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Evaluation of the World Health Organization Disability Assessment Schedule II (WHO DAS II) – German Version

Disability in Patients with Musculoskeletal Diseases, Cardiovascular and General Internal Diseases, Stroke, Breast Cancer and Depressive Disorder

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Content

Evaluation des World Health Organization Disability Assessment Schedule II (WHODAS II) – Deutsche Version

Funktionale Gesundheit und Behinderung bei Patienten mit muskuloskeletalen Erkrankungen, kardiovaskulären und allgemeinen internistischen Erkrankungen, Schlaganfall, Brustkrebs und Depressiven Störungen

ZUSAMMENFASSUNG

Hintergrund:

Der Fragebogen World Health Organization Disability Assessment Schedule II (WHODAS II) ist ein neues Messinstrument zur Erfassung von funktionaler Gesundheit und Behinderung, das konzeptuell mit dem Klassifikationssystem International Classification of Functioning, Disability and Health (ICF) übereinstimmt. Im Gegensatz zu anderen Instrumenten zur Erfassung des Gesundheitszustandes basiert der Fragebogen WHODAS II auf einem internationalen Klassifikationssystem, kann kulturübergreifend eingesetzt werden und behandelt alle Krankheiten gleichwertig bei der Bestimmung der funktionalen Gesundheit.

Zielsetzung:

Ziel der vorliegenden Arbeit ist es, herauszufinden, inwieweit der Fragebogen World Health Organization Disability Assessment Schedule II (WHODAS II) – deutsche Version - ein geeignetes Messinstrument zur Erfassung von funktionaler Gesundheit und Behinderung bei Patienten mit muskuloskeletalen Erkrankungen, kardiovaskulären und allgemeinen internistischen Erkrankungen, Schlaganfall, Brustkrebs und Depressiven Störungen ist. Spezifische Ziele sind dabei die Bewertung der psychometrischen Gütekriterien Reliabilität (internale Konsistenz, Cronbach's Alpha), Validität (Faktorenanalyse zur Beurteilung der Dimensionalität, konvergente Validität, diskriminante Validität) und Änderungssensitivität (Effektstärke, Standardized Response Mean), die Bestimmung der Korrelation mit einem traditionellen generischen Messinstrument für ge-

sundheitsbezogene Lebensqualität, dem SF36 und die Bestimmung der Änderungssensitivität nach einer rehabilitativen Behandlung, wiederum in Relation zum SF-36.

Methoden:

Patienten mit muskuloskeletalen Erkrankungen, kardiovaskulären und allgemeinen internistischen Erkrankungen, Schlaganfall, Brustkrebs und Depression nahmen an der Studie teil. Diese Patienten füllten die Fragebogen WHODAS II und SF-36 aus. Nach einer rehabilitativen Therapie beantworteten diese Patienten die Fragenbogen ein zweites Mal, damit Rückschlüsse auf die Veränderungssensitivität gezogen werden können. Analysen der Testgütekriterien wurden durchgeführt. Die Änderungssensitivität wurde anhand der Effektstärke und des SRM berechnet.

Ergebnisse:

Die Patienten erreichen einen Mittelwert von 21,98 (Std. 14,32) in der Gruppe der muskuloskeletalen Erkrankungen, 18,47 (Std. 15,32) in der Gruppe der internistischen Erkrankungen, 38,72 (Std. 24,79) in der Subgruppe Schlaganfall, 23,84 (Std. 16,61) in der Subgruppe Brustkrebs und 44,56 (Std. 18,95) in der Subgruppe Depressive Störungen. Der Fragebogen weist eine hohe Reliabilität auf. Größtenteils bestätigen die Ergebnisse der Skalenreplikation die vorgegebenen sechs Dimensionen des Fragebogens. In der Dimension „Aktivitäten des täglichen Lebens“ zeigt sich für die Subgruppen muskuloskeletale Erkrankungen und internistische Erkrankungen eine klare Trennung zwischen beruflichen Tätigkeiten und Tätigkeiten im Haushalt. Die im Vergleich mit dem SF-36 festgestellten Korrelationen deuten darauf hin, dass der Fragebogen WHODAS II die beabsichtigten Konstrukte misst. Die Effektstärken des Summenscores von WHODAS II reichen abhängig von der untersuchten Subgruppe von 0,163 bis 0,687; Effektstärken der Summenskalen des SF-36 von 0,025 bis 1,395. Für die Subgruppe der Patienten, die eine Verbesserung hinsichtlich ihres allgemeinen Gesundheitszustandes berichten, sind die Effektstärken entsprechend höher (0,220 bis 0,915 für den WHODAS II; 0.083 bis 2.023 für den SF-36).

Schlussfolgerung:

Der Fragebogen WHODAS II (deutsche Version) ist ein geeignetes Messinstrument zur Erfassung von funktionaler Gesundheit und Behinderung bei Patienten mit muskuloskeletalen Erkrankungen, kardiovaskulären und allgemeinen internistischen Erkrankungen, Schlaganfall, Brustkrebs und Depressiven Störungen. Das Messinstrument ist reliabel und valide und weist eine ähnliche Änderungssensitivität auf wie die entsprechenden Subskalen des SF-36.

Schlüsselwörter: ICF, WHODAS II, Lebensqualität, Rückenschmerzen, Rheumatoide Arthritis, Osteoarthritis, koronare Herzerkrankung, COPD & Asthma, Diabetes Mellitus, Adipositas, Brustkrebs, Schlaganfall, Depressive Störung, Änderungssensitivität

Evaluation of the World Health Organization Disability Assessment Schedule II (WHODAS II) – German Version

Functioning and Disability in Patients with Musculoskeletal Diseases, Cardiovascular and General Internal Diseases, Stroke, Breast Cancer and Depressive Disorder

ABSTRACT

Backgroud:

The World Health Organization Disability Assessment Schedule II (WHODAS II) is a new measure of functioning and disability that is conceptually compatible with the International Classification of Functioning, Disability, and Health (ICF). In contrast to other measures of health status, the WHODAS II is based on an international classification system, it is designed to be applicable across different cultures, and it treats all disorders at parity when determining the level of functioning.

Objective:

The general objective of this study is to investigate whether the WHODAS II – German version – is a useful instrument for measuring functioning and disability in patients with musculoskeletal conditions, cardiovascular and general internal conditions, stroke, breast cancer and depressive disorder. Specific objectives are to assess its psychometric properties reliability (internal consistency, Cronbach's Alpha), validity (factor analysis of dimensionality, convergent validity, discriminant validity), and sensitivity to change (effect size and standardized response mean), to determine to what extent the WHODAS II correlates with a traditional generic instrument for measuring Health Related Quality of Life, the SF-36, and to define its sensitivity to change after a rehabilitative intervention in relation to that other instrument.

Methods:

Patients with musculoskeletal conditions, cardiovascular and general internal conditions, stroke, breast cancer and depressive disorder participated. The patients completed the questionnaires WHODAS II and SF-36. After a rehabilitation treatment the same patients completed these questionnaires again in order to assess sensitivity to change. Analyses of measurement properties were conducted. Sensitivity to change was calculated by the effect size (ES) and standardized response mean (SRM).

Results:

Mean score on the WHODAS II is 21.98 (SD 14.32) for musculoskeletal conditions, 18.47 (SD 15.32) for internal conditions, 38.72 (SD 24.79) for stroke, 23.84 (SD 16.61) for breast cancer, and 44.56 (SD 18.95) for depressive disorder. High reliability is obtained. For the most part, the results of the scale replication confirm the determined six domains of the questionnaire. For the domain Activities, a clear distinction between work und household activities is apparent in both musculoskeletal and internal conditions. The correlations found in comparison to the SF-36 indicated that the WHODAS II (German version) measured indeed the expected constructs. The effect sizes of the WHODAS II Total Score range from 0.163 to 0.687 depending on the subgroup; effect sizes of the SF-36 summary scores from 0.025 to 1.395, respectively. In terms of patients reporting an improvement of general health status, effect sizes are accordingly higher (0.220 to 0.915 for the WHODAS II; 0.083 to 2.023 for the SF-36).

Conclusion:

The WHODAS II (German version) is a useful instrument for measuring functioning and disability in patients with musculoskeletal diseases, internal diseases, stroke, breast cancer and depressive disorder. It is reliable and valid and shows similar sensitivity to change scores as the SF-36 in the accordingly subscales.

Key Indexing Terms: ICF, WHODAS II, Quality of Life, Low Back Pain, Rheumatoid Arthritis, Osteoarthritis, Coronary Heart Disease, COPD & Asthma, Diabetes Mellitus, Obesity, Breast Cancer, Stroke, Depressive disorder, Sensitivity to Change

BACKGROUND

The World Health Organization (WHO) has revised the International Classification of Impairments, Disabilities and Handicaps (ICIDH) towards a biopsychosocial model – the International Classification of Functioning, Disability, and Health (ICF) – to comprehend human functioning at physical, personal, and social levels [(1)]. In order to evaluate function and disability, the WHO has developed the World Health Organization Disability Assessment Schedule II (WHODAS II) [(2)] as an instrument that arises from the same conceptual basis as the ICF. In the ICF disability is understood independent of the background disease or health condition and etiologically neutral. The ICF and WHODAS II share the same conceptual understanding of disability and its dimensions. The WHODAS II is a multidimensional questionnaire, which can be employed for measuring the level of disability across various conditions and interventions. It includes six domains: Understanding and Communicating, Getting Around, Self Care, Getting Along with Others, Household and Work Activities, Participation in Society. The WHODAS II has been translated and validated in numerous languages. Versions of the WHODAS II can be obtained through the WHO. The WHODAS II as a generic instrument should be applicable for all types of diseases, therefore we examined to what extent the WHODAS II would be a useful questionnaire in assessing disability in several different diseases, namely musculoskeletal conditions (low back pain, rheumatoid arthritis and osteoarthritis), cardiovascular and general internal conditions (coronary heart disease, COPD & asthma, diabetes mellitus, obesity), breast cancer, stroke and depressive disorder. Critical properties of an outcome measure include reliability, validity and sensitivity to change. According to Guyatt & Kirshner [(3)] goals of clinical measurement instruments are discrimination, prediction and evaluation. Within instruments that are employed for evaluation, the classical measurement properties objectivity, reliability and validity are not sufficient. Sensitivity to change must be ensured.

Outside of the WHO centers where this questionnaire was developed and tested, there has not yet been a large validation study incorporating numerous different diseases. The work presented here is the first independent attempt to confirm or refute those findings across a broad range of health conditions.

The general objective of this study is to investigate whether the WHODAS II – German version – is a useful instrument for measuring functioning and disability. Specific objectives are to assess its psychometric properties reliability, validity, and sensitivity to change, to determine to what extent the WHODAS II correlates with another generic instrument, the SF-36, and to define its sensitivity to change after a rehabilitative intervention in relation to that other instrument. As an external validation we employed the widely used generic instrument, the Short Form-36 Health Status Questionnaire (SF-36), which is used for measuring quality of life in patients suffering from the above mentioned conditions.

MATERIALS AND METHODS

♦ Design

Analyses were performed on basis of data of a multicenter, prospective cohort study with two time points of assessment (prior to rehabilitative treatment and after).

♦ Patients

The validation of the WHODAS II refers to two different condition groups: **musculoskeletal conditions** (low back pain, rheumatoid arthritis, osteoarthritis), **cardiovascular and general internal conditions** (coronary heart disease, COPD & asthma, diabetes mellitus, obesity). Three conditions were tested separately due to their relevance: breast cancer, stroke and depressive disorder (Table 1). N = 904 inpatients of 19 rehabilitation centers and clinics in Bavaria, Germany were included. These patients were suffering from at least one of the conditions mentioned above.

