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The PROMIS-10 Global Health in minor stroke and transient ischemic attack: on paper versus telephone assessment

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Title

The PROMIS-10 Global Health in minor stroke and transient ischemic attack: on paper versus telephone assessment

Running title

PROMIS-10 in minor stroke and transient ischemic attack

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Abstract

Objectives: As stroke remains an important cause of burden of disease, measuring outcome is important for continuing improvement in stroke care. As dysfunction in transient ischemic attack (TIA) and minor stroke patients is often underestimated by clinical measures and healthcare is shifting towards value-based approach, patient-reported outcomes of increasing interest. In addition, with the shift towards value-based healthcare. The PROMIS-10 Global Health is a concise patient-centered outcome measuring tool proposed for assessing health in stroke patients. This study aims to address the validity of the Dutch PROMIS-10 in stroke patients in the Netherlands and also aims to compare telephone to on paper assessment.

Design: Observational cohort study.

Setting: Single-center hospital in the Netherlands.

Participants: 75 patients who were diagnosed with TIA or minor stroke and discharged without rehabilitation treatment one year ago (between December 2014 and January 2016) completed the study.

Primary and secondary outcome measures

PROMIS-10 physical and mental health scores assessed one year post-stroke on paper (n = 37) and by telephone (n = 38) was compared to RAND-36 physical and mental component scores assessed on paper.

Results: PROMIS-10 and RAND-36 correlated significantly in physical health, r = .81, 95% CI [.69, .88], and mental health, r = .76, 95% CI [.64, .85]. Paper-and-pencil assessed correlations were r = .87 and .79 for physical and mental health, respectively. Telephone assessed correlations were r = .76 and .73 for physical and mental health, respectively. Internal consistency analysis indicated high reliabilities for both health components of the PROMIS-10, all Cronbach's αs > .70.

Conclusions: The Dutch PROMIS-10 was found to strongly correlate with the RAND-36. Paper-and-pencil assessment was found to have a higher correlation than telephone assessment. This study provides support for the use of the Dutch PROMIS-10 in assessing health status in patients after mild stroke.

Strengths and limitations of this study

- Limited sample size.
- Subject characteristics were evenly distributed among all groups.
- Different timing between on paper and telephone assessment.

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- Additional potential confounding factors for self-reported quality of life such as individual personality traits, extent of social support, socio-economic status and ethnicity were not accounted for in this study.

Keywords: quality of life, patient-reported outcomes, stroke, transient ischemic attack

Introduction

While mortality rates have declined, the incidence of ischemic stroke remained stable or even slightly increased [1]. Following stroke many patients experience persistent deficits and reduced functional independence [2]. Consequently, in 2010 stroke ranks third in leading causes of disability-adjusted life years globally, with the burden of disease increasing with age and in the more developed regions [3]. In 2013 in the Netherlands, the incidence for stroke and transient ischemic attack (TIA) was 0.25 and 0.33 per 100 inhabitants, respectively [4].

Patients usually receive further rehabilitation treatment after suffering a major stroke [2]. While full recovery is assumed in TIA and minor stroke patients who are discharged to home without further rehabilitation treatment [5]. However, previous studies in TIA and minor stroke patients found high prevalences of dysfunction across all domains of health, of which cognitive and emotional problems were most notable [6-9]. These symptoms may be overlooked with conventional clinical measures such as the neurological examination or the Barthel Index, but can be a major contributor to an impaired performance of activities of daily living and a diminished quality of life (QoL) [5,10-12].

This emphasizes the importance of patient-reported outcomes (PROs); health status reported directly from the patient [13]. Measuring PROs is also an essential principal in the emerging value-based health care [14]. As such, health measurement is shifting from process measurement towards outcome measurement to improve quality while reducing costs [15]. This initiated the proposal of a Stroke Standard Set for measuring health in stroke by the International Consortium for Health Outcomes Measurement (ICHOM) [16]. The expert group recommends the Patient Reported Outcomes Measurement Information System 10-Question Short Form (PROMIS-10 Global Health) for assessing health status after stroke [17]. In the Netherlands, the PROMIS-10 has been translated into Dutch by the Dutch-Flemish PROMIS group (http://www.dutchflemishpromis.nl) [18]. However, validity and comparisons to existing validated instruments has yet to be addressed.

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Aims

This study aims to investigate the construct validity and reliability of the Dutch PROMIS-10 in TIA and minor stroke patients in the Netherlands. We also aim to evaluate different assessment methods of the PROMIS-10: on paper (filled in by the patient) assessment versus assessment through the telephone. As telephone assessment might be more feasible in the population of stroke patients, which mainly consists of elderly patients.

Methods

Study design

This single-center observational cohort study was part of a concurrent QoL study at OLVG Oost hospital. Between January 2016 and January 2017, patients diagnosed with a TIA or minor stroke one year ago were consecutively approached by telephone for study participation. Following verbal consent, study materials were sent by mail; study information, consent form, PROMIS-10, RAND-36, and a short form for obtaining socio-demographic data. PROMIS-10 was assessed on paper during the first half of the study, and by telephone for the second half. On paper assessments of the PROMIS-10 and RAND-36 were completed by the patients at home on their own or with help of a proxy. Telephone assessments of the PROMIS-10 were carried out by one researcher by reading out the exact questions and mark the given answers. Clinical data were extracted from medical records. Full ethical approval was given by the Medical research Ethics Committees United (MEC-U), Nieuwegein. Informed consent was obtained from all individual participants included in the study.

Subjects

Eligibility included a diagnosis of TIA or minor stroke followed by discharge without inpatient rehabilitation treatment. For this study TIA and minor stroke were defined as acute neurological deficits with symptoms of stroke on admission that fully resolves within 24 hours and three days, respectively.

As standard practice TIA and stroke patients discharged to home are re-evaluated shortly after discharge by a specialized stroke nurse. If residual or new symptoms are present or suspected, patients are referred to the Beroerte Adviescentrum (BAC, 'Stroke Advice Center'), a central body that coordinates and effectuates outpatient care for stroke patients. As the BAC also measures baseline health status, which is an inclusion criterion for the

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concurrent QoL study, patients who were not referred to the BAC or did not complete baseline measurements were not included.

Exclusion criteria were: age below 18 years, persistent neurological symptoms three days post-stroke, insufficient proficiency in Dutch, dementia or any behavioral disorder that may compromise study participation.

Measures

The PROMIS-10 is a 10-item measure for self-reported QoL, physical health, and mental health. It has been shown to be reliable, precise and comparable to legacy instruments [19]. Physical health (PH) and mental health (MH) T-scores can be calculated through an online scoring service provided by Assessment Center (www.assessmentcenter.net/ac_scoringservice). The T-score distributions are standardized with mean (*SD*) of 50 (10) for the United States' (US) general population, where higher scores indicates better outcome. In this study a Dutch version of the PROMIS-10 was used [18]. As standardized scores for the Netherlands are unavailable, T-scores were calculated using the US population standard scores.

