The German Version of the Veterans Rand – 36/12 Item Health Survey: Translation and Adaptation of a Generic Health Assessment Instrument in a Sample of Inpatient Rehabilitation Patients

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1 BACKGROUND

2 Health related quality of life (HRQoL) is a crucial outcome metric used in settings from
3 clinical trials [1-2] to population health surveillance [3-7]. The Veterans Rand questionnaire
4 (VR) is a multi-attribute generic instrument measuring patient-reported HRQoL. The
5 instrument has a long (VR-36) and a short form (VR-12), both measuring a physical
6 component summary (PCS_{VR}) and a mental component summary (MCS_{VR}). The VR-36 also is
7 comprised of eight scales, which correspond closely to the Medical Outcome Study (MOS)
8 Short Form 36 version 1.0 (SF-36, [8-10]).

9 The VR instruments were created to address the veteran population in the United States
10 (US) [11]. The Veterans Health Administration (VHA) is a national health care system, which
11 serves over nine million military veterans in the US. It is one of the largest integrated health
12 care systems in the US. This patient population has special medical needs, is older, poorer,
13 sicker (with more diseases than veterans nationally) and has a higher percentage of men
14 than the general adult population [12-14]. The creation of the VR instruments has been
15 previously documented [13-16] and has been shown to be valid for the VA population [13,
16 17-27] as well as other general US populations [28-35]. The English-language VR
17 instruments have become an integral part of registries [36] and studies of National U.S.
18 health programs [18, 37-38] including the evaluation of the Medicare Advantage Program by
19 the Centers for Medicare and Medicaid Services (CMS). Advantages of the VR instruments
20 include their validity in older and sicker populations, their availability (all instruments are in
21 the public domain) and their strong psychometric properties across different and wide-
22 ranging socio-demographic and clinical groups.

23 In this study, we translated and culturally adapted the VR-36 into the German language
24 (Germany) and validated the VR-36 and VR-12 in a population of German patients

undergoing inpatient rehabilitation. The German VR-36 and VR-12 were comprehensively validated and compared to the SF-36 and SF-12 in inpatient populations of orthopedic and psychosomatic rehabilitation patients (the two largest clinical indications of German inpatient rehabilitation patients). The SF-36 and the SF-12 are considered gold standards of self-assessed generic health instruments and they have been extensively distributed and used across a wide range of countries, populations and purposes. They are recommended for measuring patient outcomes in the medical rehabilitation setting in Germany [39-42]. Since the field of medical rehabilitation has been one of the most common applications of the SF-36 in the German-speaking countries, it was important to compare the measurement properties of the VR instruments to the SF-instruments in this setting.

METHODS

The study was conducted in two phases: phase A) translating and culturally adapting the original English VR-36 into the German language (Germany); and phase B) validating the VR-36 and its short version, the VR-12, in a randomized prospective study of inpatient rehabilitation patients with orthopedic and psychosomatic conditions.

Phase A) Translation and cultural adaptation of the German VR

The translation methodology followed a rigorous iterative forward-backward format to maintain the conceptual, functional, linguistic and cultural equivalence between the original (English) and the adapted (German) questionnaire. The translation procedure is summarized in **Figure 1**. First, a German translation of the VR-36 was produced from the English original

version by an experienced translator (DB). Because the VR-36 is analogous to the SF-36, the German translation of the VR-36 items was (where ever possible) compared to items of the official German SF-36 (Version 1 [8-10] and Version 2 [43]). A first reconciled German VR-36 was produced after the forward translator (DB), the translation coordinator (TK, who was also the project manager) and the assistant to the translation coordinator (IB) discussed agreements and disagreements between the forward translation, SF-36 Version 1 and SF-36 Version 2 during a conference call. This first reconciled version of the questionnaire was then translated back into the source language (English) by an experienced translator (SF) who is a native speaker of English and fluent in German. The backward translation was compared to the original English VR-36 by the translation coordinator (TK) and the translation assistant (IB). Any discrepancies between the back translation and the English VR-36 were addressed with the back translator to determine the origins of discrepancies in the first reconciled German VR-36. After this stage, a second reconciled version of the German VR-36 was produced. This instrument was field tested with 26 general practice and rehabilitation patients with no cognitive or psychiatric impairments. Patients gave feedback about how easy it was to complete the instrument; whether items and response categories were clearly understood; and how easy it was to select the appropriate response category. After the field test, the final version of the German VR-36 was produced. The German VR-36 contains the subset of items for the VR-12.

*Please insert **Figure 1:** “Flow chart of the translation process” about here*

Phase B) Validation Study

Patient recruitment

Patient recruitment took place in five rehabilitation clinics between October 2015 and November 2017. Eight hundred rehabilitation patients undergoing a three- or six-week inpatient rehabilitation due to an orthopedic (n=400) or a psychosomatic (n=400) indication who did not have cognitive or linguistic impairments provided written informed consent and were consecutively included in the study. Because the SF-36, the VR-36, the SF-12 and the VR-12 questionnaires are very similar, participants were randomly assigned to one of four groups to complete only one of these instruments (**Figure 2**). By randomizing the patients, an indirect comparison between the long- and the short-forms of the VR and the SF could be made. Patients completed questionnaires at the beginning (t1) and at the end (t2) of rehabilitation. The study was approved by the ethics committee of the University Medicine Greifswald, Germany, and was conducted according to the Declaration of Helsinki.