Table 1: Conditions and ICD-10 Diagnoses

Condition	ICD-10 Diagnosis
Condition Group: Musculoskeletal Conditions	
Low Back Pain	Dorsalgia (M54)
Rheumatoid Arthritis	Rheumatoid Arthritis (M05-M06)
Osteoarthritis	Osteoarthritis (M19)
Condition Group: Cardiovascular and General Internal Conditions	
Coronary Heart Disease	Myocardial Infarction (I21-I25)
COPD & Asthma	Other Chronic Obstructive Pulmonary Disease (J44) Asthma (J45)
Diabetes Mellitus	Diabetes Mellitus (E10-E14)
Obesity	Obesity (E65-E68)
Single Conditions	
Stroke	Stroke, not Specified as Haemorrhage or Infarction (I64) Consequence of Stroke (I69.4)
Breast Cancer	Malignant Neoplasm of Breast (C50)
Depressive Disorder	Depressive Episode (F32) Recurrent Depressive Disorder (F33)

Inclusion criteria were 1) age ≥ 18, 2) main diagnosis of the patients corresponds to one of the ICD-10 diagnosis listed in Table 1, 3) purpose and reason for the study have been understood, and 4) signed informed consent has been provided. Patients who have had surgery and wound

has not completely healed yet and patients who have had surgery within the previous six months were excluded.

- **Data Collection Procedures**

The self-administration form of the WHODAS II and the SF-36 was filled in by the patients on their own. Health professionals were available for possible questions.

- **Measures**

WHODAS II

The World Health Organization Disability Assessment Schedule II (WHODAS II) is a measure of functioning and disability that is conceptually compatible with ICF [(1)]. This measurement instrument assesses functioning/disability across a variety of conditions and treatment interventions in six domains of life: Understanding and Communicating (cognition), Getting Around (mobility), Self Care (attending to one's hygiene, dressing, eating and staying alone), Getting Along with Others (interpersonal interactions), Household and Work Activities (domestic responsibilities, leisure, and work), Participation in Society (joining in community activities) during the last 30 days. Both a profile of functioning across these domains and an overall disability score is provided. We used the self-administered 36-item version of the WHODAS II in German. The WHODAS II consists of 36 Likert formatted questions, divided into the above-mentioned six domains. The final scores are calculated with an SPSS syntax. These scores range from 0 (best) to 100 (worst).

The Short Form-36 Health Survey

The SF-36 Health Survey [(4)] is a short-form health survey developed for the Medical Outcome Study [(5)], that is validated and normed for numerous countries. It contains 36 questions and produces an eight-scale profile of scores: Physical Functioning (limitations in physical activities because of health problems), Role Functioning-Physical (limitations in usual role activities due to physical health problems), Bodily Pain, General Health, Vitality (energy and fatigue), Social

Functioning (limitations in social activities due to physical or emotional problems), Role Functioning-Emotional (limitations in usual role activities due to emotional problems), and Mental Health (psychological distress and well-being). Furthermore the SF-36 provides a summary physical and a summary mental score, each consisting of four scales. The SF-36 is a generic measure of health status and has proven useful in comparing general and specific populations, estimating the relative burden of diseases, differentiating the health benefits resulting from different treatments, and screening individual patients [6]. The patients complete the self-administration form of this questionnaire.

- **Analysis**

Data were analyzed using SPSS 11.0 for Windows. The WHODAS II was assessed in terms of psychometric properties: reliability (internal consistency, Cronbach's Alpha), validity (factor analysis of dimensionality, convergent validity, discriminant validity), sensitivity to change in relation to another traditional generic instrument, the SF-36.

Descriptive Analyses (M, SD, Min, Max) were conducted.

Missing Values Analysis

Missing data refers to information not available for a subject (or case) about whom other information is available [7]. Missing data might be caused by the respondent's refusal to answer one or more questions. The rate of missing data is a criterion for the assessment of the data set's quality. A high percentage of missing data leads to an uncontrollable sample selection and limits the meaningfulness of the individual scales considerably. A rate of more than 10% of missing data is considered as a criterion for a meaningful and thus critical missing rate, as is the systematic appearance of missings [8].

Floor- and Ceiling Effects

Analyses regarding floor- and ceiling effects were conducted. Appearance of floor- and ceiling effects leads to the following [8]: Distinction between patients that show extreme values is not possible even if they actually differ regarding to the underlying construct. A false impression of homogeneity arises from it regarding the measured value. Distinctive floor-and ceiling effects reduce both the reliability and the validity of an instrument since they reduce its variability. In the course of the study, improvements or deteriorations of health state in patients with extreme characteristics are not detectable. This might lead to an underestimation of the treatment effect, i.e. to a lower responsiveness. Concluding that patients are not improving, when in fact, they are indeed making clinically significant changes, which cannot be detected by the measurement tool can lead to poor administrative and clinical decisions.

Reliability

An important step in instrument validation is to test the instrument for reliability to ensure measurement accuracy in order to minimize the measurement error. Cronbach's Alpha, which is calculated based on the average inter-item correlations [9], was estimated for each of the subscales in every sample to measure internal consistency.

Factor Analysis

Kaiser-Mayer-Olkin's Measure of Sampling Adequacy Test and Bartlett's Test of Sphericity were conducted to assess the suitability of the data for factor analysis. The Kaiser-Mayer-Olkin Measure of Sampling Adequacy is a statistic that indicates the proportion of variance in the variables which is common variance, i.e. which might be caused by underlying factors. This index ranges from 0 to 1, reaching 1 when each variable is perfectly predicted without error by the other variables. The measure can be interpreted with the following guidelines: 0.9 or above is marvelous, 0.8 is meritorious, 0.7 is middling, 0.6 is mediocre, 0.5 is miserable and below 0.5 is unacceptable [10, 11].

The Bartlett Test of Sphericity is a statistical test for the presence of correlations among the variables (items). It shows whether the correlation matrix is an identity matrix, which indicates that the variables (items per specific construct) are unrelated. The significance level gives the result of the test. Small values indicate that the data do not produce an identity matrix and, hence, are suitable for factor analysis. The results of Kaiser-Mayer Olkin's Measure of Sampling Adequacy and Bartlett Tests show that the data meet the fundamental requirements for factor analysis. For adequate subgroups a Principal Component Analysis with Varimax-Rotation with Kaiser Normalization and extraction of 6 factors was performed in order to show a replication of the dimensionality of WHODAS II.

Inter-Scale Correlations

In order to further test the dimensionality of WHODAS II, correlations (Pearson correlation coefficients) of the subscales and the Total Score were examined. Since the domains reflect the same construct (disability, functioning and health), they should be correlated positively and sufficiently. As they should not obtain redundant information, very high correlations are not desirable.

Convergent Validity

Convergent validity is defined as the degree to which the operationalization is similar to (converges on) other operationalizations that it theoretically should be similar to. The convergent validation was examined through correlation of the subscales with comparable scales of the SF-36. Convergent validity was estimated by Pearson correlation coefficients. Consistent with literature on convergent validity, Pearson correlation coefficient values greater than 0.7 were considered to reflect a high degree of correlation; values between 0.5 and 0.7 were regarded to reflect moderate correlation [(12)].

Discriminant Validity

The discriminant validity was assessed by a differentiation of the study population according to criteria that assume a difference regarding functioning and severity of disease. The grouping variable (discrete classification variable) was an item assessing the degree of Sensation of Pain (b280) in the International Classification of Function, Disability and Health (ICF). Answer possibilities ranged from 0 to 4 (no/mild/moderate/severe/complete impairment, respectively). The ICF Checklist was completed by health professionals in cooperation with the patients. Patients were classified into two groups, no/mild pain (0-1) and strong pain (3-4). If the number of patients in the subgroups differed very much, additional analyses were conducted according to the following criteria: patients were classified into two groups, no/mild pain (0-1) and moderate to strong pain (2-4). The purpose of this analysis was to investigate independent variable mean differences between groups formed by the dependent variable, to determine the percent of variance in the dependent variable explained by the independents, to assess the relative importance of the independent variables in classifying the dependent variable and to test the theory (discriminant function) by observing whether cases are classified as predicted [13]. For comparison reasons the discriminant analysis was performed for scales of the SF-36 as well.

Sensitivity to Change

According to Liang et al. [14] sensitivity to change is the ability of an instrument to detect changes over time. As opposed to that responsiveness is the ability of an instrument to measure a meaningful or important change in a clinical state. Sensitivity to change provides the basis for comparing measures with differing scales and can be measured using variables such as effect size [15] and standardized response mean [16]. The ability of an instrument to discern these changes can be evaluated either over a prespecified period of time or by comparison to a well-established physiologic measure. Since there is no external commonly accepted standard for disability, in the article at hand sensitivity of the WHODAS II was defined as internal sensitivity, which characterizes the ability of a measure to change over specified time frame. Additional effect sizes for

patients who assessed their perceived general health status better than before the rehabilitation treatment were analyzed. Improvement was defined as a better score in item 1 (general health) of the SF-36 after rehabilitation treatment. First, effect sizes were calculated for each subscale and the summary score of the WHODAS II and SF-36. Effect sizes were calculated as the change in mean from baseline (time 1) to the follow-up (time 2) divided by the standard deviation at baseline [15]. According to the literature, effect sizes of 0.2 to 0.5 are considered to reflect small responsiveness, effect sizes of 0.5 to 0.8 were regarded as being moderate and those greater than or equal to 0.8 as being large [17, 18]. Sensitivity of instruments may also be directly compared in that the standardized response means (SRMs) of two instruments are compared [14]. Standardized response mean is defined as mean score change divided by the standard deviation of the change score [16, 19]. The more sensitive instrument should have a larger SRM

RESULTS

- **Demographic Information and Baseline Characteristics**

Demographic Information

Demographic data and information on health status of the n=904 patients included are shown in Table 2 to 7. Patients (N=296) with musculoskeletal conditions were examined (cardiovascular and general internal conditions: N= 308, stroke: N= 116, breast cancer: N= 119, depression: N= 65) (Table 2). The percentage of females is 50% for the musculoskeletal conditions, 40.26% for internal conditions, 47.41% for stroke, 100% for breast cancer and 32.3% for depression (Table 3). The age ranges of patients are between 19 and 83 years in musculoskeletal conditions (mean 54, SD 11.28), 17 to 82 for internal conditions (mean 51.78, SD 15.14), 20 to 80 for stroke (mean 57.30, SD 12.43), 30 to 77 for breast cancer (mean 53.62, SD 9.59) and 23 to 70 for depression (mean 48.3, SD 9.48), respectively, see Table 4. Of all patients, 31% to 63.5% are employed and 9.2% to 42.2% of the subjects are retired (Table 5).

Table 2: Diagnoses, Number of Patients

Multiple diagnoses were possible.

Musculoskeletal Conditions		
	n (N=296)	%
Low back pain	200	67.60
Osteoporosis	0	0.00
Rheumatoid arthritis	40	13.50
Osteoarthritis	62	20.90
Coronary heart disease	1	0.30
COPD & asthma bronchiale	0	0.00
Diabetes mellitus	1	0.30
Obesity	8	2.70
Pain disorders	4	1.40
Stroke	0	0.00
Breast cancer	2	0.70
Depressive disorder	1	0.30

Table 2 cont.

Internal Conditions		
	n (N=308)	%
Low back pain	8	2.60
Osteoporosis	0	0.00
Rheumatoid arthritis	0	0.00
Osteoarthritis	3	1.00
Coronary heart disease	80	26.00
COPD & asthma bronchiale	92	29.90
Diabetes mellitus	77	25.00
Obesity	67	21.80
Pain disorders	3	1.00
Stroke	0	0.00
Breast cancer	0	0.00
Depressive disorder	2	0.60
Stroke		
	n (N=116)	%
Low back pain	0	0.00
Osteoporosis	0	0.00
Rheumatoid arthritis	0	0.00
Osteoarthritis	0	0.00
Coronary heart disease	0	0.00
COPD & asthma bronchiale	0	0.00
Diabetes mellitus	0	0.00
Obesity	0	0.00
Pain disorders	0	0.00
Stroke	116	100.00
Breast cancer	0	0.00
Depressive disorder	0	0.00
Breast Cancer		
	n (N=119)	%
Low back pain	2	1.70
Osteoporosis	0	0.00
Rheumatoid arthritis	0	0.00
Osteoarthritis	0	0.00
Coronary heart disease	0	0.00
COPD & asthma bronchiale	0	0.00
Diabetes mellitus	0	0.00
Obesity	0	0.00
Pain disorders	0	0.00
Stroke	0	0.00
Breast cancer	119	100.00
Depressive disorder	0	0.00

Table 2 cont.