The RAND-36 (identical to the SF-36) is a widely used QoL measure, comprising of 36 items covering a wide range of health domains [20]. Two component scores can be derived: physical (PCS) and mental (MCS) component score. PCS and MCS are standardized with mean (*SD*) of 50 (10), with higher scores reflecting better outcome. The RAND-36 has been translated and validated into multiple languages, including Dutch [21]. In this study the Dutch RAND-36 version 2 was used. However, PCS and MCS were calculated using US-standardized weights for a more equal comparison to the PROMIS-10, which was calculated similarly.

Socio-demographic data collected were: marital status, level of education (assessed on the Dutch 7-point scale 'schaal van Verhage', and afterwards stratified into three groups), living arrangement, and working status.

Data analysis

Numerical variables were summarized by the mean ± *SD*, and frequencies and percentages were used for binary and categorical variables. Differences in patient characteristics were assessed using the independent samples *t*-test and χ^2 test. For assessing construct validity, correlation between PROMIS-10 and RAND-36 was assessed by calculating Pearson's correlation coefficient (*r*), with a bias corrected and accelerated bootstrapping (BCa) method providing 95% confidence intervals. An independent samples *t*-test was performed for assessing differences between

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assessment methods of the PROMIS-10. For the internal consistency of the PROMIS-10, reliability analysis was used to calculate Cronbach's αs for both physical (4 items) and mental (4 items) subscales. A cut-off point of $\geq .70$ was chosen for indication of good reliability (α) and correlation (r) [22]. A p-value of $< .05$ was considered to be statistically significant. All statistical analysis was performed using IBM SPSS version 22.

Results

A total of 592 patients were identified who were diagnosed with a TIA or minor stroke one year prior to the assessment (from December 2014 to January 2016). Following re-evaluation by their physician, 291 patients were referred to the BAC for follow-up care. 26 patients were excluded as they originated from a different region or country and 8 died before BAC follow-up. Of the remaining 257 eligible patients, 75 patients were included for the study and 182 were non-respondents (108 had no baseline measurements, 12 were insufficient proficient in Dutch, 11 died before follow-up at one year post-stroke, 6 had dementia or a behavioral disorder, 28 refused participation, 13 were not responsive, and 4 were not reachable by phone).

Of the 75 included patients, mean age was 68.9 ± 11.2 years, 51 (68.0%) were male, 60 (80.0%) had their first-ever ischemic event, 49 (65.3%) had the diagnosis minor stroke and 26 (34.7%) TIA. The ischemic event was located in the left hemisphere in 30 (40.0%) patients, 23 (30.7%) in the right hemisphere, and 22 (29.3%) were vertebrobasilar. There were no statistically significant differences between the study population and the non-respondents. Mean (*SD*) scores for the PROMIS-10 were 45.8 (9.9) for PH, and 49.6 (9.1) for MH. Scores for the RAND-36 were 43.7 (11.4) for PCS, and 49.9 (10.7) for MCS.

In 37 patients the PROMIS-10 and RAND-36 were assessed on paper; two had missing values in the physical component, and one in both components of the PROMIS-10, another patient had missing values in both components of the RAND-36. These 37 patients formed the 'paper-and-pencil group'. 38 patients completed the PROMIS-10 by telephone (and the RAND-36 on paper), these patients formed the 'telephone group'. Patient characteristics of both groups are summarized in table 1. No statistically significant differences were observed between the two groups.

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Tabel 1. Patient characteristics between the study population (n = 75, divided in 'paper-and-pencil' and 'telephone' group) and non-respondents (n = 182)

Characteristic	Study population (*n* = 75)		Non-respondents (*n* = 182)
	'Paper-and-pencil' (*n* = 37)	'Telephone' (*n* = 38)	
Days between onset and follow-up, mean (*SD*)	374.8 (59.7)	375.7 (30.7)	n/a
Age, y, mean (*SD*)	67.4 (9.9)	70.4 (12.2)	68.5 (12.2)
Gender			
Female	9 (24.3)	15 (39.5)	82 (45.1)
Male	28 (75.7)	23 (60.5)	100 (54.9)
Diagnosis			
TIA	10 (27.0)	16 (42.1)	44 (24.2)
Minor stroke	27 (73.0)	22 (57.9)	138 (75.8)
Localization			
Right hemisphere	12 (32.4)	11 (28.9)	51 (28.0)
Left hemisphere	14 (37.8)	16 (42.1)	77 (42.3)
Vertebrobasilar	11 (29.7)	11 (28.9)	47 (25.8)
Ocular	0 (0.0)	0 (0.0)	3 (1.6)
Other/unknown	0 (0.0)	0 (0.0)	4 (2.2)
Stroke incidence			
First ever	29 (78.4)	31 (81.6)	138 (75.8)
Relapse	8 (21.6)	7 (18.4)	44 (24.2)
Marital status			
Married	22 (59.5)	22 (57.9)	n/a
Unmarried	13 (35.1)	14 (36.8)	n/a
Widowed	2 (5.4)	2 (5.3)	n/a
Education			

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Low	5 (13.9)	3 (7.9)	n/a
Average	16 (44.4)	21 (55.3)	n/a
High	15 (41.7)	14 (36.8)	n/a
Living arrangement			
Alone	15 (40.5)	15 (39.5)	n/a
With spouse/relative(s)	22 (59.5)	23 (60.5)	n/a
Current work status			
Back to work	8 (21.6)	8 (21.1)	n/a
Not (fully) back to work	6 (16.2)	7 (18.4)	n/a
Retired	23 (62.2)	23 (60.5)	n/a

Abbreviations: TIA = transient ischemic attack, n/a = not available. All data are expressed as n (%), except where specified. All differences were not statistically significant (all ps > .05).

Construct validity

PROMIS-10 and RAND-36 physical and mental scores correlated significantly, $r = .81$, BCa CI [.69, .88], $p < .001$, and $r = .76$, BCa CI [.64, .85], $p < .001$, respectively (see figure 1). When scores for the PROMIS-10 PH and MH were divided between 'paper-and-pencil' and 'telephone' groups, correlation between the PROMIS-10 and RAND-36 physical and mental health increased in the 'paper-and-pencil' group, and decreased in the 'telephone' group. The results are summarized in table 2.

Figure 1. Scatterplots of PROMIS-10 and RAND-36 physical scores (**A**) and mental scores (**B**).

[Insert Figure 1.]