*Please insert **Figure 2** "Survey study design" about here*

Measures

In addition to the VR and SF instruments, the patient questionnaires contained several other self-report measures. These measures were chosen to correspond to the eight scales and the summary scores of the VR instruments.

The EQ-5 Dimensions 5-Level (EQ-5D-5L) is an internationally widely used preference-based measure of self-assessed health [44-46]. The questionnaire measures impairments in five dimensions of health using five items, each with five levels of impairments, and a thermometer-like visual analogue scale (EQ-VAS). The values of the five items can be

converted into a preference-based single utility index. In the present study, index values were calculated using the German tariff [47].

The Centers for Disease Control and Prevention (CDC) “Healthy Days” is a generic health-related quality-of-life questionnaire (HRQOL) containing four items measuring self-rated health and the number of disability days (out of the last 30) due to physical, mental health or limitations in activities [48-49]. The instrument is valid and reliable [48].

The Hannover Functional Abilities Questionnaire (HFAQ), a 12-item functional questionnaire, is a generic measure of (physical) functional ability of daily activities [50-52]. Each item has three levels of function and the 12 items can be combined to produce an additive summary score.

The Depression, Anxiety and Stress Scale (DASS) is an extensively validated measure of mental health [53-54]. In this study, the short form (21-item, DASS21) instrument was used.

The Graded Chronic Pain Scale (GCPS) is an internationally established instrument developed by van Korff et al. [55-56]. The GCPS measures self-rated pain intensity and pain disability using a 0 to 10 numeric rating scale plus one item regarding number of disability days (in the past three months) due to pain using seven items. Summation of GCPS items produce scores describing pain intensity and pain disability.

The Index for the Assessment of Health Impairments, IMET [57-58], measures participation as defined by the WHO International Classification of Functioning, Disability and Health, ICF.

The 9-item questionnaire was applied and tested in several samples from rehabilitation patients of different clinical indications. It is suitable as a screening method to assess the risk

of a failure in the professional reintegration of rehabilitation patients. The instrument is demonstrated to be an economic, highly practicable, valid and reliable operationalization of “activities and participation” according to the concept of the ICF. Norm values for the IMET were assessed in a random sample of Lübeck inhabitants comprising subjects between 19 and 79 years of age, and enable classification of limitations in participation for people undergoing rehabilitation or suffering from chronic diseases.

The vitality subscale of the Indicators of the REhabilitation Status (IRES-VE) was included to examine the construct validity of the VR items on vitality [59]. In Germany, the IRES is recommended (in addition to the SF-36) for rehabilitation research and practice [42].

Statistical analysis

The VR-36 and the VR-12 were analyzed regarding the completeness of data on the scale-level, distributional properties, construct validity, known-groups validity, and responsiveness to change. This was done on the summary scores of the VR-36 and the VR-12 (physical component score (PCS_{VR}) and mental component score (MCS_{VR})) as well as the eight VR-36 scales: (physical functioning (PF_{VR-36}), role functioning/physical (RP_{VR-36}), role functioning/emotional (RE_{VR-36}), vitality (VT_{VR-36}), mental health (MH_{VR-36}), social functioning (SF_{VR-36}), pain (BP_{VR-36}), and general health (GH_{VR-36})). Summary scores and scales were scored according to the VR-36 and VR-12 algorithms, using a t-score transformation with a mean of 50 and a standard deviation of 10 and normed to a general sample of the US population for the summary scales (PCS and MCS) [23, 60-62]. Because the SF-36 and the SF-12 instruments are well validated across a range of populations, they were used as the comparator to the VR instruments for all analyses.

144

145 **Completeness of data** is an indicator of data quality and acceptance of the questionnaire by
146 respondents. The percentage of non-missing responses was calculated for the eight VR-36
147 scales, stratified by respondent characteristics (e.g. clinical indication, age, sex, education).

148

149 **Distributional properties** (such as means, standard deviations and range) for the VR
150 instruments were analyzed on the scale and summary score levels. To compare the
151 distributional properties of the PCS and MCS for both the VR-12 and SF-12 as well as the VR-
152 36 and the SF-36, classical statistical indices of distribution such as mean, standard deviation,
153 minimum, maximum, skewness (to assess and compare the type and strength of symmetry)
154 and kurtosis (as a measure of the steepness / flatness of the frequency distribution) were
155 assessed. Kolmogorow-Smirnov-test was used to compare the distributions of the two
156 summary scores of the VR and the SF – i.e. PCS_{VR} and PCS_{SF} as well as MCS_{VR} and MCS_{SF} . Kernel
157 density plots using the Epanechnikov function were used to visually examine distribution of
158 summary scores and scales.

159

160 **Construct validity** refers to the degree of accuracy with which a measurement instrument
161 captures the construct it claims to measure. To examine construct validity, Pearson correlation
162 coefficients (r_p) between VR summary scores (PCS_{VR} and MCS_{VR}) and other self-completed
163 health measures were assessed. We compared these to the correlations between the PCS_{SF}
164 and MCS_{SF} with other self-completed health measures. Correlation coefficients were
165 compared using significance tests for correlations for independent samples [63]. The
166 correlations between PCS_{VR} and other self-reported physical health measures (e.g. HFAQ, CDC
167 Physical unhealthy days, GPCS Disability) were expected to be higher (convergent validity)

than with self-report measures of mental health (divergent validity). Similarly, MCS_{VR} is expected to be more strongly correlated with self-reported mental health measures (e.g. DASS-Anxiety, DASS-Stress, DASS-Depression, CDC Mental unhealthy days) than with physical measures. Both PCS and MCS are expected to be similarly correlated with generic self-report measures (e.g. EQ-VAS, IMET) and GCPS-Pain.

