Examining the validity of the SALSA scale as a generic measure of activity

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Summary

Background   The SALSA scale is a questionnaire measuring activity limitation and safety awareness among people with peripheral nerve injuries. However, it is not yet validated as an instrument for people with other conditions. The objective was to examine the validity of the SALSA scale as a generic instrument to measure activity limitation in health conditions other than leprosy and diabetes.

Methods   For the examination of the validity of the SALSA scale as a generic instrument a quantitative and qualitative approach have been used. For the quantitative part, activity limitation was measured by conducting the SALSA scale and the WHO-DAS II scale with two diagnostic groups. The first group consisted of people affected by leprosy or diabetes. The second group consisted of people with a locomotor disability related to conditions other than leprosy and diabetes. The correlation coefficient, the intraclass correlation coefficient (ICC), Cohen's Kappa (*k*) and a Bland-Altman analysis were used to assess the level of agreement between the scores. For the latter two methods the scores were standardized to a 0 – 100 scale. In the qualitative part, semi-structured interviews with people with a locomotor disability and a focus group discussion with experts were conducted to assess the content validity of the scale for people with a locomotor disability.

Results   138 respondents participated in the quantitative part of the study. The SALSA scale and the WHO-DAS II scale were strongly correlated (*r*=0.79). The ICC for all paired measurements was 0.87. Cohen's Kappa showed substantial agreement (*k*=0.67). The Bland-Altman method showed limits of agreement of -30.0 to 19.1. Six people with a locomotor disability and four experts participated in the qualitative part of the study. In this part of the study the content of the SALSA scale was considered as focusing too much on the sensory loss aspects of leprosy and diabetes and too little on the lower limb aspects which are the most common in locomotor disability.

Conclusion   The quantitative study shows that the SALSA scale is a valid instrument for measuring activity limitation in persons affected by a locomotor disability. According to the qualitative method some adaptations would need to be made to improve this validity. However, adjustment may cause loss of sensitivity with regard to the special problems caused by sensory impairment. Overall we can conclude that the SALSA scale has shown to be a valid instrument for measuring activity limitation in persons affected by a locomotor disability

1.   Introduction

The concept of disability was first described in the International Classification of Impairments, Disabilities, and Handicaps (ICIDH) framework to classify consequences of disease or health condition in terms of three concepts: impairments, disabilities and handicaps (World Health Organization, 1980). After criticism, this classification has been revised. The new version was released as the International Classification of Functioning, Disability and Health (ICF). Disability was no longer conceived as solely a result of physical impairment, but as a dynamic interaction between biological, personal and social factors. The ICF concept takes in account the effects of interaction between the health condition and the contextual factors on the functioning, in terms of impairments, activity limitations and participation restrictions (World Health Organization, 2001). See Figure 1.1.
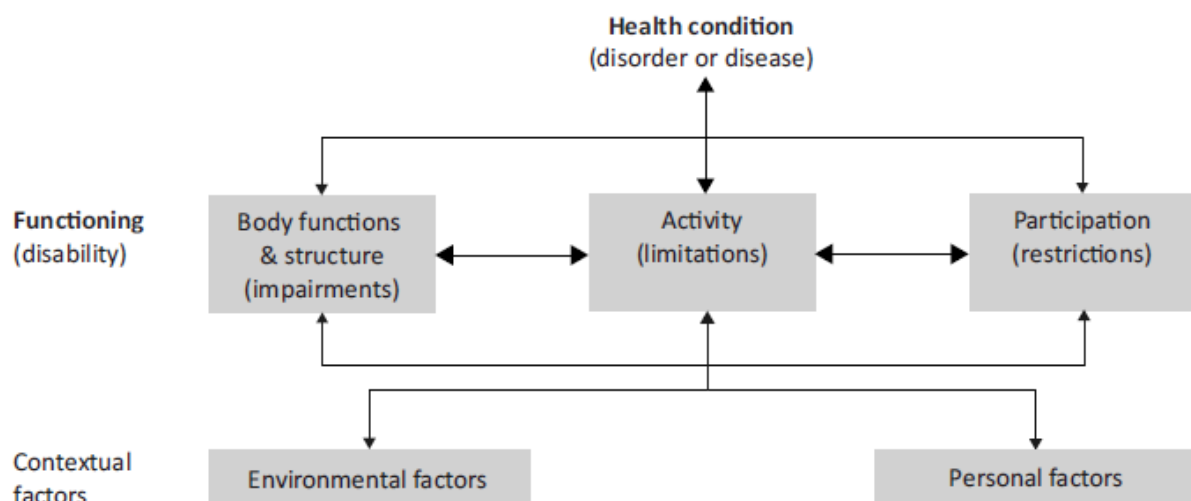
Figure 1.1: ICF model of Functioning, Disability and Health (World Health Organization, 2001)

Disability is, defined by Leonardi et *al.* (2006): "a difficulty in functioning at the body, person, or societal levels, in one or more life domains, as experienced by an individual with a health condition in interaction with contextual factors". The ICF defines impairment as "problems in body function or structure, such as a significant deviation or loss"; activity limitations as "difficulties an individual may have in executing activities" and participation restrictions as "problems an individual may experience in involvement in life situations" (World Health Organization, 2001).

According to existing estimates, more than 10 per cent of the world population has a disability. This represents a number of more than 600 million people (United Nations, 2000). Leprosy is the leading cause of permanent physical disability among communicable diseases. Leprosy affects the peripheral nerves, which causes disabilities (Van Brakel *et al.*, 1997).

The World Health Organization (WHO) disability grading for leprosy is a commonly used measure to assess the severity of impairments of eyes, hands and feet (Van Brakel *et al.*, 1999). This disability grading system uses the maximum score of the six sites evaluated. A measure which is more responsive to change is the Eyes, Hands, Feet (EHF) score. This measure uses the sum of the six sites as an individual indicator of severity of impairment (Meima *et al.*, 2001). According to the ICF, the assessment of disability should also consider activity limitations and participation restrictions. To assess the limitations in activities of daily living in people with peripheral neuropathy, as a result of leprosy and diabetes, the SALSA scale has been developed (Salsa Collaborative Study Group, 2007).

SALSA stands for Screening Activity Limitation and Safety Awareness. The SALSA scale is a cross-cultural, 20-item, interview based instrument to measure self-perceived problems in activities of daily living (ADL) and problems in safety and risk related to the sensory loss in peripheral neuropathy. The SALSA scale was developed as an ICF-based measure to assess the severity of activity limitation, in a collaborative research in five countries around the world.

The SALSA scale has good psychometric properties. The collaborative study has established face validity and internal consistency. Besides, the correlation between the SALSA scale and individual expert assessments was 0.67, showing external validity. It has been validated for people with peripheral neuropathy, as a result of leprosy and diabetes (Salsa Collaborative Study Group, 2007). A study in Nigeria examined the test re-test reliability of the SALSA scale. The scale has shown both inter- and intra interviewer agreement with both a kappa (k) > 0.6 in 15 items. The SALSA scale is thus considered as a useful tool to reliably document functional level and activity limitations as perceived by the client (Melchior, 2008; Ebenzo, 2009).

To measure functioning and disability, the WHO-DAS II was developed (World Health Organization, 1999). WHO-DAS II stands for the World Health Organization's Disability Assessment Schedule II, an instrument developed to measure functioning and disability in a manner compatible with the concepts of the ICF. The WHO-DAS II provides a profile of functioning difficulties across six domains during the 30 days before the interview, including: understanding and communicating, getting around, self-care, getting along with people, life activities, and participation in society, as well as a general disability score (World Health

Organization, 2007). It can be used across various conditions and has undergone extensive psychometric testing. The 36-item version showed a good intraclass correlation coefficient (ICC) within the domains (0.71-0.92), and the 12-item version accounted for 85% of the variance of the full item version (Andrews, 2008; Üstün *et al.*, 2010).

Since the development of the SALSA scale, it has been used in many different countries in leprosy settlements, leprosy out-patients, disability surveys and evaluation studies (Velema, 2008; Roddawar, 2008; Nascimento, 2008; Grossi, 2008; Melchior, 2008; Van Veen, 2008). Since the scale will be used in national and international programs, there is need for further research into the validity of the SALSA scale for people affected with leprosy and diabetes. The use of the SALSA scale is not limited to the use for people with peripheral nerve injuries; however, it has not yet been validated as an instrument for people with other conditions. Thus, there is need for research into the validity of the SALSA scale for people from diagnostic groups other than leprosy and diabetes.

The current study addresses the following question: *What is the validity of the SALSA scale as a generic instrument measuring activity of daily living (ADL)?* The objective of the present study is to examine the validity of the SALSA scale as a generic instrument for measuring activity limitation in health conditions other than leprosy and diabetes, by determining the content validity of the SALSA scale for other diagnostic groups and comparing the performance of the SALSA scale to another instrument which is already validated as a generic ADL measure. Such comparative research is hardly done and for the SALSA scale, only one small validation study of this type was carried out in Israel, so far (Melchior, 2008). In that study, SALSA scores were compared to outcomes of several objective measures.

Research on the applicability of the SALSA scale in other health conditions than leprosy or diabetes has never been done. It would be likely that the SALSA scale would be useful for other health conditions that lead to peripheral neuropathy. In addition, from a practical perspective it would be ideal to have one instrument which will give comparable data. This will be in favor of an inclusive focus, "where people with leprosy-related disability are seen as a sub-group of people with disability in the wider context, since many of their needs are the same as those of others" (Van Brakel, 2008).

This research is expected to provide important information which can be applied internationally. First of all, this study will reveal insight into the unique contribution of the SALSA scale in understanding disability in the context of leprosy and diabetes. Secondly, it will improve understanding of the applicability of the SALSA scale and allow selection of the most useful instrument in a given situation, both in terms of feasibility and of information gained. This

will cause an increase in comparability of research results to, which will improve the communication and scholarly discourse across disciplines and national boundaries. Eventually it will stimulate interdisciplinary research, causing improvement in clinical care, and ultimately lead to better informed health policy and management.

2.   Methods

2.1   Setting

The study was conducted at the Schieffelin Institute of Health Research and Leprosy Centre (SIHR&LC), also known as Karigiri, and surrounding areas in the Vellore district, Tamil Nadu, South India. The study was ethically approved by the Research Ethics Committee of the SIHR&LC. In this study the CIOMS guidelines, international guidelines for ethical review of epidemiologic studies, were followed (Council of International Organizations of Medical Sciences, 1991). All respondents were provided with a clear explanation of the purpose of the study. Prior to participation in the study, verbal informed consent was obtained. Written informed consent was not possible, since the study engaged people from disadvantaged and vulnerable communities where literacy and education opportunities are likely to be inadequate.

2.2   Study design

To examine the validity of the SALSA scale as a generic instrument for measuring activity limitation in health conditions other than leprosy and diabetes, a quantitative and qualitative assessment were performed. In the quantitative part an assessment of the degree of agreement between the SALSA scale and the WHO-DAS II scale was made, for which questionnaire-based interviews were conducted. In the qualitative part an assessment of the content validity of the SALSA scale for people with a locomotor disability was made, for which semi-structured interviews with people with a locomotor disability and a focus group discussion with experts were conducted, and a conceptual comparison of the measurement scales was made. According to the World Health Organization (1980), locomotor disability is defined as "a disability to an individual's ability to execute distinctive activities associated with moving, both themselves and objects, from place to place".

This was a cross-sectional study of activity limitation, a within-person comparison was made of two measurement methods. The data were collected from March 2010 to June 2010. The questionnaire-based interviews and the semi-structured interviews were conducted with help of a trained, native Tamil speaking interpreter. For the questionnaire-based interviews each respondent was randomized to score their activity limitation by the SALSA scale or the WHO-DAS II scale first. For the semi-structured interviews, the data collection was standardized by the use of a pre-scripted protocol.

