date (dd-mm-yyyy):*________________________________________________

*Medical file/dossier number:*___________________________________________

[TO ASK RESPONDENT]

*What is you full name?:*________________________________________________

*Age* __________ years

*Gender* [FILL IN AS OBSERVED]:

- ○ Male
- ○ Female

*Religion*:

- ○ Hindu
- ○ Buddhist
- ○ Muslim
- ○ Christian
- ○ Others

*Marital status* [READ OPTIONS OUT LOUD]:

- ○ Unmarried
- ○ Married
- ○ Divorced
- ○ Widow

*Living situation* [READ OPTIONS OUT LOUD]:

- ○ In depended in community
- ○ Living with assistance (family/friends)
- ○ Hospitalized/institutionalized

*Highest level of education* [READ OPTIONS OUT LOUD]:

- ○ No education
- ○ Primary education
- ○ Secondary education
- ○ High school

○ University

*Employment status* [READ OPTIONS OUT LOUD]:

○ In labour (working for someone paid)
○ Farmer
○ Self-employed (own business)
○ Officials
○ Employed in business
○ Non paid work (volunteerism)
○ Student
○ Housewife/homemaker
○ Unemployed due to health reasons
○ Unemployed due to other reasons
○ Retired
○ Other specify_____________________

*Time since diagnosis?:*_____________years

*Leprosy EHF score:*_______________

| | Left | Right |
|---|---|---|
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| Hand | | |
| Foot | | |

[The interviewer records the beginning and end time of the application of the interview, as well as the time needed for explanation].

*Start time of P-scale*. TIME:_______________________________

*End time of P-scale.* TIME:_________________________________

*Explaining of the P-scale.* TIME:____________________________

*Start time of P-scale short.* TIME:___________________________

*End time of P-scale short.* TIME:____________________________

*Explaining of the P-scale short.* TIME:________________________

*Start time of 5-QSI-AP.* TIME:______________________________

*End time of 5-QSI-AP.* TIME:________________________________

*Explaining of the 5-QSI-AP.* TIME:____________________________

## 12.9 Semi-structured interviews guide

**Steps of the interview**

1. Introduce ourselves and the study

   *Thank you for wanting to participate in this study. My name is ... from the Leprosy Mission and this is ... from the Netherlands. Together we are doing a research about stigma and social participation among people affected by leprosy. We will conduct three questionnaires and it will take around thirty to forty minutes.*

2. Ask for informed consent

   *Do you have any questions?*

3. Fill in personal information form
4. Follow the rest of the interview guide as described below
   a. **SSI1:** During the qualitative part of the study
   b. **SSI2:** During the quantitative part of the study
5. Check whether all information is completed
6. Thank the participant for the cooperation + incentive

   *Thank you Mr/Mrs ... This is the end of the interview. Thank you for your time and for the information you shared with us. We will handle the answers you gave us with care. The answers you gave us are very valuable for aiding us to control and prevent leprosy in Nepal better in the future.*

**SSI1. Qualitative semi-structured interview guide**

Start with Part A and then continue with part B for both the 5-QSI-AP and PSSS.

***Part A: Welcome***

This interview consists of three parts. First, we will ask some general questions about your experiences with having to live with leprosy. Then, in part 2 and 3, we will test a list of questions about your life and how you feel about yourself. After each list of questions, we will ask some general questions about the interview.

**Questions concerning leprosy:**

1. I understand you have leprosy. When you think about leprosy, what are the first things that come to mind?
2. Can you tell me something about how living with leprosy affects your daily life?
3. Can you tell me something about how having (had) leprosy makes you feel about yourself?
4. In what area do you feel restricted the most because of you having (had) leprosy?

**Questions concerning the 5-QSI-AP and PSSS:**

1. Can you please tell me what you think stigma is?
   a. Are there any other words that come into mind when you hear stigmatization?

2. Can you please tell me what you think social participation is?
    a. Are there any other words that come into mind when you hear social participation?

