Validation study of the Participation Scale Short version (14-items) in people affected by leprosy and other disabilities in Tamil Nadu, India

MASTER THESIS

VU University Amsterdam
Health Sciences, specialization International Public Health
November, 2012

Author: A.P.M. Jansen
Student number: 2071754
E-mail address: a.p.m.jansen@student.vu.nl

Organization: Schieffelin Institute of Health-Research & Leprosy Centre
Karigiri, Vellore, Tamil Nadu, India 632106
Supervisors: Dr. W.H. van Brakel and D. Prakash Kumar

Contents

Abstract

Aim

The aim of this research is to validate the Participation Scale Short version (PSS) in Tamil Nadu, India, in order to assess the participation of people living with a disability. A related goal was to understand the concept of ‘participation’ in this area.

Background

A large number of people in the world with a given health condition are confronted by social problems, such as stigmatization and participation restrictions. Assessing the level of participation is relevant to specifically select individuals for rehabilitation programmes, monitor the population over time and develop a personal rehabilitation programme. The Participation Scale, also known as the P-scale, is based on the classification domains of ‘participation’ according to the International Classification of Functioning, Health and Disability. Experiences from the field suggest that the P-scale is useful, but a number of participants from studies in Indonesia and Thailand noted that some items appeared similar. Therefore, five items were removed from the scale and resulted in the P-scale Short (PSS). A shorter P-scale is more useful for rapid assessment, which is relevant in certain emergency situations, e.g. surveys or as part of a toolkit of instruments. It would also result in less burden for the participant.

Methods

This study took place in the Schieffelin Institute of Health-Research & Leprosy Centre in Karigiri. Semi-structured interviews were undertaken with people who have a disability and health workers to develop an understanding about the concept of ‘participation’. The PSS was refined with the data from the semi-structured interviews before starting with the quantitative data collection. People living with leprosy, tuberculosis, HIV/AIDS and diabetes were interviewed with the PSS and, seven days later, with the gold standard, the P-scale. The conceptual and operational equivalence were measured by Herdman framework and the measurement equivalence was assessed with the use of the quality criteria of Terwee. The measurement equivalence included reliability to distinguish between groups, criterion validity, content validity, internal consistency, floor & ceiling effects and interpretability. To estimate a new cut-off point for the PSS (participation restrictions/no participation restrictions) a normative sample of people without a disability was interviewed.

Results

All 13 questions were relevant to PWD living in Tamil Nadu. The concept ‘participation’ had changed slightly over the years. Thus, a 14th question was added, as well as refinements to the other questions to upgrade the conceptual equivalence. The interviews with both the P-scale and the PSS involved 86 participants with an average of 7 days between the first and second measurement. The normative group included 50 participants. The results show that the PSS can distinguish well between different groups, for example in age, literacy and income. The PSS and the P-scale score were significantly correlated (r=0.762). The sensitivity and specificity of the PSS versus the P-scale are respectively 0.85 and 0.88. Furthermore, the PSS demonstrated good internal consistency with a Cronbach’s alpha (total score) of 0.85. Lastly, it showed a reduction in interviewing time of 3 minutes and no floor or ceiling effects.

Conclusion

The Tamil version of the Participation Scale Short version has adequate operational and (psychometric properties) measurement equality. The item and semantic equality were already assessed. To improve the conceptual equality of the scale, it is recommended to add a question about the ‘public utility services’. This completes the concept of ‘participation’ in Tamil Nadu.

1 Background

1.1 Disability & development

Over one billion people in the world are living with some form of disability (WHO, 2010). Of these, around 80% live in low-income countries and often under miserable circumstances (UN, 2008). People with a disability (PWD) are often linked to further disadvantages, especially with regard to poverty and social exclusion. They suffer from stigmatization and discrimination in their community, and this not only affects their level of participation within family and community activities, but it also reduces the opportunities to obtain education and work (Dalal, 2006). Having poor opportunities leads to a distinction between the PWD and others in the community. PWD in low-income countries are underrated in the community, are seen as being in need of charity and face poor chances to escape from poverty. This manifests in having a low self-esteem and self-efficacy (Albert et al., 2005; Thomas, 2005). Being a disabled person is more than just being a person with an impairment. But what does 'disability' mean? There are different definitions. The definition compatible with the International Classification of Functioning, Health and Disability (ICF) is: *"A difficulty in functioning at the body, person or societal level in one or more life domains, as experienced by the individual with the health condition in interaction with contextual factors"* (Leonardi et al., 2006). In this definition, the contextual factors are taken into account, which comprise personal and environmental factors. Besides this, the definition by Leonardi et al. (2006) includes not only impairment, but also the 'outcome' of the health condition namely; limitations in activities and restrictions in participation. The definition given by the World Health Organisation (WHO) is slightly different namely: *"Disability is a complex phenomenon, reflecting an interaction between features of a person's body and features of the society in which he or she lives."* (WHO, 2002). In this definition the 'outcome' of the health condition is lacking compared to the definition by Leonardi et al. (2006). In this thesis, the concept of 'disability' is used according to the definition of Leonardi et al. (2006). The experiences of people with a disability vary widely. They derive from the interaction of health conditions linked to both personal and environmental factors. For example, an estimated 20% of the quarter of a million people diagnosed with leprosy every year have physical and/or psychosocial disabilities and may need rehabilitation. This group of people may experience social problems, like stigmatization and may have restrictions in their participation, which further negatively affects their quality of life (Brouwers et al., 2011). Youth and adults with disabilities frequently have no opportunities or access to get a job or training in their community (Khasnabis et al., 2008). As a result, they face many difficulties and barriers in providing for their daily necessities. The limited opportunities for participating in social activities have a strong impact on an individual's identity, self-esteem, quality of life and social status. This often leads to poverty.

1.2 Measuring disability (ICF)

In 2001, WHO presented the ICF-model as a framework for reporting the health and health-related status of an individual. The term 'functioning' comprises all body functions and structures, activities and participation, while 'disability' can be seen as an umbrella term for impairment, activity limitations and participation restrictions in the ICF framework. However, 'disability' will not always occur in all of these components; it may also be related to just one of these. Disability is considered as the outcome of a complex relationship between a persons' health condition, personal factors (intrinsic) and the environmental factors (extrinsic) which represent the position in which the person lives. Because of this complex relationship, different environments may result in a different impact on individuals with a given health condition. Figure 1 shows the ICF-model.

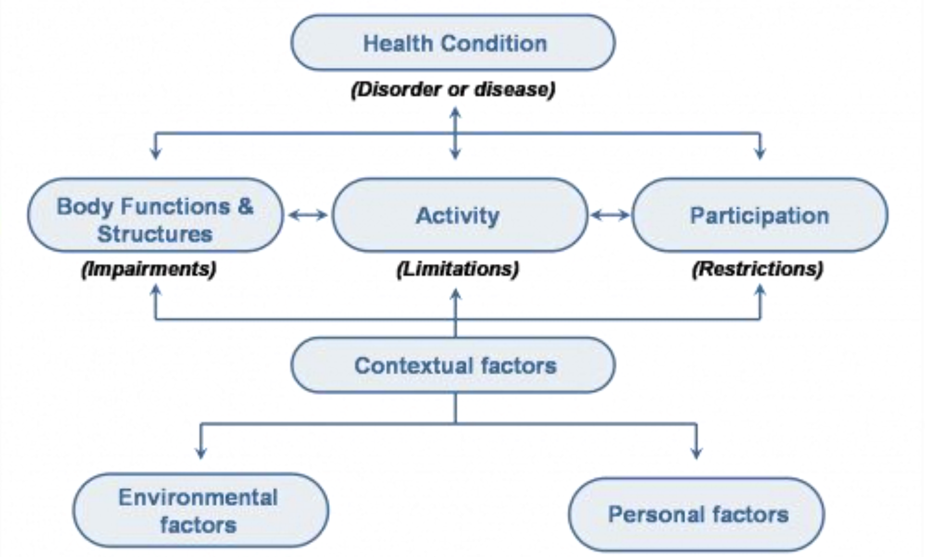

Figure 1. International Classification of Functioning, Health and Disability (WHO, 2001)

This scientific interactive model identifies three levels of functioning: at the body level, the whole person, and a unique aspect of the ICF, the inclusion of contextual factors, such as the personal (intrinsic) and the environmental factors (extrinsic). These levels define three aspects of functioning: body functions and structures, activities, and participation. The body functions and structures are arranged by body systems and other anatomical structures, which move away from the disease-based classification. Different domains to classify activities and participation are set up and make it possible to separate the individual's inherent capacity to perform actions within a domain and performance in their contextual setting. Activity is operationalized as "the execution of specific tasks or actions by an individual.", while participation is defined as "involvement in a life situation" and includes nine domains. The following section gives a detailed description of this concept. In summary, the ICF model is a universal classification of disability and health for use in health and health-related sectors, which can be used to describe disability and functioning in diverse levels of health conditions (WHO, 2002).

1.3 Participation

This concept is often recognized as the most important outcome of, and, an important indicator for assessing the effectiveness of rehabilitation programmes. What exactly do people mean by participation? In this thesis the ICF definition of 'participation' is used (WHO, 2002), because of the universal use of this model. This definition is defined as "involvement in a life situation" and is frequently referred to as 'social exclusion' or 'socio-economic problems'. The participation section of the ICF includes nine domains, namely; Learning and applying knowledge, General tasks and demands, Communication, Mobility, Self-care, Domestic life, Interpersonal interactions and relationships, Major life areas and Community, social and civic life (WHO, 2002). Participation restrictions are defined as "problems an individual may experience in involvement of life situations." Most of the affected individuals experience participation restrictions in social participation, but also in the domains of: performance of household tasks, employment and education (Dijkers et al., 2002; Üstün et al., 2003). Figure 1 shows the interaction between all the concepts. In the ICF-model, participation is linked to activity, which clarifies the occurrence of participation restrictions in activity domains. Furthermore, participation is linked to health conditions and contextual factors, because the severity of participation restriction is influenced by these factors. Another factor that can vary according to the health conditions is the visibility of the disability. The contextual component is two sided, as mentioned before. It refers to the (i) personal characteristics, for example: a person's motivation, experiences and age and the (ii) environmental factors of an individual are for example: social support by family and friends. By describing every component for an individual, a comprehensive description of a person's participation restrictions can be given.

1.4 Assessing participation

A large number of people in the world with a given health condition are confronted by social problems, such as stigmatization and participation restrictions. It is known that people affected by leprosy and other diseases, e.g. HIV/AIDS and spinal cord injury, often experience restrictions in their participation (Nardi et al., 2011; Singh et al., 2009; Rusch et al., 2004). To assess these participation restrictions and other social problems, many studies have been conducted. Currently, there are a few measures available to understand and measure 'participation'. Numeric data about participation are needed to plan, monitor and evaluate programmes and assess the impact of participation-improving interventions, as well as for increasing our knowledge about this concept. The severity of personal participation restrictions is relevant to specifically selected individuals for rehabilitation programmes and to monitor the progression of the population over time (van Brakel et al., 2006). Some examples of widely-used instruments to assess participation are the Impact on Participatory and Autonomy Questionnaire (IPAQ) (Cardol et al., 1999 ; 2001), the Assessment of Life-Habits (LIFE-H) (Noreau et al., 2002) and the Participation-Scale (P-scale) (van Brakel et al., 2006). The majority of these instruments was developed in western countries and is particularly applicable to high-income countries. A few instruments were developed especially for low- and middle income countries. An example is the P-Scale, which can also be used across the cultures.

1.4.1 Participation Scale

The Participation Scale, also known as the P-scale, consists of 18 items with ordinal score answers based on the classification domains of participation according to the ICF (see Appendix 1). The items are related to eight out of the nine domains of this model. These are respectively, Learning and applying knowledge, Communication, Mobility, Self-care, domestic-life, Interpersonal interactions and relationships, Major life areas and Community, social and civil life. The interview-based scale measures patient-perceived participation and is also useful for assessing the severity of socio-economic problems. The instrument is simultaneously developed in 6 languages across three countries namely, India, Brazil and Nepal. Therefore, it can be used more easily across different cultures and countries. Currently, the scale is available in at least 25 languages (Stevelink et al., 2011). The instrument has two levels of questions. First, the participant is asked to indicate whether it experience restrictions in their participation compared to a 'peer'. Second level, if the anwer is 'No', i.e. the participant experienced participation problems, a question will be asked to determine the magnitude of the problem. The total score of the scale is the sum of all the item scores, with a range of 0-90. A high score indicates a high level of participation restrictions and *vice versa*. Additionally, the scale uses the important concept of 'peer'. A 'peer' is defined as "those who are similar to the participant in all respects except for the disease/disability". It is used to make a comparison of the present participation level relative to that of others who are similar but do not have the disease or condition. This measure is a widely applied, reliable and a valid measurement of assessing the participation in leprosy affected people, HIV/AIDS and other disabilities (van Brakel et al., 2006; Rensen et al., 2010; Nardi et al., 2011). In addition, the scale can be used by non-professional interviewers (van Brakel et al., 2006).