Known-groups validity is a criteria-based technique to investigate the ability of a measure to discriminate between groups known to differ in the construct of interest. For this study, known-groups were defined by clinical indication (psychosomatic, orthopedic), treatment program (“curative therapy” typically for chronically ill patients, “medical follow-up treatment” generally after joint replacement, only for orthopedic patients) age (<45 years, 45-65 years, > 65 years), duration of rehabilitation (median), sick days in the past 12 month, self-rated health (“excellent/very good/good” vs. “fair/poor”). We examined if mean PCS_{VR} and mean MCS_{VR} scores were significantly different between those pre-defined groups using t-tests for two groups or ANOVA for more than two groups.

Responsiveness refers to a self-assessed health instrument’s ability to capture changes in health over time [64]. The raw difference of SF and VR summary scores from t1 to t2 were divided by the pooled standard deviation of change to produce standardized response means (SRM), or divided by baseline standard deviation to produce standardized effect size (SES). As we assess patients at the start and end of intensive therapy, we restricted this analysis to respondents who reported stable or improved health from t1 to t2 on a single self-rated health question (n=133) to assess responsiveness to health improvements. We further checked

improvement of scores (from baseline (t1) to first follow-up (t2) three to six weeks later) for all PCS- and MCS-scores of all four instruments using paired t-tests.

Data were analyzed using IBM SPSS Statistics 24 and STATA SE 13. Wherever applicable, analyses were stratified by patient clinical indication (orthopedic or psychosomatic rehabilitation).

RESULTS

A) Translation and cultural adaptation of the German VR

The field test yielded that most of the questions of the VR-36 are clear and simple to rehabilitation patients (n= 15, 4 male, 11 female, 30 to 80 years (mean 55.3 years)) and patients from general practice (n=11, 25 to 77 years (mean 57.4 years)) of all ages.

Additional file 1 shows the key differences between the English VR and the German translation. The field test yielded that most of the questions (except for RE and RP instructions, response scales and questions) in the VR-36 are clear and simple to both patients from general practice and rehabilitation patients.

Nearly every third person had problems in answering items 12 to 15 (RP) due to double negatives introduced during the translation process (e.g. “[...] nicht so lange [...]” (part of the question) “nein, nie” (response option)). These double negatives were the result of combining the questions with their response choices. Therefore “yes” and “no” were omitted for these response categories to clarify the language. From a linguistic point of view, these revised response categories resemble the English SF-36 Version 2 and the German SF-36 (versions 1 and 2). Additionally, some cultural content were edited to reflect the German context (e.g. playing golf as an example in item PF02 would not be relevant as golf is a less popular activity

in Germany). The German SF-36 was used as a guide in these decisions. The final German VR-36 is conceptually identical to the English original.

Phase B) Validation Study

Data are available from n=399 orthopedic and n=292 psychosomatic rehabilitation patients. Due to randomization, number and sample characteristics of participants were balanced across all four groups ($n_{VR-36}=169$, $n_{SF-36}=174$, $n_{VR-12}=177$, $n_{SF-12}=171$). Study participants were on average 53 years old; 67.7% were women and 48.3% were fully employed. About every fourth participant (26.8%) completed secondary education. Average duration of inpatient rehabilitation (for their primary diagnosis) was 22 days for orthopedic and 35 days for psychosomatic patients (overall mean=27.5 days). There were no systematic differences in the self-reported health status at baseline between the four study arms (CDC general health status $p(\chi^2)>0.05$).

Socio-demographic and certain clinical characteristics were comparable across the four arms of the study, which allowed for indirect comparisons (**Table 1**). The most common primary diagnosis were diseases of the musculoskeletal system and connective tissue (ICD-10: M00-M99: 48.9%), affective disorders (ICD-10: F30.0-F39.0: 19.8%) and neurotic, stress and somatoform disorders (ICD-10: F40.0-F49.0: 13.6%).

*Please insert **Table 1** about here*

Completeness of data

Missing values were acceptable (<5%) for the VR-36 and comparable to missing data patterns of the SF-36 (**Table 2**). The scale GH had the lowest percentage of completion for

both the SF-36 (91.4%) and VR-36 (93.5%). As expected, missing values increased with increasing age and lower education.