**Part B: 5- QSI - AP**

Now, in this part we will ask some questions about your life and the influence leprosy has (had) on it. You can choose from 4 answering options. They range from: 0) "*never*", "*sometimes*", "*often/usually*" to "*do not know*". Please feel free to ask any questions if you do not understand something.

Instructions for interviewer: Read the statement of the 5-QSI-AP as a question and let the participant answer by choosing the answer options. Ask questions 1-4 below after each item. Answer possible questions of participant. After finishing the questionnaire ask questions 5-8.

1. Did you understand the question?
2. Can you repeat it in your own words?
    a. If the respondent is not able to explain, discuss how it can be rephrased for better understanding.
3. Was this question about something that is important in your life?
4. Do you feel it is okay to ask a question like this?

**At the end of the questionnaire, the following questions will be asked:**

5. What do you think of this questionnaire?
6. Did you feel like the questionnaire was relevant to your situation?
7. Was a question too personal or were you unhappy to answer for any reason?
8. Do you have any questions about this interview?

**Part C: PSSS**

In this third part, we will ask similar questions as in part B. In every question of this test we ask you to compare yourself to a 'peer'. A peer is someone who is similar to you in every way, for instance a man/woman of your age with similar socio-economic status but that does not have leprosy. In addition, the 'other people' does not have to be the same person for every question. Do you understand this?

This questionnaire has different answer options and they range from "*easy*", "*a bit difficult"*, *"difficult"* to *"very difficult".* You can also choose the option "*irrelevant*", meaning you don't want to or don't have to. If you do not feel comfortable answering the question you can choose the option *"not specified, answered".*

Instructions for interviewer: Read the statement of the PSSS as a question and let the participant answer by choosing the answer options. Ask questions 1-4 below after each item. Answer possible questions of participant. After finishing the questionnaire ask questions 5-8.

1. Did you understand the question?
2. Can you repeat it in your own words?
   a. If the respondent is not able to explain, discuss how it can be rephrased for better understanding.
3. Was this question about something that is important in your life?
4. Do you feel it is okay to ask a question like this?

**At the end of the questionnaire, the following questions will be asked:**

5. What do you think of this questionnaire?
6. Did you feel like the questionnaire was relevant to your situation?
7. Was a question too personal or were you unhappy to answer for any reason?
8. Do you have any questions about this interview?

## SSI2. Quantitative semi-structured interview guide

*This interview consists of three part. We will test a list of questions about your life and the influence that leprosy has (had) on it.*

### *Part 1: 5-QSI-AP*

Now, we will ask you some questions about your life. You can choose from 4 answering options. They range from "*never*", "*sometimes*", "*often/usually*" to "*do not know*". Please feel free to ask any questions if you do not understand something.

Instructions for interviewer: Read the statement of the 5-QSI-AP as a question and let the participant answer by choosing the answer options. Answer possible questions of participant.

### *Part 2: PSS*

Now, in every question of this test we ask you to compare yourself to a 'peer'. A peer is someone who is similar to you in every way, for instance a man/woman of your age with similar socio-economic status but that does not have leprosy. In addition, the 'other people' does not have to be the same person for every question. Do you understand this?

Now, in this test you can choose the following answer options:

- "*Not specified, answered*": When you do not feel comfortable answering the question.
- "*Yes*": When you do not have problems with the item asked in the question.
- "*Sometimes*": When you feel like you sometimes have a problem with the item asked or with some people.

- "*No*": When you have problems with the item asked in the question.
- "*Irrelevant*": For example, when you don't want to, or don't have to meet new people. You can also choose this option when the problem is not because of leprosy but because of something else (like your age or gender).

Whenever you answer the question with "*no*" or "*sometimes*" it is important that we assess the degree of participation restriction you experience. This can be:

- *"No problem"*
- *"Small problem"*
- *"Medium problem"*
- *"Large problem"*

Please feel free to ask any questions if you do not understand something.