2.3   Study sample

The study sample for the quantitative study consisted of two diagnostic groups. The first group consisted of people affected by leprosy or diabetes. The second group consisted of people with a locomotor disability related to conditions other than leprosy and diabetes. The different conditions included in the second group were: cerebral palsy, spinal cord injury, brain injury, stroke, post polio residual paralysis and amputation. The desired sample size was at least 50 respondents per group. Eventually, 63 people affected by leprosy or diabetes and 75 people with a locomotor disability participated in the quantitative study, selected by stratified sampling on the basis of diagnostic group, gender and age. Six people with a locomotor disability, selected by systematic sampling, participated in the semi-structured interviews as well. The respondents were visiting or were visited by Community Health Workers of the Schieffelin Institute of Health Research and Leprosy Centre (SIHR&LC) in Karigiri, Paul Brand Integrated Health Centre (PBIHC) in Old Katpadi or the Gudiyatham Clinic in Gudiyatham. One occupational therapist and three physiotherapists participated in the focus group discussion, all working at the Schieffelin Institute of Health Research and Leprosy Centre (SIHR&LC) in Karigiri.

All persons who spoke Tamil fluently, were between 18 and 70 and who had leprosy-related disability, diabetes or locomotor disability were eligible for inclusion in the quantitative part of the study. Excluded from the study were persons with more than one of the specified health conditions, or overlap with any other condition causing motor, sensory and/or cognitive impairments, persons admitted at the hospital and/or persons with communication difficulties.

2.4   Technical methods

2.4.1   Quantitative methods

For the purpose of this study, data were obtained on the activity limitation of the study sample using two different scales. The performance of the SALSA scale was compared among a generic instrument known to accurately measure activity limitation, namely the WHO-DAS II. The outcome of the SALSA scale was a score of activity limitation ranging from 1 to 80, and the outcome of the WHO-DAS II was a score of activity limitation ranging from 0 to 48, with higher scores reflecting greater disability. The total scale scores were calculated using the simple sum score technique (The SALSA collaborative study group, 2004; Üstün *et al*., 2010).

2.4.2 Qualitative methods

The semi-structured interview and the focus group discussion points were based on the criteria for content validity assessment set by the COSMIN study (Mokkink *et al.*, 2010). An assessment was made of which items of the SALSA scale refer to relevant aspects and of items that refer to irrelevant aspects, for measuring activity limitation in people with a locomotor disability. Furthermore, we also assessed which items were missing and whether all items together comprehensively reflect activity limitation according to people with a locomotor disability. In addition, we made a conceptual comparison between the SALSA scale and the WHO-DAS II scale by analyzing the differences and similarities in content of the measurement scales.

2.5 Data analysis

2.5.1 Quantitative study

To examine whether the SALSA scale is valid as a generic instrument for measuring activity limitations in health conditions other than leprosy and diabetes in a quantitative way, an assessment of the degree of agreement between the SALSA scale and the WHO-DAS II scale was made. This agreement was assessed in a leprosy and diabetes group and in a group of people with a locomotor disability, using four methods: Pearson's correlation coefficient, the intraclass correlation coefficient (ICC), Cohen's Kappa for the dichotomized scores and the Bland-Altman method. To determine whether there were significant differences between the diagnostic groups, the Chi-square test was used. To assess similarities and differences in the profile of activity limitation, figures were made showing the scores per item. To assess similarities and differences in the determinants of activity limitation as measured by the different measurement scales, a multivariate analysis was made stratified for people with leprosy or diabetes and people with a locomotor disability. Data was analyzed using the statistical computer program Epi-Info.

2.5.1.1 *Correlation coefficient*

To assess the construct validity of the SALSA scale in relation to the WHO-DAS II scale, the correlation coefficient between the sum-scores was calculated. Since both measurement scales measure activity limitation, one would expect a correlation of at least 0.7. Thus, the correlation between the SALSA scale and the WHO-DAS II scale was considered satisfactory when >0.7 (Terwee *et al.*, 2007).

2.5.1.2   Intraclass correlation coefficient

The correlation coefficient shows a perfect agreement score of 1.0 when the scores are in a perfectly straight line, but with a constant difference. The intraclass correlation coefficient (ICC) corrects for this possible systematic difference. To assess the correlation, taking these possible systematic differences into account, the ICC was calculated as the (between-persons variance) divided by (the sum of between-persons variance and within-persons variance) (Streiner & Norman, 2008). Since both measurement scales measure activity limitation, one would expect an ICC > 0.7. Thus an ICC of >0.7 was considered as satisfactory and an ICC>0.75 was considered as 'excellent' (Terwee *et al.*, 2007; Fleiss, 1986).

2.5.1.3   Cohen's Kappa

To assess the agreement between the SALSA scale and the WHO-DAS II scale when the scores were dichotomized, Cohen's Kappa was calculated. The cut-off used for these dichotomous scores was based on the answer categories: the options 'very difficult' , 'I physically cannot' and 'I avoid because of risk' of the SALSA scale were considered similar to the options 'severe difficulty' and 'extremely difficult/cannot do' of the WHODAS, reflecting substantial activity limitation. Therefore, the maximum score without these answer categories was used as a cut-off, which was 40 points for the SALSA scale and 24 points for the WHO-DAS II scale. These cut-off points are also the median of the total scores. Using the magnitude guidelines of Landis & Koch (1977), who characterized values < 0 as indicating no agreement and 0–0.20 as slight, 0.21–0.40 as fair, .41–.60 as moderate, .61–.80 as substantial, and .81–1 as almost perfect agreement.

2.5.1.4   Bland-Altman method

The correlation coefficient measures the degree of association between the two scores; however, it does not reflect the direction of this association. To assess whether there is a pattern in differences and to overcome constant differences, the Bland-Altman method was used. This method consists of calculating the difference between the activity limitation scores of the SALSA scale and the WHO-DAS II scale. Since the scales have a different range, the scores were recoded to a range from 0 to 100. The distribution of this difference is examined in relation to the severity of activity limitation, represented by the mean of both measurement scores. The limits of agreement were calculated by the mean difference between the scores ± 1.96 × the standard deviation of these changes (Bland & Altman, 1986).

2.5.2 Qualitative study

To examine whether the SALSA scale is valid as a generic instrument for measuring activity limitations in health conditions other than leprosy and diabetes in a qualitative way, an assessment of the content validity of the SALSA scale for people with a locomotor disability was made. We assessed content validity using three methods: semi-structured interviews, a focus group discussion and a conceptual comparison.

The semi structured interviews and the focus group were recorded and transcribed. The Tamil transcripts of the semi-structured interviews were translated into English. These transcripts were analyzed using the computer program Kwalitan.

2.5.2 Qualitative study

3. Results

The study sample consisted of 138 respondents; 63 persons affected by leprosy or diabetes and 75 persons with a locomotor disability (LD). Six persons of the LD-group participated also in the qualitative part of the study. There were no significant differences in the demographic characteristics or the total SALSA and WHO-DAS II scores between respondents whose first interview concerned the SALSA scale and those who first answered the WHO-DAS II scale.

All respondents lived in rural areas. Although, there were slight differences in the other demographic characteristics between the leprosy and diabetes and the LD-group, as shown in Table 3.1. The study sample consisted of 68 males and 70 females. The mean age of the overall sample was 48.6 (SD= 12.4); 51.1 (SD= 11.0) for persons affected by leprosy or diabetes and 46.5 (SD= 13.3) for the LD-group. Most of the respondents (60.9%) were educated; either incomplete or completed primary school (55.8% and 2.2% respectively) or graduated (2.9%). Furthermore, the study sample consisted of 70.3% married respondents and the rest was either 'never married', 'separated' or 'widowed' (16.7%, 0.7% and 12.3% respectively).

Table 3.1: Socio-demographic characteristics of the respondents

Variable	Leprosy and diabetes (n=63)	Locomotor disability (n=75)	Total (n=183)	Difference* (χ^2 tested)
Sex				NS
Male	31 (49.2%)	37 (49.3%)	68 (49.3%)	
Female	32 (50.8%)	38 (50.7%)	70 (50.7%)	
Age				NS
< 50	28 (44.4%)	42 (56.0%)	70 (50.7%)	
≥ 50	35 (55.6%)	33 (44.0%)	68 (49.3%)	
Education				NS
Yes**	37 (58.7%)	47 (62.7%)	84 (60.9%)	
No	26 (41.3%)	28 (37.3%)	54 (39.1%)	
Married				NS
Yes	49 (77.8%)	48 (64.0%)	97 (70.3%)	
No***	14 (22.2%)	27 (36.0%)	41 (29.7%)	
Children				p=0.006
Yes	56 (88.9%)	52 (69.3%)	108 (78.3%)	
No	7 (11.1%)	23 (30.7%)	30 (21.7%)	

Occupation				p=0.012
Yes	26 (41.3%)	16 (21.3%)	42 (30.4%)	
No****	37 (58.7%)	59 (78.7%)	96 (69.6%)	
Income				NS
Yes	37 (58.7%)	33 (44.6%)	70 (51.1%)	
No	26 (41.3%)	41 (55.4%)	67 (48.9%)	
Time of diagnosis (years ago)				p=0.008
≤ 10 years ago	37 (58.7%)	27 (36.0%)	64 (46.4%)	
> 10 years ago	26 (41.3%)	48 (64.0%)	74 (53.6%)	
Assistive devices				p=0.014
Yes	41 (65.1%)	33 (44.0%)	74 (53.6%)	
No	22 (34.9%)	42 (56.0%)	64 (46.4%)	
* NS= Not significant **Incomplete schooling/ complete schooling/ graduate *** Never married/ separated/widowed **** Unemployed/retired/housewife				

Only 21.7% of the respondents did not have children, however, 88.9% of the leprosy and diabetes group did have children, compared to 69.3% of the LD-group and this difference was significant (p=0.006). Also more persons affected by leprosy or diabetes were employed (41.3%) in comparison to the LD-group (21.3%), this difference in occupation was also significant (p=0.012). 69.6% of the total study sample was either unemployed, retired or housewife (35.5%, 5.1% and 29.0% respectively). Approximately half of the study sample had no income (48.9%).

The time of diagnosis ranged from < 1 year to 63 years ago, with a mean for the different groups of 13.1 years ago (SD=12.4) for the leprosy and diabetes group and 23.7 years ago (SD=18.1) for the LD-group. There was a significant difference between the different diagnostic groups in this time of diagnosis (p=0.008), for 64.0% of the LD-group the diagnosis was more than 10 years ago, compared to 41.3% of the leprosy and diabetes group. Another significant difference was in the usage of assistive devices; more respondents in the leprosy and diabetes group (65.1%) used one or more assistive devices in comparison to the LD-group (44.0%). Figure 3.1 shows the usage percentages of the various types of assistive devices. The differences in the use of assistive devices were significant, except of 'adapted eating utensils' and 'working tools'. 'Special footwear' is the most common assistive device in the leprosy and diabetes group, and a 'walking stick or frame' for the LD-group.
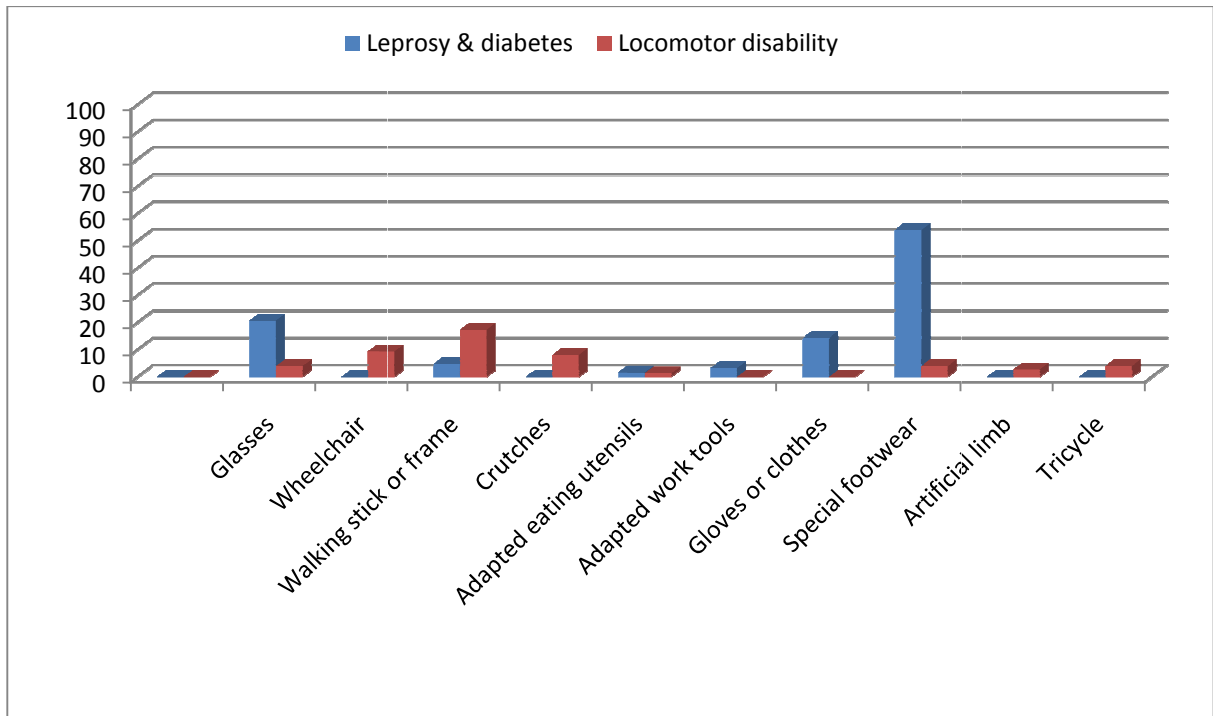
Figure 3.1: Percentage of study sample using the various assistive devices