Depression		
	n (N=65)	%
Low back pain	1	1.50
Osteoporosis	0	0.00
Rheumatoid arthritis	0	0.00
Osteoarthritis	0	0.00
Coronary heart disease	0	0.00
COPD & asthma bronchiale	0	0.00
Diabetes mellitus	0	0.00
Obesity	2	3.10
Pain disorders	13	20.00
Stroke	0	0.00
Breast cancer	0	0.00
Depressive disorder	65	100.00

Table 3: Gender

Musculoskeletal Conditions		
	n (N=296)	%
Male	148	50.00
Female	148	50.00
Missing	0	0.00
Total	**296**	**100.00**
Internal Conditions		
	n (N=308)	%
Male	179	57.47
Female	127	40.26
Missing	2	2.27
Total	**308**	**100.00**
Stroke		
	n (N=116)	%
Male	61	52.59
Female	55	47.41
Missing	0	0.00
Total	**116**	**100.00**
Breast Cancer		
	n (N=119)	%
Male	0	0.00
Female	119	100.00
Missing	0	0.00
Total	**119**	**100.00**
Depression		
	n (N=65)	%
Male	44	67.70
Female	21	32.30
Missing	0	0.00
Total	**65**	**100.00**

Table 4: Age

Musculoskeletal Conditions	
	n (N=296)
N	296
Min	19.83
Max	83.50
Mean	54.00
SD	11.28
Internal Conditions	
	n (N=308)
N	308
Min	17.87
Max	82.76
Mean	51.78
SD	15.14
Stroke	
	n (N=116)
N	116
Min	20.50
Max	80.92
Mean	57.30
SD	12.43
Breast Cancer	
	n (N=119)
N	119
Min	30.59
Max	77.09
Mean	53.62
SD	9.59
Depression	
	n (N=65)
N	65
Min	23.38
Max	70.74
Mean	48.30
SD	9.48

Table 5: Current Occupation

Musculoskeletal Conditions		
	n (N=296)	%
Paid employment	188	63.51
Self-employed	11	3.72
Non-paid employment	1	0.34
Student	0	0.00
House maker	13	4.39
Retired	63	21.28
Unemployed (due to health reasons)	8	2.70
Unemployed (due to other reasons)	8	2.70
Other	3	1.01
Missing	1	0.30
Total	**296**	**100.00**
Internal Conditions		
	n (N=308)	%
Paid employment	147	47.70
Self-employed	10	3.20
Non-paid employment	0	0.00
Student	10	3.20
House maker	14	4.50
Retired	85	27.60
Unemployed (due to health reasons)	7	2.30
Unemployed (due to other reasons)	14	4.50
Other	14	4.50
Missing	7	2.30
Total	**147**	**47.70**
Stroke		
	n (N=116)	%
Paid employment	36	31.00
Self-employed	5	4.30
Non-paid employment	1	0.90
Student	0	0.00
House maker	5	4.30
Retired	49	42.20
Unemployed (due to health reasons)	6	5.20
Unemployed (due to other reasons)	0	0.00
Other	7	6.10
Missing	7	6.00
Total	**116**	**100.00**

Table 5 cont.

Breast Cancer		
	n (N=119)	%
Paid employment	56	47.06
Self-employed	2	1.68
Non-paid employment	0	0.00
Student	0	0.00
House maker	23	19.33
Retired	20	16.81
Unemployed (due to health reasons)	10	8.40
Unemployed (due to other reasons)	8	6.72
Other	0	0.00
Missing	0	0.00
Total	**56**	**47.06**
Depression		
	n (N=65)	%
Paid employment	40	61.50
Self-employed	5	7.70
Non-paid employment	0	0.00
Student	1	1.50
House maker	1	1.50
Retired	6	9.20
Unemployed (due to health reasons)	7	10.80
Unemployed (due to other reasons)	1	1.50
Other	3	4.60
Missing	1	1.50
Total	**65**	**100.00**

Descriptive Statistics

Mean, SD

As displayed in Table 6 mean score of the WHODAS II is 21.98 (SD 14.32) for musculoskeletal conditions, 18.47 (SD 15.32) for internal conditions, 38.72 (SD 24.8) for stroke, 23.84 (SD 16.61) for breast cancer and 44.56 (SD 18.95) for depression. All subgroups show greatest impairments concerning the subscales Activities or Participation. The least impairment was obtained in terms of Self Care and Getting Along with Others.

Table 6: Descriptive Statistics at Baseline

WHODAS II

Musculoskeletal Conditions					
WHODAS II	**N**	**Min**	**Max**	**Mean**	**Std**
Understanding and Communicating	292	0.00	75.00	17.52	17.55
Getting Around	293	0.00	95.00	29.64	21.78
Self Care	293	0.00	87.50	8.72	15.10
Getting Along with Others	291	0.00	91.67	12.43	15.21
Activities	288	0.00	100.00	33.12	24.96
Participation	293	0.00	75.00	23.51	17.32
Total Score	285	0.00	80.79	21.98	14.32
Internal Conditions					
WHODAS II	**N**	**Min**	**Max**	**Mean**	**Std**
Understanding and Communicating	298	0.00	100.00	18.81	17.78
Getting Around	302	0.00	100.00	19.51	20.38
Self Care	303	0.00	100.00	6.47	14.97
Getting Along with Others	297	0.00	100.00	13.93	16.58
Activities	293	0.00	100.00	22.73	24.27
Participation	297	0.00	100.00	23.15	19.36
Total Score	286	0.00	100.00	18.47	15.32
Stroke					
WHODAS II	**N**	**Min**	**Max**	**Mean**	**Std**
Understanding and Communicating	107	0.00	95.00	31.26	23.79
Getting Around	109	0.00	100.00	42.20	34.58
Self Care	109	0.00	100.00	30.58	31.90
Getting Along with Others	109	0.00	100.00	24.60	24.39
Activities	102	0.00	100.00	53.24	35.39
Participation	108	0.00	100.00	41.18	25.31
Total Score	101	0.00	94,31	38.72	24.80
Breast Cancer					
WHODAS II	**N**	**Min**	**Max**	**Mean**	**Std**
Understanding and Communicating	118	0.00	75.00	23.80	18.79
Getting Around	118	0.00	85.00	19.48	18.99
Self Care	118	0.00	68.75	7.42	13.23
Getting Along with Others	118	0.00	90.00	18.65	17.33
Activities	118	0.00	100.00	34.33	27.30
Participation	117	0.00	90.63	27.75	19.39
Total Score	117	0.00	69.45	23.84	16.61
Depression					
WHODAS II	**N**	**Min**	**Max**	**Mean**	**Std**
Understanding and Communicating	65	8.33	87.50	48.17	21.36
Getting Around	65	0.00	90.00	30.22	26.70
Self Care	65	0.00	100.00	16.44	20.15
Getting Along with Others	65	0.00	90.00	44.58	25.43
Activities	64	3.13	100.00	54.26	25.58
Participation	65	10.71	95.83	54.46	19.79
Total Score	64	9.72	89.58	44.56	18.95

Health Related Quality of Life was examined by the SF-36 (Table 7). Greatest impairments are reported in the domain Role Functioning-Physical by patients with musculoskeletal conditions and breast cancer, in the domain Vitality by patients with internal conditions and stroke. Patients in the depression group show lowest values on the Mental Health scale. These findings correspond with the main characteristics of these diseases, which are mastering physical challenges and psychological challenges, respectively. Least impairment (i.e. best health status) is obtained regarding Role Functioning-Emotional in the musculoskeletal and internal conditions. Patients with stroke and breast cancer experience least impairment in Social Functioning, whereas patients with depression have best values concerning Physical Functioning. With respect to the scales Role Functioning-Emotional and Social Functioning patients across subgroups report the best health status. Regarding the summary measures patients report stronger impairment in the Physical Health Index Score than in the Mental Health Index Score, except patients suffering from depression.

Table 7: Descriptive Statistics at Baseline

SF-36

Musculoskeletal Conditions					
SF-36	**N**	**Min**	**Max**	**Mean**	**Std**
Physical Functioning	292	0.00	100.00	59.59	25.41
Role Functioning-Physical	289	0.00	100.00	33.28	38.24
Bodily Pain	294	0.00	100.00	35.27	19.43
General Health	287	0.00	87.00	49.39	17.63
Vitality	291	0.00	90.00	43.01	17.99
Social Functioning	294	0.00	100.00	71.13	25.81
Role Functioning-Emotional	287	0.00	100.00	74.45	39.59
Mental Health	289	0.00	100.00	62.60	19.61
PHYSICAL HEALTH INDEX SCORE	280	7.18	57.23	34.12	9.96
MENTAL HEALTH INDEX SCORE	280	11.50	73.76	48.45	11.47

Table 7 cont.

Internal Conditions					
SF-36	**N**	**Min**	**Max**	**Mean**	**Std**
Physical Functioning	305	0.00	100.00	66.01	27.59
Role Functioning-Physical	292	0.00	100.00	49.09	43.08
Bodily Pain	301	0.00	100.00	59.18	31.15
General Health	296	0.00	97.00	50.12	19.77
Vitality	297	0.00	100.00	48.64	20.57
Social Functioning	304	0.00	100.00	73.27	26.21
Role Functioning-Emotional	285	0.00	100.00	73.45	39.96
Mental Health	293	10.00	100.00	64.91	20.58
PHYSICAL HEALTH INDEX SCORE	273	14.44	62.62	40.62	11.37
MENTAL HEALTH INDEX SCORE	273	11.97	69.70	47.47	11.60
Stroke					
SF-36	**N**	**Min**	**Max**	**Mean**	**Std**
Physical Functioning	107	0.00	100.00	43.67	33.90
Role Functioning-Physical	96	0.00	100.00	22.66	37.71
Bodily Pain	107	0.00	100.00	58.06	31.79
General Health	104	0.00	97.00	45.69	20.10
Vitality	103	0.00	100.00	38.92	23.37
Social Functioning	107	0.00	100.00	60.51	27.96
Role Functioning-Emotional	90	0.00	100.00	46.30	46.79
Mental Health	99	8.00	100.00	55.44	21.72
PHYSICAL HEALTH INDEX SCORE	82	14.46	57.48	35.15	10.20
MENTAL HEALTH INDEX SCORE	82	18.19	71.20	42.06	12.06
Breast Cancer					
SF-36	**N**	**Min**	**Max**	**Mean**	**Std**
Physical Functioning	117	0.00	100.00	67.19	23.10
Role Functioning-Physical	117	0.00	100.00	38.60	38.71
Bodily Pain	118	0.00	100.00	59.84	27.45
General Health	116	18.75	100.00	56.55	18.89
Vitality	118	0.00	95.00	44.52	22.27
Social Functioning	118	0.00	100.00	70.44	27.13
Role Functioning-Emotional	114	0.00	100.00	62.57	44.60
Mental Health	118	8.00	100.00	60.86	20.73
PHYSICAL HEALTH INDEX SCORE	111	19.65	60.00	40.92	10.24
MENTAL HEALTH INDEX SCORE	111	15.71	62.64	44.33	12.64
Depression					
SF-36	**N**	**Min**	**Max**	**Mean**	**Std**
Physical Functioning	65	0.00	100.00	65.75	28.11
Role Functioning-Physical	62	0.00	100.00	37.90	39.66
Bodily Pain	65	0.00	100.00	40.94	32.60
General Health	64	0.00	87.00	39.11	19.21
Vitality	65	0.00	55.00	21.69	12.48
Social Functioning	65	0.00	100.00	31.54	22.00
Role Functioning-Emotional	64	0.00	100.00	17.71	30.27
Mental Health	65	0.00	68.00	31.18	16.90
PHYSICAL HEALTH INDEX SCORE	62	22.19	69.99	41.86	11.86
MENTAL HEALTH INDEX SCORE	62	8.97	47.62	24.42	8.57

Missing Values Analysis

Missing values do not occur systematically and in most variables the missing value rate is below the critical limit of 10% [8]. Regarding all variables, except questions concerning work activities and sexual activities, in the subgroup of patients with musculoskeletal conditions only 1% to 4.4% of the items are missing data, in general and internal conditions 6% to 14.7%, in the subgroup stroke 6% to 14.7%, in the subgroup breast cancer 0.8 to 7.6% and in the depression group 0% to 7.7%. Up to 65.5 % of answers are missing concerning work activities, partly due to unemployment. The question about sexual activities was not answered by up to 18.1%.