Tabel 2. Bivariate correlations between PROMIS-10 and RAND-36

	RAND-36		
	PCS	MCS	*n*

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PROMIS-10			
PH	.82* [.70, .90]	—	71
MH	—	.70* [.57, .82]	73
PROMIS-10 (paper-and-pencil)			
PH	.88* [.78, .90]	—	33
MH	—	.70* [.54, .84]	35
PROMIS-10 (telephone)			
PH	.77* [.54, 91]	—	38
MH	—	.70* [.50, .86]	38

***p < .01. BCa bootstrap 95% CIs reported in brackets. Abbreviations: PCS = physical component score, MCS = mental component score, PH = physical health, MH = mental health.**

When comparing assessment methods, the mean PH score was lower in the 'paper-and-pencil' group than in the 'telephone' group. This difference was not statistically significant. The mean MH score was also lower in the 'paper-and-pencil' group than in the 'telephone' group. This difference however, was statistically significant (see figure 2). Mean scores of the RAND-36 PCS and MCS were not statistically significantly different among the two groups based on assessment method of PROMIS-10. The results are summarized in table 3.

Figure 2. Boxplots of PROMIS-10 physical health (**A**) and mental health (**B**), divided between paper-and-pencil and telephone assessment.

[Insert Figure 2.]

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Tabel 3. Independent samples t-tests comparing PROMIS-10 and RAND-36, between 'paper-and-pencil' and 'telephone' group

	'Paper-and-pencil'		'Telephone'				
	Mean (*SD*)	*n*	Mean (*SD*)	*n*	95% CI for mean difference	*t*-value (df)	*p*-value
PROMIS-10 PH	44.1 (10.1)	34	47.2 (9.5)	38	-7.67, 1.57	-1.32 (70)	.192
PROMIS-10 MH	45.6 (8.5)	36	53.4 (8.0)	38	-11.57, -3.90	-4.02 (72)	.001
RAND-36 PCS	48.7 (12.2)	36	51.0 (11.8)	38	-7.86, 3.27	-0.82 (72)	.414
RAND-36 MCS	34.7 (8.4)	36	37.7 (7.6)	38	-6.64, 0.80	-1.56 (72)	.122

Abbreviations: PH = physical health, MH = mental health, PCS = physical component score, MCS = mental component score.

Internal consistency

The PROMIS-10 demonstrated high reliabilities for both PH, Cronbach's α = .79, and MH, Cronbach's α = .83. Similar αs were observed for the PROMIS-10 assessed by paper-and-pencil and telephone: α = .82 and .81 for PH and MH, respectively, in the 'paper-and-pencil' group; α = .77 and .80 for PH and MH, respectively, in the 'telephone' group.

Discussion

In this study we used the Dutch PROMIS-10 to assess QoL in patients at one year after TIA or minor stroke. Our results indicate an overall strong correlation between the PROMIS-10 and the RAND-36. QoL attributed to physical health was found to have a higher correlation than QoL attributed to mental health. This could be explained due to physical health tending to be more objective and consistent over time. Whereas mental health is generally more subjective and prone to fluctuations. Nonetheless, both correlations were within the range considered to be moderate to high.

Subsequently, we compared two assessment methods of the PROMIS-10. In both physical and mental health, telephone assessment was found to be inferior to assessment by paper-and-pencil. No studies were found that addressed the validity of telephone assessment of the PROMIS-10. Two studies however, evaluated telephone assessment of other PROMIS measures [23,24]. In line with our results, both studies provide support for telephone assessment. One of the studies compared telephone to self-administered assessment; aside from small mode effects

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most likely related to study design, no apparent differences were reported as was found in our study [24]. In our study we suspect that lack of visual support when choosing a score within a range might have been contributing to a lower correlation. Other noted caveats in telephone assessment in our study were hesitation, choosing scores in between, and the tendency to substantiate choices during assessment.

When comparing PROMIS-10 and RAND-36 scores between the 'paper-and-pencil' and 'telephone' group, it is notable that scores of the on paper assessed RAND-36 were similar in both physical and mental health, whereas PROMIS-10 scores were significantly higher (i.e. better) in the 'telephone' group compared to the 'paper-and-pencil' group. We speculate that patients could be inclined to appear better, answer more socially desirable, and are less inclined to open up about mental problems in a direct telephone interview, as opposed to on paper assessment.

Gender could be another possible contributing factor for the observed difference in mental health in our two groups. Although not significant, there were slightly more women in our 'telephone' group compared to the 'paper-and-pencil' group. Muus et al. (2010), who studied a similar population, reported that women tend to have ischemic stroke at a higher age and having more severe strokes compared to men [7]. In our study however, mental health was found to be similar between both genders. The difference in mental health between our 'telephone' and 'paper-and-pencil' group is therefore not likely to be attributable to gender.

Other possible causes of the difference between our PROMIS-10 'telephone' and 'paper-and-pencil' group could be that the former group comprises of healthier patients. Although not significant, our 'telephone' group comprised of slightly more TIA patients, who are expected to have better outcomes than minor stroke patients. However, when taking diagnosis into account, physical and mental scores between the two groups did not significantly differ for both PROMIS-10 and RAND-36. The remaining patient characteristics obtained in this study were nearly identically distributed among both groups, and are therefore unlikely to have confounded the results.

Limitations

The generalizability of our results is reduced due to our small sample size. Moreover, our study population does not cover the full range of stroke patients. Aside from exclusion of major stroke, as our target population were TIA and minor stroke patients, a large number of patients were not included as referral to the BAC based on symptoms was not indicated. Nonetheless, these relatively mildly affected patients still represent part of our target population. The

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same applies to patients who were excluded due to an insufficient proficiency in Dutch. In contrast to generalizability, these limitations should barely affect our results, as patient characteristics were similar among the included patients and the non-respondents.

Noteworthy is the mean (*SD*) of 9.4 (14.7) days between assessment of RAND-36 on paper and assessment of PROMIS-10 by telephone in our 'telephone' group. On the other hand, on paper assessment of the PROMIS-10 is (assumed to be) completed on the same day. Health status might change over these few days. Moreover, three items of PROMIS-10 are concerned with the past seven days (fatigue, emotional problems, and pain).

Time of measurement of health status in stroke should also be taken into account. We assessed the PROMIS-10 at one year post-stroke, in contrast to the 3 months post-stroke proposed by the ICHOM consensus group[16]. As Mierlo et al. (2016) reported improvement of quality of life occurs up to one year after stroke, with most changes occurring within the first six months [25].

Lastly, possible confounding factors such as individual personality traits, extent of social support, socio-economic status and ethnicity was not accounted for in this study, while these factors undoubtedly impact self-reported quality of life.