Of the total study sample, 50% of the respondents rated their overall health over the last 30 days as 'moderate'. There were no significant differences in the way the different respondent groups rated their health. See Figure 3.2.
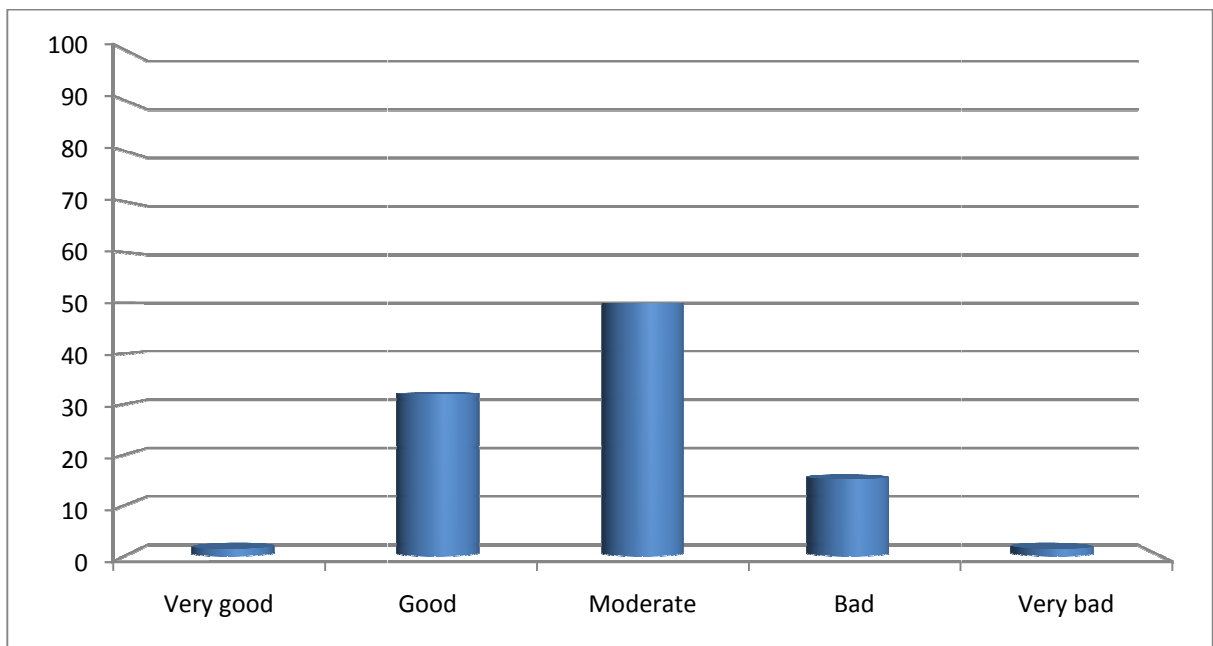

Figure 3.2: Rated overall health in the past 30 days (% of total study sample)

3.1 Measurement of agreement

To measure the agreement between the SALSA scale and the WHO-DAS II scale, different methods were used. Table 3.2 shows the mean scores of the SALSA scale and the WHO-DAS II scale for the subgroups in diagnosis, sex and age.

Table 3.2: Mean scores for subgroups

			SALSA score (SD)	WHO-DAS II score (SD)
Leprosy & diabetes (n=63)	Male (n=31)	<50 years (n=15)	33.4 (12.4)	10.9 (9.3)
		>50 years (n=16)	33.4 (12.2)	11.1 (11.2)
	Female (n=32)	<50 years (n=13)	29.6 (6.4)	10.3 (6.9)
		>50 years (n=19)	43.2 (16.3)	22.2 (13.2)
Locomotor disability (n=75)	Male (n=37)	<50 years (n=18)	39.1 (13.9)	20.3 (11.7)
		>50 years (n=19)	51.0 (17.3)	28.1 (13.2)
	Female (n=38)	<50 years (n=24)	43.8 (16.5)	21.3 (12.0)
		>50 years (n=14)	47.8 (16.8)	25.1 (12.2)

3.1.1 Correlation

The plot of the paired measurements of the SALSA scale and the WHO-DAS II is shown in Figure 3.3. There was a strong significant correlation between the SALSA score and the WHO-DAS II score, with a correlation coefficient (R) of 0.89 (p<0.001), see Table 3.3. The coefficient of determination (R^2) was 0.79, suggesting that 79% of the variance in the WHO-DAS II score can be explained by the SALSA score.

Table 3.3: Correlation SALSA scale and WHO-DAS II scale

	Correlation coefficient, R	P-value	R^2
Total	0.89	<0.001	0.79
Leprosy and diabetes	0.92	<0.001	0.85
Locomotor disability	0.85	<0.001	0.73
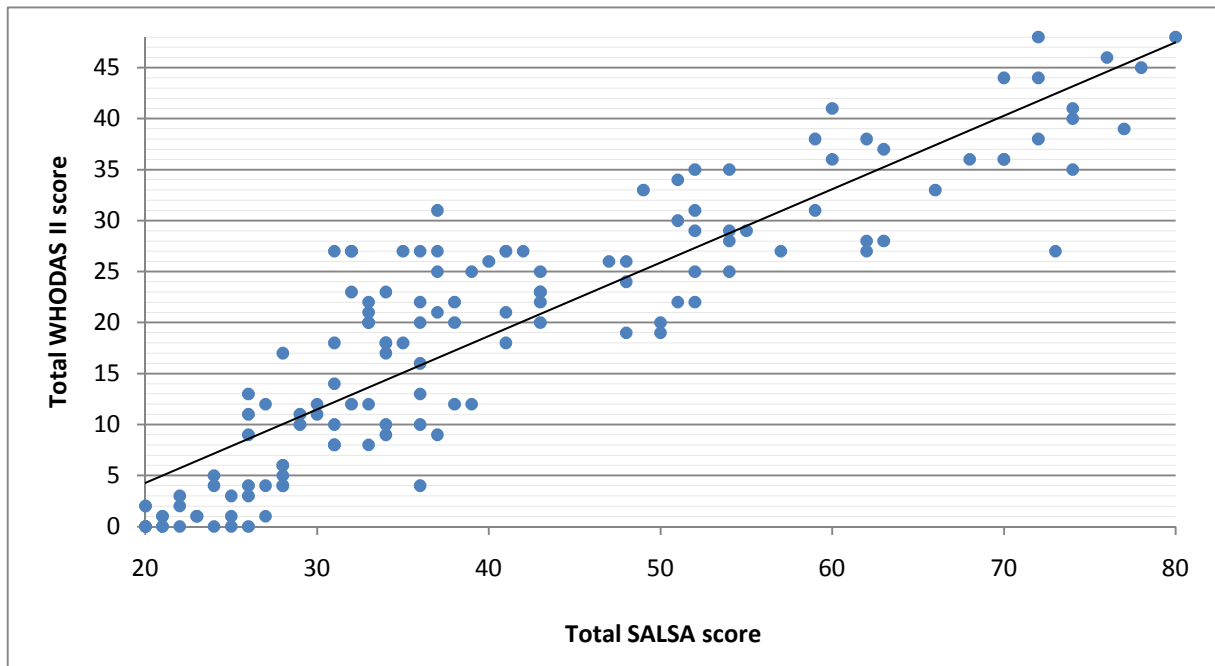
Figure 3.3: Total study sample scatter plot; the WHO-DAS II score against the SALSA score

Comparing the correlation between the different diagnostic groups, a stronger correlation was found in the leprosy and diabetes group compared to the LD-group. As shown in Table 3.3, the correlation coefficient was 0.92 (p<0.001) for the leprosy and diabetes group and 0.85 (p<0.001) for the LD-group. See Figure 3.4 and 3.5 for the separate correlation plots.
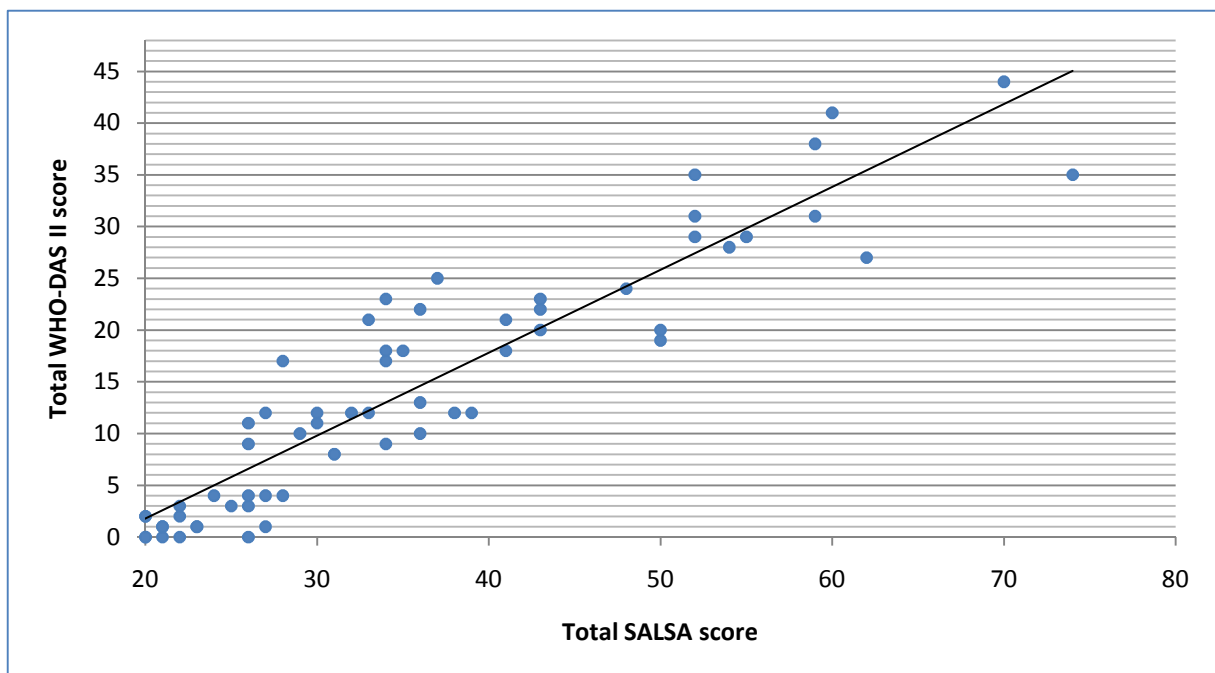
Figure 3.4: Leprosy and diabetes scatter plot; the WHO-DAS II score against the SALSA score
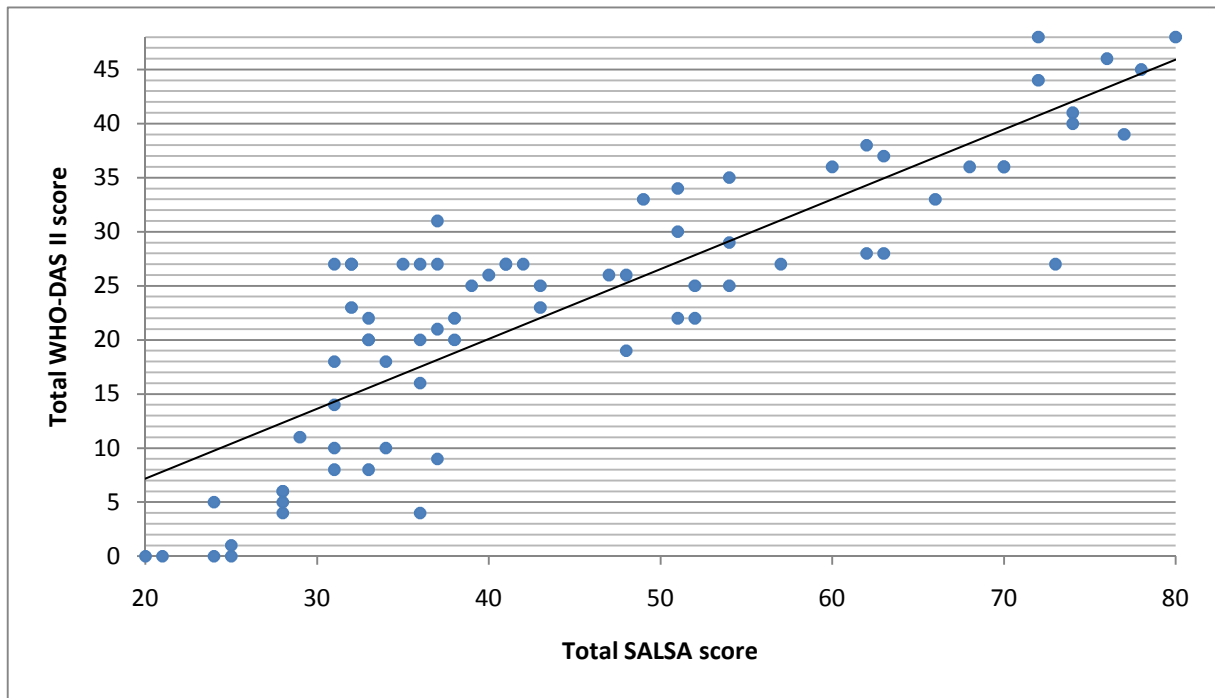
Figure3.5: Locomotor disability scatter plot; the WHO-DAS II score against the SALSA score