Floor- and Ceiling-Effects

In part, the ability to respond to change can be assessed in terms of the proportion of patients at floor (i.e. the worst score) or ceiling (i.e. the best score) of each scale [20].To assess the ability to respond to change the floor and ceiling effects were determined at baseline. The subscales of the WHODAS II show partially strong floor effects. In the domain Self Care, 33% to 70.3% of the patients report best possible score 0, i.e. no limitations, at baseline (Table 8).

Table 8: Floor-Effects (Percentage of Patients Featuring the Score 0 in Subscales of WHODAS II at Baseline)

WHODAS II	Musculo-skeletal	Internal	Stroke	Breast Cancer	Depression
Understanding and Communicating	24.3	18.8	11.2	8.5	3.1
Getting Around	8.2	24.5	16.5	20.3	20.0
Self Care	56.0	70.3	33.0	61.0	35.4
Getting Along with Others	37.8	34.0	22.9	20.3	4.6
Activities	11.1	24.9	12.7	14.4	1.6
Participation	6.1	7.7	3.7	7.7	1.5

- **Reliability**

Table 9 displays the results of the reliability analysis. The Cronbach's alpha values range from 0.70 to 0.97. There is no standard cut-off point for the alpha coefficient, but the generally agreed upon lower limit for Cronbach's alpha is 0.7 required for group comparisons [7]. Thus, all sub-

scales meet the requirements. However, only the scales activities almost fulfill the level of 0.95 across subgroups required for use in individual patients according to Nunally [21]. When interpreting these values, one has to take the floor- and ceiling-effects into account, both of which bias the Cronbach's alpha.

Table 9 Cronbach's Alpha

Musculoskeletal Conditions	
WHODAS II	**Cronbach's Alpha**
Understanding and Communicating	0.87
Getting Around	0.85
Self Care	0.82
Getting Along with Others	0.70
Activities	0.94
Participation	0.82
Internal Conditions	
WHODAS II	**Cronbach's Alpha**
Understanding and Communicating	0.87
Getting Around	0.84
Self Care	0.87
Getting Along with Others	0.72
Activities	0.94
Participation	0.87
Stroke	
WHODAS II	**Cronbach's Alpha**
Understanding and Communicating	0.86
Getting Around	0.95
Self Care	0.92
Getting Along with Others	0.84
Activities	0.97
Participation	0.87
Breast cancer	
WHODAS II	**Cronbach's Alpha**
Understanding and Communicating	0.86
Getting Around	0.84
Self Care	0.70
Getting Along with Others	0.69
Activities	0.97
Participation	0.88

Table 9 cont.

Depression	
WHODAS II	**Cronbach's Alpha**
Understanding and Communicating	0.83
Getting Around	0.91
Self Care	0.70
Getting Along with Others	0.81
Activities	0.95
Participation	0.77

- **Factor Analysis**

Factor Analysis was only conducted regarding musculoskeletal and internal conditions. The subgroups stroke, breast cancer and depression did not meet the requirements for factor analysis, as explained below.

The Kaiser-Mayer-Olkin's Measure of Sampling Adequacy Test and Bartletts`s Test of Sphericity: For both groups of diseases (musculoskeletal conditions and internal conditions) the Kaiser-Mayer-Olkin's (KMO) measure is 0.88, which is classified as "meritorious" [10, 11]. A value close to 1 indicates that patterns of correlations are relatively compact and factor analysis should yield distinct and reliable factors. Bartlett's Test is highly significant in both cases as well, and therefore factor analysis is appropriate. The groups stroke, breast cancer and depression show unsatisfactory values regarding the KMO-Measure (smaller than 0.4, which is unacceptable according to Kaiser [10]). According to the Subjects-to-Variables ratio [22] as well as to the rule of 200 [23] the sample size of patients with stroke, breast cancer and depression is not sufficient. Thus, no factor analysis was conducted. In order to show a replication of the dimensionality of WHODAS II for musculoskeletal and internal conditions a Principal Component Analysis (PCA) with Varimax-Rotation with Kaiser Normalization and Extraction of 6 factors was performed. In Table 10 and 11, the communalities (h^2) of the variables and their loadings on the factors are shown. For reasons of clarity, all loadings less than 0.3 are suppressed in the output. Regarding musculoskeletal conditions, the total variance explained by six factors is 63,89%.

Replication of scales: The five items in the domain Understanding and Communicating have loadings on the same component, with item 1.3 ("solutions to problems in day to day life") being a splitter-item, i.e. an item that loads comparably high onto different factors. Items of the subscale Getting Around replicate one domain, while item 2.4 ("getting out of your home") loads

onto another factor as well. Items of the domain Self Care do not replicate a scale. There are cross-loadings on factors with items of the domains Activity/Work and Getting Around. In the area Activities, there is a division between items that are related to accomplishing a job and those that are related to household activities. Job-related items show very high loadings (0.835 to 0.870) onto one particular factor. Household-related items load onto a different factor with comparably high loadings. The domain Participation consists of splitter-items. Thus, the original scale could not be replicated.

Table 10: Rotated Component Matrix, Musculoskeletal Conditions

	h^2	1	2	3	4	5	6
D4.1 Getting Along, Dealing w people you don't know	0.557	0.713					
D4.4 Getting Along, Making new friends	0.571	0.690					
D1.6 Understanding, Starting conversation	0.670	0.685			0.403		
D4.2 Getting Along, Maintaining a friendship	0.540	0.652					
D4.3 Getting Along, People you are close to	0.487	0.597					
D6.1 Participation, Joining in community activities	0.582	0.556	0.369				
D6.3 Participation, Living with dignity	0.599	0.549					0.532
D6.2 Participation, Barriers or hindrances	0.523	0.505					0.479
D6.7 Participation, Family	0.409	0.444		0.310			
D4.5 Getting Along, Sexual activities	0.350	0.352	0.344				
D5.6 Activities, Doing most important work well	0.877		0.870				
D5.7 Activities, Getting all the work done	0.887		0.870				
D5.5 Activities, Day to day work	0.875		0.864				
D5.8 Activities, Getting work done as quickly …	0.864		0.835	0.325			
D6.5 Participation, Emotionally affected	0.562	0.409	0.507				
D5.3 Activities, Getting all work done	0.874			0.869			
D5.2 Activities, Most important household tasks	0.852			0.847			
D5.1 Activities, Household responsibilities	0.858			0.838			
D5.4 Activities, Household work as quickly	0.821		0.340	0.794			
D6.4 Participation, Time	0.511	0.322		0.512			
D6.8 Participation, Relaxation or pleasure	0.474	0.434		0.468			
D1.1 Understanding, Concentrating for ten minutes	0.666				0.774		
D1.2 Understanding, Remembering important things	0.695	0.329			0.761		
D1.5 Understanding, Understanding what people say	0.569	0.338			0.643		
D1.4 Understanding, Learning a new task	0.565	0.394			0.595		
D1.3 Understanding, Finding solutions to problems	0.592	0.481			0.545		
D3.2 Self Care, Getting dressed	0.679		0.403		0.449	0.435	
D3.1 Self Care, Washing whole body	0.652		0.350		0.441	0.402	0.313
D2.2 Getting Around, Standing up from sitting	0.616					0.730	
D2.5 Getting Around, Walking a long distance	0.647					0.714	
D2.1 Getting Around, 30min standing	0.591					0.710	
D2.3 Getting Around, Moving around inside	0.687				0.326	0.636	0.336
D2.4 Getting Around, Getting out of your home	0.660					0.502	0.472
D3.3 Self Care, Eating	0.610				0.463		0.577
D3.4 Self Care, Staying by yourself	0.521	0.314					0.573
D6.6 Participation, Financial resources	0.490		0.391				0.542

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization. Rotation converged in 93 iterations.

Referring to internal conditions, the percentage of variance accounted for by the six component model is 65.79%.

Replication of scales: With respect to Understanding and Communicating full replication of subscale is possible, with item 1.3 being a splitter-item. The other items contain high loadings (larger than 0.637). Four out of five items of the subscale Getting Around yield one factor with items of the subscale Self Care. The item 2.1 (“30 min standing”) loads onto that factor as well as onto a factor together with items of the domain Participation. As mentioned above, Self Care yields a factor with items of the subscale Getting Around; item 3.4 (“staying by yourself”) loads onto a different factor with items of the subscale Getting Along with Others. The subscale Getting Along with Others replicates one factor, except item 4.5 (“Sexual activities”), which loads onto another factor. In analogy to the replication of scales in musculoskeletal conditions, in the domain Activities, a division between items that are related to a job and items that are related to household activities is obtained. Job-related items show very high loadings (0.885 to 0.918) onto one particular factor. Household-related items load onto a different factor. Items of the field Participation constitute one factor, but also containing splitter-items, that load onto the factors Getting Around, Activities and Getting Along with Others.

Table 11: Rotated Component Matrix, Internal Conditions

	h^2	1	2	3	4	5	6
D3.2 Self care, Getting dressed	0.765	0.806					
D2.3 Getting Around, Moving around inside	0.762	0.785					
D3.1 Self Care, Washing whole body	0.764	0.748					0.346
D3.3 Self Care, Eating	0.716	0.699		0.344			
D2.4 Getting Around, Getting out of your home	0.627	0.694					
D2.2 Getting Around, Standing up from sitting	0.536	0.641					
D2.5 Getting Around, Walking a long distance	0.583	0.512	0.395		0.378		
D5.7 Activities, Getting all the work done	0.944		0.918				
D5.5 Activities, Day to day work	0.895		0.908				
D5.6 Activities, Doing most important work well	0.915		0.894				
D5.8 Activities, Getting work done as quickly …	0.909		0.885				
D4.2 Getting Along, Maintaining a friendship	0.691			0.778			
D4.1 Getting Along, Dealing with people you don't know	0.658			0.751			
D4.3 Getting Along, People you are close to	0.649			0.716			
D4.4 Getting Along, Making new friends	0.625			0.665			0.323
D3.4 Self Care, Staying by yourself	0.472			0.600			
D4.5 Getting Along, Sexual activities	0.506				0.638		
D6.5 Participation, Emotionally affected	0.575			0.347	0.605		
D6.2 Participation, Barriers or hindrances	0.658	0.309		0.438	0.584		
D2.1 Getting Around, 30min standing	0.651	0.517	0.327		0.521		
D6.4 Participation, Time	0.541	0.339			0.513		
D6.8 Participation, relaxation or pleasure	0.532		0.334		0.502		
D6.3 Participation, Living with dignity	0.568	0.373		0.381	0.491		
D6.1 Participation, Joining in community activities	0.602		0.412	0.344	0.470		
D6.6 Participation, Financial resources	0.402				0.464		
D6.7 Participation, Family	0.405		0.368		0.417		
D1.1 Understanding, Concentrating for ten minutes	0.634					0.758	
D1.2 Understanding, Remembering important things	0.634					0.747	
D1.5 Understanding, Understanding what people say	0.630					0.711	
D1.6 Understanding, Starting conversation	0.591			0.302		0.678	
D1.4 Understanding, Learning a new task	0.561	0.314				0.637	
D1.3 Understanding, Finding solutions to problems	0.514			0.307	0.312	0.498	
D5.1 Activities, Household responsibilities	0.822	0.346					0.715
D5.3 Activities, Getting all work done that you needed..	0.816	0.344	0.314		0.312		0.690
D5.2 Activities, Most important household tasks	0.784	0.389	0.330				0.670
D5.4 Activities, Household work as quickly as needed	0.730	0.36	0.371		0.321		0.585

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization. Rotation converged in 7 iterations.