Conclusions

This study provides support for the use of the Dutch version of the PROMIS-10 in patients after minor stroke or TIA in the Netherlands. Despite satisfactory validity of telephone assessment, careful interpretation is advised, especially when addressing mental health status. Additional data and further research with the PROMIS-10 in stroke patients is desirable for establishing more firm results.

Contributorship statement

K.H. Lam and V.I.H. Kwa state that the following criteria for contributorship, in accordance to the ICMJE criteria for authorship, are met:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

- Drafting the work or revising it critically for important intellectual content; AND

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- Final approval of the version to be published; AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work the authors have done, all authors are able to identify which co-authors are responsible for specific other parts of the work. In addition, the authors have confidence in the integrity of the contributions of our co-authors.

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Competing interests

The authors declare that they have no competing interests.

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Data sharing statement

Individual participant data collected during the study that underlie the results reported in the manuscript, after deidentification (text, tables and figures), will be available for data sharing. The data will be available immediately after publication and ends 36 months after publication. The data will be available to investigators whose proposed use of the data has been approved by an independent review committee. Up to 36 months after publication, the data can be requested and accessed electronically.

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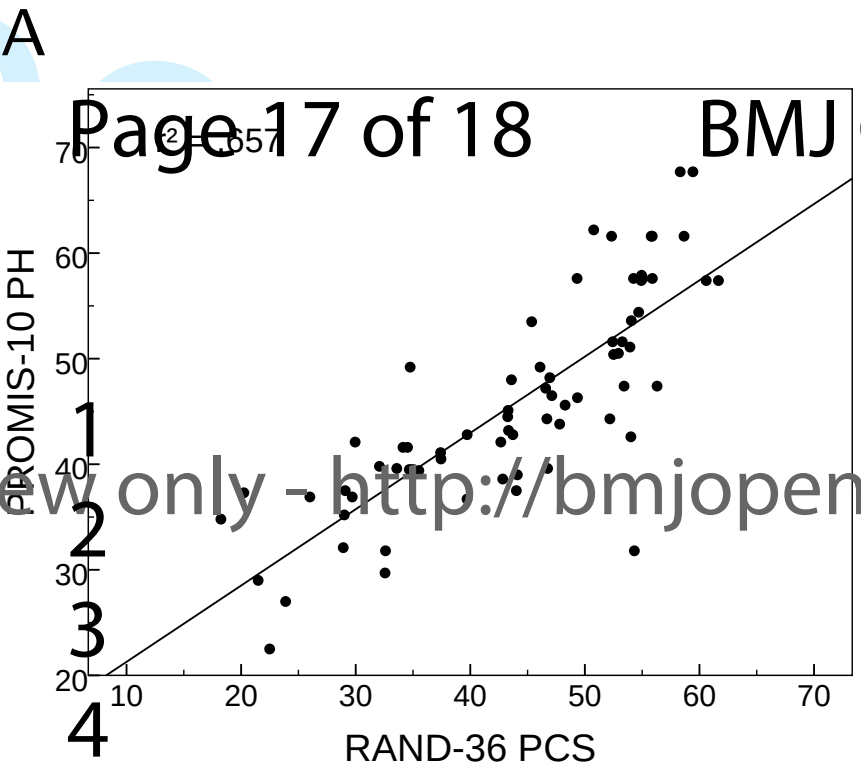

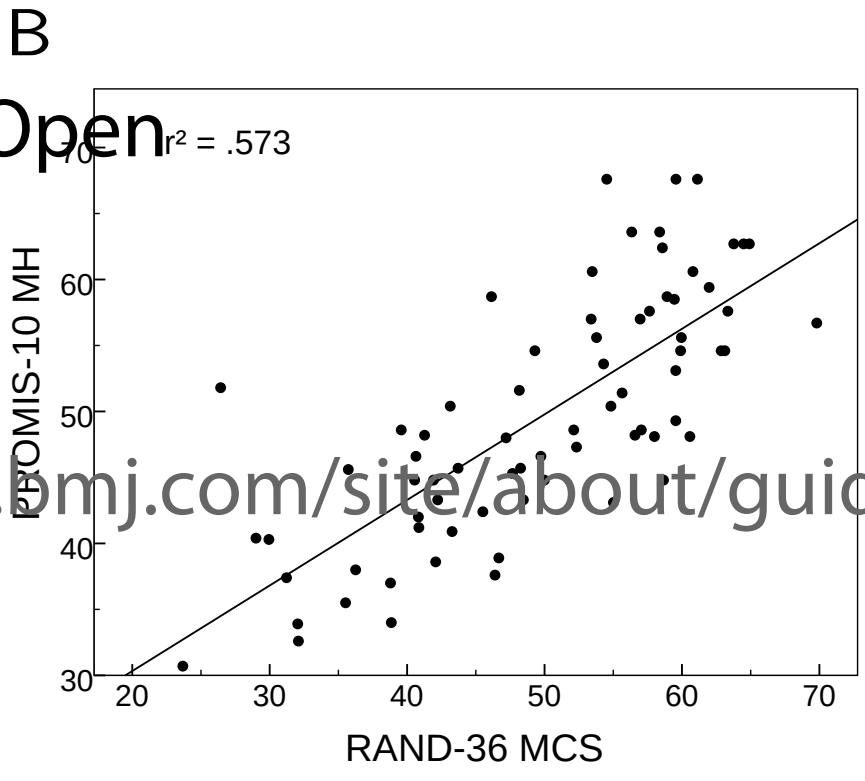

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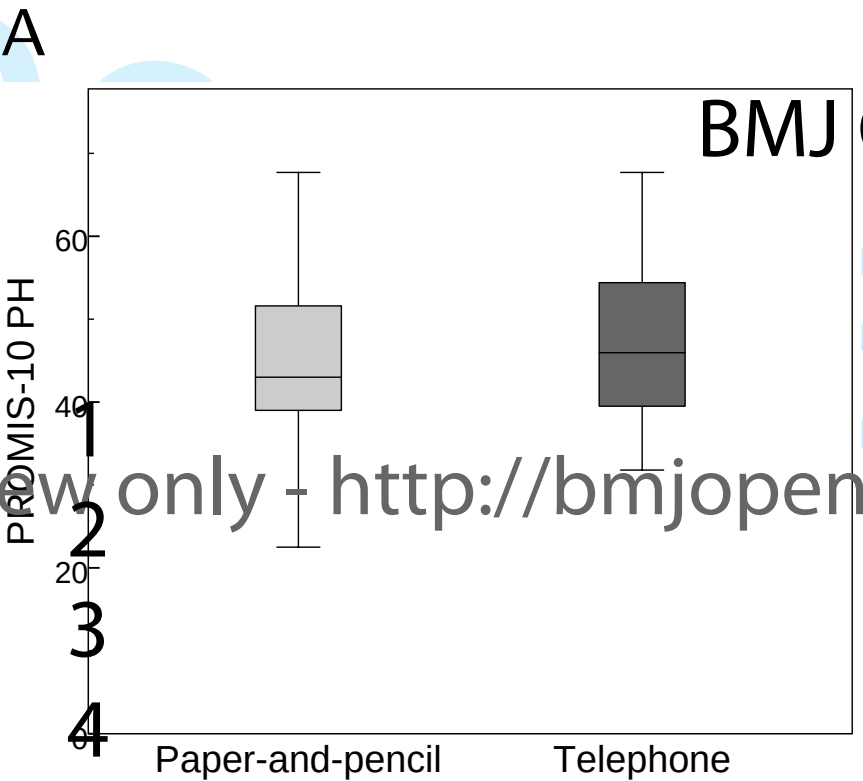