Instructions for interviewer: Read the statement of the PSS as a question and let the participant answer by choosing the answer options. Answer possible questions of participant.

***Part 3: PSSS***

Now, in every question of this test we ask you to compare yourself to other people. This has to be someone who is similar to you in every way, for instance a man/woman of your age with similar socio-economic status but that does not have leprosy. In addition, the 'other people' does not have to be the same person for every question. Do you understand this?

In this test, you can choose from 5 answering options. These are: "*Easy*", "*a bit difficult*", "*difficult*" to "*very difficult*". You can also choose the option "*irrelevant*", meaning you don't want to or don't have to. For example, this can be when you don't want to meet new people. You can also choose this option when the problem is not because of leprosy but because of something else (like your age or gender). Finally, if you do not feel comfortable answering the question you can choose the option "*not specified, answered".* Please feel free to ask any questions if you do not understand something.

Instructions for interviewer: Read the statement of the PSSS as a question and let the participant answer by choosing the answer options. Answer possible questions of participant.

## 12.10 Socio-demographic characteristics of the semi-structured interview participants

**Table 1.** Socio-demographic characteristics participant semi-structured interviews (n=8).

| Respondent | Age | Sex | Religion | Marital status | Education | Employment | Year since diagnosis | EHF score |
|---|---|---|---|---|---|---|---|---|
| 1 | 41 | Male | Hindi | Married | Primary | Farmer | 4 | 3 |
| 2 | 19 | Male | Hindi | Unmarried | Secondary | Student | 7 | 3 |
| 3 | 35 | Male | Hindi | Married | Primary | In labour | 2 | 6 |
| 4 | 41 | Female | Hindi | Widow | No education | In labour | 1 | 2 |
| 5 | 35 | Male | Muslim | Married | Primary | Self-employed | 21 | 7 |
| 6 | 51 | Male | Hindi | Married | Primary | In labour | 31 | 5 |
| 7 | 32 | Female | Hindi | Unmarried | Primary | In labour | 7 | 0 |
| 8 | 50 | Male | Hindi | Married | No education | Unemployed due to health reason | 16 | 11 |

## 12.11 Socio-demographic characteristics of the participants quantitative part.

**Table 1.** Socio-demographic characteristics of the quantitative part (n=160).

| | | **Cases** ***n (%)*** | **Controls** ***n (%)*** |
|---|---|---|---|
| Sex | Male | 61 (55.5%) | 26 (52%) |
| | Female | 49 (44.6%) | 24 (48%) |
| Age in years | Mean (min-max) | 48.0 (18 – 85) | 44.6 (18 – 95) |
| Marital status | Married | 78 (70.9%) | 39 (78%) |
| | Unmarried | 16 (14.6%) | 6 (12%) |
| | Divorced | 6 (5.5%) | - |
| | Widow | 10 (9.1%) | 5 (10%) |
| Religion | Buddhist | 5 (4.65) | 10 (20%) |
| | Christian | 27 (24.6%) | 6 (12%) |
| | Hindu | 73 (66.4%) | 31 (62%) |
| | Muslim | 1 (0.9%) | 1 (2%) |
| | Other | 4 (3.6%) | 2 (4%) |
| Education level | No education | 62 (56.4%) | 19 (38%) |
| | Primary education | 28 (25.5%) | 6 (12%) |
| | Secondary education | 11 (10.0%) | 3 (6%) |
| | High school | 6 (5.5%) | 16 (32%) |
| | University | 3 (2.7%) | 6 (12%) |
| Employment status | Labourer | 28 (25.5%) | 8 (16.3%) |
| | Farmer | 25 (22.7%) | 8 (16.3%) |
| | Self-employed (own business) | 1 (0.9%) | 6 (12.2%) |
| | Officials | 5 (2.6%) | 1 (2.0%) |
| | Non-paid work (volunteering) | 2 (1.8%) | - |
| | Student | 2 (1.8%) | 4 (8.2%) |
| | Housewife/homemaker | 17 (15.5%) | 12 (24.5%) |
| | Unemployed due to health reasons | 29 (26.4%) | 6 (12.2%) |
| | Retired | 1 (0.9%) | 4 (8.2%) |
| EHF score# | Mild (0-3) | 17 (15.5%) | |
| | Moderate (4-5) | 46 (41.8%) | |
| | Severe 6-12 | 47 (42.7%) | |
| Time since diagnose (years)* | Mean (min-max) | 20.1 (1 – 69) | |
| <u>Scores</u> | Median (IQR) | | |
| 5-QSI-AP | | 6 (3 – 8) | - |
| PSS | | 18 (8 – 30) | 3 (0 – 6) |
| PSSS | | 14 (6 – 21) | 5 (2 – 8) |