In summary the factor analyses of the subgroups musculoskeletal conditions and internal conditions show a satisfactory replication of subscales. Convergent validity was obtained because almost all items load strongly on their associated factors (loadings larger than .50) and most of the items load stronger on their associated factors rather than on any other factors [(24)]. In a successful factor analysis, a few factors should explain a substantial proportion of the variance and

the remaining factors explain relatively small amounts of variance, which is the case in these results. Even though there is no absolute threshold that can be adopted, a combination of factors that accounts for 60% of the total variance is deemed satisfactory [7]. Based on these findings, it can be concluded that the six factors are suitable to investigate disability and functioning. The variance accounted for confirms the multidimensionality of the construct portrayed by the questionnaire, whereas, one third of the variance remains unexplained, which indicates that there are aspects of disability and functioning that are not being covered by the factors identified here.

- **Inter-Scale Correlations**

For further testing of the dimensionality of WHODAS II, correlations of the subscales and the Total Score were examined by means of Pearson correlation coefficient (Table 12). Almost all subscales correlate strongly. The Total Score shows highest correlations with the domains Activities and Participations, except for the subgroup stroke, which obtains highest correlations with the subscales Activities and Getting Around. Low correlations are found between Understanding and Activities for musculoskeletal conditions, Getting Around and Getting Along for internal conditions and Getting Along and Self Care for breast cancer and depression.

Table 12: Inter-Scale Correlations (Pearson's Correlation Coefficients)

Musculoskeletal Conditions							
	Under-standing	**Getting Around**	**Self Care**	**Getting Along**	**Activities**	**Parti-cipation**	**Total Score**
Understanding	1	0.366**	0.451**	0.578**	0.214**	0.443**	0.610**
Getting Around	0.366**	1	0.593**	0.274**	0.626**	0.587**	0.775**
Self Care	0.451**	0.593**	1	0.423**	0.544**	0.523**	0.722**
Getting Along	0.578**	0.274**	0.423**	1	0.278**	0.488**	0.596**
Activities	0.214**	0.626**	0.544**	0.278**	1	0.668**	0.836**
Participation	0.443**	0.587**	0.523**	0.488**	0.668**	1	0.850**
Total Score	0.610**	0.775**	0.722**	0.596**	0.836**	0.850**	1

Table 12 cont.

Internal Conditions							
	Under-standing	**Getting Around**	**Self Care**	**Getting Along**	**Activities**	**Parti-cipation**	**Total Score**
Understanding	1	0.468**	0.492**	0.590**	0.470**	0.524**	0.729**
Getting Around	0.468**	1	0.629**	0.390**	0.661**	0.617**	0.792**
Self Care	0.492**	0.629**	1	0.498**	0.587**	0.510**	0.726**
Getting Along	0.590**	0.390**	0.498**	1	0.472**	0.522**	0.706**
Activities	0.470**	0.661**	0.587**	0.472**	1	0.645**	0.869**
Participation	0.524**	0.617*	0.510**	0.522**	0.645**	1	0.849**
Total Score	0.729**	0.792**	0.726**	0.706**	0.869**	0.849**	1
Stroke							
	Under-standing	**Getting Around**	**Self Care**	**Getting Along**	**Activities**	**Parti-cipation**	**Total Score**
Understanding	1	0.536**	0.552**	0.713**	0.528**	0.513**	0.742**
Getting Around	0.536**	1	0.788**	0.495**	0.782**	0.660**	0.881**
Self Care	0.552**	0.788**	1	0.592**	0.726**	0.588**	0.856**
Getting Along	0.713**	0.495**	0.592**	1	0.493**	0.492**	0.729**
Activities	0.528**	0.782**	0.726**	0.493**	1	0.766**	0.907**
Participation	0.513**	0.660**	0.588**	0.492**	0.766**	1	0.850**
Total Score	0.742**	0.881**	0.856**	0.729**	0.907**	0.850**	1
Breast Cancer							
	Under-standing	**Getting Around**	**Self Care**	**Getting Along**	**Activities**	**Parti-cipation**	**Total Score**
Understanding	1	0.614**	0.491**	0.635**	0.561**	0.545**	0.776**
Getting Around	0.614**	1	0.596**	0.527**	0.711**	0.650**	0.836**
Self Care	0.491**	0.596**	1	0.437**	0.535**	0.502**	0.669**
Getting Along	0.635**	0.527**	0.437**	1	0.522**	0.715**	0.766**
Activities	0.561**	0.711**	0.535**	0.522**	1	0.696**	0.896**
Participation	0.545**	0.650**	0.502**	0.715**	0.696**	1	0.866**
Total Score	0.778**	0.836**	0.669**	0.766**	0.896**	0.866**	1
Depression							
	Under-standing	**Getting Around**	**Self Care**	**Getting Along**	**Activities**	**Parti-cipation**	**Total Score**
Understanding	1	0.544**	0.565**	0.640**	0.587**	0.470**	0.771**
Getting Around	0.544**	1	0.722**	0.518**	0.561**	0.677*	0.808**
Self Care	0.565**	0.722**	1	0.429**	0.627**	0.519**	0.757**
Getting Along	0.640**	0.518**	0.429**	1	0.532**	0.676**	0.776**
Activities	0.587**	0.561**	0.627**	0.532**	1	0.749**	0.868**
Participation	0.470**	0.677**	0.519**	0.676**	0.749**	1	0.870**
Total Score	0.771**	0.808**	0.757**	0.776**	0.868**	0.870**	1

** The correlation is significant on a level of 0.01 (two-tailed).

- **Validity**

Convergent Validity

For the assessment of convergent validity (as in the sensitivity to change analyses), the subscales of the instruments were organized into dimensions of impairment, activity limitations and participation according to Chwastiak et al. [25] (Table 13). It is hypothesized that subscales of the WHODAS II and the SF-36, which produce strong correlations reflect the same ICF dimensions.

Table 13: Organization of Subscales

Impairment	SF-36 Mental Health SF-36 Vitality SF-36 Pain
Activity Limitations	SF-36 Physical Functioning WHODAS II - Understanding and Communicating WHODAS II - Getting Around WHODAS II - Self Care
Participation	SF-36 Role Functioning-Physical SF-36 Role Functioning-Emotional SF-36 Social Functioning WHODAS II - Interpersonal WHODAS II - Activities WHODAS II - Participation

Results of convergent validity testing are displayed in Tables 14 to 18. Negative correlations between the WHODAS II and the SF-36 reflect the scoring of the instruments: a higher score on the WHODAS II means greater functional impairment, a higher SF-36 score reflects better functioning. The WHODAS II subscale Getting Around is highly correlated with SF-36 Physical Functioning subscale (correlations of -0.68 to -0.79). The Participation subscale of the WHODAS II is adequately correlated with the Social Functioning subscale of the SF-36 (r = -0.51 to –0.69). Similar results are obtained for scales that reflect participation as well, that is Activities and Role Functioning-Physical (-0.56 musculoskeletal conditions, -0.52 for internal conditions, -0.67 for stroke, -0.70 for breast cancer). In patients with depression, the scale Activities is connected with Role Functioning-Emotional more than Role Functioning-Physical. Correlations around 0.5 are obtained for the scales Activities (WHODAS II) and Social Functioning (SF-36). The SF-36 subscale Role-Functioning Emotional shows low correlations with the WHODAS II scales in most cases. An exception is the breast cancer and depression sample, which show higher cor-

relations. The Activities subscale is moderately correlated with the Role Functioning-Emotional subscale of the SF-36. Depending on the condition group, the WHODAS II Total Score shows highest correlations with the SF-36 subscales Physical Functioning (musculoskeletal conditions, stroke), with Social Functioning (internal conditions) and with Vitality (breast cancer and depression).

Table 14: Convergent Validity, Musculoskeletal Conditions

	Understanding	Getting Around	Self Care	Interpersonal	Activities	Participation	Total Score
Impairment							
SF-36 Mental Health	-0.377**	-0.183**	-0.327**	-0.398**	-0.306**	-0.462**	-0.430**
SF-36 Vitality	-0.313**	-0.363**	-0.285**	-0.300**	-0.447**	-0.506**	-0.498**
SF-36 Pain	-0.140*	-0.571**	-0.334**	-0.073	-0.569**	-0.473**	-0.534**
Activity Limitations							
SF-36 Physical Functioning	-0.226**	-0.785**	-0.482**	-0.129*	-0.592**	-0.480**	-0.619**
Participation							
SF-36 Role Physical	-0.105	-0.499**	-0.300**	-0.071	-0.559**	-0.405**	-0.488**
SF-36 Role Emotional	-0.357**	-0.295**	-0.310**	-0.307**	-0.247*	-0.367**	-0.393**
SF-36 Social Functioning	-0.384**	-0.414**	-0.390**	-0.466**	-0.466**	-0.634**	-0.603**
Composite							
SF-36 mcs	-0.454**	-0.104	-0.279**	-0.470**	-0.198**	-0.442**	-0.398**
SF-36 pcs	-0.048	-0.687**	-0.354**	-0.190	-0.638**	-0.403**	-0.534**

* p<0.05, ** p<0.01

Table 15: Convergent Validity, Internal Conditions

	Understanding	Getting Around	Self Care	Interpersonal	Activities	Participation	Total Score
Impairment							
SF-36 Mental Health	-0.542**	-0.357**	-0.305**	-0.427**	-0.398**	-0.531**	-0.562*
SF-36 Vitality	-0.383**	-0.477**	-0.282**	-0.357**	-0.514**	-0.539**	-0.564**
SF-36 Pain	-0.257**	-0.520**	-0.270**	-0.173**	-0.395**	-0.397**	-0.432**
Activity Limitations							
SF-36 Physical Functioning	-0.274**	-0.716**	-0.379**	-0.176**	-0.514**	-0.497**	-0.563**
Participation							
SF-36 Role Physical	-0.217**	-0.532**	-0.286**	-0.186**	-0.517**	-0.414**	-0.492**
SF-36 Role Emotional	-0.415**	-0.409**	-0.216**	-0.353**	-0.334**	-0.433**	-0.464**
SF-36 Social Functioning	-0.424**	-0.448**	-0.368**	-0.497**	-0.490**	-0.596**	-0.609**
Composite							
SF-36 mcs	-0.513**	-0.260**	-0.219**	-0.492**	-0.333**	-0.502**	-0.503**
SF-36 pcs	-0.151*	-0.626**	-0.305**	-0.101	-0.521**	-0.404**	-0.477**

p<0.05, ** p<0.01

Table 16: Convergent Validity, Stroke

	Under-standing	Getting Around	Self Care	Inter-personal	Work	Partici-pation	Total Score
Impairment							
SF-36 Mental Health	-0.429**	-0.387**	-0.377**	-0.253*	-0.454**	-0.530**	-0.521**
SF-36 Vitality	-0.423**	-0.440**	-0.427**	-0.323**	-0.573**	-0.571**	-0.616**
SF-36 Pain	-0.450**	-0.343**	-0.248**	-0.291**	-0.264**	-0.301**	-0.395**
Activity Limitations							
SF-36 Physical Functioning	-0.404**	-0.749**	-0.618**	-0.368**	-0.566**	-0.538**	-0.666**
Participation							
SF-36 Role Physical	-0.477**	-0.411**	-0.297**	-0.304**	-0.665**	-0.506**	-0.623**
SF-36 Role Emotional	-0.382**	-0.379**	-0.306**	-0.299**	-0.483**	-0.472**	-0.505**
SF-36 Social Functioning	-0.432**	-0.355**	-0.254**	-0.437**	-0.510**	-0.511**	-0.555**
Composite							
SF-36 mcs	-0.403**	-0.269*	-0.244*	-0.366**	-0.491**	-0.550**	-0.504**
SF-36 pcs	-0.485**	-0.636**	-0.487**	-0.417**	-0.528**	-0.484**	-0.621**