3.1.2   Intraclass Correlation Coefficient

To assess the correlation, taking possible systematic differences into account, the intraclass correlation coefficient (ICC) was calculated. The ICC between the SALSA scale and the WHO-DAS II scale was 0.87 for the total study sample. In the leprosy and diabetes group there was a stronger intraclass correlation visible, as with the normal correlation coefficient shown in section 3.1.1, with an ICC of 0.94, compared to 0.88 in the LD-group. See Table 3.4. The high ICCs indicate that the within-person variance is small compared to the between-person variance.

Table 3.4: Intraclass Correlation Coefficient

	Between-persons variance	Within-persons variance
Total	84106.77	12163.20
Leprosy and diabetes	29620.63	1892.80
Locomotor disability	48982.45	6845.33
ICC Total = 0.874 **ICC Leprosy and diabetes = 0.940** **ICC Locomotor disability = 0.877**		

3.1.3   Cohen's Kappa

For the quantifying of the agreement between the measurement scales using Cohen's Kappa (k), the total scores were transformed into binary variables on basis of the cut-offs as described in the Methods section 2.5. The observed agreement in the total study sample was 84%. The probability of random agreement was 0.52, thus the Kappa of the total study sample was k=0.67. See Table 3.5. According to the guidelines of Landis and Koch (1977) this Kappa is demonstrating substantial agreement.

Table 3.5: Total study sample – observed agreement

	WHO-DAS II positive	WHO-DAS II negative	Total
SALSA positive	44	12	56
SALSA negative	10	72	82
Total	54	84	138
	Observed agreement = 84% Probability of random agreement = 52% Cohen's kappa (*k*)= 0.67		

Table 3.6 shows the calculation of Kappa for the different diagnostic groups separately. The observed agreement in the leprosy and diabetes group was 86% and the probability of random agreement was 62%, which makes the Kappa is k= (0.86-0.62)/ (1-0.62) =0.63. The observed agreement in the LD-group was lower than in the leprosy and diabetes group, namely 83%. However, due to the lower probability of random agreement, which was 0.50, the Kappa was higher than in the leprosy and diabetes group, namely k= (0.83-0.50)/ (1-0.50) = 0.66. According to the Landis and Koch guidelines, the Kappa values of both diagnostic groups are demonstrating substantial agreement between the SALSA scale and the WHO-DAS II scale.

Table 3.6: Stratified – observed agreement

	Leprosy and diabetes			Locomotor disability		
	WHO-DAS II positive	WHO-DAS II negative	Total	WHO-DAS II positive	WHO-DAS II negative	Total
SALSA positive	11	8	19	33	4	37
SALSA negative	1	43	44	9	29	38
Total	12	51	63	42	33	75
	Observed agreement= 86% Probability of random agreement= 62% Cohen's kappa=0.63			Observed agreement= 83% Probability of random agreement= 50% Cohen's kappa= 0.66		

3.1.4 Bland & Altman method

Despite the high degree of correlation as described in section 'correlation' (3.1.1), from Figure 3.3 it can be seen that for any given value of the SALSA or WHO-DAS II scale there was considerable variation in the corresponding activity limitation score between the two scales. This variability is demonstrated in the Bland-Altman plot, showing the differences between the measurement scales (SALSA score minus WHO-DAS II score) plotted against the average of both scores. See Figure 3.6. There was no obvious pattern in the differences over the severity of the activity limitation, though there appeared to be a higher agreement at the extremes of activity limitation. To perform this method, both scores were transformed to a 0-100 range.
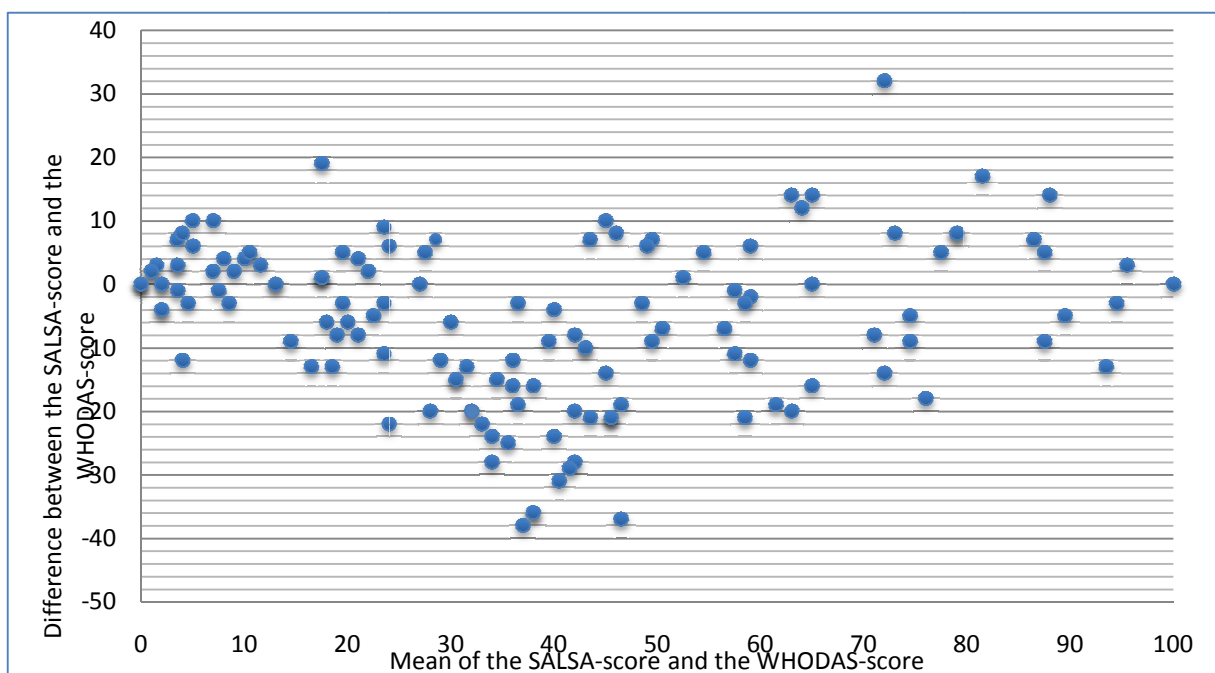
Figure3.6: Bland-Altman plot of the difference between the SALSA-score and the WHO-DAS-score against the mean of the scores.

The differences between the SALSA scale and the WHO-DAS II scale ranged from -38.0 to 32.0 as shown in Table 3.7. The mean difference was -5.5, suggesting that the WHO-DAS II score was structurally 5.5 points higher than the SALSA scale. 95 % of the differences between the measurements lay within -30.0 to 19.1 points. The difference between the measurement scales did not significantly change according to which scale was used to score activity limitation first. There were also no significant associations found with the age or sex of the respondent, or any other demographic factors.

Table 3.7: Mean differences between de SALSA score and the WHO-DAS II score

	N	Minimum	Maximum	Mean	Std. Dev.	Limits of agreement
Total	138	-38.0	32.0	-5.5	12.5	-30.0 – 19.1
Leprosy and diabetes	63	-25.0	17.0	-3.8	9.4	-22.2 – 14.7
Locomotor disability	75	-38.0	32.0	-6.8	14.5	-35.3 – 21.6