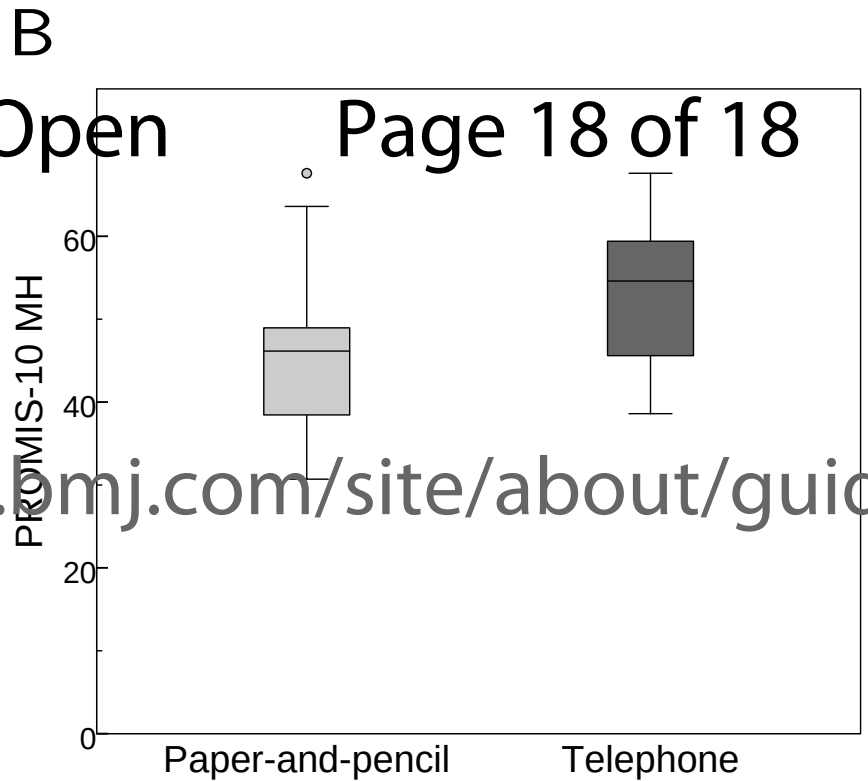

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Validity of the PROMIS-10 Global Health assessed by telephone and on paper in minor stroke and transient ischemic attack in the Netherlands

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Title

Validity of the PROMIS-10 Global Health assessed by telephone and on paper in minor stroke and transient ischemic attack in the Netherlands

Running title

PROMIS-10 in minor stroke and transient ischemic attack

Authors

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Abstract

Objectives: Dysfunction after transient ischemic attack (TIA) and minor stroke is often underestimated by clinical measures. Patient-reported outcome measures used in value-based healthcare may help detecting these problems. The PROMIS-10 Global Health is a concise patient-centered outcome measuring tool proposed for assessing health status in stroke patients. This study aims to address the validity of the Dutch PROMIS-10 in stroke patients in the Netherlands and also aims to compare telephone versus on-paper assessment.

Design: Observational cohort study.

Setting: Single-centre hospital in the Netherlands.

Participants: 75 patients who were diagnosed with TIA or minor stroke and discharged without rehabilitation treatment one year ago (between December 2014 and January 2016) completed the study.

Primary and secondary outcome measures

PROMIS-10 physical and mental health scores assessed one year post-stroke on paper (n = 37) and by telephone (n = 38) was compared to RAND-36 physical and mental component scores assessed on paper.

Results: PROMIS-10 and RAND-36 correlated significantly in physical health, r = .81, 95% CI [.69, .88], and mental health, r = .76, 95% CI [.64, .85]. Paper-and-pencil assessed correlations were r = .87 and .79 for physical and mental health, respectively. Telephone assessed correlations were r = .76 and .73 for physical and mental health, respectively. Internal consistency analysis indicated high reliabilities for both health components of the PROMIS-10, all Cronbach's αs > .70.

Conclusions: The Dutch PROMIS-10 was found to strongly correlate with the RAND-36. Paper-and-pencil assessment was found to have a higher correlation than telephone assessment. This study provides support for the use of the Dutch PROMIS-10 in assessing health status in patients after TIA and minor stroke.

Strengths and limitations of this study

- This is the first study that addresses the PROMIS-10 as measuring tool for health status in TIA and minor stroke patients in the Netherlands.
- Subjects were very similarly distributed in terms of clinical and socioeconomic factors between different comparator groups.
- Generalizability of the study results is reduced due to a relatively small sample size.

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- There was a time window between assessment of paper-based RAND-36 and telephone-based PROMIS-10.
- PROMIS-10 was assessed at one time point only; this study provides no insight on test-retest reliability of the PROMIS-10.
- Additional potential confounding factors for self-reported quality of life such as individual personality traits, extent of social support, socio-economic status and ethnicity were not accounted for in this study.

Keywords: quality of life, patient-reported outcomes, stroke, transient ischemic attack

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Introduction

Following a stroke many patients experience persistent deficits and reduced functional independence [1], while full recovery is assumed in TIA and minor stroke patients who are discharged to home without further rehabilitation treatment [2]. However, previous studies in TIA and minor stroke patients found high prevalence of dysfunction across all domains of health, of which cognitive and emotional problems were most notable [3-6]. These symptoms may be overlooked with conventional clinical measures such as the neurological examination or the Barthel Index, but can be a major contributor to an impaired performance of activities of daily living and a diminished quality of life (QoL) [2,7-9]. This emphasizes the importance of patient-reported outcomes (PROs), which measure health status reported directly from the patient [10]. Measuring PROs is also an essential principal in the emerging value-based healthcare [11]. As such, health measurement is shifting from process measurement towards outcome measurement to improve quality while reducing costs [12]. This initiated the proposal of a Stroke Standard Set for measuring health in stroke by the International Consortium for Health Outcomes Measurement (ICHOM) [13]. The expert group recommends the Patient Reported Outcomes Measurement Information System 10-Question Short Form (PROMIS-10 Global Health) for assessing health status after stroke [14]. The PROMIS-10 has been translated into Dutch by the Dutch-Flemish PROMIS group (http://www.dutchflemishpromis.nl), but has not yet been validated or compared with existing validated instruments in stroke patients [15].