1.4.2 Participation Scale Short version

Experiences from the field suggest that the P-scale is useful (Stevelink et al., 2012). However, a number of participants from a study in Indonesia (Kelders et al., 2011; Stevelink et al., 2012) and Thailand (Stevelink et al., 2012) mentioned that some of the questions in the P-scale sounded very similar. This indicated that, possibly, some questions could be removed from the scale. A shorter P-scale (see Appendix 2) would make the scale more useful for rapid assessment which is relevant in certain situations, e.g. surveys or as part of a toolkit of instruments. It would result in a less burden for the patients and will decrease the administration time which makes the instrument more attractive compared to other participation instruments. Stevelink et al. (2012) showed that five questions could be removed from the original P-scale. This was the result of an analysis carried out in 11 databases with P-scale data from previous studies in 6 different countries, with a total of 5,125 participants affected by leprosy and other disabilities. Four questions could be removed based on statistical grounds namely: ‘learning new things’ (Q18), ‘Helping other people’ (Q16), ‘Caring for oneself’ (Q9) and ‘Maintaining a relationship/marriage’ (Q15). ‘Socially active’ (Q7) was removed because of field experiences where participants perceived overlap with the question ‘Do you take part in religious festivals and rituals’ (Q5) and ‘Do you take part in social and recreational activities?’(Q6). This resulted in the PSS of13-items, with a score ranging from 0-65 points. The PSS has a good internal consistency (Cronbach’s alpha of 0.91) and was highly correlated (Pearson of 0.99) to the original P-scale. However, these outcomes are based on results of data from previous P-scale studies and are not based on ‘new’ field data. Data for testing the PSS in the field are lacking. Therefore, a validity assessment of the PSS was the focus of this study.

1.5 Socio-graphic data of the research area

The research took take place in the Schieffelin Institute of Health-Research & Leprosy Centre (SIH-R&LC), Karigiri, Tamil Nadu, India. This is a tertiary care institution which provides specialized services for leprosy patients since 1955. It has 150 hospital beds and apart from its primary focus on leprosy, it also provides general health care in dermatology, ophthalmology, orthopaedics surgery, general surgery and paediatrics. The institute provides health services with rehabilitation and research programmes. More recently, the centre started giving special attention to people affected by tuberculosis, HIV/AIDS and diabetes. Many of its training programmes are recognized by the Christian Medical Association of India and Central and State Governments. They also conduct special courses for Governmental and NGO staff. Furthermore, since 1998 the institute runs a Department of Community Health, through which self-help groups and vocational training are initiated (Invitation letter, Dr. M. Ebenezer).

2 Objectives, conceptual framework and research questions

2.1 Overall objective

The research objective is to validate the Participation Scale Short version with the aid of the gold standard, the original Participation-Scale, for people affected by leprosy and other disabilities in Tamil Nadu, India.

2.2 Main research question

The main research question is: Does the Participation-Scale Short version measure ‘participation’ as well as the original P-scale in people affected by leprosy and other disabilities in Tamil Nadu, India?

2.3 Conceptual framework

Many models can be used as a conceptual framework. In this research two models were combined namely (i) the model of Herdman et al. (1998) which explains the cross-cultural adaptation of health-related quality of life questionnaires and (ii) the quality criteria of Terwee et al. (2007) which further refines psychometric quality criteria for the development and evaluation of health status questionnaires by setting benchmarks. These frameworks are briefly explained below, while appendix 4 gives an extended explanation. The model of Herdman et al. (2008) explains the concept of ‘equivalence’ which is relevant to adapt health-related quality of life questionnaires across two or more cultures. The following types of equivalence are defined: conceptual equivalence, item equivalence, semantic equivalence, operational equivalence and measurement equivalence. In addition, Herdman discussed also the concept *functional equivalence*, this can be seen as an umbrella term for the above mentioned types of ‘equivalence’. The definition of *functional equivalence* is “the extent to which an instrument does what it is supposed to do equally well in two or more cultures”. The quality criteria of Terwee provides specific benchmarks to assess the measurement properties of questionnaires. These criteria are based on the Scientific Advisory Committee (SAC) of the Medical Outcomes Trust which defined eight measurement properties. This enables questionnaires to be evaluated and can give the questionnaire a label: “good measurement properties”. Terwee made a distinction between the following quality criteria: content validity, internal consistency, criterion validity, construct validity, reproducibility, responsiveness and floor or ceiling effects.

Stevelink et al. (2011) also used these two frameworks in her dissertation to assess instruments which measured health-related stigma and social participation. The quality criteria of Terwee fits perfectly within the measurement section of the model of Herdman. This is extending and operationalizing the concept of measurement equivalence. Stevelink replaced the concept ‘*functional equivalence’* of the Herdman model by ‘*cultural equivalence*’ which is defined as “the extent to which an instrument is suitable for use in a different culture from the one it was initially developed for”. Since this study focussed on only one culture the term ‘*cultural equivalence*’ is not applicable. Therefore, the terms ‘*equality’*, which refers to comparing the quality of two scales and ‘*functional equality’* are chosen. ‘*Functional equality*’ is defined as: “the extent to which a new instrument measures what the gold standard is measuring in a given culture” and is derived from the definition of ‘*Functional equivalence*’. Figure 2 shows the refined framework of this study. Herdman developed a model which can be used to assess health-related measures across different cultures with reference to their ‘equivalence’. The original P-scale was validated in the Tamil language and is valid across different cultures. However, it is possible that items relevant for Tamil Nadu were removed during the development process of the original P-scale. The reason for this can be that these questions were less relevant in other cultures since the PSS development study was targeting equivalence across the culture instead of the equality of two instruments in one culture. The PSS comprises a sub-set of items of the P-scale, this means that the concept item and semantic equivalence of the PSS are valid and do not need to be reassessed. The concept reproducibility and responsiveness were not included because of the limited time frame. The aspect of construct equivalence was also not included since the construct of the scale is the same. According to these arguments the conceptual framework, as shown in figure 2, is created to validate the PSS in Tamil Nadu, India.

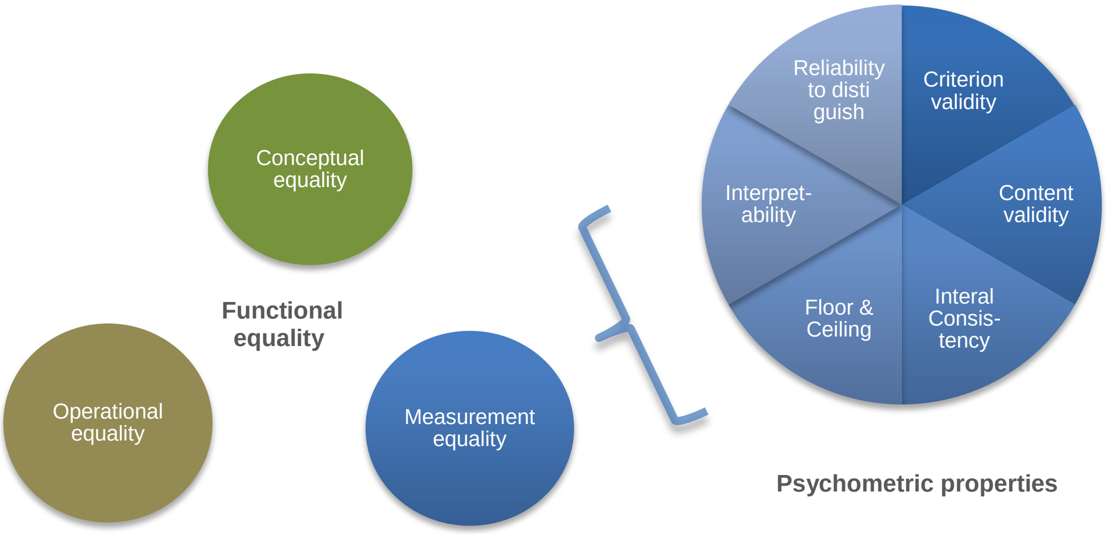

Figure 2. Conceptual framework of validating the Participation-Scale Short version in Tamil Nadu

---

The conceptual, operational, measurement and cultural equality are defined with the help of the concept definitions of Herdman et al. (1998) and Terwee et al. (2007). These are the following:

- Conceptual equality: The same relationship of the underlying concepts between the instruments, primarily in terms of the domains included and the emphasis placed on different domains in the instrument. It includes also the judgment of the study subjects about the appropriateness of the instrument.
- Operational equality: The possibility of using a similar questionnaire format, instructions, mode of administration and measurement methods as used in the gold standard. It also includes the percentage of missing data and possible solutions to solve operational problems.
- Measurement equality: The equality of the measurement functions of the Participation Scale Short version and the Participation Scale. These measurement functions are also known as the psychometric properties of the instrument. The psychometric properties comprise of the internal consistency, content validity, criterion validity and the floor and ceiling effect, these concepts are defined and tested according to the quality criteria of “good” measurement properties by Terwee et al. (2007). In addition, the sensitivity, specificity and positive and negative predicted value were also included in this concept, even as the Bland and Altman method (Bland & Altman, 1986).

Psychometric properties (measurement equality):	Benchmark:
Content validity: The extent to which the domains of interest is comprehensively represented by the items in the questionnaire.	Clear description is given of the measurements aim, target population, concepts that are being measures and the item selection
Internal consistency: The extent to which items in a questionnaire (sub)scale are correlated (homogeneous), thus measuring the same concept.	Factor analysis performed on adequate sample size (7 cases per item; minimum of 100). Cronbach's alpha calculated per dimension; should be between 0.70 and 0.95
Criterion validity: The extent to which scores on a particular instrument relate to a gold standard.	Convincing arguments that gold standard is "gold" and correlation standard >0.70
Floor or ceiling effects: The number of respondents achieved the lowest or highest possible score.	< 15% of the respondents achieve the highest of lowest possible scores
Interpretability: The degree to which one can assign qualitative meaning to quantitative scores.	Mean and standard deviation score presented of at least four relevant subgroups of persons
Reliability to distinguish in groups: The reliability to distinguish between groups of participants which are expected to have a different participation level.	Comparing the mean scores in which a significant difference ($p \leq 0.05$) needs to be found between the subgroups

- *Functional equality*: The umbrella term of all the concepts given above. It shows if the tested instrument does what it is supposed to do compare to the gold standard. If the functional equality is achieved, the instrument is valid and equal to the gold standard in the given culture.

2.4 Specific research questions

The specific research questions are formulated according to the conceptual framework. The main research question is: Does the Participation-Scale Short version measure 'participation' as well as the original P-scale in people affected by leprosy and other disabilities in Tamil Nadu, India?

Sub questions include the following:

1. What is the meaning and understanding of the concept of 'participation' among people living with a disability and health workers of the Schieffelin Institute of Health-Research and Leprosy Centre?
2. To what extend is the Participation Scale Short version equal to the gold standard, the Participation-Scale?
3. To what extent are the psychometric properties of the Participation-Scale Short equal to the Participation-Scale?
4. What is the time benefit of using the Participation-Scale Short compared to the Participation-Scale?

3 Methods

3.1 Study design

The study has a *comparative within-person* design, including qualitative and quantitative research methodology. The qualitative data was collected by semi-structured interviews, while the quantitative data was collected by two questionnaire-based-interviews (structured interviews). These were (i) the Participation Scale Short version and its original version, (ii) the Participation-Scale. Figure 3, shows a flow chart of this study. The (semi) structured interviews were completed with the help of an interpreter. The interpreter was confident in spoken English and Tamil and completed a short training course, given beforehand by the researcher and an experienced social worker in order to be familiarized with the background, goal and the instruments of the study.

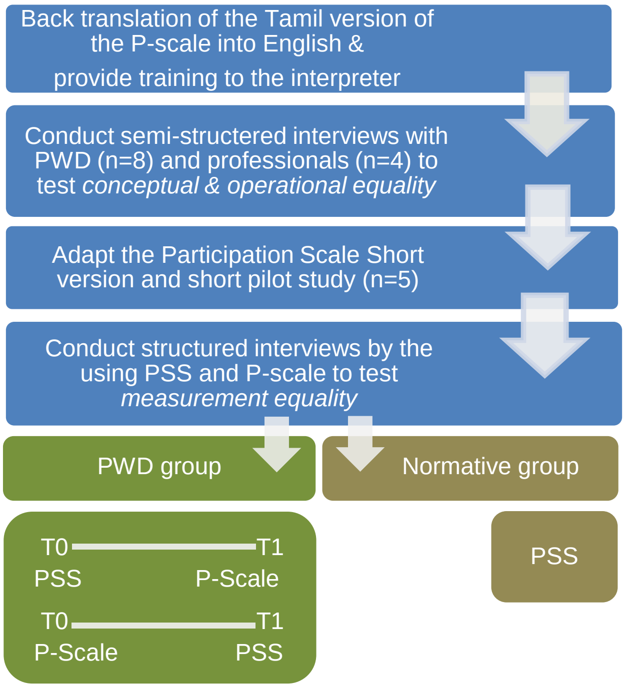

Figure 3. Flowchart of the PSS validation study

3.2 Study site, population and sample

The data was collected from mid-March to mid-June 2012 in Tamil Nadu, India. It took place in the Schieffelin Institute of Health–Research & Leprosy Centre (SIH-R&LC), Karigiri. This centre is specialized in leprosy and other stigmatized diseases like tuberculosis, HIV/AIDS and diabetes. The SIH-R&LC was also involved in the development of the original P-scale.