* p<0.05, ** p<0.01

Table 17: Convergent Validity, Breast Cancer

	Under-standing	Getting Around	Self Care	Inter-personal	Activities	Partici-pation	Total Score
Impairment							
SF-36 Mental Health	-0.541**	-0.530**	-0.385**	-0.520**	-0.566**	-0.644**	-0.682**
SF-36 Vitality	-0.488**	-0.548**	-0.345**	-0.438**	-0.752**	-0.589**	-0.718**
SF-36 Pain	-0.311**	-0.438**	-0.195*	-0.263**	-0.488**	-0.348**	-0.457**
Activity Limitations							
SF-36 Physical Functioning	-0.449**	-0.784**	-0.373**	-0.360**	-0.715**	-0.504**	-0.688**
Participation							
SF-36 Role Functioning	-0.370**	-0.483**	-0.373**	-0.343**	-0.701**	-0.465**	-0.621**
SF-36 Role Emotional	-0.625**	-0.484**	-0.380**	-0.485**	-0.556**	-0.611**	-0.659**
SF-36 Social Functioning	-0.453**	-0.512**	-0.380**	-0.521**	-0.603**	-0.689**	-0.678**
Composite							
SF-36 mcs	-0.629**	-0.471**	-0.407**	-0.563**	-0.546**	-0.675**	-0.683**
SF-36 pcs	-0.315**	-0.632**	-0.331**	-0.266**	-0.636**	-0.362**	-0.554**

* p<0.05, ** p<0.01

Table 18: Convergent Validity, Depression

	Under-standing	Getting Around	Self Care	Inter-personal	Activities	Partici-pation	Total Score
Impairment							
SF-36 Mental Health	-0.566**	-0.307*	-0.271*	-0.515**	-0.446**	-0.424**	-0.531**
SF-36 Vitality	-0.426**	-0.499**	-0.476**	-0.464**	-0.532**	-0.556**	-0.608**
SF-36 Pain	-0.268*	-0.431**	-0.298*	-0.339**	-0.375**	-0.455**	-0.454**
Activity Limitations							
SF-36 Physical Functioning	-0.346**	-0.678**	-0.485**	-0.346**	-0.369**	-0.498**	-0.549**
Participation							
SF-36 Role Physical	-0.336**	-0.539**	-0.385**	-0.352**	-0.379**	-0.495**	-0.513**
SF-36 Role Emotional	-0.404**	-0.314*	-0.250*	-.361**	-0.480**	-0.429**	-0.485**
SF-36 Social Functioning	-0.347**	-0.400**	-0.200	-0.535**	-0.558**	-0.689**	-0.595**
Composite							
SF-36 mcs	-0.461**	-0.133	-0.127	-0.464**	-0.481**	-0.418**	-0.458**
SF-36 pcs	-0.258*	-0.646**	-0.434**	-0.324*	-0.337**	-0.512**	-0.510**

* p<0.05, ** p<0.01

Discriminant Validity

One purpose of the discriminant analysis was to investigate independent variable mean differences between groups formed by the dependent variable. For musculoskeletal diseases, highly significant mean differences between groups (no/mild pain, N=91 vs. strong pain, N=73) exist regarding the following subscales: Getting Around**, Self Care**, Activity** and Participation**. In the subgroup internal conditions (no/mild pain, N=238 vs. moderate to strong pain, N=45) Wilk's Lambda is significant by the F-Test for the subscales Getting Around** and Activities**. Patients in the group stroke (no/mild pain, N=87 vs. moderate to strong pain, N=11) show significant differences in the scale Activities**, patients in the group breast cancer (no/mild pain, N=81 vs. moderate to strong pain, N=35) in the scales Understanding*, Getting Around**, Getting Along with Others*, Activities* and Participation **, patients with depression (no/mild pain, N=37 vs. strong pain, N=12) in the scales Getting Around**, Self Care* and Participation* (* p<0.05, **p<0.01). Squared canonical correlation is the percent of variation in the dependent explained by the independents. In musculoskeletal conditions, internal conditions, breast cancer and depression the eigenvalue of the discriminant function is significant (Table 19). For patients with musculoskeletal conditions, 17.22% of the variation in the dependent variable is discriminated by the independent variables (internal conditions: 8.41%, breast cancer: 19.18%, depres-

sion: 36.48%). The variance explained by the SF-36 is distinctly higher (musculoskeletal conditions: 21.44%, internal conditions: 15.21%, breast cancer: 39.81% and depression: 39.19%, respectively), resulting from the fact, that the SF-36 possesses a scale that measures bodily pain directly. In this study, severity of disease is operationalized by the value of Sensation of Pain.

Table 19: Discriminant Validity

Discriminant Validity	
Musculoskeletal Conditions	
WHODAS II (no/mild pain, N=91 vs. strong pain, N=73)	
Canonical correlation coefficient	0.415
Wilks Lambda	0.828**
SF-36 (no/mild pain, N=87 vs. strong pain, N=69)	
Canonical correlation coefficient	0.463
Wilks Lambda	0.786 **
Internal Conditions	
WHODAS II (no/mild pain, N=238 vs. moderate to strong pain, N=45)	
Canonical correlation coefficient	0.290
Wilks Lambda	0.915**
SF-36 (no/mild pain, N=226 vs. moderate to strong pain, N=44)	
Canonical correlation coefficient	0.390
Wilk's Lambda	0.852**
Stroke	
WHODAS II (no/mild pain, N=87 vs. moderate to strong pain, N=11)	
Canonical correlation coefficient	0.242
Wilk's Lambda	0.942(ns.)
SF-36 (no/mild pain, N=70 vs. moderate to strong pain, N=9)	
Canonical correlation coefficient	0.432
Wilk's Lambda	0.813 (n.s.)
Breast Cancer	
WHODAS II (no/mild pain, N=81 vs. moderate to strong pain, N=35)	
Canonical correlation coefficient	0.438
Wilk's Lambda	0.808**
SF-36 (no/mild pain, N=76 vs. moderate to strong pain, N=34)	
Canonical correlation coefficient	0.631
Wilk's Lambda	0.602**

Table 19 cont.

Depression	
WHODAS II (no/mild pain, N=37 vs. strong pain, N=12)	
Canonical correlation coefficient	0.604
Wilk's Lambda	0.635**
SF-36 (no/mild pain, N=37 vs. strong pain, N=11)	
Canonical correlation coefficient	0.626
Wilk's Lambda	0.609**

p<0.05, ** p<0.01

The standardized discriminant function coefficients indicate the relative importance of the independent variable in the predicting the dependent. In musculoskeletal conditions the subscales Getting Around and Activities are the most important variables (standardized discriminant function coefficients: 0.720 and 0.514), in internal conditions and breast cancer the scale Getting Around is the most important variable as well. In the depression sample Participation is the most explaining variable. Regarding the SF-36 the most important variables are Bodily Pain or Physical Functioning in all subgroups. Finally the theory (discriminant function) was tested by observing whether cases are classified as predicted (Table 20). In the subgroup musculoskeletal conditions the discriminant function correctly classifies about 67% of the cases predicting strong pain, no/mild pain was classified correctly in 83.5% of the cases, making more proportion of mistakes in the category strong pain. Regarding internal conditions the model correctly classifies 98.3% in the category no/mild pain and only 4.4% in the category moderate to strong pain. In breast cancer 90.1% of the cases in the category no/mild pain are classified correctly and 37.1% in the category moderate to strong pain. In the subgroup depression 91.9% of the cases in the category no/mild pain are classified correctly and 66.7% in the category strong pain. The classification by means of the SF-36 leads to comparable (to slightly better) results (Table 20).

Table 20: Discriminant Function: Classification Results

Musculoskeletal Conditions				
WHODAS II				
		Predicted Membership		
		no/mild pain	strong pain	Total
Original	no/mild pain (N=91)	83.52	16.48	100.00
%	strong pain (N=73)	32.88	67.12	100.00
	ungrouped (N=121)	61.98	38.02	100.00
76,2% of original grouped cases correctly classified.				
SF-36				
		Predicted Membership		
		no/mild pain	strong pain	Total
Original	no/mild pain (N=87)	82.76	17.24	100.00
%	strong pain (N=69)	17.39	82.61	100.00
	ungrouped (N=124)	57.26	42.74	100.00
82,7% of original grouped cases correctly classified.				
Internal Conditions				
WHODAS II				
		Predicted Membership		
		no/mild pain	moderate to strong pain	Total
Original	no/mild pain (N=238)	98.32	1.68	100.00
%	moderate to strong pain (N=45)	95.56	4.44	100.00
	ungrouped (N=3)	100.00	0.00	100.00
83,4% of original grouped cases correctly classified.				
SF-36				
		Predicted Membership		
		no/mild pain	moderate to strong pain	Total
Original	no/mild pain (N=87)	97.35	2.65	100.00
%	moderate to strong pain (N=69)	90.91	9.09	100.00
	ungrouped (N=3)	100.00	0.00	100.00
83% of original grouped cases correctly classified.				
Breast Cancer				
WHODAS II				
		Predicted Membership		
		no/mild pain	moderate to strong pain	Total
Original	no/mild pain (N=91)	90.12	9.88	100.00
%	moderate to strong pain (N=73)	62.86	37.14	100.00
	ungrouped (N=1)	100.00	0.00	100.00
74,1% of original grouped cases correctly classified.				

Table 20 cont.

SF-36				
		Predicted Membership		
		no/mild pain	moderate to strong pain	Total
Original %	no/mild pain (N=87)	89.47	10.53	100.00
	moderate to strong pain (N=69)	38.24	61.76	100.00
	ungrouped (N=1)	100.00	0.00	100.00
80,9% of original grouped cases correctly classified.				
Depression				
WHODAS II				
		Predicted Membership		
		no/mild pain	strong pain	Total
Original %	no/mild pain (N=91)	91.89	8.11	100.00
	strong pain (N=73)	33.33	66.67	100.00
	ungrouped (N=15)	93.33	6.67	100.00
85,7% of original grouped cases correctly classified.				
SF-36				
		Predicted Membership		
		no/mild pain	strong pain	Total
Original %	no/mild pain (N=87)	89.19	10.81	100.00
	strong pain (N=69)	36.36	63.64	100.00
	ungrouped (N=14)	92.86	7.14	100.00
83,3% of original grouped cases correctly classified.				

- **Sensitivity to Change**

To examine differences between baseline and follow-up t-test for paired samples was performed. If this test yields significant mean differences, a certain sensitivity to change of the scale can be assumed [(26)]. As inference-statistical methods are not sufficient - the result of a test of significance is dependent on the sample size [(27)] - sensitivity of each subscale of the WHODAS II and the SF-36 from baseline to follow-up was evaluated by the effect size and the standardized response mean (Table 21). Among the Total Scores of the WHODAS II and the SF-36, in the musculoskeletal conditions subgroup the SF-36 Physical Health Index Score shows the highest sensitivity from baseline to follow-up, in internal conditions and stroke the WHODAS II Total Score, and in breast cancer and depression the SF-36 Mental Health Index Score. The depression sample produces the highest sensitivity over all subscales of the WHODAS II. The

calculation of SRM generally yielded somewhat smaller numbers but did not change the interpretation of the data.