*Please insert **Table 2** about here*

TABLE 1 Sample characterization

	VR-12	SF-12	VR-36	SF-36
Number of cases (n), of which were	177	171	169	174
Orthopedics (%)	58.2	57.9	57.4	57.5
Psychosomatic (%)	41.8	42.1	42.6	42.5
Age (M±SD)	52.0±11.3	53.2±11.3	54.1±8.9	52.0±10.7
Sex (% women)	68.0	69.6	68.1	65.1
Marital status (%)				
Single	13.4	13.9	8.6	17.3
Married/living with partner	65.1	67.5	65.6	63.7
Highest school graduation (%)				
High school	28.8	25.2	24.3	28.7
Secondary school (10 years)	56.5	55.6	53.8	53.4
Employment status (%)				
Fully employed	45.8	48.0	49.1	50.6
Pension application (% „yes“)	10.2	11.3	8.5	14.9
Duration of rehabilitation (mean days)	26.8	28.2	27.4	27.7
Sick leave (days in the last year, M±SD)	183±217	164±209	169±211	155±200

M mean, SD standard deviation, SF-12 Short Form 12 Items Health Survey, SF-36 Short Form 36 Items Health Survey. All group comparisons were not significant ($p>0.05$).

TABLE 2 Percent complete items in each scale by instrument and patient subgroup

	Instrument (n)	PF	RP	BP	GH	VT	SF	RE	MH
Total	VR-36 (n=169)	94.7	93.5	97.0	93.5	96.4	98.2	95.3	95.9
	SF-36 (n=174)	95.4	97.7	96.6	91.4	96.6	97.7	98.9	96.6
Clinical indication									
Orthopedic	VR-36 (n=97)	93.8	91.8	96.9	92.8	95.9	97.9	93.8	92.8
	SF-36 (n=100)	94.0	98.0	97.0	90.0	95.0	97.0	99.0	95.0
Psychosomatic	VR-36 (n=72)	95.8	95.8	97.2	94.4	97.2	98.6	97.2	100.0
	SF-36 (n= 74)	97.3	97.3	95.9	93.2	98.6	98.6	98.6	98.6
Sex									
Female	VR-36 (n=111)	91.9	94.6	96.4	94.6	96.4	98.2	94.6	96.4
	SF-36 (n=112)	94.6	97.3	95.5	87.5	95.5	97.3	98.2	95.5
Male	VR-36 (n=52)	100.0	90.4	98.1	92.3	96.2	98.1	96.2	94.2

	SF-36 (n=60)	96.7	97.3	98.2	98.3	98.3	98.3	100.0	98.3
Age (median split)									
≤ 54 years	VR-36 (n=77)	96.1	94.8	97.4	96.1	97.4	100.0	97.4	96.1
≤ 53 years	SF-36 (n=87)	97.7	97.7	97.7	93.1	98.9	98.9	98.9	98.9
> 54 years	VR-36 (n=86)	93.0	91.9	96.5	91.9	95.3	96.5	93.0	95.3
> 53 years	SF-36 (n=84)	92.9	97.6	95.2	89.3	94.0	96.4	98.8	94.0
Education									
≤ 10 years	VR-36 (n=115)	93.0	91.3	95.7	92.2	95.7	98.3	93.0	93.9
	SF-36 (n=117)	94.9	98.3	95.7	91.5	95.7	97.4	99.1	95.7
> 10 years	VR-36 (n=46)	97.8	97.8	100.0	95.7	97.8	97.8	100.0	100.0
	SF-36 (n=55)	96.4	96.4	98.2	90.9	98.2	98.2	98.2	98.2

PF Physical Functioning, RP Role Physical, BP Bodily Pain, GH General Health, VT Vitality, SF

Social Functioning, RE Role Emotion, MH Mental Health, n sample size

Distributional properties

Table 3 gives the distributional properties of the PCS and MCS for the VR and SF short and long form versions. Means, standard deviations and ranges for PCS were very similar between SF-36 and VR-36, SF-12 and VR-12. For MCS, mean differences (e.g. mean VR-36: 36.2, mean SF-36: 39.0), skewness, kurtosis and boundary values of the distribution were larger between the SF-36 and VR-36 than between the SF-12 and VR-12.

*Please insert **Table 3** about here*

For the long and the short form versions of the VR and the SF, the PCS has normal distributions ($p=0.057$ to 0.097) while the MCS does not ($p<0.05$, **Table 3**). The findings do not substantively change when stratified by study arm and clinical indication (results not shown).

TABLE 3 Distribution properties of PCS and MCS by instrument and version

Instrument	n	M ± SD	Min-Max	Kurtosis	Excess	K-S-Test
PCS _{VR-36}	155	38.50 ± 10.15	11.74-67.81	0.151	-0.226	0.200
MCS _{VR-36}	155	36.18 ± 14.21	12.92-66.56	0.437	-0.817	0.049
PCS _{VR-12}	173	36.30 ± 11.55	12.7-59.3	0.141	-0.969	0.057

MCS _{VR-12}	173	37.23 ± 13.82	8.36-70.16	0.389	-0.527	0.001
PCS _{SF-12}	150	36.95 ± 10.95	15.5-61.6	0.27	-0.724	0.060
MCS _{SF-12}	150	39.04 ± 12.33	17.6-65.4	0.268	-1.001	0.002
PCS _{SF-36}	168	37.50 ± 11.67	13.8-66.12	0.289	-0.465	0.097
MCS _{SF-36}	168	39.03 ± 15.62	2.04-73.17	0.055	-0.989	0.005

K-S-Test Kolmogorov-Smirnov-Test, M mean, SD standard deviation, n sample size

The VR-36 scales distribute toward slightly lower scores than the SF-36 on the MCS, but not for the PCS. Kernel density plots show that the four instruments were more similar in PCS for orthopedic and MCS for psychosomatic patients. The distributions were more similar between the SF-12 and the SF-36 than between the SF and the VR instruments in PCS for psychosomatic and MCS for orthopedic patients (**Figure 3a**). Differences were observed after stratifying by clinical indication. For the scales of the instruments, kernel plots of the VR-36 and the SF-36 are comparable for PF and BP, RP and RE, while kernel plots of SF_{VR-36}, VT_{VR-36} and MH_{VR-36} are slightly more left skewed compared to the SF-36 (**Figure 3b**).