3.2.1 PWD sample

The P-scale is a valid scale for people affected by leprosy and other stigmatized conditions of individuals above 15 years of age (van Brakel et al., 2006). People who are affected by leprosy or other disabilities were chosen as the main target for the study because of the high variety of diseases in the SIH-R&LC. The group was marked as People with a Disability (PWD) and had the following:

Inclusion criteria:

- People who went for a consultation with a doctor at the SIH-R&LC
- People who were affected by leprosy, HIV/AIDS, tuberculosis or diabetes
- People who were >15 years or age
- People who gave verbally informed consent (see Appendix 5)

Exclusion criteria:

- People who were ill/disabled for <2 months (e.g. broken leg)
- People who do not speak the Tamil language or had other communication difficulties
- People who were not willing to come back for a follow-up measurement

3.2.2 Normative sample

To give an interpretation of the quantitative score of the PSS a normative group was interviewed. This group was only interviewed with the PSS since the cut-off point of the original P-scale had already been estimated. The normative group had the following:

Inclusion criteria:

- People who went for a consultation with a doctor at the SIH-R&LC
- People who were >15 years or age
- People who gave verbal informed consent (see Appendix 5)

Exclusion criteria:

- People who were affected by leprosy or other stigmatized diseases (HIV/AIDS, spinal cord injury, polio, tuberculosis, diabetes, vertigo and psoriasis)
- People who were relatives of the PWD
- People who do not speak the Tamil language or had other communication difficulties

3.2.3 Professionals in SIH-R&LC sample

The aim was to gain a background understanding about the concept ‘participation’ and to collect information about the operational use of the P-scale from professionals working in the SIH-R&LC. The professional group had the following inclusion with no exclusion criteria:

- Health employees of the SIH-R&LC (professionals)
- Professionals who were familiar with the Participation-Scale
- Professionals who gave verbal informed consent

3.3 Sample size and sampling methods

3.3.1 Sample size

The study started with semi-structured interviews. For interviews with the PWD, approximately eight interviews were needed until data saturation could be achieved. For the professional group approximately five interviews were needed. In the pilot study, five participants were required to pre-test the translated and adapted version of the PSS. For calculating the sample size of the structured interviews the COSMIN checklist (EMGO, 2010) and the study of Terwee et al. (2011) were used. These mentioned a sample size of (at least) 100 participants and a control group of (at least) 50 participants. This was the target in the study.

3.3.2 Sampling methods

For the semi-structured interviews (qualitative), choosing the professionals of the SIH-R&LC and the PWD was based on a convenience sampling method. To select the participants for the structured interviews (measurement tools) in the PWD group, convenience sampling was also used because of the limited timeframe and follow-up procedure. This was the same in the short pilot study. In and outpatients from the hospital were asked to participate in the study. The normative group was sampled by a systematic random sampling method, in which every second person who went for consultation with a doctor and was eligible to the inclusion and exclusion criteria was asked by the doctor to participate in the study.

3.4 Data collection methods

After the hiring and training procedure of the interpreter, the Tamil version of the P-Scale (version 6) was back translated and prepared to be used as the short version of the P-Scale (Appendix 3). Data collection of the qualitative data started after the translation procedure as written in Section 3.4.1. The PSS was revised with the collected data from the semi-structured interviews, unplanned chats with locals and cultural experiences of the researcher. A short pilot study (n=5) of the PSS was performed to test the refined scale and became the definitive version of the PSS.

3.4.1 Conceptual, Operational equality and Content validity (qualitative data)

Semi-structured interviews were conducted for collecting the qualitative data. The aim of these interviews was to assess the conceptual and operational equivalence and the content validity (part of psychometric properties) of the PSS. People with a disability and professionals (key informants) of the centre were interviewed after giving verbal informed consent. Since the P-scale was translated into Tamil and the PWD were not familiar with the English language, the interviews were administered in Tamil, accompanied by the researcher. The interviews with professionals were administered in English by the researcher and started with an explanation of the study as well as the informed consent procedure. After enrolment, the first part of the interview began; the socio-demographic questions, followed by the second part of the interview; open questions about diseases and experiences of living with a disease and their meaning of participation (restrictions). These questions were meant to obtain a background understanding about the concept ‘participation’ and to assess conceptual equality. In addition, next to planned interviews, a high number of unplanned chats took place to create an understanding and to fill the gaps in knowledge about the concept. After the open questions the third part of the interview continued; questions of the PSS with the potential answers were read out loud and the participant had to answer the question with one of the following answers: “yes”, “sometimes”, “no” or “not relevant”. If the participant answered with “sometimes” or “no” the next question was asked: “How big is that problem for you?” in which the participant had an answering choice of: “no problem”, “small problem”, “medium problem” or “large problem”. At the end of each question, the interviewer asked further questions to verify how the participant interpreted the questions and to check if they understood the questions, the concepts and the instructions. With this information operational equality was assessed. All interviews took place in hospital rooms were (acceptable) privacy was guaranteed.

3.4.2 Measurement equality (quantitative data)

For collecting the quantitative data, structured interviews were conducted via the Participation Scale version 6 (van Brakel et al., 2006) and the Participation Scale Short version (Stevelink et al., 2012). The Participation-Scale (Appendix 1) is a widely applied, reliable and a valid measurement to measure participation by people affected by leprosy and other disabilities. It is especially developed for use in low and middle income countries and can be used by non-professional interviewers. (van Brakel et al., 2006; Rensen et al., 2010; Nardi et al., 2011) The PSS of 13-items (Appendix 2) has a good internal consistency, a Cronbach’s alpha 0.91 for the total score of the PSS and the Pearson correlation shows that the scales are highly correlated (Stevelink et al., 2012). The aim of these interviews was to assess the measurement equality (psychometric properties). This consists of two measurement moments: t0 on day 1 and t1 on day 7 (see Figure 3). The first ten participants started with the P-scale and ended with a follow-up after seven days with the PSS. The next ten participants started with the PSS and ended with the P-scale and this system continued. These interviews were not voice-recorded but timed with the use of a stopwatch. The interview started with an explanation of the study and informed consent procedure. After enrolment, the first part of the interview started; the socio-demographic questions, followed by the second part of the interview; the P-scale or PSS questions were read aloud one by one. The participant gave an answer to the question and the interpreter wrote down the answer on the score form even as the duration of the interview (only the instrument questions). At the end of the interview, a new appointment was made for follow-up. The time between the measurements was chosen to reduce the likelihood of the participant remembering of previous answers. During the follow-up, the remaining instrument was used to complete the data collection of one case.

3.5 Data management and analysis

3.5.1 Conceptual, Operational equality and Content validity

3.5.1.2 Preparation of qualitative data

These interviews were voice-recorded and transcribed afterwards into English with the use of Windows Media Player and Word. To gain time, the interviews were transcribed by the interpreter without fillers like; “Uh’s” and “Oh’s”. Random fragments of every transcript were verified by a ‘third person’ to conform the translation. The outcome measures of the qualitative part are words and narrative. Moments of silence or other striking observations were noted in brackets.

3.5.1.2 Framework analysis

To analyze the data, a deductive framework was used based on the PSS domains which is related to the domain of participation in the ICF-model. The questions about ‘participation’ were useful to assess conceptual equality. The questions, answering-template and the instructions from the PSS were necessary to assess the operational equality. The analysis was also focused on the match between the given answer of the question itself (yes/no: small, medium, large problem) and the explanation by the participant after the question.

3.5.2 Measurement equality (quantitative data)

3.5.2.1 Preparation of quantitative data

The quantitative data consists of digits and scores from the instruments. They were essential to assess the measurement equality or the psychometric properties of the PSS. At the end of each day, the data were entered in a SPSS v.20 database which was prepared in advance. After data entry, automatic variables were calculated to prevent manual errors. Descriptive statistics were used to explore the data, to become familiar with the data and to find possible entry errors. Impossible scores were deleted and entered again by checking the original score form. Score forms were double checked to prevent missing values. A missing value was only possible because of personal circumstances in which a participant did not want to give an answer to a question or if the participant did not show up for the follow-up measurement. Participants gave verbal informed consent in which the participants were not required to give answers to all the questions. If one record contained two or more missing values, the whole record was excluded from the study. During measurement analysis with parametric tests, the logarithm of the dependent variable was used, total score of the PSS, since the original variable was not normally distributed.

3.5.2.2 Psychometric properties

The content validity shows if the concept of ‘participation’ is represented adequately in the question’ framework of the PSS. *Reliability to distinguish between groups* was assessed by comparing different subgroups that were expected to be different in level of participation. For example age groups and people with and without visible signs. The univariate linear regression must be significant in the certain group to make a reliable distinction. The *criterion validity* shows if the scores of the PSS are related to the P-scale. The hypothesis was that the correlation would be at least 0.70. The numeric total score of the PSS and the P-scale was used to calculate a Spearman’s Rank Order Correlation because of the ordinal outcome variable of the PSS and the P-scale. The ordinal outcome of the PSS was dichotomized (restriction/ no restriction) on the basis of statistical outcome in the normative group (control group). An optimal cut-off point was calculated by applying a Receive Operating Characteristic curve (ROC) and maximal area under the curve (AUC). When an optimal cut-off point was estimated, the sensitivity, specificity, negative and positive predicted values including their 95% confidence intervals were calculated by a 2-by-2 contingency table. In addition, with the mean and difference total score of the PSS and the P-scale a Bland and Altman plot was created. Beforehand, the scores were standardized to a 0-100 score. *Internal consistency* shows if the items in a questionnaire are related to each other, this was achieved when the Cronbach’s alpha would be between 0.70 and 0.95. *Floor & ceiling effects* shows the proportion of participants who scored the lowest and the highest score. There are no floor & ceiling effects when less than 15% of the participants scored 0 or 70 point in the PSS. *Interpretability* shows the qualitative meaning of the quantitative scores and was achieved when mean values and standard deviations of four relevant subgroups of patients were defined.

3.6 Expected outcome of research

3.6.1 Conceptual, Operational equality and Content validity (qualitative data)

With the results of the semi-structured interview, the researcher should be able to adapt the PSS in such a way that local Tamil people would recognize the concept of participation in their culture and would be able to correctly understand the questions from the PSS. Furthermore, another expectation was the addition of participation-based questions to complete the concept of 'participation' in Tamil Nadu since the original P-scale is validated across different cultures. There was a possibility that the relevant questions were removed since they were not suitable in the 'cross-cultural'-validation. Besides that, the concept of participation is continuously changing.

3.6.2 Measurement equality (quantitative data)

With the scores of the P-scale and the PSS the researcher was able to assess the psychometric properties which were presented in the conceptual framework in Section 2.3. The expected outcomes are in agreement with the quality criteria of Terwee.

3.7 Ethical considerations

The research proposal was approved by the Ethics Committee of SIH-R & LC before starting the study. Prior to the interviews each participant gave verbal informed consent. Moreover, an incentive of 30 rupees was given to participants who finished both the structured interviews. This was to stimulate the participants to complete the two measurement moments. Other participants who were included in this study did not receive a financial incentive.

4 Results

4.1 Conceptual, Operational equality and Content validity (qualitative results)

From April to May 2012, eight PWD, respectively four persons affected by leprosy, one by diabetes, one by vitiligo, one by tuberculosis, one psoriasis patient and four professionals from the SIH-R&LC were interviewed to collect the qualitative data. The PWD group included five male and three female participants with a wide spread in age. Five were from rural residency and three from an urban location, participants in this group had visible signs. In the group of professionals, one physiotherapist and three social workers were interviewed; all were male. Three completed a master degree and one had completed only primary school. Table 1, shows the socio-demographic characteristics of these groups. Participants #5 and #8 in the PWD-group were removed from the study because their voices were not loud enough and in combination with background noises, difficult to transcribe. In the professional group, the information about the assessment of the operational use of the P-scale was skipped of PROF #3 since the researcher noticed that the professional only used the P-scale once. During the analysis almost every domain according to the definition of the ICF concept ‘participation’ was mentioned. A brief analysis is shown below. Appendix 6, shows the extended framework analysis of the PWD and professionals.

Table 1. Socio-demographic characteristics of the qualitative study

Participant	Sex	Age	Residency	Level of education	Disease	Visible sign
PWD #1	Male	38	Rural	Primary education	Leprosy	Yes
PWD #2	Male	51	Rural	Read and write only	Leprosy	Yes
PWD #3	Male	38	Rural	Secondary education	Diabetes	Yes
PWD #4	Female	19	Urban	Bachelor	Vitiligo	Yes
PWD #6	Male	19	Rural	Secondary education	Leprosy	Yes
PWD #7	Female	53	Urban	Illiterate	Leprosy	Yes
Participant	**Sex**	**Age**	**Residency**	**Level of education**	**Profession**	
PROF #1	Male	25	Urban	Master	Physiotherapist	
PROF #2	Male	55	Rural	Secondary education	Social worker	
PROF #3*	Male	52	Urban	Master, PhD	Social worker / Researcher	
PROF #4	Male	54	Urban	Master	Social worker / Researcher	

Only data about the concept participation was used

4.1.1 Assessing Conceptual equality and Content validity in PWD and professionals

With the use of open questions, the PWD spoke about their diseases, experiences and their meaning of participation. Professionals also spoke about their meaning and thoughts concerning the concept of participation in combination with their profession.

The highest number of examples given by both of the groups was related to the domain *Interpersonal interactions & Relationships,* followed by *Community, Social and Civic life* and *Communication*.