Aims

This study aims to investigate the construct validity and reliability of the Dutch PROMIS-10 in TIA and minor stroke patients in the Netherlands. We also aim to evaluate different assessment methods of the PROMIS-10: on paper

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(filled in by the patient) assessment versus assessment through the telephone. As telephone assessment might be more feasible in the population of stroke patients, which mainly consists of elderly patients.

Methods

Study design

This single-centre observational cohort study was part of a concurrent quality of life study at OLVG Oost hospital. Between January 2016 and January 2017 medical records of patients diagnosed with a TIA or minor stroke one year ago were screened for eligibility, as Mierlo et al. (2016) reported improvement of quality of life occurring the most in the first six months and up to one year after stroke [16]. Eligible patients were approached by telephone for study participation. Following verbal consent to study participation, study materials were sent by mail; study information, consent form, PROMIS-10, RAND-36 (a health-related quality of life measure), and a short form for obtaining socio-demographic data. PROMIS-10 was assessed on paper from January 1 to July 31, 2016 and by telephone from August 1, 2016 to January 31, 2017. On paper assessments of the PROMIS-10 and RAND-36 were completed by the patients at home on their own or with help of a proxy. Telephone assessments of the PROMIS-10 were carried out by reading out the exact questions and marking the given answers. Clinical data were extracted from medical records. Full ethical approval was given by the Medical Research Ethics Committees United (MEC-U), Nieuwegein. Informed consent was obtained from all individual participants included in the study. Clinical data (age, gender, diagnosis, stroke localization and incidence) of non-participating and excluded eligible patients were recorded in a non-identifiable manner without requiring consent.

Subjects

Eligibility included a clinical diagnosis of TIA or minor stroke followed by discharge without inpatient rehabilitation treatment. MRI is not part of the standard diagnostic work-up of stroke but was performed whenever other causes than ischemia could not be ruled out. For this study TIA and minor stroke were defined as acute neurological deficits with symptoms of stroke on admission that fully resolves within 24 hours and three days, respectively.

As standard practice TIA and stroke patients discharged to home are re-evaluated shortly after discharge by a specialized stroke nurse. If during the re-evaluation residual or new symptoms are present or suspected, patients are referred to the Beroerte Adviescentrum (BAC, 'Stroke Advice Centre'), a central body that coordinates and

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effectuates outpatient care for stroke patients. As the BAC measures baseline health status, which is an inclusion criterion for the concurrent QoL study, patients who were not referred to the BAC or did not complete baseline measurements were deemed ineligible.

Exclusion criteria were: age below 18 years, persistent neurological symptoms three days post-stroke, insufficient proficiency in Dutch, dementia or any behavioural disorder that may compromise study participation.

Measures

The PROMIS-10 is a 10-item measure for self-reported QoL, physical health, and mental health. It has been shown to be reliable, precise and comparable to legacy instruments [17]. Physical health (PH) and mental health (MH) T-scores can be calculated through an online scoring service provided by Assessment Center (www.assessmentcenter.net/ac_scoringservice). The T-score distributions are standardized with mean (*SD*) of 50 (10) for the United States' (US) general population, where higher scores indicate better outcome. In this study a Dutch version of the PROMIS-10 was used [15]. As standardized scores for the Netherlands are unavailable, T-scores were calculated using the US population standard scores.

The RAND-36 (identical to the SF-36) is a widely used QoL measure, comprising of 36 items covering a wide range of health domains [18]. Two component scores can be derived: physical (PCS) and mental (MCS) component score. PCS and MCS are standardized with mean (*SD*) of 50 (10), with higher scores reflecting better outcome. The RAND-36 has been translated and validated into multiple languages, including Dutch [19]. In this study the Dutch RAND-36 version 2 was used. However, PCS and MCS were calculated using US-standardized weights for a more equal comparison to the PROMIS-10, which was calculated similarly.

Socio-demographic data collected were: marital status, level of education (assessed on the Dutch 7-point scale 'schaal van Verhage', and afterwards stratified into three groups: low (primary school), average (secondary school low or medium level), and high (highest level secondary school, and/or college degree, and/or university degree) [20], living arrangement, and work status.

Data analysis

Numerical variables were summarized by the mean ± *SD*, and frequencies and percentages were used for binary and categorical variables. Differences in patient characteristics were assessed using the independent samples *t*-test and χ^2

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test for continuous and categorical variables, repectively. For assessing construct validity, correlation between PROMIS-10 and RAND-36 was assessed by calculating Pearson's correlation coefficient (*r*), with a bias corrected and accelerated bootstrapping (BCa) method providing 95% confidence intervals. Agreement between PROMIS-10 and RAND-36 was assessed by constructing Bland-Altman plots with horizontal lines representing the mean difference and 95% limits of agreement (LOA) (mean difference ±1.96 SD). An independent samples *t*-test was performed for assessing differences between assessment methods of the PROMIS-10. For the internal consistency of the PROMIS-10, reliability analysis was used to calculate Cronbach's *α*s for both physical (4 items) and mental (4 items) subscales. A cut-off point of ≥ .70 was chosen for indication of good reliability (*α*) and correlation (*r*) [21]. A *p*-value of < .05 was considered to be statistically significant. All statistical analysis was performed using IBM SPSS version 22.

Patient and public involvement

The development of the research question was based on earlier research on patients' experience of our care after a TIA or minor stroke. Many patients had hidden signs and symptoms that were not recognized by doctors at first sight. We are now developing 'Value-based healthcare' with help of patient related outcome measures like the one that is investigated in this study, to be able to detect these hidden signs and symptoms. In the informed consent form we stated that after the end of the study we will send a letter to the participants to inform them about the results of the study.

Results

A total of 592 patients were identified who were diagnosed with a TIA or minor stroke one year prior to the assessment (from December 2014 to January 2016). Following re-evaluation by their physician, 301 patients were not referred to BAC for follow-up care, 26 patients originated from a different region or country, and 8 died before BAC follow-up. Of the remaining 257 eligible patients, 182 were non-respondents (108 had no baseline measurements, 12 were insufficient proficient in Dutch, 11 died before follow-up at one year post-stroke, 6 had dementia or a behavioural disorder, 28 refused participation, 13 were not responsive after initial consent, and 4 were not reachable by phone) and 75 patients were included for the study (see figure 1).