Table 21: Sensitivity to Change

Musculoskeletal Conditions						
WHODAS II	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Understanding/Communicating*	17.52	17.55	14.69	17.25	-0.16	-0.16
Getting Around*	29.64	21.78	23.34	21.41	-0.29	-0.29
Self Care	8.72	15.10	7.10	14.91	-0.11	-0.11
Getting Along with Others	12.43	15.21	11.23	15.44	-0.08	-0.08
Activities*	33.12	24.96	24.09	25.82	-0.36	-0.35
Participation*	23.51	17.32	19.18	19.28	-0.25	-0.22
Total Score*	21.98	14.32	17.33	16.10	-0.32	-0.29
SF-36	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Physical Functioning*	59.59	25.41	65.09	27.48	0.22	0.20
Role Functioning-Physical*	33.28	38.24	48.54	42.51	0.40	0.36
Bodily Pain*	35.27	19.43	48.84	21.96	0.70	0.62
General Health*	49.39	17.63	55.02	18.88	0.32	0.30
Vitality*	43.01	17.99	53.19	20.17	0.57	0.50
Social Functioning*	71.13	25.81	76.73	26.08	0.22	0.21
Role Functioning-Emotional	74.45	39.59	74.16	40.08	-0.01	-0.01
Mental Health*	62.60	19.61	69.20	19.33	0.34	0.34
PHYSICAL HEALTH INDEX SCORE*	34.12	9.96	38.52	10.58	0.44	0.42
MENTAL HEALTH INDEX SCORE*	48.45	11.47	50.41	10.87	0.17	0.18
Internal Conditions						
WHODAS II	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Understanding/Communicating*	18.81	17.78	14.14	16.11	-0.26	-0.29
Getting Around*	19.51	20.38	14.85	17.97	-0.23	-0.26
Self Care*	6.47	14.97	4.27	10.73	-0.15	-0.20
Getting Along with Others*	13.93	16.58	11.65	15.75	-0.14	-0.15
Activities*	22.73	24.27	18.20	22.54	-0.19	-0.20
Participation*	23.15	19.36	18.97	17.11	-0.22	-0.24
Total Score*	18.47	15.32	14.65	13.64	-0.25	-0.28
SF-36	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Physical Functioning*	66.01	27.59	72.33	25.91	0.23	0.24
Role Functioning-Physical*	49.09	43.08	56.64	43.71	0.18	0.17
Bodily Pain*	59.17	31.15	66.11	28.43	0.22	0.24
General Health*	50.12	19.77	55.65	20.61	0.28	0.27
Vitality*	48.64	20.57	58.21	19.30	0.47	0.50
Social Functioning*	73.27	26.21	78.45	24.78	0.20	0.21
Role Functioning-Emotional	73.45	39.96	75.09	38.32	0.04	0.04
Mental Health*	64.91	20.58	70.69	18.75	0.28	0.31
PHYSICAL HEALTH INDEX SCORE*	40.62	11.37	42.88	11.03	0.20	0.20
MENTAL HEALTH INDEX SCORE*	47.47	11.60	49.80	10.52	0.20	0.22

Table 21 cont.

Stroke						
WHODAS II	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Understanding/Communicating	31.26	23.79	35.96	24.41	0.20	0.19
Getting Around	42.20	34.58	41.88	33.55	-0.01	-0.01
Self Care	30.58	31.90	29.62	32.38	-0.03	-0.03
Getting Along with Others*	24.60	24.39	28.93	24.19	0.18	0.18
Activities	53.24	35.39	57.97	33.77	0.13	0.14
Participation	41.18	25.31	43.68	24.28	0.10	0.10
Total Score	38.72	24.79	42.76	24.69	0.16	0.16
SF-36	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Physical Functioning	43.67	33.90	48.55	34.09	0.14	0.14
Role Functioning-Physical	22.66	37.71	20.00	32.50	-0.07	-0.08
Bodily Pain	58.06	31.79	56.40	31.03	-0.05	-0.05
General Health	45.69	20.10	43.08	20.20	-0.13	-0.13
Vitality	38.92	23.37	42.44	19.80	0.15	0.18
Social Functioning	60.51	27.96	58.76	28.59	-0.06	-0.06
Role Functioning-Emotional	46.30	46.79	40.82	44.88	-0.12	-0.12
Mental Health	55.44	21.72	56.86	19.12	0.07	0.07
PHYSICAL HEALTH INDEX SCORE	35.15	10.20	35.41	10.81	0.03	0.02
MENTAL HEALTH INDEX SCORE	42.06	12.06	41.32	10.77	-0.06	-0.07
Breast Cancer						
WHODAS II	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Understanding/Communicating*	23.80	18.79	19.77	18.55	-0.21	-0.22
Getting Around*	19.48	18.99	15.76	18.77	-0.20	-0.20
Self Care*	7.42	13.23	4.57	9.56	-0.21	-0.30
Getting Along with Others*	18.65	17.33	15.56	16.57	-0.18	-0.19
Activities*	34.33	27.30	28.25	26.36	-0.22	-0.23
Participation*	27.75	19.39	24.03	18.36	-0.19	-0.20
Total Score*	23.84	16.61	20.03	16.05	-0.23	-0.24
SF-36	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Physical Functioning*	67.19	23.10	72.34	20.38	0.22	0.25
Role Functioning-Physical*	38.60	38.71	45.23	38.83	0.17	0.17
Bodily Pain*	59.84	27.45	66.75	25.57	0.25	0.27
General Health	56.55	18.89	58.38	18.12	0.10	0.10
Vitality*	44.52	22.27	55.34	20.18	0.49	0.54
Social Functioning*	70.44	27.13	78.13	25.90	0.28	0.30
Role Functioning-Emotional	62.57	44.60	61.86	44.23	-0.02	-0.02
Mental Health*	60.86	20.73	69.46	20.42	0.41	0.42
PHYSICAL HEALTH INDEX SCORE*	40.92	10.24	42.83	8.71	0.19	0.22
MENTAL HEALTH INDEX SCORE*	44.33	12.64	47.49	12.28	0.25	0.26

Table 21 cont.

Depression						
WHODAS II	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Understanding/Communicating*	48.17	21.36	36.16	21.16	-0.56	-0.57
Getting Around*	30.22	26.70	22.50	25.46	-0.29	-0.30
Self Care*	16.44	20.15	10.60	15.35	-0.29	-0.38
Getting Along with Others*	44.58	25.43	31.91	21.94	-0.50	-0.58
Activities*	54.26	25.58	37.16	28.66	-0.67	-0.60
Participation*	54.46	19.79	39.64	21.57	-0.75	-0.69
Total Score*	44.56	18.95	31.55	19.17	-0.69	-0.68
SF-36	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Physical Functioning*	65.75	28.11	74.74	27.93	0.32	0.32
Role Functioning-Physical*	37.90	39.66	54.02	40.39	0.41	0.40
Bodily Pain*	40.94	32.60	54.52	30.18	0.42	0.45
General Health*	39.11	19.21	52.05	21.73	0.67	0.60
Vitality*	21.69	12.48	43.48	21.31	1.75	1.02
Social Functioning*	31.54	22.00	53.13	23.63	0.98	0.91
Role Functioning-Emotional*	17.71	30.27	44.24	41.10	0.88	0.65
Mental Health*	31.18	16.90	52.00	20.41	1.23	1.02
PHYSICAL HEALTH INDEX SCORE*	41.86	11.86	45.23	11.06	0.28	0.30
MENTAL HEALTH INDEX SCORE*	24.42	8.57	36.37	11.93	1.39	1.00

Difference mean t1, t2 by t-Test: * $p<0.05$, ** $p<0.01$

As sensitivity to change is the consequence of interaction between treatment, scale and population [(28)], we analyzed the effect sizes for patients who assessed their perceived general health status better than before the rehabilitation treatment. Improvement was defined as a better score in item 1 (general health) of the SF-36 (Table 22). With only a few exceptions (e.g. for stroke: Getting Along with Others), effect size and SRM are larger when only patients who reported an improvement in general health had been selected.

Among the Total Scores of the WHODAS II and the SF-36, for the musculoskeletal and internal conditions, the SF-36 Physical Health Index Score shows the highest sensitivity from baseline to follow-up, in stroke and breast cancer the WHODAS II Total Score, and in depression the SF-36 Mental Health Index Score. All in all, moderate to large effect sizes are obtained. Especially in the subgroup depression effect sizes are large (WHODAS II Total Score: -0.915). In this subgroup, larger changes are shown by the Mental Health Index Score (2.023) than by the Physical Health Index Score (0.467) of the SF-36.

Among the six domains of the WHODAS II, the responsiveness indices on the scale Activities are the highest for musculoskeletal conditions and breast cancer, respectively the scale Self Care for stroke, Getting Around for internal conditions and Participation for depression.

Table 22: Sensitivity to Change – Improvement Concerning the Item General Health (SF-36)

Musculoskeletal Conditions						
WHODAS II	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Understanding/Communicating*	15.58	17.23	12.46	14.58	-0.18	-0.21
Getting Around*	27.84	19.85	19.18	20.46	-0.44	-0.42
Self Care*	6.63	10.83	4.73	10.46	-0.18	-0.18
Getting Along with Others*	11.55	15.00	9.15	12.67	-0.16	-0.19
Activities*	35.17	24.96	20.72	23.59	-0.58	-0.61
Participation*	23.01	16.95	15.98	16.50	-0.41	-0.43
Total Score*	21.44	13.55	14.51	13.87	-0.51	-0.50
SF-36	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Physical Functioning*	62.51	23.16	70.81	27.64	0.36	0.30
Role Functioning-Physical*	29.17	37.17	56.80	41.58	0.74	0.66
Bodily Pain*	32.99	18.29	55.55	21.10	1.23	1.07
General Health*	47.58	16.09	60.28	17.22	0.79	0.74
Vitality*	41.93	16.22	55.88	18.63	0.86	0.75
Social Functioning*	71.85	27.40	80.11	23.81	0.30	0.35
Role Functioning-Emotional	77.49	38.02	78.36	37.36	0.02	0.02
Mental Health*	62.22	18.84	70.13	17.35	0.42	0.46
PHYSICAL HEALTH INDEX SCORE*	33.56	8.98	41.60	9.76	0.90	0.82
MENTAL HEALTH INDEX SCORE*	48.71	10.67	50.48	9.78	0.17	0.18
Internal Conditions						
WHODAS II	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Understanding/Communicating*	20.45	17.37	14.88	17.46	-0.32	-0.32
Getting Around*	18.91	18.41	12.76	17.80	-0.33	-0.35
Self Care	7.68	16.40	5.69	12.31	-0.12	-0.16
Getting Along with Others*	15.12	16.75	12.20	16.17	-0.17	-0.18
Activities*	25.11	23.73	19.01	24.32	-0.26	-0.25
Participation*	23.54	18.71	18.66	17.48	-0.26	-0.28
Total Score*	19.19	14.10	15.26	15.25	-0.28	-0.26
SF-36	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Physical Functioning*	65.48	25.39	74.58	25.77	0.36	0.35
Role Functioning-Physical*	46.39	40.98	57.58	45.13	0.27	0.25
Bodily Pain*	54.25	29.05	66.84	27.13	0.43	0.46
General Health*	45.57	19.32	58.40	19.39	0.66	0.66
Vitality*	45.24	17.79	59.50	18.56	0.80	0.77
Social Functioning*	72.28	26.20	79.58	23.44	0.28	0.31
Role Functioning-Emotional*	65.53	43.31	74.71	36.99	0.21	0.25
Mental Health*	62.54	20.26	70.29	18.09	0.38	0.43
PHYSICAL HEALTH INDEX SCORE*	39.44	10.46	44.07	10.47	0.44	0.44
MENTAL HEALTH INDEX SCORE*	45.46	11.81	49.56	9.68	0.35	0.42

Table 22 cont.