Lots of activities related to the domain *Communication* were mentioned by the PWD. PWD #1, #2, #3 and #7 faced difficulties in communication with unknown people because of their condition. PWD #1 spoke about his value of having a conversation or discussion with people he knows: *“When I am home I talk a lot, I discuss everything with my family that makes me feel good [..]”*

Three out of six PWD (#2, #3, #6) mentioned indirectly *Mobility* as part of participation. All of the three participants had physical problems with their hands or leg which manifested in difficulties to executive work and/or self-care activities.

In the domain of *Domestic life* only PWD #2, #6 and PROF #4 pointed out participation activities. PWD #2 mentioned a problem in subdomain household-tasks in which doing tasks with a single hand posed

difficulties. PWD #6 faced problems in building and arranging a home in which he wants to take care of his parents. PROF #4 spoke about taking food and dressing which was related to domestic life.
Most of the examples were given in the domain *Interpersonal interaction and Relationship.* Those who mentioned that relationships are important to them (#1, #2, #6, #7) were affected by leprosy. These PWD (except for #6) and PROF #1, #2, #4 spoke about family relationships. PWD #6 mentioned that creating a relationship with a partner for a certain period of time is important and PROF #1 mentioned (helping) friends.

Three male PWD (#1, #2 and #3) came up with activities related to *Major life areas*. All pointed out the work-related part of this domain. The problem of PWD #1 and #2 were emphasized on the physical activity of labour. For PWD #3 it was related to find a job because of his age. He explained: *"I am old and I can't get any job [...] There is no work for me, I'm too old, people will pick the youngster, not me."* PROF #4 was the only one who spoke about education and studying.

A high number of activities were related to the domain *Community, Social and Civic life*. Three participants affected by leprosy (PWD #2, #6, #7) and two social workers (PROF #2, #4) brought up visiting marriages, festivals and funerals as a part of participation in their community. PWD #6 and PROF #1 spoke about sports: *"playing cricket, carom board, chess and kepadi"* and going to the teashop: "[…] *often going to the teashop to meet other people"* as participation activities in life.

Not many issues came up that were related to *Self-care*. Participant #2 spoke about his impaired right hand. Besides the cultural value of the right hand, a number of self-care tasks were difficult to perform. *PWD #2 said: "I feel really sad because I eat, wash and clean my body with my left hand […] Then when I am bathing, how can I bath and put soap all around my body with my left hand? It is almost impossible to just take care of myself."* PROF #2 mentioned hygiene in general as part of participation in which PROF #4 gave examples like brushing and visiting the barbershop.

None of the PWD said something about *Learning and applying knowledge*. This was only argued by PROF #2 and #3. PROF #2 only spoke about educating people regarding their disease which was related to his work. PROF #3 only mentioned briefly that "[…] *going for any education and study […]"* is a part of participation.

Two professionals (PROF #3, #4) mentioned the inequality between different groups in Tamil Nadu which suited to the domain *General tasks* and *demands*. PWD have special rights and privileges but cannot realize these benefits since they do not know how to address the authorities. PROF #4 said: "*The government is not functioning well. There is inequality. Those who are living above poverty have all the privilege, they know the route [….] They receive all the privileges. The poor, the disabled, the women most of the people don't know where to get the benefits, they are easily neglected."*

4.1.2 Assessing Operational equality

In general people understood the meaning of the questions. One question (respect during discussion) was misinterpreted twice by PWD #3 and #6. Both of the participants had a different definition of 'discussion'. The question was answered as follows: "*Yes, since I am the only son.. If I ask for tea, they will make it for me*" and "*When we are discussing about other people they will respect me in my family*." While most of the questions were clear, PWD #2 faced one difficulty in the answering-template. He had problems with finding a definition of a 'medium problem' for himself. At the end of each interview, participants were asked about their opinion and to react on the interview. None of the participants mentioned any problems with the scale and said they understood all the concepts and did not feel uncomfortable while being questioned. Except for PWD #4, an 19-year old girl who was diagnosed (vitiligo) 4 months ago, she explained: *"I don't feel any difference between me and any others, I am normal. But when you started asking all those questions I feel uncomfortable".* PWD #4 had not any participation problems. Nevertheless, after asking the questions of the scale the participant started thinking about how people could feel when they are disabled and felt uncomfortable. The professionals gave some relevant feedback on the scale itself: PROF #1, #2 and #4 pointed out difficulties with the married question. This question was often very uncomfortable to ask especially when the participant is unmarried and/or is female. PROF #4 also mentioned that the question "participating in temples or 'panjayat problems'" is not relevant since only a few people were involved in these activities because of the rural area. Besides this, PROF #1 asked for a shortened version of the P-scale: *“I got the experience, since I went to homes of patients, that most of them concentrate not on all the questions about the p-scale because it has lot of questions. If there will be a shorten version it will be easier for the patient.”*

4.1.3 Amendments after quantitative results

The amendments which were tested in the pilot-study before the scale was used during the quantitative part of the study were the following: a 14th question was added to the scale to improve the content validity, namely: *“Are you able to get your privileges and benefits from the government? (e.g. Pensions, family card, bus and train card.)”.* Furthermore, the back translated version of the Tamil P-scale question 1: *“Can you find a job like other men, women and children in your village do?”* was refined into (back translation PSS) *“Do you have the same chances to find a job like other men or women in your village do?”*, since the scale was not applicable in children and to return the concept of ‘having the possibilities’. The activity going to school was refined to going to a barbershop in Q10. “*Can you go to teashops, markets and schools in your village like others in your village do?”* The researcher noticed that visiting a barbershop was an important activity and together with the teashop and the market the most important public places. ‘School’ was skipped since this scale was not applicable for children. Q12: *“Does your family respect your words?”* (back translation Tamil version) of the PSS was specified as followed *“Does your family respect your words during important decision making?”*, since participants (PWD#3, 6) did not understood the questions correctly. During the pilot study no particularities were found in the amended version of the PSS.

4.2 Measurement equality (quantitative results)

From mid-April to mid-June, 118 participants were included in the PWD group and 50 participants in the normative group. 32 participants (17 female and 15 male) did not show up for the follow-up measurement in the PWD group. These cases were excluded from this study because of the high number of missing data. Of the 86 participants in the PWD group, 52 were affected by leprosy (male: 43), 12 by tuberculosis (male: 6), 12 were persons with diabetes (male: 6) and 10 were affected by HIV/AIDS (male: 6). In the PWD group, the mean score of the PSS was 12.3 points. The average time of assessing the P-scale was 9.26 minutes (ranged from 3.34-24.54 minutes) and of the PSS was 6.30 minutes (ranged from 53 seconds–18.25 minutes).

Table 2. Socio-demographic characteristics of quantitative study

Characteristic		PWD group			Normative group		Characteristic		PWD group			Normative group	
		n	**%**	**PSS** score (mean)	**n**	**%**			**n**	**%**	**PSS** score (mean)	**n**	**%**
Total		86	100		50	100	**Visible sign**	yes no	51 35	59.3 40.7	14.61 9	NA	
Sex	male female	62 24	72.1 27.9	12.8 11.2	23 27	46 54	**Time** since diagnose	months	138 (170) 3-720*			NA	
Age	years	46 (16) 17-79*			40 (16) 16-71*		**Residency**	urban rural	24 62	27.9 72.1	13.46 11.89	10 40	20 80
Disease	leprosy tuberculosis diabetes HIV/AIDS	52 10 12 12	60.5 14 14 11.5	13.83 5.67 11.58 13.40	NA		**Marital status**	single married divorced widowed	16 54 1 15	18.6 62.8 1.2 17.4	6.13 13.80 52 11	11 33 0 6	22 66 0 12
Education	illiterate primary school** secondary school***	25 14 47	25 14 47	16.68 11.69 7	7 8 35	14 15 70	**Income**	≤₹1000 ≥₹1001	46 40	53.5 46.5	15.65 8.50	30 20	30 60
P-scale	score (0-90)	12.95 (13.29) 0-61*			NA		**PSS**	score (0-70)	12.33 (12.37) 0-54*			4 (5) 0-22*	

*NA=not applicable, *=mean values (SD) range, **=includes also read and write only, ***=secondary school and higher*

Therefore the average benefit in time was 2.56 minutes. The average days in time between the first and the second measurement were 7.4 days with a range of 4-28 days. 45 participants started with the P-scale interview followed by the PSS and 41 participants started with the PSS followed by the P-scale. The normative group included 23 male and 27 female participants and had a mean score of 4 in the PSS. The data of the normative group was only used for the interpretation of the quantitative scores and to determine the cut-off point "participation restrictions" / "no participation restrictions" in the PSS. The socio-demographic characteristics are shown in table 2 and are calculated separately for the PWD group and normative group.

Figure 4 gives an overview of the mean scores of the questions in the PSS and the mean score of the related question on the P-scale. The PSS questions and the removed P-scale questions are situated on the Y-axis. The X-axis shows the mean scores. The light blue bars are the scores of the PSS whereas the dark blue bars illustrate the P-scale scores. Most of the questions removed, except for Q7 "*Are you as socially active as your peers?"* had a lower score than the other questions in the PSS. None of the questions in the PSS had a lower score than the removed questions. Q2 "*Do you work as hard as your peers do?"* together with Q3 "*Do you contribute to the household economically in a similar way to your peers?*" and Q14 "*Are you able to get your privileges and benefits from the government?* received the highest scores. In general the PSS had a slightly higher score in 6 questions (respectively 1, 2, 3, 5, 7 and 11) and the P-scale had also a slightly higher score in 6 questions (respectively 4, 6, 8, 9, 10 and 12). The scores of Q13 "*In your village, do you visit public places as often as other people do?"* were equal to each other. Q14 was newly added to the PSS and did not have a related question in the P-scale.

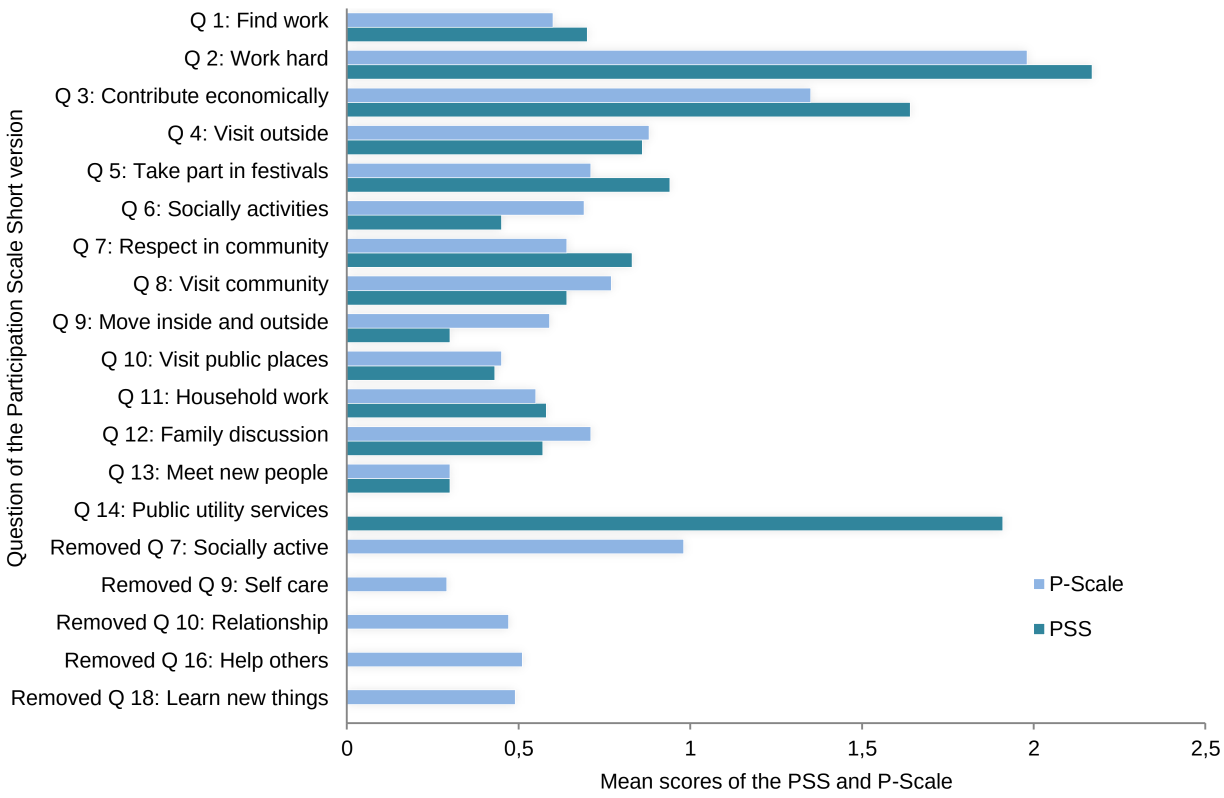

Figure 4. Overview of the mean scores in the P-scale and P-scale per question in the PWD group

4.2.1 Results of the Reliability to distinguish between groups

The reliability to distinguish between groups was calculated with the use of (univariate) linear regression, therefore the logarithm of the PSS total score was used. The total mean score in gender was for male 13.37 and for female 11.88. This difference was not significant (*p*=0.13). The mean score of the PWD group was 12.3 (95% CI of 9.67-15) and participants without a disability (normative group) was 4 with a 95% CI of 2.61-5.23, the regression showed a significant result of *p*<0.001. The difference between participants with or without a visible signs was in the expected direction, but did not reach significance at the 5% level. Table 3 shows the results of different characteristic distinctions, indicating the significant effects of age, time since diagnosis, illiteracy and income. There was no significant difference in participants who came from ward or from outside the hospital, nor between the participants from the other locations of the SIH-R&LC or between participants who started first with the PSS or P-scale.