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Figure 1. Flow chart of the study population

[insert figure 1.]

Of the 75 included patients, mean age was 68.9 ± 11.2 years, 51 (68.0%) were male, 60 (80.0%) had their first-ever ischemic event, 49 (65.3%) had the diagnosis minor stroke and 26 (34.7%) TIA. The ischemic event was located in the left hemisphere in 30 (40.0%) patients, 23 (30.7%) in the right hemisphere, and 22 (29.3%) were vertebrobasilar. There were no statistically significant differences between the study population and the non-respondents. Mean (*SD*) scores for the PROMIS-10 were 45.8 (9.9) for PH, and 49.6 (9.1) for MH. Scores for the RAND-36 were 43.7 (11.4) for PCS, and 49.9 (10.7) for MCS.

In 37 patients the PROMIS-10 and RAND-36 were assessed on paper; two had missing values in the physical total score, and one in both physical and mental total score of the PROMIS-10, another patient had missing values in both component scores of the RAND-36. These 37 patients formed the 'paper-and-pencil group'. 38 patients completed the PROMIS-10 by telephone (and the RAND-36 on paper), these patients formed the 'telephone group'. Patient characteristics of both groups are summarized in table 1. No statistically significant differences were observed between the two groups.

Table 1. Patient characteristics between the study population (n = 75, divided in 'paper-and-pencil' and 'telephone' group) and non-respondents (n = 182)

Characteristic	Study population (*n* = 75)			Non-respondents (*n* = 182)	*p*-value
	'Paper-and-pencil' (*n* = 37)	'Telephone' (*n* = 38)	*p*-value		
Days between onset and follow-up, mean (*SD*)	374.8 (59.7)	375.7 (30.7)		n/a	
Age, y, mean (*SD*)	67.4 (9.9)	70.4 (12.2)	.258[a]	68.5 (12.2)	.810[a]
Gender			.160[b]		.053[b]
Female	9 (24.3)	15 (39.5)		82 (45.1)	
Male	28 (75.7)	23 (60.5)		100 (54.9)	

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Diagnosis			.170[b]		.086[b]
TIA	10 (27.0)	16 (42.1)		44 (24.2)	
Minor stroke	27 (73.0)	22 (57.9)		138 (75.8)	
Localization			.921[b]		.505[b]
Right hemisphere	12 (32.4)	11 (28.9)		51 (28.0)	
Left hemisphere	14 (37.8)	16 (42.1)		77 (42.3)	
Vertebrobasilar	11 (29.7)	11 (28.9)		47 (25.8)	
Ocular	0 (0.0)	0 (0.0)		3 (1.6)	
Other/unknown	0 (0.0)	0 (0.0)		4 (2.2)	
Stroke incidence			.729[b]		.469[b]
First ever	29 (78.4)	31 (81.6)		138 (75.8)	
Relapse	8 (21.6)	7 (18.4)		44 (24.2)	
Marital status			.988[b]		
Married	22 (59.5)	22 (57.9)		n/a	
Unmarried	13 (35.1)	14 (36.8)		n/a	
Widowed	2 (5.4)	2 (5.3)		n/a	
Education			.561[b]		
Low	5 (13.9)	3 (7.9)		n/a	
Average	16 (44.4)	21 (55.3)		n/a	
High	15 (41.7)	14 (36.8)		n/a	
Living arrangement			.925[b]		
Alone	15 (40.5)	15 (39.5)		n/a	
With spouse/relative(s)	22 (59.5)	23 (60.5)		n/a	
Current work status			.969[b]		
Back to work	8 (21.6)	8 (21.1)		n/a	
Not (fully) back	6 (16.2)	7 (18.4)		n/a	

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to work					
Retired	23 (62.2)	23 (60.5)		n/a	

Abbreviations: TIA = transient ischemic attack, n/a = not available. All data are expressed as n (%), except where specified. [a] *t*-test; [b] χ^2 test..

Construct validity

PROMIS-10 and RAND-36 physical and mental scores correlated significantly, $r = .81$, BCa CI [.69, .88], $p < .001$, and $r = .76$, BCa CI [.64, .85], $p < .001$, respectively (see figure 2). Figure 3 shows the Bland-Altman plots for PROMIS-10 and RAND-36 physical and mental health. The continuous line represents the mean difference and the dotted lines represent the 95% levels of agreement between both measures.

Figure 2. Scatterplots of PROMIS-10 and RAND-36 physical (**A**) and mental health scores (**B**).

[Insert Figure 2.]

Figure 3. Bland-Altman plots of PROMIS-10 and RAND-36 physical (**A**) and mental health scores (**B**).

[Insert Figure 3.]

When scores for the PROMIS-10 PH and MH were divided between 'paper-and-pencil' and 'telephone' groups, correlation between the PROMIS-10 and RAND-36 physical and mental health increased in the 'paper-and-pencil' group and decreased in the 'telephone' group. The results are summarized in table 2. Mean PH score was lower in the 'paper-and-pencil' group than in the 'telephone' group. This difference was not statistically significant. The mean MH score was also lower in the 'paper-and-pencil' group than in the 'telephone' group. This difference however, was statistically significant. Mean scores of the RAND-36 PCS and MCS were not statistically significantly different among the two groups based on assessment method of PROMIS-10. The results are summarized in table 3.

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Table 2. Bivariate correlations between PROMIS-10 and RAND-36

	RAND-36		
	PCS	MCS	*n*
PROMIS-10			
PH	.82* [.70, .90]	—	71
MH	—	.70* [.57, .82]	73
PROMIS-10 (paper-and-pencil)			
PH	.88* [.78, .90]	—	33
MH	—	.70* [.54, .84]	35
PROMIS-10 (telephone)			
PH	.77* [.54, 91]	—	38
MH	—	.70* [.50, .86]	38

***p < .01. BCa bootstrap 95% CIs reported in brackets. Abbreviations: PCS = physical component score, MCS = mental component score, PH = physical health, MH = mental health.**

Table 3. Independent samples t-tests comparing PROMIS-10 and RAND-36, between 'paper-and-pencil' and 'telephone' group

	'Paper-and-pencil'		'Telephone'				
	Mean (*SD*)	*n*	Mean (*SD*)	*n*	95% CI for mean difference	*t*-value (df)	*p*-value
PROMIS-10 PH	44.1 (10.1)	34	47.2 (9.5)	38	-7.67, 1.57	-1.32 (70)	.192

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PROMIS-10 MH	45.6 (8.5)	36	53.4 (8.0)	38	-11.57, -3.90	-4.02 (72)	.001
RAND-36 PCS	48.7 (12.2)	36	51.0 (11.8)	38	-7.86, 3.27	-0.82 (72)	.414
RAND-36 MCS	34.7 (8.4)	36	37.7 (7.6)	38	-6.64, 0.80	-1.56 (72)	.122

Abbreviations: PH = physical health, MH = mental health, PCS = physical component score, MCS = mental component score.