For the leprosy and diabetes group, 95% of the differences were between -22.2 and 14.7 points. This range was smaller compared to the LD-group, where 95% of the differences lay within -35.3 and 21.6 points. The mean difference was also smaller in the leprosy and diabetes group, namely -3.8 versus -6.8 in the LD-group; however, this difference was not significant. This difference became also visible also when the Bland-Altman plots of the different diagnostic groups were compared. Figure 3.7 and 3.8 show the differences between the diagnostic groups in the pattern of the differences in scores over the severity of activity limitation. The Bland-Altman plot of the leprosy and diabetes group indicates a higher agreement in the lower activity limitations. In the LD-group, the pattern of the Bland-Altman plot seemed quite similar to the plot of the total study sample.
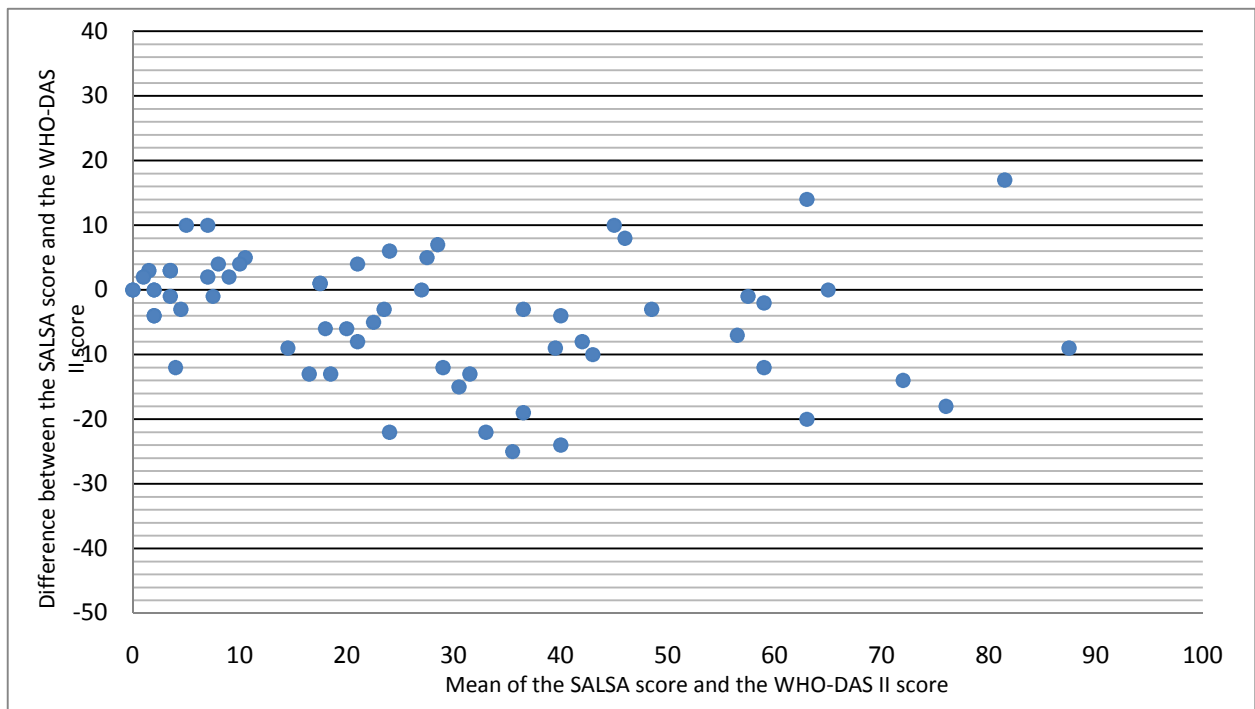
Figure3.7: Bland-Altman plot of the SALSA and WHO-DAS II score in the leprosy and diabetes group.
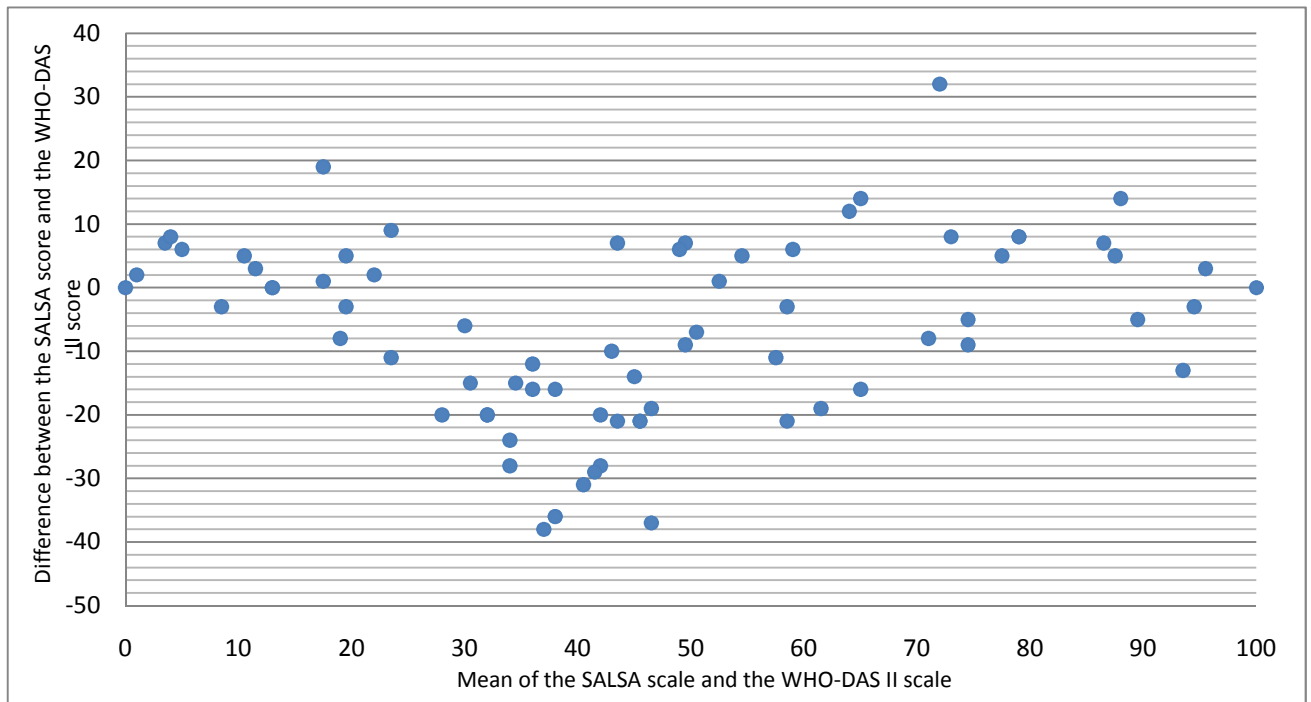
Figure3.8: Bland-Altman plot of the SALSA and WHO-DAS II score in the LD-group

3.2   Content validity assessment

To assess the content validity of the SALSA scale for the locomotor disability population, semi-structured interviews and a focus group discussion were conducted and a conceptual comparison was made.

3.2.1   Semi-structured interviews

Six persons with a locomotor disability were interviewed about the content validity of the SALSA scale, after conducting the structured scale interviews. Two persons of the interview sample were female, the age was ranging from 19 to 54 years old and five of them were unemployed. Four of the respondents said that all the items of the SALSA scale were relevant according to them, and that there were no items missing in the SALSA scale. One person said the issue of 'back pain' was missing. Another respondent felt that none the items mentioned in the questionnaire were really impairing, "none of these questions is relevant for limitation, it is the lack of financial resources that is limiting", arguing that only the economical status is a limiting factor.

3.2.2   Focus group discussion

The focus group discussion was held with four experts, three physiotherapists and one occupational therapist, of the SIHR&LC, Karigiri. In the discussion, the SALSA scale items 'do you thread needles', 'do you cook' and 'do you pour hot liquids' were considered as least relevant; "*pouring hot liquids is a question which is very specific in safety, and it is more related to sensation than to locomotor problems*". In contrast to this, the items 'do you sit or squad on the ground', 'do you walk on uneven ground' and 'do you walk longer distances' were considered as the most relevant items according to people with a locomotor disability; "*many conditions are in the lower limb, so people with locomotor disabilities will not be able to do this*". The issues considered as missing in the SALSA scale were 'travelling', 'standing for a prolonged time' and 'stair climbing'. The participants agreed that the SALSA scale mainly focuses on the leprosy and diabetes-specific issue of sensory loss, while locomotor disability mainly affects the lower limbs.

3.2.3   Conceptual comparison

To distinguish differences in the content of the SALSA scale and the WHO-DAS II scale, a conceptual comparison was made. The SALSA scale and the WHO-DAS II scale are both based on the ICF-model, the International Classification of Functioning, Disability and Health. This model classifies disability in terms of three concepts: impairments, activity limitations and participation restrictions, see Figure 1.1 (p. 6).

The version of the SALSA scale used in this study consists of 20 items with six answer possibilities. At first one has to distinguish whether they can perform the activity or not. If the respondents say 'yes' they have to determine how easy the activity is, the answer options are 'easy' (1 point), 'little difficult' (2 points) and 'very difficult' (3 points). If the respondents say they cannot perform the activity they have to explain why, the answer options are 'I do not need to do this' (0 points), 'I physically cannot' (4 points) and 'I avoid because of risk' (4 points). The items of the SALSA scale cover the domains of self care, mobility, work and a combination of mobility and work.

The version of the WHO-DAS II scale used in this study consists of 12 items with five answer possibilities on the question 'in the last 30 days how much difficulty did you have' in the activity, namely: 'none' (0 points), 'mild' (1 point), 'moderate'(2 points), 'severe' (3 points) and 'extreme/cannot do' (4 points). Activity limitation as measured in the WHO-DAS II scale includes the domains 'cognition (understanding and communication)', 'mobility (ability to move and get around)', 'self care (ability to attend to personal hygiene, dressing and eating and to live alone)', 'getting along (ability to interact with other people)', 'life activities (ability to carry out

responsibilities at home, work and school)', and participation in society (ability to engage in community, civil and recreational activities)'.

Both measurement scales include items on self care, mobility and work. However, in the SALSA scale 15 out of 20 items involve hand activity while the WHO-DAS II scale contains only four items involving hand activity. In addition, the SALSA scale takes problems of safety and the risk of worsening of existing impairments related to the sensory-loss in peripheral neuropathy into account. Furthermore, the SALSA scale includes items exclusively on the lower limb as well on the upper limb, but the WHO-DAS II includes only exclusive items on the lower limbs. Moreover, the WHO-DAS II scale places a particular emphasis on the influence of participation on an individual's level of functioning. To be precise, the WHO-DAS II scale includes items on joining community activities, dealing with people you do not know and maintaining friendship, and in addition, the aspects of learning new tasks, emotional affection and concentration are covered in the WHO-DAS II. On the other hand, the SALSA scale examines activity limitation in a direct way: what a respondent can do, can do with difficulty, cannot do, or avoids because of risk. The WHO-DAS II was developed to correspond with the ICFs activity and the participation dimension, while the SALSA scale was solely focused on the activity dimension (Üstün *et al.*, 2010, The SALSA Collaborative Study Group, 2006).

3.3 Linear regression analysis

3.3.1 The SALSA scale

The mean SALSA-scale score of the total study sample was 40.8 (SD=15.9). The respondents in the LD-group had a higher score (mean=45.2) in comparison with the leprosy and diabetes group (mean=35.6). The linear regression analysis showed that this difference between the mean SALSA scores was highly significant (p<0.001), indicating that the leprosy and diabetes respondents encountered less activity limitation, 9.7 points lower on the SALSA-scale, than LD respondents. After adjustment for the determinants health status, age and education, the resulting coefficient was still significant with a value of 10.6 (p<0.001). See Table 3.8.

Table 3.8: Linear regression analysis SALSA*

	Univariate			Multivariate**		
	Coefficient	Std. Error	P-value	Coefficient	Std. Error	P-value
Type of respondent	9.67	2.60	**<0.001**	10.57	2.14	**<0.001**
Health status	10.57	1.57	**<0.001**	9.30	1.48	**<0.001**
Age	6.29	2.66	**0.019**	4.72	2.20	**0.034**
Sex	1.95	2.71	**0.474**			**NS**
Education	-10.26	2.64	**<0.001**	-5.53	2.33	**0.019**
Occupation	-11.85	2.77	**<0.001**			**NS**
Income	-6.89	2.65	**0.010**			**NS**
*Only significant values are shown. NS= not significant.						
*R²= 0.40						

The stratified analysis is shown in Table 3.9. To predict the determinants of the SALSA score, a multiple linear regression model was constructed for each of the respondent groups. All variables that were significantly associated with the SALSA score were entered in the model. Subsequently, with backwards elimination the final prediction model was constructed. This final model had a predictive value of 0.40 for the leprosy and diabetes group and comprises the determinants health status and assistive devices. 33% of the variance in the SALSA scores in the LD-group could be explained by the final prediction model, consisting of the variables health status, age and occupation as predictive factors.

Table 3.9: Stratified analysis SALSA scale*

	Leprosy and diabetes (n=63)						Locomotor disability (n=75)					
	Univariate			Multivariate**			Univariate			Multivariate***		
	Coefficient	Std. Error	P-value	Coefficient	Std. Error	P-value	Coefficient	Std. Error	P-value	Coefficient	Std. Error	P-value
Health status	10.01	1.79	**<0.001**	9.01	1.78	**<0.001**	11.23	2.31	**<0.001**	9.84	2.28	**<0.001**
Age	7.04	3.34	**0.040**			**NS**	7.87	3.74	**0.039**	6.50	3.22	**0.047**
Sex	4.27	3.40	**0.214**			**NS**	0.02	3.83	**0.998**			**NS**
Education	-10.58	3.22	**0.002**			**NS**	-10.75	3.75	**0.005**			**NS**
Occupation	-7.82	3.35	**0.023**			**NS**	-12.76	4.42	**0.005**	-8.14	4.01	**0.046**
Income	-4.75	3.44	**0.172**			**NS**	-6.47	3.78	**0.091**			**NS**
Marital status	-9.94	3.94	**0.014**			**NS**	1.28	3.98	**0.749**			**NS**
Assistive devices	10.42	3.35	**0.003**	6.96	2.91	**0.020**	0.89	3.85	**0.817**			**NS**

*Only significant variables are shown. NS=not significant.