Table 3. Results of the reliability to distinguish between different groups

Group		n	mean	95% CI	*p*-value	Group		n	mean	95%CI	*p*-value
Disability	PWD group Normative group	86 50	12.3 4	9.67-15 2.61-5.23	<0.001*	Visible sign	yes no	51 35	14.6 8	14.6-18.6 6.12-11.9	0.08
Age	≥41 years ≥41 years	35 50	8.43 14.5	5.13-11.7 10.8-18.1	0.008*	Illiterate	yes no	25 61	16.7 10.5	10.9-22.5 7.66-13.4	0.05*
Time since diagnose	≤72 months ≥73 months	45 40	8.60 15.6	6.10-11.1 11.8-31.3	0.005*	Income	≤₹1000 ≥₹1001	40 46	15.7 8.50	11.5-19.8 5.66-11.3	0.01*

**=significant value*

4.2.2 Results of Criterion validity

Table 4 presents the correlation of the total score in the PSS and P-scale. There is a significant (*p*<0.001) correlation coefficient of 0.76 in the total group with a coefficient of determination of 0.56. It describes that 56% of the variance in the P-scale score can be explained by the score of the PSS. The PSS is highly correlated (>0.70) with the P-scale. During analysis of the diseases separately, the highest correlation coefficient of 0.85 was found in the leprosy group which was significant (*p*<0.001). This group was followed by the diabetes group with a significant correlation coefficient of 0.78 (*p*=0.003). The tuberculosis and HIV/AIDS group did not show a significant correlation.

Table 4. Results of the correlation of the PSS and P-scale

Group	**n**	**Correlation coefficient, r**	***p*-value**	**R square**	**Group**	**n**	**Correlation coefficient, r**	***p*-value**	**R square**
Total group	86		<0.001*	0.56					
Leprosy	52	0.85	<0.001*	0.71	**HIV/AIDS**	12	0.257	0.47	-
Tuberculosis	10	0.44	0.15	-	**Diabetes**	12	0.782	0.003*	0.61

**=significant value*

The ordinal total score of the PSS was dichotomized (restrictions/no restrictions in participation) on the basis of the ROC-curve and the scores of the normative group. The ROC-curves showed an optimal cut-off point at 13.5. The normative group showed a mean score of 4 with a range from 0-22 as shown in Figure 6. One outlier was detected with a score of 22 points. Besides the single score of 22 the scores of the group ranged from 0-13, with several scores of 11, 12 and 13 points. Sensitivity and specificity of different cut-off points were calculated and the cut-off was defined at 13 points. The sensitivity and specificity was respectively 0.85 (95% CI 0.69-0.95) and 0.88 (0.79-0.95) and its' positive and negative predicted value 0.76 (95% CI 0.59-0.89) and 0.93 (95% CI 0.85-0.98). A 2-by-2 contingency table is shown in Table 5.

Table 5. Results of sensitivity and specificity of the PSS against the P-scale

	PSS* Participation restrictions	**PSS** No participation restrictions	Total
P-scale** Participation restrictions	22	7	29
P-scale No participation restrictions	4	53	57
Total	26	60	86

**Cut-off value of 13, **Cut-off value of 12*

The variation in responses is visually illustrated in the Bland & Altman plot which is shown in Figure 5. The difference in total scores of the P-scale and PSS is presented on the Y-axis, whereas the mean score of the P-scale and PSS is illustrated on the X-axis. The differences between the P-scale and the PSS ranged from -13 to 27.5 points on the scale. The central line in the graph shows the mean difference of 3.65. This suggests that the total score of the PSS was structurally 3.65 points higher (on a standardized score of 0-100) than the total score of the P-scale. The first line shows the upper limit (16.2) and the third line the lower (-9) of the 95% confidence interval. 8% (7 of 86) of the scores were outliers; six exceeded the upper limit and one the lower limit of agreement. No odd characteristics were found in the outlying values.

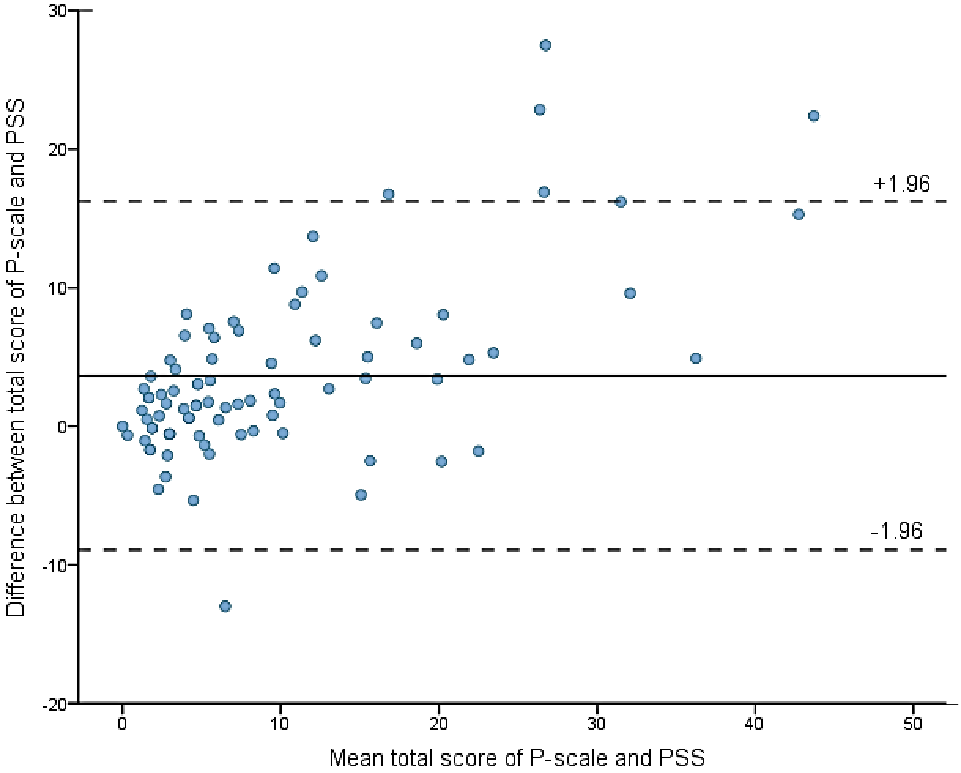

Figure 5. Bland-Altman plot of P-scale and PSS

4.2.3 Results of Internal consistency

Cronbach's alpha of all the questions (14 items) results in 0.85 which is the same for the original version of the P-scale. An explanatory factor analysis was performed to assess the item-test correlations of the scale. All the questions scored well on the item-test correlation accept for Q9 (0.25) "Do you move inside and outside the house and around the village just as other people do?". After removing Q9 out of the scale, the Cronbach's alpha will slightly improve. Indirectly, it shows that the new added item (Q14) fits next to the other questions in the PSS.

4.2.4 Results of Floor and Ceiling effects

In the PSS four participants scored 0 points (4.7%) and none scored the maximum score of 70 points.

Table 6. Mean and 95% CI of the PSS scores in subgroups

		PWD group		Normative group	
Subgroup		mean	95% CI	mean	95% CI
Sex	male female	12.8 11.2	9.61 - 15.9 5.92 - 16.5	5 3	2.53 - 7.47 1.71 - 4.29
Age in years	≤40 ≥41	8.43 14.5	5.13 - 11.7 10.8 - 18.1	4.20 3.64	2.07 - 6.33 1.95 - 5.33
Illiterate	yes no	16.7 10.5	10.9 - 22.5 7.66 - 13.4	1.86* 4.26*	0.61 - 3.10 2.76 - 5.76
Income	≤₹1000 ≥₹1001	15.7 8.50	11.5 - 19.8 5.66 - 11.3	4.83 2.55	2.83 - 6.84 1.25 - 3.85

**Illiterate: yes: n=7 and no: n=43*

4.2.5 Interpretability of the quantitative scores

Interpretability of the quantitative score was investigated with the help of the normative and the PWD group. The mean values of the PSS in both groups are shown in Table 6. Illiterate participants in the PWD group had a mean score of 16.7 (95% CI of 10.9 – 22.5) and the non-illiterate participants 10.5 (95% CI of 7.66 – 13.4), for the normative group the score in illiterate participants was 1.86 (95% CI of 0.61 – 3.10) and for the non-illiterate participants, a remarkable score, of 4.26 (95% CI of 2.76 – 5.76). This score could be explained by the small group sizes in this subgroup, respectively n=7/43. Figure 6, gives the distribution of the PSS total scores in the normative group. The Y-axis shows the number of participants in the normative group and the X-axis shows the scores of the PSS. In this figure is shown that participants scored a total score of maximum 22 points. Only one scored 22 points. This confirms also the cut-off point of 13 to distinguish "participation restrictions" and "no participation restrictions" were most of the participants scored a maximum of 13. In addition, 95% in the PWD group scored between 10 and 15 points.

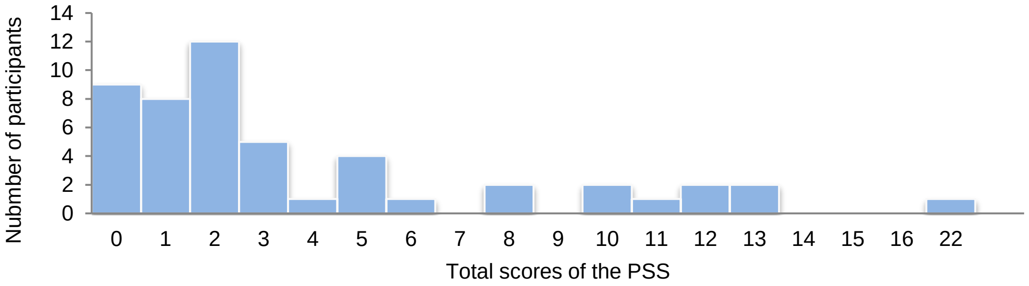

Figure 6. Distribution of the PSS total scores in the normative group

5 Discussion

The key objective of this study was to answer the following research question: “Does the Participation-Scale Short version measure ‘participation’ as well as the original P-scale in people affected by leprosy and other disabilities in Tamil Nadu, India?”

The results of this study show that the concept ‘participation’ has changed over the years. Certain social activities and recreational activities which were popular even six years ago are no longer popular. The problems associated with applying for and receiving public utility services is a recent participation issue which plays a huge role in improving the level of participation of people living with a disability. For example, PWD can receive a bus or train card which gives them the ability to travel for free or with a discount. According to the (semi) interviews, most of them did not know about the existence or did not know how to address the authorities. This question received the second highest score in the PSS (Figure 4). To improve the concept of participation in the PSS, it is recommended to add an item about the ‘public utility services’ and to refine some social and recreational activities.

The quantitative results show firstly that the PSS is able to make a reliable distinction between different groups, for example between people with and without a disability, or people with different age categories, time since diagnosis, illiteracy and level of income. Secondly, the criterion validity analysis shows a high correlation between PSS and the P-scale ($r=0.76$, $p<0.001$). Taking a closer look at the data from those affected by leprosy, the correlation between the PSS and the P-scale is even higher ($r=0.85$; coefficient of determination 0.71). This indicates that 71% of the variance in the P-scale can be explained by the PSS. Moreover, with the cut-off score in the P-scale of 12 points and 13 points in the PSS. The sensitivity and specificity were respectively 0.85 and 0.88 with its’ positive and negative predicted value of 0.76 and 0.93. Also, 85% of the participants who were identified as ‘restrictions in participation’ by the P-scale had the same diagnosis in the PSS. It means that this test is sensitive and specific but still 15% of the cases were not right interpreted by the PSS. The Bland and Altman plot shows a pattern in which the total scores of the PSS are structurally 3.65 points higher than the total score of the P-scale (on a score range of 0-100). Thirdly, the internal consistency of the PSS is very good (Cronbach’s alpha 0.85) and is the same as for the original P-scale in this study). Fourthly, only 4.7% of the participants scored the lowest score possible and none scored the highest score; therefore the PSS shows no floor or ceiling effects. Lastly, the P-scale was administered in an average time of 9.26 minutes, whereas for the PSS it was an average of only 6.30 minutes. This represents a gain of almost 3 minutes; this is making it a very short instrument, suitable for use in surveys and other circumstances where time is short. The quantitative data in the PSS refers to “good measurement properties” according to Terwee (et al., 2007).

However, the Tamil version of the original Participation scale was back translated into English. With this version and the analysed data of the semi-structured interviews, amendments were made in the PSS version. Due to the limited time frame, not all the data was analysed before the quantitative part of the research started. The focus group which was planned beforehand was skipped also because of the limited timeframe and the inexperienced interpreter. The semi-structured interviews were of good quality but did not contain enough information to achieve saturation in every domain of the ICF definition of participation. Nevertheless, enough data was collected for data analysis and to reach a reliable conclusion.

5.1 Conceptual equality and Content validity

In the first part of the semi-structured interviews, the researcher asked open questions about people's diseases, experiences and their understanding of participation. During this part of the interview, none of the participants mentioned examples or activities which could be linked to the ICF domain *Learning and Applying knowledge*. The reason for this could be that having or finding a job to earn money and contribute to the family income is a higher priority than to learn something new or to apply knowledge they may have gathered. The researcher also noticed that the PWD often consider themselves as having low self-esteem and perceiving themselves as having little knowledge.