Stroke						
WHODAS II	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Understanding/Communicating	37.95	20.72	35.00	26.81	-0.14	-0.11
Getting Around	38.39	29.34	36.00	31.85	-0.08	-0.07
Self Care*	34.64	27.21	23.00	31.60	-0.43	-0.37
Getting Along with Others	21.61	16.14	22.39	23.13	0.05	0.03
Activities*	54.02	29.27	44.70	34.88	-0.32	-0.27
Participation	40.77	22.06	37.50	23.30	-0.15	-0.14
Total Score*	40.02	18.76	35.90	24.99	-0.22	-0.17
SF-36	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Physical Functioning	39.27	30.81	48.73	31.49	0.31	0.30
Role Functioning-Physical*	4.17	12.86	14.77	29.54	0.82	0.36
Bodily Pain	56.84	32.04	57.20	27.44	0.01	0.01
General Health*	39.40	16.84	48.12	23.31	0.52	0.37
Vitality*	35.87	17.75	45.87	19.90	0.56	0.50
Social Functioning	60.00	27.72	62.50	27.00	0.09	0.09
Role Functioning-Emotional	35.42	44.67	45.45	47.75	0.22	0.21
Mental Health*	47.62	18.15	54.61	20.23	0.39	0.35
PHYSICAL HEALTH INDEX SCORE	34.91	7.88	35.56	9.70	0.08	0.07
MENTAL HEALTH INDEX SCORE	40.18	9.84	41.02	11.66	0.09	0.07
Breast Cancer						
WHODAS II	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Understanding/Communicating*	28.47	20.99	18.89	17.05	-0.46	-0.56
Getting Around*	24.00	18.82	15.17	17.98	-0.47	-0.49
Self Care*	10.83	16.89	3.75	5.59	-0.42	-1.27
Getting Along with Others*	23.89	17.62	14.88	15.19	-0.51	-0.59
Activities*	45.04	25.34	29.35	26.26	-0.62	-0.60
Participation*	32.10	16.78	22.87	14.02	-0.55	-0.66
Total Score*	29.74	15.86	18.75	13.16	-0.69	-0.84
SF-36	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Physical Functioning*	63.72	20.32	75.28	14.78	0.57	0.78
Role Functioning-Physical*	23.28	34.02	41.38	32.92	0.53	0.55
Bodily Pain	53.27	28.22	59.53	20.69	0.22	0.30
General Health*	50.41	17.10	61.30	16.52	0.64	0.66
Vitality*	37.11	21.40	54.00	18.45	0.79	0.92
Social Functioning*	61.25	28.49	78.33	24.77	0.60	0.69
Role Functioning-Emotional	58.33	45.02	66.67	42.72	0.19	0.20
Mental Health*	56.97	20.09	69.87	17.97	0.64	0.72
PHYSICAL HEALTH INDEX SCORE*	36.96	9.37	42.21	6.68	0.56	0.79
MENTAL HEALTH INDEX SCORE*	41.98	13.40	48.56	11.51	0.49	0.57

Table 22 cont.

Depression						
WHODAS II	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Understanding/Communicating*	50.12	23.47	32.11	20.40	-0.77	-0.88
Getting Around*	30.48	26.92	17.79	22.70	-0.47	-0.56
Self Care	14.34	22.80	7.17	14.69	-0.31	-0.49
Getting Along with Others*	49.45	24.52	27.50	20.99	-0.90	-1.05
Activities*	52.78	27.76	31.97	29.75	-0.75	-0.70
Participation*	55.32	20.95	36.03	20.99	-0.92	-0.92
Total Score*	45.41	20.23	26.88	18.49	-0.92	-1.00
SF-36	**T1 mean**	**T1 SD**	**T2 mean**	**T2 SD**	**Effect Size**	**SRM**
Physical Functioning*	65.40	25.86	79.38	25.03	0.54	0.56
Role Functioning-Physical*	40.63	42.48	58.09	41.16	0.41	0.42
Bodily Pain*	37.62	32.83	55.38	32.15	0.54	0.55
General Health*	36.37	14.41	59.00	16.69	1.57	1.36
Vitality*	22.06	12.44	48.68	20.10	2.14	1.32
Social Functioning*	28.31	22.26	54.78	24.23	1.19	1.09
Role Functioning-Emotional*	15.15	28.98	52.53	39.99	1.29	0.93
Mental Health*	27.65	15.01	54.24	19.38	1.77	1.37
PHYSICAL HEALTH INDEX SCORE*	41.73	11.49	47.10	9.88	0.47	0.54
MENTAL HEALTH INDEX SCORE*	22.71	7.65	38.19	11.93	2.02	1.30

Difference mean t1, t2 by t-Test: * $p<0.05$, ** $p<0.01$

DISCUSSION

WHODAS II, the generic instrument for measuring disability, functioning and health, which is conceptually compatible with the International Classification of Disability, Functioning and Health (ICF), has been investigated in patients with musculoskeletal conditions, cardiovascular and general internal conditions, stroke, breast cancer and depressive disorder. All subgroups show a wide range of diseases, complaints and symptoms. The advantage of this approach is to enhance the generalizability of the results [(29)].

A wide range in scores on the subscales and the Total Score of WHODAS II is found (0 to 100 in all subscales and the Total Score). According to van Tubergen et al. [(29)] stating a submitted study [(30)], as a generic instrument, the WHODAS II would especially be useful for studies designed to compare across different disease entities or interventions, similar to other generic instruments such as the SF-36. In contrast to that instrument for health status, the WHODAS II is based on an international classification system, it is designed to be applicable across different cultures, and it treats all disorders at parity when determining the level of functioning. The physical, personal and social levels of disability are well represented in the WHODAS II in this study: scores on the WHODAS II were significantly correlated with an external criterion, the SF-36.

The results of a psychometric properties analysis allow statements concerning both the quality of the instrument and the sample [(31)], as the measurement properties of an instrument are relative concepts, which vary with regard to the sample, the objective of the study, the type of the study and the duration [(8)].

Quality of Data

Data quality is an indispensable requirement for meaningful data interpretation. The data set's quality can be evaluated by means of the rate of missing values. In this study relatively few missing values are obtained. Missing values can be found most prominently in questions that are regarded irrelevant or not applicable, i.e. questions concerning a job in the domain Activities. In the data set on which this study is based, missing values do not occur systematically and in most variables the missing value rate is below the critical limit of 10%.

Floor- and Ceiling Effects

The subscales of the WHODAS II show partially high floor effects. In the domain Self Care up to 70.3% of the patients report no impairment (best possible score 0).

Reliability

Cronbach's Alpha was estimated for each of the subscales in every sample to measure internal consistency. The internal consistency of the scales of WHODAS II is found to be high. All subscales meet the required Cronbach's alpha equal or greater than 0.7 for group comparisons [7]. Only the domain Activities would fulfill the level of 0.95 required for use in individual patients according to Nunally [21]. Methodological issues have to be considered: First, floor and ceiling effects bias the results. Secondly, the WHODAS II was not administered twice to a group that remained stable over time, i.e. was not expected to show any change over time. Thus, we cannot draw any conclusions about the reproducibility of the WHODAS II in the tested samples. Reproducibility is very important when the instrument is to be applied in longitudinal studies. Further studies will be needed to establish reproducibility. According to van Tubergen [29], in extensive testing that has not yet been published [32], the WHODAS II has been shown to have a test-retest reliability ranging from 0.91 to 0.95 (within class correlations) across respondents from different geographical regions and from physical disorder.

Factor Analysis

By means of a factor analysis we examined to what extent the items can be assigned to their scales. All in all, the exploratory factor structure of the German version of the WHODAS II contains high correspondence with the original structure. The Principal Component Analysis shows a stable factor structure that is replicable in musculoskeletal and internal conditions, and unidimensionality of domains (loadings greater than 0.5). For the most part, the results of the scale replication confirm the determined six domains of the questionnaire. For the domain Activities, a clear distinction between work und household activities is apparent in both musculoskeletal and internal conditions. Some cross-loadings are obtained, e.g. the mobility item 2.1 ("30 min standing") loads onto the mobility factor as well as onto a factor together with items of the domain

Participation. This is plausible as regards content, since these areas mutually determine each other.

Inter-Scale Correlations

In order to further test the dimensionality of WHODAS II, correlations of the subscales and the inter-scale correlations by means of Pearson correlation coefficients show strong correlations in almost all subscales. Low correlations exist between Understanding and Activities for musculoskeletal conditions, Getting Around and Getting Along for internal conditions and Getting Along and Self Care for breast cancer and depression. In this context it has to be taken into consideration whether a summary score makes sense at all. Noticing that the sum score correlates the most with Participation and Activities, and that there are few but some low correlation between subscales, one has to keep in mind that the sum-scale is leveling the result. It is not apparent any more whether the patient has average values in all subscales or extremely high values in some and extremely low values in other domains.

Validity

The different domains of the WHODAS II show a fair correlation with another well-established instrument, the SF-36. As hypothesized, scores that represent the same area (activities limitations, participation) correlate strongly, indicating that both questionnaires measure a similar construct. Consistent with findings of Chwastiak & Von Korff [(25)], tests of convergent validity of the WHODAS II subscales with subscales of the SF-36 that produced strong correlations (i.e., Getting Around and Physical Functioning, Participation and Social Functioning) reflect the same ICF dimensions. The SF-36 subscale Role-Functioning Emotional shows low correlations with the WHODAS II scales in most cases. This leads to the conclusion that this aspect is not covered by the WHODAS II. Exceptions are the breast cancer and depression samples, which show higher correlations. The Activities subscale is moderately correlated with the Role Functioning-Emotional subscale of the SF-36, analogous to findings of Chwastiak & Von Korff [(25)].

Ability to differentiate is confirmed by the results of the discriminant analyses, where 83.52% to 98.32% of cases (no/mild pain) are classified correctly. To assess different specification of disease, Sensation of Pain is used as a grouping variable. The WHODAS II does not assess bodily

pain directly, as opposed to the SF-36. It has to be taken into account that the operationalization through the variable pain is critical, as pain must not be an indicator of severity of disease, but can derive from concomitant diseases as well.

Although the activity limitations and participation indices examined in this study are related, they are not equivalent, and should not be regarded as interchangeable.

Sensitivity to Change

As no test-retest analyses were conducted, we have no information on to what degree the responsiveness scores of the WHODAS II may be determined by a potential degree of lack of reproducibility. However, the level of responsiveness was similar to the SF-36 that has been shown to be reproducible and responsive [4, 6].

According to van Tubergen et al. [29] in patient populations with schizophrenia, depression, and alcohol dependence, the effect size of the WHODAS II was 1.46, 1.05 and 1.35 respectively [32, 33], showing that it is able to detect even larger changes than the fair, although comparable, effect sizes in this study.

When interpreting sensitivity to change, floor- and ceiling effects have to be considered. The scale Self Care shows immense floor effects for t1 and in the majority of cases least sensitivity to change across subgroups. Considering the floor effects (Table 8), it can be concluded that the WHODAS II shows satisfactory sensitivity to change, which is comparable to that of the SF-36. If subjects cluster at one end of the distribution, change is not detectable. At baseline 33% to 70.30% of patients reported best possible score in the domain Self Care, making detection of further improvement impossible. The floor effects for the other subscales are lower.

The responsiveness statistics are dependent on the size of the intervention's effect and its variance, as is obvious by their defining formulas. Without control group (group without treatment) it is difficult to distinguish between actual improvements or deterioration and methodological artefacts. One is restricted to answering the question whether WHODAS II or its subscales are able to detect changes at all.

Another fundamental question has to be addressed: Does it make sense to assess Activities after a rehabilitation treatment of several weeks, where people do not tend to perform a job or

household duties? According to Zwingmann [34] questions about Activities asked directly after rehabilitation lead to a high rate of missing values and validity has to be seen critically.

In conclusion, the WHODAS II is a useful instrument for measuring disability in musculoskeletal conditions, cardiovascular and general internal conditions, stroke, breast cancer and depression. It shows high reliability and validity and responsiveness scores that are comparable with SF-36.

In 1993, Anderson et al. claimed in a review of the international adaptation and use of generic Health Related Quality of Life measures that progress towards cross-national measurement equivalence in Health Related Quality of Life (HRQL) measures has been uneven and the development of language-adapted versions of Health Related Quality of Life measures up to that date have mostly concerned translation issues, within the context of independently conducted studies. According to the authors substantially less focus has been placed on psychometric equivalence across language versions. This lack of prominent differences found between countries in ranking of health states in major HRQL measures supports the feasibility of developing internationally applicable HRQL instruments [35].

It seems that with development and validation of WHODAS II and its linkage to the ICF a new era of measuring functioning, disability and health has begun.

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Veröffentlichungen

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