*R^2=0.40

** R^2=0.33

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3.3.2 The WHO-DAS II scale

The mean WHO-DAS II score of the total study sample was 19.3 (SD=12.9). The respondents in the LD-group had a higher score (mean=23.5) in comparison with the leprosy and diabetes group (mean=14.3). The linear regression analysis of the WHO-DAS II scores indicates that the leprosy and diabetes respondents encountered significantly less activity limitation than the LD respondents, with 9.2 points lower (p<0.001). After adjustment for the determinants health status, age and education, the model still showed a significant coefficient of 10.0 (p<0.001). See Table 3.10.

Table 3.10: Linear regression analysis WHO-DAS II*

	Univariate			Multivariate**		
	Coefficient	Std. Error	P-value	Coefficient	Std. Error	P-value
Type of respondent	9.21	2.07	**<0.001**	9.95	1.68	**<0.001**
Health status	8.73	1.27	**<0.001**	7.77	1.16	**<0.001**
Age	5.08	2.17	**0.021**	4.01	1.73	**0.022**
Sex	1.99	2.20	**0.367**			**NS**
Education	-8.09	2.16	**<0.001**	-4.17	1.83	**0.024**
Occupation	-10.40	2.23	**<0.001**			**NS**
Income	-5.79	2.16	**0.008**			**NS**
*Only significant values are shown. NS= not significant. ****R^2=0.44**						

Table 3.11 presents the stratified analysis. A multiple linear regression model was constructed in order to predict the determinants of the WHO-DAS II score, for each of the different respondent groups. All significantly associated variables with the WHO-DAS II score were entered in the prediction model, whereupon the insignificant variables were eliminated. The final model had a predictive value of 0.39 for the leprosy and diabetes group and consisted the determinant health status. 43% of the variance in the WHO-DAS II scores in the LD-group could be explained by the final prediction model, consisting of the variables health status, education, occupation, sex and time of diagnosis as predictive factors.

Table 3.11: Stratified analysis WHO-DAS II scale*

	Leprosy and diabetes (n=63)						Locomotor disability (n=75)					
	Univariate			Multivariate**			Univariate			Multivariate***		
	Coefficient	Std. Error	P-value	Coefficient	Std. Error	P-value	Coefficient	Std. Error	P-value	Coefficient	Std. Error	P-value
Health status	8.89	1.53	**<0.001**	8.89	1.53	**<0.001**	8.70	1.74	**<0.001**	6.15	1.68	**<0.001**
Age	6.50	2.88	**0.028**			NS	5.99	2.83	**0.038**			NS
Education	-8.61	2.82	**0.003**			NS	-8.37	2.83	**0.004**	-6.79	2.60	**0.011**
Occupation	-6.98	2.89	**0.019**			NS	-10.68	3.30	**0.002**	-7.08	3.12	**0.027**
Income	-4.94	2.96	**0.101**			NS	-4.33	2.90	**0.139**			NS
Sex	6.34	2.87	**0.031**			NS	-1.64	2.89	**0.572**	-5.46	2.52	**0.034**
Marital status	-9.41	3.38	**0.007**			NS	1.54	3.01	**0.611**			NS
Assistive devices	6.89	3.00	**0.025**			NS	3.01	2.89	**0.302**			NS
Time of diagnosis	-0.68	3.03	**0.823**			NS	7.95	2.87	**0.007**	5.13	2.52	**0.045**
*Only significant variables are shown. NS=not significant.												
**R^2=0.39												
*** R^2=0.43												

3.4 Profiling the measurement scales

3.4.1 The SALSA scale

To obtain insight into the differences in activity limitation between the leprosy and diabetes group and the LD-group, a profile was made of the SALSA-scale. Respondents in the LD-group generally scored higher than the leprosy and diabetes group on the items of the SALSA scale, see Figure 3.9. This suggests that the burden of activity limitation is higher for people with a locomotor disability than for people affected by leprosy and diabetes. Only on the item 'seeing' the leprosy and diabetes group experienced more difficulties, namely 8.7% of the leprosy and diabetes group said that seeing is very difficult or that they cannot do it compared to 5.3% in the LD-group. This difference was not significant (p=0.54). Furthermore, the differences in 'sitting/squatting on the ground', 'walking barefoot', 'pouring hot liquids', 'threading needles' and 'picking things up from the floor' were also not significant.

The pattern in answer profile of the SALSA scale shows reasonable similarities between the leprosy and diabetes group and the LD-group. The item 'lifting objects above the head' seemed to cause most of the difficulties in both groups, 89.3% of the LD-group and 64.5% of the leprosy and diabetes group answered that this activity was either very difficult, they cannot do it or they avoid the activity because of risk. However, of the items on walking, most of the LD-group reported difficulties with 'walking longer distances', while in the leprosy and diabetes group 'walking barefoot' seemed to cause the greater part of the difficulties.
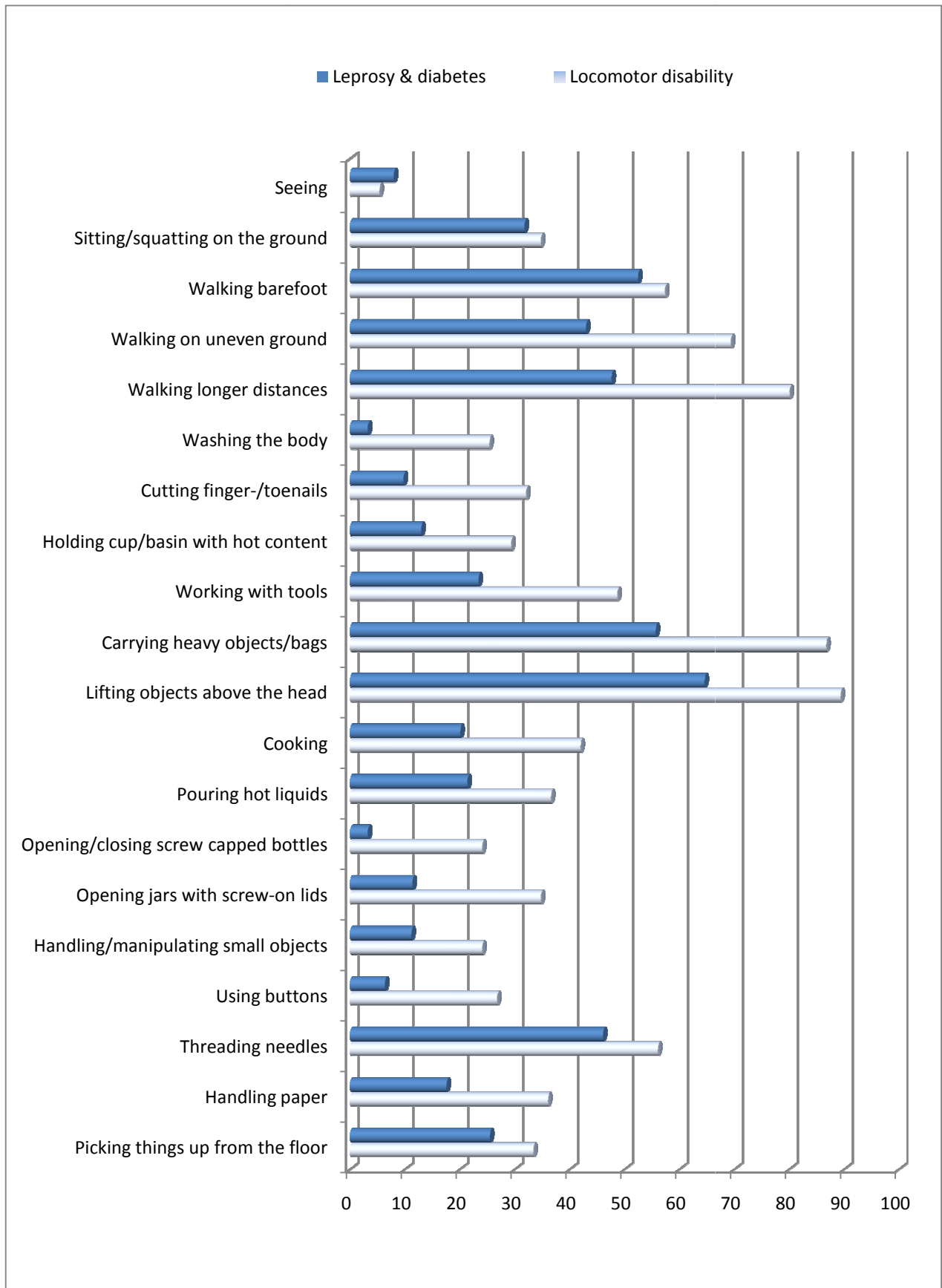
Figure 3.9: Profile of the SALSA scale items (% very difficult/cannot do/avoiding because of risk)

3.4.2 The WHO-DAS II scale

A profile of activity limitation according to the WHO-DAS II scale was created, in the same way as in section 3.4.1 for the SALSA scale, in order to gain insight into the differences in activity limitation between the leprosy and diabetes group and the LD-group. The respondents in the LD-group generally scored higher than the leprosy and diabetes group, as shown in Figure 3.11. Moreover, all the differences in the items on the domains 'life activities', 'self care' and 'getting around' were significant with p-values ranging from <0.001 to 0.005. The number of respondents reporting that these activities were either severely difficult, extremely difficult or could not do it, ranged from more or less than 20 % to 80 %. These results indicate that respondents in the LD-group experienced more limitations in their daily tasks, self care and mobility. Most of the difficulties were encountered with the items concerning the domain 'getting around', namely 'walking for a long distance' and 'standing for a long period'.

In the domains 'understanding and communicating', 'getting along with people' and 'participation in society' the LD-group scored in general higher than the leprosy and diabetes group, except of the item 'concentrating', however this difference was not significant. Only the differences in the items 'being emotionally affected' (p=0.001), 'joining community' and 'learning a new task', were significant (both p<0.001). These outcomes suggest that the burden of limitation in emotionally affection, participation and understanding was higher among respondents in the LD-group than the leprosy and diabetes group.
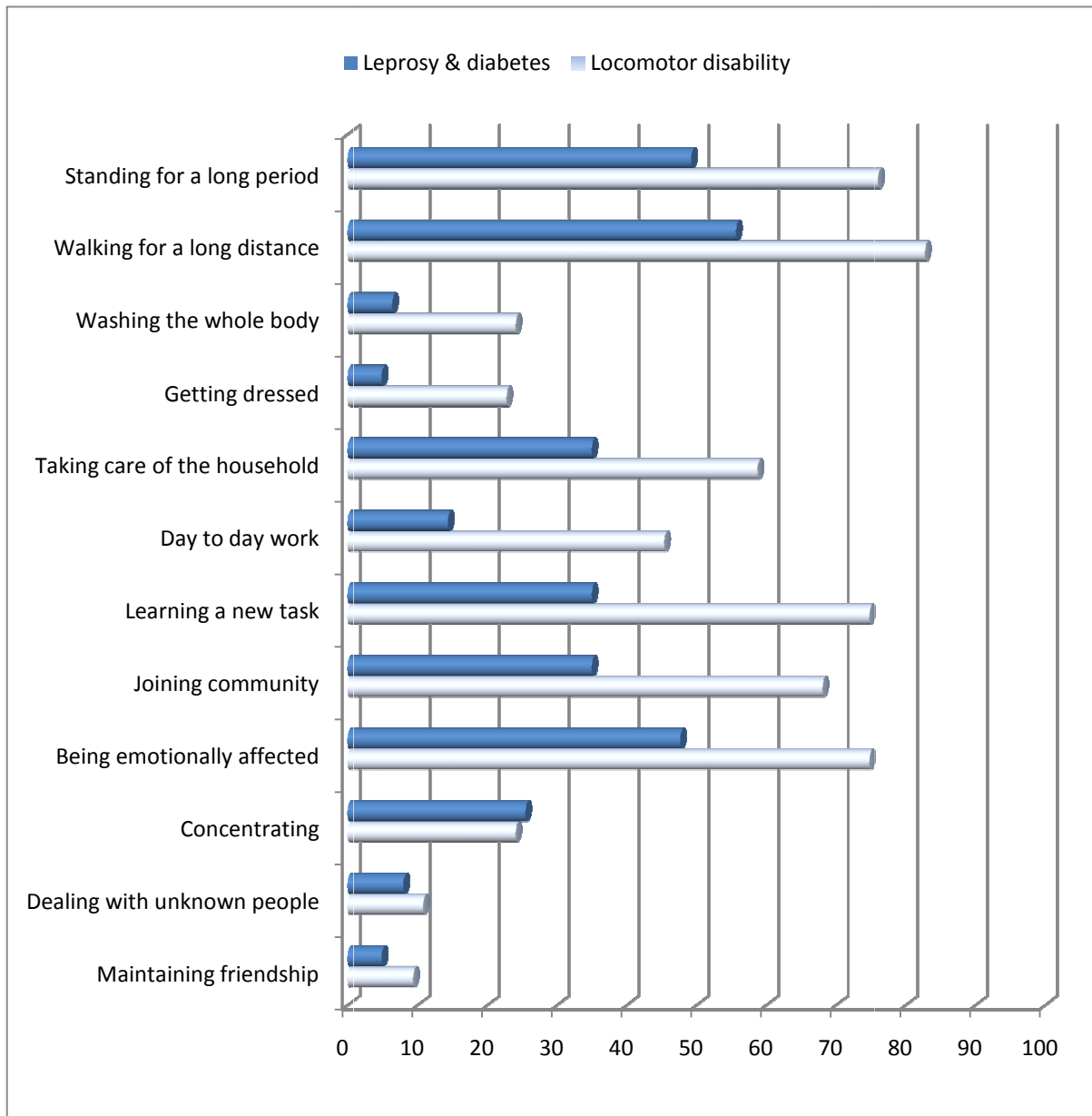
Figure 3.11: Profile of the WHO-DAS II scale items (% severe difficulty/extreme difficulty/cannot do).