*Please insert **Figure 3a** “Kernel density estimation for PCS and MCS” about here*

*Please insert **Figure 3b** “Kernel plots of the scales of the VR-36 and SF-36” about here*

Construct validity

Table 4 presents the correlations between VR and SF component scores and other self-reported measures. Moderate to high correlations were observed between convergent measures with similar correlations observed across the VR-12 and SF-12, and VR-36 and SF-36. r_p between PCS and HFAQ, CDC Physical unhealthy days, GCPS Level and GCPS Disability ranged from $r_p=0.50$ to $r_p=0.76$; r_p between MCS and DASS-measures, CDC Mental unhealthy days and IRES-VT ranged from $r_p=0.5$ to $r_p=0.8$.

Correlation coefficients with generic measures ranged from $r_p=0.08$ to $r_p=0.49$ for the VR-36 and from $r_p=0.012$ to $r_p=0.42$ for the SF-36. For the short versions, those correlations varied from $r_p=0.06$ to $r_p=0.62$ for the VR-12 and from $r_p=0.17$ to $r_p=0.51$ for the SF-12. Differences (Δ) of correlations between corresponding measures (PCS: HFAQ, CDC healthy days physical unhealthy days; MCS: DASS, IRES-VT, CDC mental unhealthy days) were below $r_p=0.090$ and with one exception (IRES-VT vs. MCS for the short versions) statistically not significant ($p>0.5$).

The PCS_{VR} had moderate correlations ($r_p=0.33$ to $r_p=0.62$) with generic measures and moderate to strong correlations ($r_p=-0.55$ to $r_p=0.76$) with physical health measures. The MCS_{VR} had small to moderate correlation with generic health measures ($r_p=0.32$ to $r_p=0.49$) and moderate to strong correlations with mental health measures ($r_p=-0.60$ to $r_p=0.78$).

At $r_p=-0.5$ (PCS_{SF-12}) and $r_p=-0.6$ (PCS_{VR-12}), the correlation between the short versions of the PCS and the GCPS Pain was greater than for the long versions (both PCS_{SF-36} and PCS_{VR-36} $r_p=-0.4$). The MCS of all versions was almost uncorrelated with the GCPS Pain ($r_p=-0.172$ to $r_p=0.013$).

*Please insert **Table 4** about here*

TABLE 4 Construct validity: Comparison of Pearson correlation coefficients (r_p) across SF-12/VR-12 and SF-36/VR-36

Physical Component score (PCS)	PCS _{SF-12}	PCS _{VR-12}	$\Delta_{SF-12-VR-12}$	p-value	PCS _{SF-36}	PCS _{VR-36}	$\Delta_{SF-36-VR-36}$
<i>Generic</i>							
EQ-VAS	0.480	0.327	0.153	0.052	0.348	0.328	0.020
IMET	-0.499	-0.514	0.015	0.429	-0.362	-0.457	0.095
GCPS Pain	-0.514	-0.620	0.106	0.082	-0.420	-0.412	-0.008
<i>Convergent</i>							
HFAQ	0.670	0.759	-0.089	0.052	0.746	0.660	0.086
CDC physical healthy days	-0.604	-0.669	0.065	0.165	-0.569	-0.554	-0.015

GCPS Pain Intensity	-0.547	-0.624	0.077	0.149	-0.664	-0.632	-0.032
GCPS Pain Disability	-0.581	-0.615	0.034	0.319	-0.661	-0.586	-0.075
<i>Divergent</i>							
DASS Anxiety	-0.156	0.003	-0.159	0.085	0.143	-0.094	0.237
DASS Depression	0.023	0.124	-0.101	0.183	0.164	-0.005	0.169
DASS Stress	0.063	0.109	-0.046	0.340	0.297	0.104	0.193
IRES –VT	0.106	-0.082	0.188	0.415	-0.151	-0.015	-0.136
CDC Mentally healthy days	0.174	0.119	0.055	0.309	0.234	0.118	0.116

Mental Component score (MCS)	MCS _{SF-12}	MCS _{VR-12}	$\Delta_{SF-12-VR-12}$	p-value	MCS _{SF-36}	MCS _{VR-36}	$\Delta_{SF-36-VR-36}$
<i>Generic</i>							
EQ-VAS	0.311	0.321	-0.010	0.461	0.282	0.451	-0.169
IMET	-0.420	-0.426	0.006	0.474	-0.392	-0.490	0.098
GCPS Pain	-0.172	-0.062	-0.110	0.162	0.013	-0.080	0.093
<i>Divergent</i>							
HFAQ	0.054	-0.137	0.191	0.045	-0.141	0.036	-0.177
CDC Physical healthy days	-0.046	0.064	-0.110	0.166	0.020	-0.146	0.166
GCPS Pain Intensity	-0.154	-0.013	-0.141	0.069	0.091	-0.100	0.191
GCPS Pain Disability	0.072	-0.031	0.103	0.182	0.022	-0.159	0.181
<i>convergent</i>							
DASS Depression	-0.772	-0.729	-0.043	0.192	-0.788	-0.734	-0.054
DASS Anxiety	-0.524	-0.596	0.072	0.177	-0.603	-0.609	0.006
DASS Stress	-0.673	-0.702	0.029	0.314	-0.796	-0.729	-0.067
IRES-VT	0.701	0.784	-0.083	0.050	0.806	0.763	0.043
CDC Mentally healthy days	-0.744	-0.746	0.002	0.484	-0.684	-0.704	0.020