A topic discussed in most of the interviews was 'marriage', which fits in the domain of *Interpersonal interaction & Relationships.* The item was removed on statistical ground in which the item analysis showed poor properties during the 'goodness of fit' process (Stevelink et al., 2012). Professionals noted in their interviews that biased answers can be given especially by women and youngsters in the question related to this domain namely "Do you have the same opportunity as your peers to start or maintain a long relationship with a life partner?" Finding a life partner is, traditionally, an event which is organized by the family and mostly out of the league of the woman. Moreover, women and youngsters do not like to talk openly about this sensitive topic since the status of an unmarried person is extremely low. Data from the semi-structured interviews showed that this item is an important part of the concept participation. Results of this study show that this item about maintaining a relationship/marriage could not only be removed on statistical grounds but also according the experiences of health workers in the field which noticed biased answers during administering this item.

The original P-scale is based on eight out of nine domains of the ICF definition of participation. Since five questions from the P-scale were removed on statistical grounds, the domains *self-care* and *Learning and Applying knowledge* of the ICF are no longer included in the PSS. This may raise the question as to whether or not the content of participation is still adequately covered in the scale. As mentioned before, no narratives were given by the participants related to the domain *Learning and applying knowledge.* However, during the second part of the semi-structured interview, the questions from the P-scale were asked. These were confirmed as being part of participation as well as the other questions, which illustrates that they are relevant and accepted in the culture. For the domain *Self-care*, the mean scores are shown in Figure 4 which shows that the smallest problems were found in this domain. Besides this, on theoretical grounds, other researchers were of the opinion that the most important domains of the concept are still covered by the PSS (Stevelink et al., 2012). According to the results of this study, the statement above can be confirmed since only one PWD and two professionals mentioned problems in the domain *Self care*. PWD can improve their *Self care* most of the time by using aids. These can easily supplied by health care workers, especially occupational and physical therapists. It is possible that this is the reason why half of the professionals mentioned the *Self care* issues in since they can relatively easy anticipate on these issues. For this reason, the PWD should not face big troubles in this domain, but should face bigger problems in the domains were PWD are depend on other persons or the community. For example finding work, visiting people in the community or during a discussion.

The authors Bowden and Fox (2003) published a systematic review of adapting health-related measurements in different regions all over the world. In their review, they mentioned that validation studies often are emphasized only on the measurement properties (psychometric properties) of an instrument were other important properties of the scale are often neglected, such as the conceptual and operational equivalence. This is also in line with Herdman et al. (1998) which mentioned that quantitative data is necessary in particular to assess conceptual equivalence and to provide valuable information for interpreting quantitative results.

5.2 Operational equality

One of the professionals gave the next comment, which emphasized the need to shorten the scale and confirmed the benefit of reducing the burden of the participant. *"I got the experience, since I went to homes of patients that most of them concentrate not on all the questions about the p-scale because* *it has lot of questions. If there will be a shorten version it will be easier for the patient."* In the validation study of the simplified P-scale (Kelders et al., 2011), participants were complaining about the duration of the scale which also confirms the desirability to shorten the scale. Besides the relevance of shortening the scale, there are some notions related to the operational use of the Tamil PSS. There is a possibility that the 'peer' concept does not come across very clearly in the Tamil scale of the PSS, since there is no specific translation of the word 'peer' in the Tamil language. The concept is now translated as 'others in your village'. During the research no problems or questions were raised about this matter by any participants or the interpreter. However, after analyzing the data of the semi-structured interviews again in the Netherlands, the researcher was not fully satisfied with the translation of the concept 'peer'. The researcher thinks that the Tamil translation of 'peer' does not fully cover the concept, since the participants did not often mentioned the comparison between themselves and someone else in their answers, while the questions in the transcript still included the Tamil version of 'peer'. However, this is only based on the transcripts and not discussed with the interpreter or participants. In the same study of Kelders et al. (2011), which administered the simplified scale in two different languages, also no directly translation of 'peer' was available. Participants in this study showed difficulties to compare themselves with someone else. Using the translation "other people" considered to be too general, therefore a solution was to discuss with the participant on beforehand a real life 'peer' to whom they have to compare themselves. This solved the problem in this study and could be a solution if the 'peer' concept cannot be fully translated into a local language. In general, more studies showed translations problems in questionnaires such as Dijkers et al. (2002), who did a validation study of a Turkish health-related measurement which measured social participation and mentioned "we cannot always be certain that exactly the same information is collected" and Misajon et al. (2008), which was based on a Thai version of the Perceived Impact of Problem Profile and referred specific to difficulties in translating 'Western English concepts'.

5.3 Measurement equality (psychometric properties)

An interesting outcome of this study was the score of the removed Q7, "Are you as socially active as your peers are?", as shown in Figure 4. While administering the P-scale, this question illustrates the 3rd highest score on the scale. Q7 was the only item removed on the basis of field experiences where participants marked that there was an overlap with Q5 "Do you take part in religious festivals and rituals?" and Q6 "Do you take part in social and recreational activities?" The average score in both these items are lower than the score of the removed Q7. The results show that the removed item could be interpreted as an overall question about being socially active whereas Q5 and Q6 are more specific to religious and social activities. Therefore, it can be explained that this item had a high score and it also confirmed the overlap in the questions.

5.3.1 Reliability to distinguish between groups

According to the hypothesis, the scale can distinguish between people having or not having a disability. In contrast to the hypothesis and to the findings of Rensen et al. (2010), there is a considerable difference in having or not having a visible sign but this outcome did not reach significance at the 5% level, namely p=0.08. An explanation could be the high variability among those with visible signs. This would have diluted the association between the presence of visible signs and the participation score. Rensen et al. (2010) only included people affected by leprosy and no other disabilities. Besides this, it is also still possible that the sample size was too small (visible sign y/n, 51/35) to detect a significant distinction in visible signs. In conclusion, the findings indicate the ability of the PSS to discriminate between different groups (as shown in Figure 3). Further research is necessary to confirm and assess other comparisons in a larger sample.

5.3.2 Criterion validity

As expected, the PSS was highly correlated (0.76) with the gold standard according to the quality criteria of Terwee et al. (2007). Of the total score, 56% of the variance in the P-scale was explained by the PSS. The PSS shows a sensitivity of 0.85 and a specificity of 0.88. It says that 15% (in this study 13 participants) are false diagnosed with 'no participation restrictions'. This percentage could be adjusted by changing the cut-off for 'restriction', but a higher sensitivity would be desired. In the literature no benchmark for good or worse sensitivity is found and a perfect sensitivity of 100% is not achievable. The study of the simplified P-scale (Kelders et al., 2011) showed a sensitivity and specificity of 0.88 and 0.80 which is comparable to the PSS. Therefore the PSS can be assessed as having adequate sensitivity and specificity.

5.3.3 Internal consistency and Floor and ceiling effects

Confirming the hypothesis and the work of Stevelink et al. (2012), the PSS shows a Cronbach's alpha of 0.85 for a unidimensional scale. However, the PSS in the study of Stevelink showed alpha of 0.91 and the study of the simplified P-scale (Kelders et al., 2011) also showed an alpha of 0.91. These values refer to 'excellent' internal consistency. Nevertheless, still the internal consistency of the PSS can be labeled as 'good'.

All the questions in the PSS scored well on the item-test correlation accept for Q9; "Do you move inside and outside the house and around the village just as other people do?". Q9 is part of the domain *Mobility* of the ICF definition of participation. This is the only question which is linked to the physical skills of a person. The other questions in the PSS are more related to the social aspect of participation. This could be the reason why Q9 fits badly with the remaining items in the scale. Comparing this result to the current literature, one omitted item of the simplified study of the P-scale (Kelders et al., 2011) was the same item related to *Mobility*. This item was also removed on the basis of poor correlation with other items in the item-analysis. Besides this result, it shows indirectly that the new item about *Public Utility Services*, Q14, fits between the other items in the scale and that Q9 could be removed since the item-test correlation is low. The internal consistency will still remain after its removal. The sample size in this study was too small to produce an adequate factor analysis and because Stevelink et al. (2012) has already analyzed the factor structure of the PSS, the structure found in her study will be assumed to apply to the current data also. Stevelink et al. (2012) showed a two factor structure, in which it is possible to use the first 3 questions as a sub-scale to assess work-related participation. These refer to the subdomain 'work and employment' in the domain *Major life area* of the ICF and can be useful to quickly assess the level of work participation in a person. The other questions in the PSS assess 'general-participation'. Still, the PSS can be used as a unidimensional scale since Stevelink et al. (2012) showed that, based on a sample of 5,125 records, the two factors during the Confirmatory Factor Analysis were strongly correlated with each other. This suggests the presence of a 'high order' general participation factor.

No floor or ceiling effects were observed in the PSS.

5.4 Limitations

5.4.1 Language

There were some difficulties during transcription of the qualitative interviews. It is possible that (essential) information was lost, since the interpreter transcribed directly into English because of the limited timeframe. To guarantee a correct and literal translation, random sentences were checked in each interview. The literally translation was not always given by the interpreter, but rather a detailed summery of the interviews. The interpreter was not computer literate and thus every transcript was written by hand. This, as well as the time limitation, resulted in only eight interviews with the PWD.

5.4.2 Data collection

During the semi-structured interviews the researcher noticed that some participants felt either shy and afraid or, excited and honored by the presence of the researcher. This was an issue of unavoidable culture differences. A recurrent problem, especially in women, was the extra family member, most of the time their spouse, which was present in the same room. This could causes 'third-party bias' in which the participant could not speak freely about every topic without taking into account the extra person in the room. For these reasons some interviews were not optimal, whereas other interviews were very open and in-depth. In the quantitative data collection 118 participants were included in the PWD group of whom 32 participants did not showed up for the follow-up measurement. The main reason for this was the lack of public transport to the SIH-R&LC and the income-dependency of the participants. The incentive given to the participants was not high enough to compensate a one day loss of income. Of the total participants, 27.9% were female and 72.1% male. In general, more males visited the hospital, since disabled women face a double burden (Vlassoff et al., 1996). The different proportions in gender influenced the representativeness of this study. Also the proportion of leprosy participants (60.5%) in comparison with the other diseases was high, since leprosy is the focus of the hospital and within the limited timeframe it was not possible to include a larger number of diseases. However, this study consisted of a comparative within-person design in which a random sample was not required. The normative group was sampled systematic randomly and was representative for Karigiri. In addition, a limited number of psychometric properties were analysed. Relevant properties which were not tested include reproducibility and responsiveness.

5.4.3 Interpreter and researcher

The researcher believes that the interpreter received adequate training both from the researcher and from an experienced social worker of the SIH-R&LC. Although the interpreter was relatively young in age and inexperienced in doing research and especially in conducting interviews, she had excellent skills in showing empathy and using of body language as well as being open for feedback. The major recurrent problem was asking in-depth questions to participants during the interviews. The interpreter was often quickly satisfied with the answers. Therefore, feedback was continuously given before starting the next interview. During quantitative measurement no major issues occurred.

The data in this study were collected and analyzed by one researcher. This could lead to several types of information bias. In each phase of the study, the researcher applied every opportunity to remain neutral.

5.5 Recommendations

Further research is necessary to confirm the results in this study and to improve some psychometric properties. For example, the sensitivity & specificity evaluation in different samples and a test-retest study need to be carried out to improve or assess the reliability, reproducibility and responsiveness of the PSS. In addition, a pilot study should be done in which the 'peer' concept can be fully explored with an imaginary real life 'peer' to whom the participant has to compare themselves. Moreover, the number of items in the scale can be reduced. It is recommended to remove Q9, "Do you move inside and outside the house and around the village just as other people do?", to reduce the scale and improve the time for its completion. Presently, the scale is valid for four different diseases. Further research is needed to extend the validity of the scale for other populations, for example people affected by skin diseases or in elderly.

6 Conclusion

The main research question of the study was: Does the Participation-Scale Short version measure ‘participation’ as well as the original P-scale in people affected by leprosy and other disabilities in Tamil Nadu, India? The results of this study shows that the Tamil version of the Participation Scale Short version has adequate operational and (psychometric properties) measurement equality, whereas the item and semantic equality was already assessed and found to be good. To achieve the conceptual equality of the scale it is recommended to add the question “*Are you able to get your privileges and benefits from the government?”* to improve the concept of ‘participation’ of the scale in Tamil Nadu. The average duration in time for using the P-scale is 9.26 minutes in which the PSS can be assessed within the time frame of 6.30 minutes. The benefit in time gained can be an advantage, for example, during toolkit measurements and rapid assessment, such as surveys. The scale can be used as one overall scale or as two subscales which assess ‘work-related participation’ and ‘general participation’. In conclusion, this study shows that the PSS is a valid tool to measure participation, sufficiently equal to the gold standard and, because of the smaller number of questions, showing benefits in time administration and in reducing the burden of the patients. However, further research is necessary to confirm these results in larger and different samples.