4. Discussion

The objective of this study was to obtain insight into the validity of the SALSA scale as an activity limitation measure among people with disabilities other than those caused by peripheral nerve damage, by performing the SALSA scale with a group of people affected by locomotor disability.

The results of this study show significant agreement between the SALSA scale and the WHO-DAS II. First, the correlation coefficient in this study was 0.89 for the total study sample, with 0.92 for the people affected by leprosy or diabetes and 0.85 for the people affected with a locomotor disability. This confirms the hypothesis that the scales are well correlated. Since correlation coefficients are considered satisfactory when >0.7, the correlation between the SALSA scale and WHO-DAS II scale can be considered as highly significant (Terwee *et al.*, 2007). Secondly, the Intraclass Correlation Coefficient demonstrated in this study was 0.87 for the total study sample, with 0.94 for the leprosy and diabetes group and 0.88 for the locomotor disability group. According to Fleiss (1986) these ICCs can be considered as excellent. Thirdly, when comparing agreement between the scores, dichotomized to 'limitation' versus 'no limitation' for both scales, Cohen's Kappa was 0.67 for the total study sample, with 0.62 for the people affected by leprosy or diabetes and 0.66 for the people affected with a locomotor disability. Since the Kappas are between 0.61 and 0.80, these indicate substantial agreement (Landis & Koch, 1977). Finally, the Bland-Altman method demonstrated a considerable variability of differences between the scores in the plot. To apply this method both scores were recoded to 0 – 100. This method demonstrated that the limits of agreement were -30.0 – 19.1 for the total study sample, indicating that the SALSA scale may give values between 30.0 points below the WHO-DAS II score to 19.1 points above it. The limits of agreement for the leprosy and diabetes group and for the locomotor disability group were -22.2 to 14.7, and -35.3 to 21.6 respectively. The difference between scores was not explained by the demographic factors of the respondent, or the order of scales used to score the activity limitation. Neither did the variation in difference depend on the mean score.

The SALSA scale can be applied in different ways. First, the scale can be used to screen and identify activity limitation and to refer individuals. Secondly, SALSA can be used to assess and quantify the level of activity limitation. Thirdly, the SALSA scale can be used to compare populations and to compare different moments in time (The SALSA Collaborative Study Group, 2010). The Bland-Altman method showed a substantial wide span of the limits of agreement, however, for the purposes of the SALSA scale the discriminative character is most important.

Therefore the reliability measures, the ICC and Cohen's Kappa, are considered of higher relevance for this study, indicating the extent to which similar conclusions are being reached by the different measurement scales.

The Bland-Altman method was used because the correlation coefficient is considered as inappropriate as a standalone statistic (Bland & Altman, 1986). However, the COSMIN study – a study in which consensus was reached on psychometric properties for measurement scales – states that correlation is an appropriate measure of construct validity, which was the purpose of using it in the current study. Hence, if we consider the WHO-DAS II score to be a criterion for assessing 'generic activity limitation', the correlation coefficient would be an acceptable measure. Moreover, the Bland-Altman method, as well as the ICC, requires equal outcome values. For the use of these methods the scale outcomes were recoded, since they were not equal initially. (Mokkink *et al.*, 2010).

The pattern of the Bland-Altman plot shows peaks at the extremes and a dip in the moderate scores. To examine the significance of this pattern, a larger study sample is needed. The dip suggests that in moderate severity range of activity limitation the WHO-DAS II scores are systematically higher than the SALSA scores. After stratifying the Bland-Altman method for the different diagnostic groups, this dip is only visible in the LD-group. This outcome suggests that the WHO-DAS II has a higher sensitivity for people with locomotor disability experiencing moderate activity limitation. A possible explanation might be that the WHO-DAS II mainly focuses on gross locomotion rather than dexterity. Another explanation might be that the SALSA lacks sensitivity in the mid-severity range. However, further research is needed to draw conclusions on the significance of this difference in pattern.

The assessment of the content validity with people affected by locomotor disability themselves is possibly limited by the culture and social desirability. Respondents may have been inclined to answer positively; therefore, they may have refrained from criticizing the SALSA scale. This may have been a reason why most of the respondents participating in the interview said that all the SALSA items were relevant and nothing was missing. Therefore, the content validity assessment was done merely in an indirect way in the FGD with experts.

The main outcome of the Focus Group Discussion to assess the content validity of the SALSA scale for the locomotor disability population was that the scale focuses too much on the sensory loss aspects of leprosy and diabetes and too little on the lower limb aspects, which are the most common in LD. This is also demonstrated in the use of assistive devices; special footwear is the most common device for the leprosy and diabetes group and a walking stick or frame for the LD-group. Furthermore, the profile of the SALSA scale shows that in walking related activities, LD-

respondents encountered most difficulties with walking long distances while leprosy and diabetes respondents said walking barefoot caused difficulties for the greater part. This might reveal the sensory-loss aspects of leprosy and diabetes. The experts said a balance is needed between the sensory-loss focused and the lower-limb focused items of the SALSA scale to increase the content validity for the LD population.

The results of the conceptual comparison show considerable differences between the measurement scales, hence one would expect higher sensitivity of the SALSA scale in the leprosy and diabetes group, because the SALSA scale includes items focusing on the hands and sensory loss. On the other hand, a higher sensitivity of the WHO-DAS II scale is expected in the locomotor disability group given the result that the WHO-DAS II covers activities exclusively focused on the lower limb and it does not cover items specific for the upper limbs. Besides, the conceptual comparison showed that the WHO-DAS II scale includes the participation domain as well, while the SALSA scale examines activity in a direct way and was intended to be used in combination with the Participation scale (P-scale) to measure the participation domain (Van Brakel *et al.*, 2006).

To improve the validity of the SALSA scale for the locomotor disability population, some adaptations would need to be made. A balance would need to be created between the sensory loss focused items needed for leprosy and diabetes and the locomotor disability-specific lower limb focused items. Nevertheless, we have to consider whether such adjustments in the SALSA scale would be desirable. The higher agreement in the leprosy and diabetes group shows the unique contribution of the SALSA scale in understanding disability in the context of leprosy and diabetes. Adjustment may cause loss of sensitivity with regard to the special problems caused by sensory impairment.

The agreement between the SALSA scale and the WHO-DAS II scale is higher in the leprosy and diabetes group: a higher correlation, a smaller mean difference and smaller limits of agreement have been found. This higher agreement in the leprosy and diabetes group might reflect a higher sensitivity of the SALSA scale to the leprosy and diabetes group. Since the WHO-DAS II shows good psychometric properties for a generic population, one would expect similar sensitivity for activity limitation of the WHO-DAS II scale in both diagnostic groups, and higher sensitivity for activity limitation of the SALSA scale in the leprosy and diabetes group than in the locomotor disability group. The higher SALSA score among the people with leprosy or diabetes demonstrates the relative advantage of the SALSA scale in assessing activity limitation in people with disability resulting from peripheral nerve damage.

The difference in Kappa found in this study between the diagnostic groups depends on the cut-off used to transform the scale scores into binary variables. The answer categories used to make cut-offs were not the same for both scales. Furthermore, of the WHO-DAS II scale is no cut-off known which is used in practice.

In a similar validation study, Post et al. compared a new measure, the Impact-S, against the WHO-DAS II scale in the criterion validity test. The authors concluded the Impact-S to be a reliable and valid generic measure with the correlations found (0.66-0.81) between the alternative activity limitation and participation restrictions measure in the new instrument and the WHO-DAS II (Post *et al.*, 2008).

In the total study sample the determining factors appeared to be the same for the SALSA scale and the WHO-DAS II scale, suggesting that the scales measure activity limitation in a similar way. Nevertheless, in the stratified analysis, assistive devices is a determinant for the SALSA score in the leprosy and diabetes group and not for the WHO-DAS score. In the LD-group age is a determining factor for the SALSA score and not for the WHO-DAS II score, on the other hand education, sex and the time of diagnosis appeared to be predictive factors only for the WHO-DAS II score. This suggests that the activity limitation as measured with these scales is of a different nature. This is also visible in the conceptual comparison of the scales, although the pattern in answer profile on the measurement scales shows reasonable similarities between the leprosy and diabetes group and the LD-group.

Significant differences were found between the two diagnostic groups in the demographic characteristics, namely in having children, occupation, time of diagnosis and use of assistive devices. This might have had influence on the reported variations in agreement between the diagnostic groups.

Applicability of measurement scales is an international concern in assessing disability in terms of activity limitation. Until now, no other research has compared the SALSA scale to other questionnaires measuring activity limitation or assessed the validity of the SALSA scale for other populations than people affected by leprosy or diabetes. The study of Melchior (2008) compared the SALSA scale with other hand function assessments with regard to their validity in assessing hand-related activities. This study used the correlation coefficient as measure of association and concluded that the SALSA scale is a reliable and useful tool and that this study enhanced credibility (Melchior, 2008).

The WHO-DAS II scale was chosen because of the good psychometric qualities it showed in a generic population in terms of sensitivity, specificity, reliability, validity and cross-population comparability (Üstün *et al.*, 2010a). Even though the WHO-DAS II is commonly used, the WHO-DAS II cannot be considered as a golden standard since the WHO-DAS II measures functioning across other domains than the SALSA scale. Therefore, further research is needed in which the SALSA scale can be compared to other scales measuring activity limitation, like the Barthel Index, DASH, FIM and the activity section of the SF-36 (Mahoney & Barthel, 1965; Hudak *et al.*, 1996; Stineman *et al.*, 1996; Ware *et al.*, 1993).

5. Conclusions

The research question of this study was: "What is the validity of the SALSA scale as a generic instrument measuring activity of daily living?". Looking at the quantitative results, the SALSA scale can be considered as a valid measure of activity limitation. The qualitative results suggest that some adaptations would need to be made to improve this validity. However, adjustment may cause loss of sensitivity with regard to the special problems caused by sensory impairment. Overall, we believe we have shown the SALSA scale to be a valid instrument for measuring activity limitation in persons affected by a locomotor disability.