CDC healthy days, EQ-5D-5L EuroQol-5 Dimensions, HFAQ Hannover Functional Ability

Questionnaire, IMET Index of the Assessment of Health Impairments, IRES-VT Subscale

Vitality of the “Indicators of Rehabilitation Status”, GCPS Graded Chronic Pain Scale, SF-12

Short-Form 12 Items Health Survey, SF-36 Short Form 36 Items Health Survey, VR-12

Veterans Rand 12 Items Health Survey, VR-36 Veterans Rand 36 Items Health Survey; p-value

for the comparison of two correlation coefficients from independent samples [63].

Known-groups validity

Table 5a illustrates the PCS_{VR-36} and MCS_{VR-36} scores in sub-samples of known groups. Lower mean PCS_{VR-36} was found for orthopedic patients while lower mean MCS_{VR-36} was found for psychosomatic patients. In line with our hypothesis, higher mean PCS_{VR-36} and MCS_{VR-36} scores were found in younger patients with fewer sick days in the last year and a shorter

duration of rehabilitation. As expected, at baseline, orthopedic patients reported better mental health compared to psychosomatic patients and the other way around for mental health, which is reflected by higher mean MCS_{VR-36} scores in orthopedic and higher mean PCS_{VR-36} scores in psychosomatic patients. Results were similar for VR-12 and VR-36 suggesting that both instruments perform similarly with respect to known-groups validity (Table 5b).

Please insert Table 5a and 5b about here

TABLE 5a Known groups validity for the PCS_{VR-36} and the MCS_{VR-36}

Subgroups	PCS _{VR-36}		MCS _{VR-36}	
	mean $\pm$ SD	p-value	mean $\pm$ SD	p-value
Clinical Indication				
Psychosomatic patients (n=68)	44.08 $\pm$ 8.78	<0.001	28.86 $\pm$ 11.01	<0.001
Orthopedic patients (n=87)	34.18 $\pm$ 8.99		41.90 $\pm$ 13.85	
Type of therapy¹				
Medical follow-up-treatment (n=30)	29.57 $\pm$ 8.90	<0.001	44.11 $\pm$ 13.92	0.149
Curative treatment (n=54)	36.70 $\pm$ 8.13		39.63 $\pm$ 13.26	
Age				
< 45 years (n=25)	41.34 $\pm$ 8.38	0.181	31.77 $\pm$ 13.60	0.133
45-65 years (n=114)	38.34 $\pm$ 10.67		37.53 $\pm$ 14.38	
> 65 years (n=16)	35.45 $\pm$ 7.96		33.45 $\pm$ 12.91	
Duration of rehabilitation				
$\leq$ 27 days (n=71)	35.21 $\pm$ 9.15	<0.001	40.65 $\pm$ 13.52	<0.001
> 27 days (n=66)	42.41 $\pm$ 10.28		32.52 $\pm$ 13.10	
Sick days²				
$\leq$ 100 days (n=76)	40.30 $\pm$ 10.62	0.081	38.14 $\pm$ 14.10	0.281
>100 days (n=66)	37.29 $\pm$ 9.66		35.59 $\pm$ 13.95	
SRH³				
Excellent/very good/good (n=60)	42.68 $\pm$ 10.97	<0.01	43.40 $\pm$ 13.33	<0.001
Fair/poor (n=92)	35.65 $\pm$ 8.66		31.81 $\pm$ 13.01	

¹Orthopedic patients only. ²Days of sick leave in the last 12 month. ³SRH Self-rated health.

Patients reporting “excellent”, “very good” or “good” health and those reporting “poor” or “fair” health were aggregated. SD standard deviation.

TABLE 5b Known groups validity for the PCS_{VR-12} and MCS_{VR-12}

Subgroups	PCS _{VR-12}	MCS _{VR-12}
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	mean ± SD	p-value	mean ± SD	p-value
Clinical Indication				
Orthopedic patients (n=100)	31.20 ± 9.49	<0.001	42.21 ± 13.73	<0.001
Psychosomatic patients (n=73)	43.13 ± 10.55		30.41 ± 10.74	
Type of therapy¹				
Medical follow-up treatment(n=37)	28.37 ± 9.67	0.023	44.56 ± 15.34	0.187
Curative therapy (n=67)	32.88 ± 9.20		40.58 ± 12.42	
Age				
< 45 years (n=42)	37.15 ± 11.77	0.079	35.84 ± 14.14	0.004
45-65 years (n=111)	36.86 ± 11.37		36.02 ± 12.94	
> 65 years (n=20)	30.78 ± 11.13		46.87 ± 14.77	
Duration of rehabilitation				
≤ 27 days (n=85)	31.69 ± 10.74	<0.001	42.45 ± 13.64	<0.001
> 27 days (n=71)	41.77 ± 9.91		31.89 ± 11.64	
Sick days²				
≤100 days (n=82)	38.56 ± 10.71	0.021	37.58 ± 13.66	0.667
>100 days (n=82)	34.41 ± 12.04		36.65 ± 13.96	
SRH³				
Excellent/very good/good (n=67)	41.56 ± 11.49	<0.001	43.42 ± 13.81	<0.001
Fair/poor (n=104)	32.38 ± 10.19		33.50 ± 12.37	

¹Orthopedic patients only. ²Days of sick leave in the last 12 month. ³SRH Self-rated health.