7 Acknowledgement

First of all, I would like to thank my supervisor, Dr. W.H. van Brakel. I appreciate all the helpful and inspiring conversations, the content of the received feedback and the way of communication. I would also thank my supervisor in India, D. Prakash Kumar for guiding me through the data collection phase of the study in Karigiri. Many thanks to Dr. Mannam Ebenezer, Director of the Schieffelin Institute of Health – Research & Leprosy Centre, and his staff for making my research possible. In particular, Ms. V. Augustine, clinical psychologist, for finding a suitable interpreter and giving useful feedback and advice during the study abroad. Special thanks go to my interpreter, Ms. Anika Satiarasj. Thank you for all the efforts you put into the study, for giving me insights into the Indian culture and for being my Indian friend. Finally, I would like to thank all the participants who were part of the study and also the Netherlands Leprosy Relief for their financial support.

8 Bibliography

Albert, B., Hurst, R. (2005). Disability and a human rights approach to development *Disability KaR Report*.

Bland, J.M., & Altman, D.G. (1986). Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet*, 327 (8476), 307-310.

van Brakel W.H., Anderson A.M., Mutatkar R.K., Bakirtzief Z., Nicholls P.G., Raju M.S., Das-Pattanayak R.K., (2006). The Participation Scale: measuring a key concept in public health. *Disabil Rehabil*, *28;28(4):*193-203.

Bowden A., Fox-Rushby J.A. (2003). A systematic and critical review of the process of translation and adaptation of generic health-related quality of life measures in Africa, Asia, Eastern Europe, the Middle East, South America. *Soc Sci Med,* 2003;57:1289–1306.

Brouwers C., van Brakel W.H., Cornielje H., (2011). Quality of life, perceived stigma, activity and participation of people with leprosy-related disabilities in south-east Nepal. *Asia Pacific Disability Rehabilitation Journal*, Vol 22, No 1.

Cardol M., de Haan R.J., van den Bos G.A., de Jong B.A., de Groot I.J. (1999).The development of a handicap assessment questionnaire: the Impact on Participation and Autonomy (IPA). *Clin Rehabil.* 1999 Oct;13(5):411-9.

Cardol M, de Haan R.J., de Jong B.A., van den Bos G.A.M., de Groot I.J.M. Psychometric properties of the impact on participation and autonomy questionnaire. *Arch Phys Med Rehabil* 2001;82(Feb):210-215.

Dalal, A. K. (2006). Social interventions to moderate discriminatory attitudes: The case of the physically challenged in India. *Psychol.Health Med., 11*(3), 374-382.

Dijkers, M.P.J.M., Yavuzer, G., Ergin, S., Weitzenkamp, D., Whiteneck, G.G. (2002). A tale of two countries: environmental impacts on social participation after spinal cord injury. *Spinal Cord, 40*:351-362.

DeCoster, J. (1998). Overview of Factor Analysis. Retrieved on 07-03-2012 from: http://www.stat-help.com/notes.html

EMGO Institute of Health and Care Research, COSMIN checklist manual (2010). Retrieved on 29-01-2012, from: http://www.cosmin.nl/images/upload/File/COSMIN%20checklist%20manual%20v6.pdf

ESCAP (2010). Guidelines for cognitive and pilot testing of disability questions for use in surveys. ESCAP Project for improving disability measurement and statistics in the Asia Pacific Region. Retrieved on 02-02-2012, from: http://www.unescap.org/stat/disability/Disability-question-testing-guidelines.pdf

Fayers P.M., Curran D., Machin D. Incomplete quality of life data in randomized trials: missing items. *S tat Med.* 1998;17:679-96.

Field A. (2009). *Discovering statistics using Spss, Third edition*. London: Sage Publications.

Green J., Thorogood N., (2009). *Qualitative Methods for Health Research*. London: Sage Publications.

Khasnabis, C., Heinick Motsch, K. (2008). The participatory development of international guidelines for CBR. *Lepr Rev 79*: pp. 17-29.

Klinic S., Campbell C., (2009). “It shouldn’t be something that’s evil, it should be talked about”: A phenomenological approach to epilepsy. *Seizure-European Journal of Epilepsy and stigma*. 18(20);665-71.

Habing B., (2003*). Exploratory Factor Analysis*. University of South Carolina. Retrieved on 01-10-2012, from: http://www.stat.sc.edu/~habing/courses/530EFA.pdf

Hanneman S.K., (2008). Design, Analysis and Interpretation of Method-Comparison Studies. *AACN Adv Crit Care. Apr–Jun; 19(2): 223–234.*

Herdman, M., Fox-Rushby, J., Badia, X. (1998). A model of equivalence in the cultural adaptation of HRQoL instruments: the universalist approach. *Quality of Life Research, 7*:323-335.

Ho Yu C., An introduction to computing and interpreting Cronbach Coefficient Alpha in SAS. *Statistics, Data Analysis, and Data Mining*; 246-26. Year of publication unknown.

Leonardi, M., Bickenbach, J., Ustun, T. B., Kostanjsek, N., & Chatterji, S. (2006). The definition of disability: what is in a name? *Lancet, 368*(9543), 1219.

Magasi S., Post M.W., (2010). A comparative review of contemporart participation measrures’ psychometric porporties and content coverage*. Arch Phys Med Rehabil. ;91*:S17-28.

Misajon, R., Pallant, J.F., Manderson, L., Chirawatkul, S. (2008). Measuring the impact of health problems among adults with limited mobility in Thailand: further validation of the Perceived Impact of Problem Profile. *Health and Quality of Life Outcomes*, 6:1-8.

Noreau L., Fougeyrollas P., Vincent C. (2002). The LIFE-H: Assessment of the quality of social participaton. *Technology and Disability,* 14:113-118.

Peters E.S. Eshier A.L. (2002). Male-female (sex) differences in leprosy patients in south eastern Nigeria: females present late for diagnosis and treatment and have higher rates of deformity. *Lepr Rev*. Sep;73(3):262-7.

Rensen, C., Bandyopadhyay, S., Gopal, P.K., Van Brakel, W.H. (2010). Measuring leprosy-related stigma – a pilot study to validate a toolkit of instruments. *Disability and Rehabilitation*, 1-9.

Rusch M., Nixon S., Schilder A., Braitstein P., Chan K., Hogg R.S., (2004). Impairments, activity limitations and participation restrictions: prevalence and associations among persons living with HIV/AIDS in British Columbia. *Health Qual Life Outcomes, 6*;2:46.

Singh S., Sinha A.K., Banerjee B.G., Jaswal N., (2009). Participation level of the leprosy patients in society*. Indian J Lepr, 81(4):*181-7.

Stevelink S.A.M, W.H. van Brakel, N. Banstola, C.B. Terwee, (2011). Testing the psychometric properties of the Participation scale in Eastern Nepal. *Quality of Life Research*, accepted chapter 3

Stevelink S.A.M., Hoekstra T., Nardi S.M.T., van der Zee C.H., Banstola N., Premkumar R., van Brakel W.H., (2012). Development and structural validation of a shortened version of the Participation Scale. *Disability and Rehabilitation*. 02/2012, London.

Stutterman S. E., Bos A.E.R., Shiripinda I., de Bruin M., Pryor J.B., Schaalma H.P.,(2009). HIV-related stigma in African and Afro-Carribean communities in the Netherlands: Manifestations, consequences and coping. *Psychology and Health.*

Terwee C.B., Bot S.D., de Boer M.R., van der Windt D.A., Knol D.L., Dekker J., Bouter L.M., de Vet H.C., (2007). Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol, 60(1)*:34-42.

Terwee C.B., Mokkink L.B., Knol D.L., Ostelo R.W.J.G., Bouter L.M., de Vet H.C.W. (2011). Rating the methodological quality in systematic reviews of studies on measurement properties: a scoring system for the COSMIN checklist. *Qual Life Res*. 2011 jul 6.

Thomas, P. (2005). Mainstreaming disability in development: India country report *Disability KaR Report*.

Ustün T.B., Chatterji S., Bickenbach J., Kostanjsek N., Schneider M. (2003). The International Classification of Functioning, Disability and Health: a new tool for understanding disability and health. *Disabil Rehabil.* 2003 Jun 3-17;25(11-12):565-71.

UN. (2008). Mainstreaming disability in the development agenda *United Nations Report*.

Vlassoff C., Khot S., Rao S. (1996). Double jeopardy: women and leprosy in India. *World Health Stat Q.*1996;49(2):120-6.

World Health Organization, (2011). Disabilities and rehabilitation, *World report on disability*.

World Health Organization. (2001*). International Classification of Functioning, Disability and Health* (ICF)

The World Bank, (2007). Human Development Unit, South Asia Region. *People with disabilities in India*: From commitments to Outcomes.

9 Appendices

Appendix 1. Participation Scale (version 6)

No	Participation Scale v6.	Not specified, not	Yes	Sometimes	No	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 / neighborhood as much as your peers do? (except for treatment) e.g. bazaars, markets		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
5	Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
6	Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
7	Are you as socially active as your peers are? (e.g. in religious/community affairs)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
8	Do you have the same respect in the community as your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
9	Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
10	Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
11	Do you visit other people in the community as often as other people do?		0			0					

	[if sometimes or no] How big a problem is it for you?						1	2	3	5	
12	Do you move around inside and outside the house and around the village / neighbourhood just as other people do?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
13	In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
14	In your home, do you do household work?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
15	In family discussions, does your opinion count?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
16	Do you help other people (e.g. neighbours, friends or relatives)?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
17	Are you comfortable meeting new people?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
18	Do you feel confident to try to learn new things?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	

Time in minutes:____________________

TOTAL

Name: ____

Age: ____

Gender: ______

Interviewer: _________________________________

Date of interview: ___ / ___ / ____

Grades of participation restriction

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

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

Appendix 2. Participation Scale Short version

No	Participation Scale Short version	Not specified, not	Yes	Sometimes	No	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 as your peers do? (e.g. 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	
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 during important decision making?		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	
14	Are you able to get your privileges and benefits from the government? (e.g. Pension, family card, bus and train card)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	

Time in minutes:____________________

TOTAL

Name: ____

Age: ____

Gender: ______

Interviewer: __________________________________

Date of interview: ___ / ___ / ____

Appendix 3. Back-translation of PSS (with marked refinements)

Translated by Anika Sariarasj.

1. Do you have the same chances to find a job as other men or women (deleted: “children”) in your village do?
If it is sometimes or no, how big is the problem?

2. In your village, can you work as hard and long like people in your age and qualification do?

3. Can you earn money for your family as much as others in your village do?

4. Can you travel outside your neighbourhood like the people in your village do? (except for treatment)

5. Can you participate in marriage, death funeral or any festivals like others in your village do?

6. To men: Can you sit in a teashop and talk with others or play chess like other men in your village do?
To women: Can you sit with your neighbourhood ladies in a teashop and speak with them like other women in your village do?

7. Do you get the same respect as others in your village?

8. Can you mingle with everyone or can you go to your friends or relatives homes like other people in your village do?

9. Can you walk around freely in your own place like others in your village do?

10. Can you go to a teashop, (added:) barbershop and markets in your village like others in your village do?

11. Men: Can you do household work like others in your village do? (e.g. Repairing, taking care of sons)
Women: Can you do household like others in your village do? (e.g. Cooking, take care of children and cleaning the home)

12. Does your family respect your words during (added:) important decision making?

13. Can you mingle with new people like other people in your village do?

14. (added:) Are you able to get your privileges and benefits from the government? (e.g. Pensions, family card, bus and train card.)

Appendix 4: Model of Herdman and Model of Terwee

Model of Herdman et al. (1998)

In figure 7 an overview of the model of Herdman is given. This model shows the framework of adapting health-related quality of life questionnaires across two or more cultures. The following types of equivalence are defined in the model: Conceptual equivalence, item equivalence, semantic equivalence, operational equivalence and measurement equivalence.

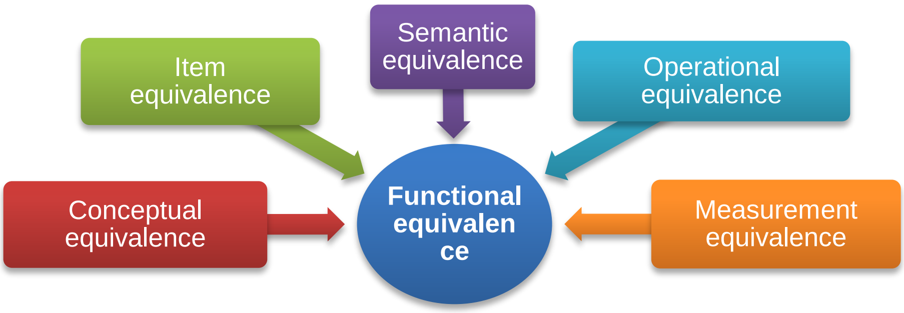

Figure 7. Model of equivalence in the cultural adaptation (Herdman et al., 1998)

- *Conceptual equivalence*: “The instrument has the same relationship to the underlying concept in both cultures, primarily in terms of the domains included and the emphasis placed on different domains”.
- *Item equivalence:* “Items estimate the same parameters on the latent trait being measured and when they are equally relevant and acceptable in both culture s”.
- *Semantic equivalence*: “The meaning of the items is the same across languages, achieving a ‘similar effect’ on respondents who speak different languages”.
- *Operational equivalence*: “Possibility of using a similar questionnaire format, instructions, mode of administration and measurement methods”.
- *Measurement equivalence*: “Psychometric properties of the adapted version of the instrument are equivalent to the original.” (Herdman et al., 2008)

Quality criteria of Terwee et al. (2007)

The quality criteria of Terwee et al. (2007) referred to the quality criteria of the Scientific Advisory Committee (SAC) of the Medical Outcomes Trust by giving benchmarks. The SAC defined eight measurement properties to develop and evaluate health status questionnaires. In figure 8 an overview of the model is given followed by the explanations of the concepts en its benchmarks.