5. Conclusions

Acknowledgement

Acknowledgement

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Appendices

Form 1: SALSA scale

	SALSA scale Screening of Activity Limitation & Safety Awareness Tick one box on each line in response to each question.	If Yes, how easy is it for you?			If No, why not?		
		Easy	A Little difficult	Very difficult	I don't need to do this	I physically cannot	I avoid because of risk
1	Can you see (enough to carry out your daily activities)?	1	2	3		4	
2	Do you sit or squat on the ground?	1	2	3	0	4	4
3	Do you walk barefoot? e.g. most of the time	1	2	3	0	4	4
4	Do you walk on uneven ground?	1	2	3	0	4	4
5	Do you walk longer distances? i.e. longer than 30 minutes	1	2	3	0	4	4
6	Do you wash your whole body? (using soap, sponge, jug; standing or sitting….)	1	2	3	0	4	4
7	Do you cut your finger or toenails? e.g. using scissors or clippers…	1	2	3	0	4	4
8	Do you hold a cup or basin with <u>hot</u> contents? e.g. drinks, food …	1	2	3	0	4	4
9	Do you work with tools? i.e. tools which you hold in your hands to help you work …	1	2	3	0	4	4
10	Do you carry heavy objects or bags? e.g. shopping, food, water, wood …	1	2	3	0	4	4
11	Do you lift objects above your head? e.g. to place on a shelf, on your head, to hang clothes to dry …	1	2	3	0	4	4
12	Do you cook? i.e. prepare food both hot and cold	1	2	3	0	4	4
13	Do you pour hot liquids?	1	2	3	0	4	4
14	Do you open/close screw capped bottles? e.g. oil, water ..	1	2	3	0	4	4
15	Do you open jars with screw-on lids? e.g. jam…	1	2	3	0	4	4
16	Do you handle or manipulate small objects? e.g. coins, nails, small screws, grains and seeds …	1	2	3	0	4	4
17	Do you use buttons? e.g. buttons on clothing, bags…	1	2	3	0	4	4
18	Do you thread needles? i.e. pass thread through the eye of a needle	1	2	3	0	4	4
19	Do you pick up pieces of paper, handle paper or put it in order?	1	2	3	0	4	4
20	Do you pick up things from the floor?	1	2	3	0	4	4
	Subtotal scores(*add up the column*)						
	SALSA score (*add up all subtotal scores*)						

Form 2: WHO-DAS II

WORLD HEALTH ORGANIZATION

DISABILITY ASSESSMENT SCHEDULE

H1	How do you rate your <u>overall health in the past 30 days?</u> *Read choices to respondent.*	Very good	Good	Moderate	Bad	Very Bad

SHOW FLASHCARD #2 to participant

In the last 30 days <u>how much difficulty did you have in</u>:

		None	Mild	Moderate	Severe	Extreme /Cannot Do
S1	<u>Standing</u> for <u>long periods</u> such as <u>30 minutes</u>?	1	2	3	4	5
S2	Taking care of your <u>household responsibilities</u>?	1	2	3	4	5
S3	<u>Learning</u> a <u>new task</u>, for example, learning how to get to a new place?	1	2	3	4	5
S4	How much of a problem did you have <u>joining in community activities</u> (for example, festivities, religious or other activities) in the same way as anyone else can?	1	2	3	4	5
S5	How much have <u>you</u> been <u>emotionally affected</u> by your health problems?	1	2	3	4	5

Continue to next page…

Form 2: WHO-DAS II

In the last 30 days how much difficulty did you have in:		None	Mild	Moderate	Severe	Extreme /Cannot Do
S6	Concentrating on doing something for ten minutes?	1	2	3	4	5
S7	Walking a long distance such as a kilometre [or equivalent]?	1	2	3	4	5
S8	Washing your whole body?	1	2	3	4	5
S9	Getting dressed?	1	2	3	4	5
S10	Dealing with people you do not know?	1	2	3	4	5
S11	Maintaining a friendship?	1	2	3	4	5
S12	Your day to day work?	1	2	3	4	5

		None	Mild	Moderate	Severe	Extreme /Cannot Do
H2	Overall, how much did these difficulties interfere with your life? *Read choices to respondent.*	1	2	3	4	5
H3	Overall, in the past 30 days, how many days were these difficulties present?	RECORD NUMBER OF DAYS __/__				
H4	In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition?	RECORD NUMBER OF DAYS __/__				
H5	In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition?	RECORD NUMBER OF DAYS __/__				

N.B.: In the Tamil version of the WHO-DAS II scores ranged from 0 to 4 instead of 1 to 5

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Form 3: General questionnaire

1. RESPONDENT NUMBER: …………………………..

2. DATE OF INTERVIEW   ………/……../……...

3. SEX   €MALE   €FEMALE

4. AGE   ………………*years*

5. EDUCATIONAL LEVEL: €NONE
                            €INCOMPLETE SCHOOLING
                            €COMPLETE SCHOOLING
                            €GRADUATE
                            €POST-GRADUATE

6. MARITAL STATUS   €NEVER MARRIED
                            €CURRENTLY MARRIED
                            €SEPARATED
                            €DIVORCED
                            €WIDOWED

7. CHILDREN   €NO   €YES, Sons: ……… Daughters: ……

8. OCCUPATION

	Respondent	Spouse
1. Unemployed	€	€
2. Retired	€	€
3. Housewife	€	€
4. Trainee (vocational)	€	€
5. Trade/business (self-employed)	€	€
6. Unskilled labour (farmer)	€	€
7. Skilled labour (service, weaver)	€	€
8. Professional	€	€

9. INCOME

		Respondent	Family
1. No income	Rupees per month	€	€
2. less than 1000	"	€	€
3. 1001 – 3000	"	€	€
4. 3001 – 5000	"	€	€
5. >5000	"	€	€

10. RESIDENCY   €URBAN   € RURAL

11. LIVING SITUATION   €INDEPENDENT
                                 €ASSISTED LIVING
                                 €HOSPITALIZED

12. DIAGNOSIS   €LEPROSY   €SPINAL CORD INJURY   €CVA/CEREBRAL
PALSY

12.1 How long ago were you diagnosed?   ....*years*

12.2 Use of assistive devises: €Glasses
                                       €Wheelchair
                                       €Walking stick or frame
                                       €Crutches
                                       €Callipers
                                       €Straps or splints
                                       €Adapted eating utensils
                                       €Adapted work tools
                                       €Gloves or clothes
                                       €Special footwear
                                       €Other: ....

Name Respondent   :…………………………………………………………

Interviewer   :…………………………………………………………

Comments   :…………………………………………………………

Form 4: Informed consent

You are invited to participate in a research project studying the validity of the SALSA scale as a generic instrument. The purpose of this research is to gain a better understanding in the applicability of the SALSA scale.

The lead researcher on this project is **Suzanne Mol,** Master of Science (MSc) candidate in Management, Policy Analysis and Entrepreneurship in Health and Life Sciences at the VU University of Amsterdam. The study is guided by David Prakash, Head of the department of Physical Therapy of the Schieffelin Institute of Health Research and Leprosy Centre (SIHR&LC) Karigiri, and under supervision of Dr. Ebenezer, Director of the SIHR&LC. The plan for this study has been reviewed for its adherence to ethical guidelines and approved by the Research Committee of the Schieffelin Institute of Health Research and Leprosy Centre (SIHR&LC) Karigiri.

 Participant Ethics Consent Form

 I consent that **Suzanne Mol,** accompanied by a research assistant, may interview me and ask me questions (for around 60 minutes) about my Activity of Daily Living (ADL).

I confirm that in advance of this interview I have had all of my questions addressed to my satisfaction.

I understand that data resulting from my participation in this interview will not identify me in any way and that all of my responses are private and confidential. I also understand that I am free to opt out of the interview at any time and have any collected data removed from the database, or that I may decline to answer specific questions without penalty.

Questionnaires
I hereby give my permission to be interviewed.
I understand that the questionnaires will be used for research purposes only, including research articles and presentations.

In-depth interview and focus groups
I understand that the interview will be audio recorded and that the recordings, interview transcripts, and field notes will be used for research purposes only, including research articles and presentations.

Participant:
€Yes I agree.
€No I disagree.

Interviewer's Signature:
_____
Date:

Form 5: In-depth interview guide

Examining the validity of the SALSA scale as a generic measure of activity. South India, Tamil Nadu.

Interview guide for semi-structured interviews.

Before starting the interview:

- Test the voice recorder.

- Welcome participant and express appreciation.

- Introduce yourself and your colleague (observant/assistant).

- Give an introduction on the purpose of the interview.

- Explain that the interview should be recorded for the reliability and validity of the data.

- Assure the confidentially of the data.

" This interview is being recorded in order to gain the fullest information from the comments you make. The tapes will be transcribed and listened to or read only in strict confidentiality. This information will only be used for study purposes."

- Emphasize the importance of their input.

- Ask if there are any questions about foresaid.

- Write down observations during the interview.

Interview questions:

- Which items of the SALSA scale are most relevant according to you?

  o In what way/why?

- Which items of the SALSA scale are less relevant according to you?

  o In what way/why?

- Are there any items missing in the SALSA scale according to you?

  o In what way/why?

- Is there anything else changed which you like to mention?

After the interview

- Ensure all questions are asked and all material is collected and recorded.

- Ask whether the participant wants to mention anything else.

- Express appreciation

- Thank the participant for participating in the interview.

- Write a complete transcript of the interview, i.e. write down exactly every question you asked and every answer given. The transcribing should be done as soon as possible after conducting the interview. The interview should at first be fully transcribed in Tamil, afterwards it should be translated to English. The observations done during the interview should be translated and added to the end of the transcript.

Important to keep in mind:

- The main purpose of the in-depth interviews is to validate the quantitative data, i.e. to check if the respondents answers of the scale-based interviews agree with these qualitative in-depth interviews.

- Make the respondent feel at ease; the interview should be conducted in a 'safe' environment (preferably at the respondents home), without spectators (the respondent should be able to speak freely). Develop rapport, comfort!
  Show empathy.

- Questions to expand a respondent's answer:

  o Can you expand on that?

  o Can you be more specific on that?

  o Can you clarify that?

Form 6: Focus group guide

Examining the validity of the SALSA scale as a generic measure of activity. South India, Tamil Nadu.

Interview guide for focus groups.

Before starting the interview

- Test the voice recorder.

- Welcome participant and express appreciation.

- Give an introduction on the purpose of the focus group.

- Explain that the focus group discussion should be recorded for the reliability and validity of the data.

- Confirm the confidentially of the data.

" These sessions are being taped in order to gain the fullest information from the comments you make. The tapes will be transcribed and listened to or read only in strict confidentiality. This information will only be used for study purposes."

- Emphasize the importance of their input.

- Ask if there are any questions about foresaid.

- Write down observations during the focus group.

- Let everybody introduce themselves by their first name, start with yourself and your colleagues (observant/assistant).

Focus group questions:

- Which items are most relevant items of the SALSA scale to measure activity limitation in people with locomotor diability?

  o In what way/why?

  → Let FGD participants range the mentioned items.

- Which items are less relevant items of the SALSA scale to measure activity limitation in people with locomotor diability?

  o In what way/why?

→ Let FGD participants range the mentioned items.

- Which items are missing in the SALSA scale to measure activity limitation in people with locomotor diability?

    o   In what way/why?

    → Let FGD participants range the mentioned items.

- Discuss the WHO-DAS II items

- Discuss respondents' input

- Discuss comprehensiveness of the SALSA scale.

After the focus group

- Ensure all questions are asked and all material is collected and recorded.

- Ask whether the participants want to mention anything else.

- Express appreciation.

- Thank the participants for participating in the interview.

- Write a complete transcript of the focus group, i.e. write down exactly every question you asked and every answer given. The transcribing should be done as soon as possible after conducting the focus group. The focus group should at first be fully transcribed in Tamil, afterwards it should be translated to English. The observations done during the focus group should be translated and added to the end of the transcript.

Important to keep in mind:

- The purpose of the focus group is to assess the content validity of the SALSA scale for diagnostic groups other than leprosy/diabetes, causing motor and/or sensory impairments.

- Be the facilitator, not the participant.

- Make the respondents feel at ease; the focus group should be conducted without spectators (the respondent should be able to speak freely). Develop rapport, comfort! Show empathy.

- Questions to expand a respondent's answer:

    o   Can you expand on that?

- o Can you be more specific on that?

  o Can you clarify that?

- Questions to probe a respondent's answer:

  o Do you agree with that?

  o Do you feel that way too?

  o Is there anything you can add?

- Questions to probe any answer:

  o Does anyone else have something to say about this idea?

  o Does anyone feel different about this?

  o We are not asking everyone to agree, all opinions are valued and will be heard.