Patients reporting “excellent”, “very good” or “good” health and those reporting “fair” or “poor” health were aggregated. SD standard deviation.

Responsiveness

Responsiveness to change analysis included the n=50 to n=88 cases with no deterioration in SRH from baseline (t1) to follow-up (t2), stratified as necessary by study arm (**Table 6**). For PCS, SES varied from 0.102 (VR-36 Psychosomatic) to 0.398 (SF-12 Orthopedic) and SRM varied from 0.127 (VR-36 Psychosomatic) to 0.695 (VR-12 Orthopedic) with better responsiveness across all instruments for orthopedic patients. Effect sizes of the short versions (VR-12, SF-12) were larger than those of the long versions (VR-36, SF-36). In psychosomatic patients, responsiveness to change of MCS was at least twice as large as responsiveness of PCS, while in orthopedic patients there were less obvious differences in responsiveness to change between PCS and MCS. Responsiveness of the PCS_{VR-36} for psychosomatic patients was smaller than the other instruments. Score improvements for all four instruments were statistically significant at p<0.001 (paired t-tests).

Please insert **Table 6 about here**

TABLE 6 Standardized Response Means (SRM) and Standardized Effect Sizes (SES) by instrument and clinical indication

	Orthopedics					Psychosomatics				
		SES		SRM			SES		SRM	
Version	n _{i/s} (n _c)	PCS	MCS	PCS	MCS	n _{i/s} (n _c)	PCS	MCS	PCS	MCS
VR-36	78 (82)	0.235	0.298	0.328	0.452	56 (61)	0.102	0.522	0.127	0.527
SF-36	83 (88)	0.317	0.165	0.460	0.241	59 (60)	0.250	0.818	0.331	0.820
VR-12	88 (93)	0.381	0.357	0.545	0.586	50 (57)	0.218	1.027	0.317	0.876
SF-12	63 (69)	0.398	0.482	0.695	0.586	50 (54)	0.277	0.840	0.357	1.060

SES standardized effect size, SRM standardized response mean, n_{i/s} number of patients

reporting improved or stable health defined by GHP1 (self-rated health, item 1 of the SF-36),

n_c n complete: number of all cases, PCS physical summary score, MCS mental summary score

DISCUSSION

This research project 1) translated and culturally adapted the English VR-36 to the German language (Germany) and 2) validated the adapted VR-36 and VR-12 in German orthopedic and psychosomatic inpatient rehabilitation patients. This article provides details of the translation and cultural adaptation process of the German VR and the main findings of the validation study.

The German translation of the VR was prepared according to "state of the art" criteria for cultural adaptation of self-assessed health questionnaires using forward and backward translations. The study produced a self-report questionnaire that is conceptually and semantically equivalent to the English language VR-36. The only difficulty during translation was the role physical (RP) and role emotional (RE) items which produced double negatives

when the question stems and responses were taken together. This was resolved by a slight change in response category wording.

The German VR-36 is the third cultural adaptation and translation of the VR after the Spanish and the Chinese version. Three more language versions (Japanese, Russian, Polish) are being planned.¹

The validation phase of this study found the VR instruments to be acceptable, valid and moderately to strongly responsive to improvements in health. We indirectly compared the German VR-36 and VR-12 to the well-established SF-36 and SF-12, and found the instruments to be comparable in their distribution properties, validity, and responsiveness. Data quality indicators, such as the extent of item non-response, show the VR to be acceptable instruments in a German rehabilitation population, and were similar compared to the SF instruments. PCS score distributions were similar for VR and SF instruments. However, the MCS_{VR} was distributed more in the lower range of the scale than the MCS_{SF}. The VR scales and summary scores were moderately to strongly correlated with expected external measures such as self-reported pain, physical functioning, mental functioning and disability. Both the long and the short form of the VR could distinguish between patient type (orthopedic and psychosomatic), duration of rehabilitation and self-rated health while the PCS_{VR-12} could also distinguish between type of therapy and whether the patient had over 100 sick days in the year. The short version (VR-12) was similarly responsive as the VR-36 and SF-36. Thus, the VR was established as a valid and responsive measure of quality of life in orthopedic and psychosomatic samples of German inpatient rehabilitation patients.

¹ To request free access to the instruments, information on terms of use, name and institution can be found at Boston University's website [65]. The scoring algorithms for SAS, R, SPSS and Stata are available from Prof. L.E. Kazis.

The number of studies using one of the instruments of the VR family is increasing every year with well over 400 publications [65]. The developers of the VR family provided the original psychometric evidence for the VR-36 and VR-12 [13;15-16;23].