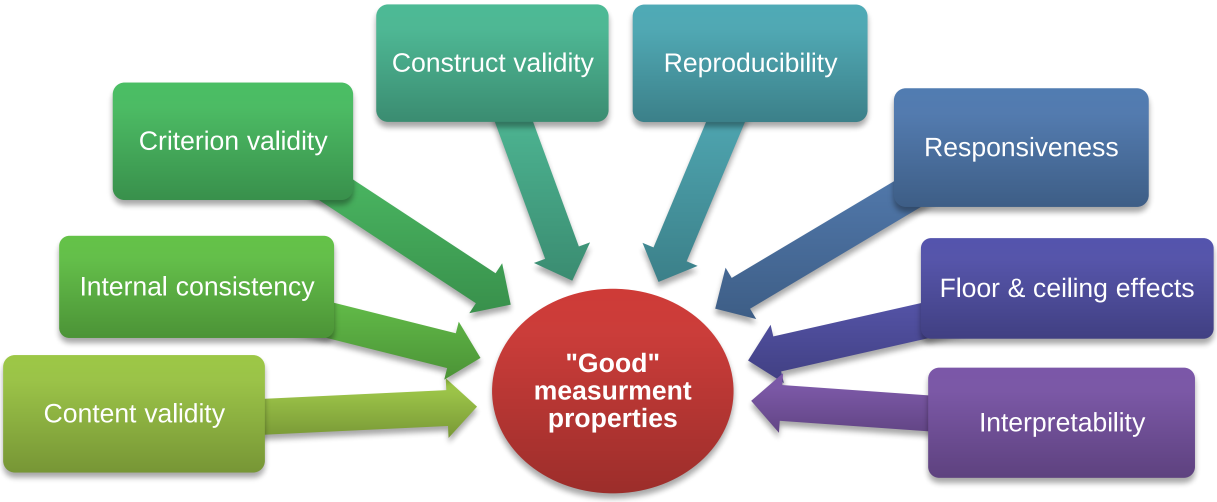

Figure 8. Model to achieve “good” measurement properties in health questionnaires (Terwee et al., 2007)

• *Content validity:* “the extent to which the domains of interest is comprehensively represented by the items in the questionnaire”.	Clear description is given of the measurements aim, target population, concepts that are being measures and the item selection.
• *Internal consistency:* “the extent to which items in a questionnaire (sub)scale are correlated (homogeneous), thus measuring the same concept”.	Factor analysis perform on adequate sample size (7* # > 100). Cronbach’s alpha calculates per dimension and Cronbach’s alpha between 0.70 and 0.95
• *Criterion validity:* “the extent to which scores on a particular instrument relate to a gold standard”.	Convincing arguments that gold standard is “gold” and correlation standard >0.70
• *Construct validity:* “the extent to which scores on a particular instrument relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured”.	Specific hypothesis are formulated and at least 75% of the results are in accordance of the hypothesis
• *Reproducibility:* Agreement: “the extent to which the score on repeated measures are close to each other”. Reliability: “the extent to which patients can be distinguished from each other, despite measurement errors	Minimal importance change < smallest detectable change or convincing arguments Intraclass correlation or weighted Kappa > 0.70
• *Responsiveness:* “the ability of a questionnaire to detect clinically important changes over time, even if these changes are small”.	Smallest detectable change < minimal important change outside the limits of agreement or relative risk > 1.96 or Area under the curve > 0.70
• *Floor or ceiling effects*: “the number of respondents achieved the lowest or highest possible score”.	< 15% of the respondents achieve the highest of lowest possible scores
• *Interpretability:* “the degree to which one can assign qualitative meaning to quantitative scores.	Mean and standard deviation score presented of at least four relevant subgroups of patients and minimal important change defined

(Terwee et al., 2006)

Appendix 5: Informed consent

INFORMED CONSENT FORM
INTERVIEW

(Validation of the Participation Scale Short version)

Your voluntary participation is needed in this study to adapt a research instrument, namely the Participation Scale Short version. This instrument is necessary to plan, monitor and evaluate rehabilitation programmes and assess the impact of participation reduced interventions in people affected by leprosy.

If you decide to participate, we will interview you maximum 40 minutes. Questions are about your experiences of your own participation restrictions / experiences of patients who have participation restriction and the P-scale. The whole interview will be tape recorded. The information you give is confidential and will be used only for this study.

Whether you choose to participate, you do not have to answer all of the questions, you are also free to stop your participation at any time without giving a reason.

If you have any questions pertaining to this study, please contact Ms. Angela Jansen at phone no: +919489032013

Verbal informed consent: "I have read and understood the information of the Informed consent and decided to participate in this study."

VU University Amsterdam

Appendix 6. Assessing Conceptual and Operational equality

ICF domains of participation

Communication	
PWD #1	*"I won't go to anyone's homes, also not of my neighbors or the teashop until they respect me or call me, I don't want to talk with them. […] If I look to my wife; she goes to the teashop and chat with other women, socialize with them. When I am home I talk a lot, I discuss everything with my family that makes me feel good [..] I don't talk with strangers."- " […] won't talk because I don't want to tell anything about my condition and earn sympathy.", "I speak only to the people who want to mingle with me."*
PWD #2	*"If I went to a teashop everybody avoid me because I am a leper, I can see it in the way they act. Even in my own family they restrict and avoid me."- "Everyone is going to the teashop to chat and gossip with each other"*
PWD #3	*"Mingle with people.. I can but I will be in a limit with everyone. If people talk to me than I will talk to them, that's it."*
PWD #7	*"I'm afraid to talk with other people, at my home it is safe.. everyone will accept me as I am. People outside.. I don't know. They don't speak nice to me."*
PROF #3	*"because leprosy patient or any deformity patient will usually be avoid, they are not willing to talk, to speak, it's hard for them"*

Mobility	
PWD #2	*"I couldn't even catch a glass", "There is a difference because my hand is disabled. I can't work with my hand. I can't even wash my own cloths with my hand.", "My left hand is better and good but I couldn't use my single hand for everything. That is really really hard."*
PWD #3	*"At this moment I am not able to walk […] I was working in a cement shop as labour now I couldn't do that. I have to find an alternative job since I cannot work with my leg. Staying at home means no money to buy food."*
PWD #6	*"I have to take care of my hand and its' health and hope to get work and married soon."*

Domestic life	
PWD #2	*"There is a difference because my hand is disabled. I can't work with my hand. I can't even wash my own cloths with my hand."*
PWD #6	*"To build a home and take care of my parents. When I get children I should marry them and settle in my life, also take care of them."*
PROF #4	*"participation is also your daily activities, like personal care, brushing, taking food, clothe yourself, visiting the barbershop, going for work and going for any education, going for study and also participating in family affairs, participation in community affairs."*

Interpersonal Interaction & Relationships	
PWD #1	*"I have to be away from my family since I can spread leprosy. […] The disease must not affect my family, it is so sad because my family is important to me, they are the only people I have".*
PWD #2	*"If I went to a teashop everybody avoid me because I am a leper, I can see it in the way they act. Even in my own family they restrict and avoid me", "The thing we need is love, I don't have that anymore. I'm happy with this conversation, you both are my only friends.", "If I am accepted by at least my family that will be fine, I can't struggle with my disease in this old age", "Some people who are generous and speak kind to me but some will always ignore me. I like to speak with you both, you are my only friend. ", "I have two children even they never mind me due to my leprosy [….] [about his son] He don't like to keep me in his home, he thinks leprosy is spreadable so he don't want me in his home", "The doctor took my diary and called all my relatives but none of them came even my son and daughter. Then I was taken cared by a nurse. I would have been died they*

	saved to see all these nonsense. And those are my relatives and children. I am really not lying they treated me in such way. I can feel how sad I am”
PWD #6	*“I have to take care of my hand and its’ health and hope to get married soon.”*
PWD #7	*“Since I am a patient, I could not be mingle with all the people.. most of my relatives and friend won’t avoid me but other people will [….] some will accept me and some will avoid me that depends on the person”*
PROF #1	*“For example there is a ‘friend-clan’ and not everyone and if there are 5 friends and we just want to have fun and spend some good time and if a person in that clan has a problem or something with his health, he won’t be able to socially come out and participate with everyone. Relationship with other and being there for each other is important”, “I am a sports person, so playing is a very good social participation, I go to my friends and play with them, every day that’s one think and every weekend we go to some places, to the cinema theatre or something and then in Sundays we go to church”, “I give preference to my parents I go with them, especially with my dad is here alone, my mom is abroad”*
PROF #2	*“We are not alone, we are in the community so we have our different relationships with friend, family and locals”*
PROF #4	*“Participation is looking after my family affairs”*

Major life areas	
PWD #1:	*“If I work in the field, I will get hurt; wounds on my legs and the wound need a long time to heal, to work is difficult.”, “I could get a job but it is hard for me to do it”*
PWD #2	*“I am old and I can’t get any job [….] There is no work for me, I’m too old, people will pick the youngster, not me.”*
PWD #3:	*“I was working but I couldn’t do that now. […] I was working in a cement shop as a labour now I couldn’t do that. I have to find an alternative job since I cannot work with my leg.”*
PROF#4:	*“participation is also your daily activities, like personal care, brushing, taking food, clothe y yourself, visiting the barbershop, going for work and going for any education, going for study and also participating in family affairs, participation in community affairs”*

Community, Social and Civic life	
PWD #2	*“What is there for me to go to festivals and celebrations.. I won’t even go to temples. People also don’t invite me”*
PWD #6	*“Joining with everybody and joining at marriages and death funerals.. things like that I really like”, “Like it to listen to music, call and text with my friends”, “Roaming with my friends, they will come to my house and I would like to go to their homes and we used to go to the movies and going to neighbours […] often going to the teashop to meet other people”, “Playing cricket, carom board, chess and kepadi”*
PWD #7	*“I don’t go out, staying at home is save.. For any marriages or death funeral.. I won’t go. It is due to my disease, I don’t know”*
PROF #1	*“I am a sports person, so playing is a very good social participation, I go to my friends and play with them, every day that’s one think and every weekend we go to some places, to the cinema theatre or something and then in Sundays we go to church”* *- “The patients they think different about participation. They do not come out and don’t come out, going to churches, cannot work, or going to marriages. They don’t participate themselves in normal community life”, “You have a meeting or functioning in your place and you need to participate for the meeting and I will be ready and I will tell them: “I’m ok and I will come and participate”. But If you come and go ask a leprosy patient to come and participate in that function, he feel.. he got a deformity or something like that and that he won’t be in a state of participating he surely decline you.”*
PROF #2	*“We are used to participate in festivals, marriages, death funerals and we get together”*
PROF #4	*“Going to marriages, festivals, death funerals, leisure time activities like site seeing, teashop [….] Games/chess, watching tv, going to the cinema, playing games with my children, going to the church” -*

Learning and Applying Knowledge	
PROF #2	*“We have to educate the patient regarding their way of living, to participate in the community only than the personal will change”, “We educate them regarding the disease or other problems, so daily we promote to come out of their restriction”, “First we have to inform them about the disease, what is it and what happens. We have to educate the people [….] So we want to give the patients the understanding of the disease. Also every one of the community.[….] We are giving them the skills, how to handle. We make them ready to face the consequences of the disease.”*
PROF #4	*“participation is also your daily activities, like personal care, brushing, taking food, clothe yourself, visiting the barbershop, going for work and going for any education, going for study and also participating in family affairs, participation in community affairs”*

General tasks and Demands	
PROF #3	*”I want to help a particular patient. [….] If they need any help. In particular if they need a bus pass I have to go and get it from a higher authority. In that way my participation will be there. I have to help them.” “helping in the sense, just superficial things. If a person is not possible to walk, I have to help the person to move from one place to another place.”, “Usually the higher caste people for example have their own principles. Usually they don’t help.. people affected by leprosy or any other disease, in particular the deformed people. So as a middle man. I know how to our approach the higher caste people, we asked them to accept such people. Such people to involve them in things. So they will get recognition from the community. So as a middle men, people like us, we have to reduce the gap that means, the rich people and the poor people, particularly the disabled people.”, “if the need any help particularly from a government officer or form the higher sector or from any other people, people means we have to really approach these people and get some benefits for the people […]. For example, they need a bus pass, train pass, they need some loan from banks,”*
PROF #4	*“The governments system and legislation is not working. There are so many laws but they don’t work appropriately. The government is not functioning well. There is inequality. Those who are living above poverty have all the privilege, they know the route [….] They receive all the privileges. The poor, the disabled, the women most of the people don’t know where to get the benefits, they are easily neglected.”*

Self-care	
PWD #2	*“I feel really sad because I eat and wash and clean my body with my left hand.[…] I cannot at and bath with the same hand.”, “Then I am bathing, how can I bath and put soap all around my body with my left hand? It is really hard.”*
PROF #2	*“The cleanness in the villages, rural and urban, you don’t have toilets, they are used to put it on the road to dispose their stool, so we tell the people not to do that and use the toilet and take care of them self. Hygiene is also participation.”*
PROF #4	*“participation is also your daily activities, like personal care, brushing, taking food, clothe yourself, visiting the barbershop, going for work and going for any education, going for study and also participating in family affairs, participation in community affairs”*