# n=104, 6 people were excluded due to missing EHF scores.

* n=108, 3 missing values.

EHF; Eye, Hand and Feet score, IQR; Interquartile range

## 12.12 Bland and Altman plot

**Figure 1** Bland-Altman plot of the mean PSSS score against the difference in PSSS score of the first and the repeated interview.

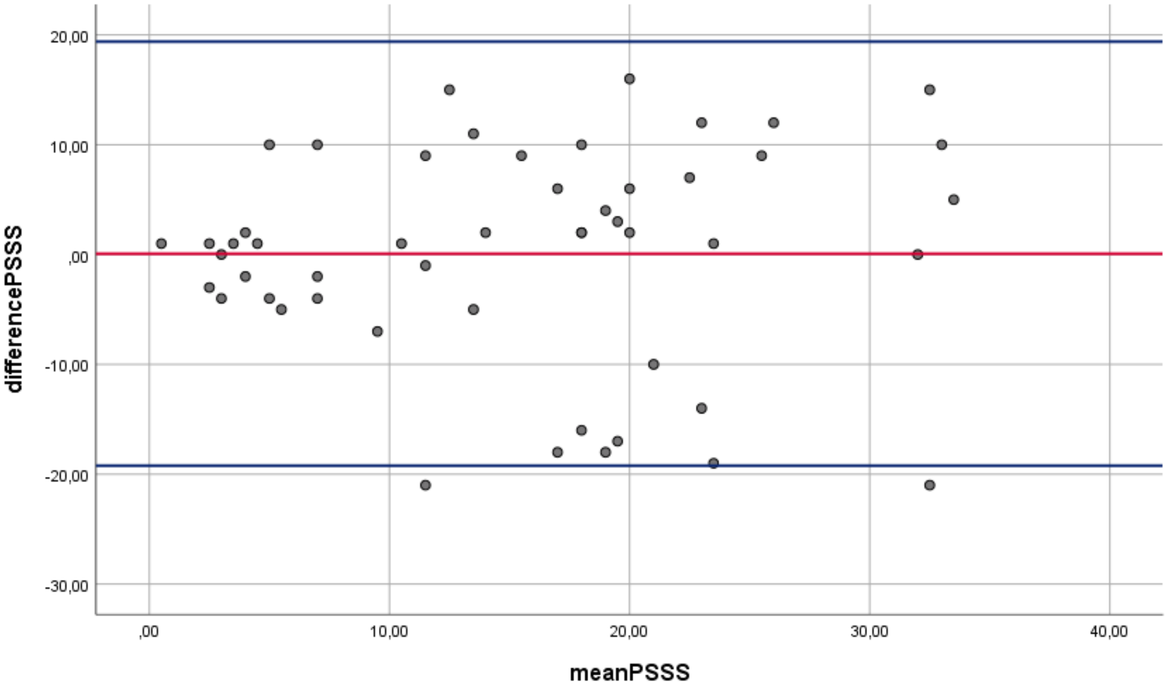

**Figure 2** Bland-Altman plot of the mean 5-QSI-AP score against the difference in 5-QSI-AP score of the first and the repeated interview.