Item level missing values were low and comparable to other studies suggesting high acceptability. While in this study 1.8% to 6.5% were missing per question for the baseline VR-36, Kronzer et al. [67] reported missing values in adult patients undergoing elective surgery on the baseline VR-12 from 1.5% to 3.7% per question and from 3.3% to 8.9% on the follow-up VR-12 (median 56 days).

Descriptive statistics indicated acceptable distributional characteristics. Summary scale means and SD of the PCS_{VR-36} are comparable with the results of the Veterans Health Study, in which the VR-36 was administered to nearly 2,500 veterans receiving ambulatory care (VHS PCS_{VR-36}: 37.12±11.85, this study: 38.50±10.2), but MCS_{VR-36} is different (VHS: 47.81±12.23, this study: 36.2±14.2) [17]. The differences in MCS may be a function of the populations sampled; while the means were different the SD are quite similar.

The validity results are comparable with other studies investigating physically impaired patients: a study with patients undergoing knee arthroplasty [31] found a moderate correlation between the PCS_{VR-12} and a disease-specific measure (KOOS-pain score: 0.57). Few studies investigated the factor structure of the VR-36 and found its structure to be comparable to the SF-36 [60].

Oak et al [31] found the PCS_{VR-12} to capture statistically significant improvements in the score in n=45 pre- and postoperatively tracked patients who underwent knee arthroplasty. They

found no statistical differences in internal or external responsiveness to change among the EQ-5D, VR-12 and PROMIS 10 physical instruments with SRMs of the PCS_{VR-12} of 0.681 and for the MCS_{VR-12} of 0.103 (SRM EQ-5D: 0.704, PROMIS 10 physical 0.721, PROMIS 10 mental 0.083). SRM of VR-12 scores at baseline and at the end of therapy (0.549) can be calculated from results of Levy et al.'s (2015) study of physical therapy received through tele-rehabilitation [68]. This is extremely similar to what we found for the VR-12 in orthopedic patients. Bedigrew et al.'s [69] study of an orthotic and rehabilitation program found statistically significant improvements only in the PCS and not in the MCS. For orthopedic patients, we found PCS to be less sensitive to changes in both SF and VR than the MCS, with the VR-12 similar or more sensitive to improvements than the SF instruments. However, the VR 36 was found to be slightly less sensitive to improvements than the SF-36 for psychosomatic patients.

Although the VR-36 and VR-12 are based on version 1 of the SF-36 and SF-12, the VR instruments use the five-level response format of the role functioning and role emotional scales whereas the SF version 1 instruments use the two-level format. The SF version 2 uses five-level response scales for those scales, but has slightly different wording and is in general a different instrument than version 1. This difference is likely the source of differences in distribution and responsiveness in our comparison of the VR to SF version 1 instruments. The floor was raised and ceiling lowered with the 5-point set of response choices for the role physical and role emotional scales compared with the dichotomized choices for the SF version 1 instruments [16]. Previous findings suggest that this could also be a possible explanation for the differences in responsiveness [16]. Gornet et al. [35] investigated the conversion of the SF-36 to PCS_{VR-12} and MCS_{VR-12} in 1,968 patients who underwent lumbar

(n=1,559) and cervical (n=409) surgery between 1998 and 2013. They found the SF-36 and converted VR-12 mean scores, the mean (pre to post) change scores for PCS and MCS, and the minimum detectable change (MDC) to be extremely similar. However, as their study only collected SF-36 data, they could not compare how a 2-level and 5-level response category in the two scales might differ.

The primary limitation of this study is the indirect comparison of the instruments: the VR-36, VR-12, SF-36 and SF-12 were completed by different patients. The design choice was to minimize respondent burden and frustration as the four instruments are very similar. Although patients were randomized to the study arms, there could be underlying differences across the groups not captured by demographic or patient characteristics. Thus, it is possible that the detected distribution and responsiveness differences may in part be due to differences in the sample characteristics and perhaps unmeasured variables and not due to the instruments themselves.

Furthermore, the German VR was validated in an inpatient rehabilitation setting, and the results may not be generalizable to other populations nor to outpatient rehabilitation settings. Future research applying the German VR in other settings is necessary. The instruments were also administered only as a paper-and-pencil survey. As self-assessment questionnaires are increasingly being used in electronic formats, the comparison between the classical paper-pencil and other new computer platform applications should be studied.

CONCLUSIONS

The VR is a credible measure in the public domain that can be applied in the German rehabilitation context. The VR measure may be appropriate for use in clinical research and

clinical practice, but further research is needed to evaluate its usefulness in other populations in German. Due to the high demand for the German VR during the study period, it can be assumed that in the foreseeable future more data from different clinical settings and administrative modes will be available. The scoring algorithms also have been developed by the project working group for common statistical programs (e.g. SPSS, Stata, R) and is, as well as the questionnaires, freely available for use to the research community.

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ADDITIONAL FILES

Additional file 1

Title of data: Key differences between the original English and the German Translated VR-36

Description of data: This file provides information on the key differences between the original English VR and its German translation. It shows an extract of the translation protocol and helps the reader to identify and retrace main semantical and conceptual differences between both versions due to cultural and linguistic adaptations during the translation process.

Figures

Figure 1

Flow chart of the translation process

Figure 2

Survey study design

Figure 3

A) Kernel density estimation for PCS and MCS B) Kernel plots of the scales of the VR-36 and SF-36

Supplementary Files

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