Internal consistency

The PROMIS-10 demonstrated high reliabilities for both PH, Cronbach's α = .79, and MH, Cronbach's α = .83. Similar αs were observed for the PROMIS-10 assessed by paper-and-pencil and telephone: α = .82 and .81 for PH and MH, respectively, in the 'paper-and-pencil' group; α = .77 and .80 for PH and MH, respectively, in the 'telephone' group.

Discussion

In this study we used the Dutch PROMIS-10 to assess QoL in patients at one year after TIA or minor stroke. Our results indicate an overall strong correlation between the PROMIS-10 and the RAND-36. QoL attributed to physical health was found to have a higher correlation than QoL attributed to mental health. This could be explained due to physical health tending to be more objective and less multidimensional in nature. Whereas mental health is generally more subjective and an exact cause is less easy to pinpoint, which makes mental health more prone to recall bias. Additionally, physical health tends to be more consistent over time, while mental health is more prone to fluctuations. As PROMIS-10 and RAND-36 measures self-reported health over a period in time, timing of assessment is more likely to affect mental health than physical health. Nonetheless, both correlations were within the range considered to be moderate to high. Visual inspection of Bland-Altman plots between PROMIS-10 and RAND-36 physical and mental health revealed no obvious trend or inconsistent variability.

Subsequently, we compared two assessment methods of the PROMIS-10. Both physical and mental health assessed by telephone, although slightly inferior to on-paper assessment, was found to have a strong correlation with on-paper assessed RAND-36. No studies were found that addressed the validity of telephone assessment of the PROMIS-10. Two studies however, evaluated telephone assessment of other PROMIS measures [22,23]. In line with our results, both studies provide support for telephone assessment. One of the studies compared telephone to self-administered assessment; aside from small mode effects most likely related to study design, no

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apparent differences were reported as was found in our study [23]. In our study we suspect that lack of visual support when choosing a score within a range might have been contributing to a lower correlation. Other noted caveats in telephone assessment in our study were hesitation, choosing scores in between, and the tendency to substantiate choices during assessment.

When comparing PROMIS-10 and RAND-36 scores between the 'paper-and-pencil' and 'telephone' group, it is notable that scores of the on paper assessed RAND-36 were similar in both physical and mental health, whereas PROMIS-10 scores were significantly higher (i.e. better) in the 'telephone' group compared to the 'paper-and-pencil' group. We speculate that patients could be inclined to appear better, answer more socially desirable, and are less inclined to open up about mental problems in a direct telephone interview as opposed to on-paper assessment. This speculation can be supported by findings by Perkins et al. (1998) and Erhart et al. (2009), who reported statistical significant differences for mental health components in favour of telephone assessment, compared to self-administration by mail [24,25].

Gender could be another possible contributing factor for the observed difference in mental health in our two groups; although not significant, there were slightly more women in our 'telephone' group compared to the 'paper-and-pencil' group. However, mental health was found to be similar when comparing gender. In addition, Muus et al. (2010), who studied a similar population, reported that women tend to have ischemic stroke at a higher age and have more severe strokes compared to men [4]. Rather, an opposite result (i.e. higher scores in the 'telephone' group, compared to 'paper-and-pencil' group) would then be expected in our study. The difference in mental health between our 'telephone' and 'paper-and-pencil' group is therefore not likely to be attributable to gender.

Other possible causes of the difference between our PROMIS-10 'telephone' and 'paper-and-pencil' group could be that the former group comprises of healthier patients. Although not significant, our 'telephone' group comprised of slightly more TIA patients, who are expected to have better outcomes than minor stroke patients. However, when taking diagnosis into account, physical and mental scores between the two groups did not significantly differ for both PROMIS-10 and RAND-36. The remaining patient characteristics obtained in this study were nearly identically distributed among both groups and are therefore unlikely to have confounded the results.

Limitations

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The generalizability of our results is reduced due to our small sample size. Moreover, our study population does not cover the full range of stroke patients. Aside from exclusion of major stroke, as our target population were TIA and minor stroke patients, a large number of patients were not included as referral to the BAC based on symptoms was not indicated. Nonetheless, these relatively mildly affected patients still represent part of our target population. The same applies to patients who were excluded due to an insufficient proficiency in Dutch. In contrast to generalizability, these limitations should barely affect our results, as patient characteristics were similar among the included patients and the non-respondents.

Noteworthy is the mean (*SD*) of 12.5 (7.6) days between assessment of RAND-36 on paper and assessment of PROMIS-10 by telephone in our 'telephone' group. On the other hand, on paper assessment of the PROMIS-10 is (assumed to be) completed on the same day. Health status might change over these few days. Moreover, three items of PROMIS-10 are concerned with the past seven days (fatigue, emotional problems, and pain).

Timing of measurement of health status in stroke should also be taken into account. We assessed the PROMIS-10 at one year post-stroke, in contrast to the 3 months post-stroke proposed by the ICHOM consensus group [13]. In our current study one year post-stroke was chosen based on the results of Mierlo et al. (2016), who reported improvement of quality of life occurring up to one year after stroke, with most changes occurring within the first six months [16]. Another limitation is that there is no information regarding test-retest reliability of PROMIS-10 as is was only assessed at one time point.

Lastly, possible confounding factors such as individual personality traits, extent of social support, socio-economic status and ethnicity was not accounted for in this study, while these factors undoubtedly impact self-reported quality of life.

Conclusions

This study provides support for the use of the Dutch version of the PROMIS-10 in patients after minor stroke or TIA in the Netherlands. Despite satisfactory validity of telephone assessment, careful interpretation is advised, especially when addressing mental health status. Additional data and further research with the PROMIS-10 in stroke patients is desirable for establishing more firm results.

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Contributorship statement

K.H. Lam and V.I.H. Kwa state that the following criteria for contributorship, in accordance to the ICMJE criteria for authorship, are met:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

- Drafting the work or revising it critically for important intellectual content; AND

- Final approval of the version to be published; AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work the authors have done, all authors are able to identify which co-authors are responsible for specific other parts of the work. In addition, the authors have confidence in the integrity of the contributions of our co-authors.

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Competing interests

The authors declare that they have no competing interests.

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Data sharing statement

Individual participant data collected during the study that underlie the results reported in the manuscript, after deidentification (text, tables and figures), will be available for data sharing. The data will be available immediately

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after publication and ends 36 months after publication. The data will be available to investigators whose proposed use of the data has been approved by an independent review committee. Up to 36 months after publication, the data can be requested and accessed electronically.

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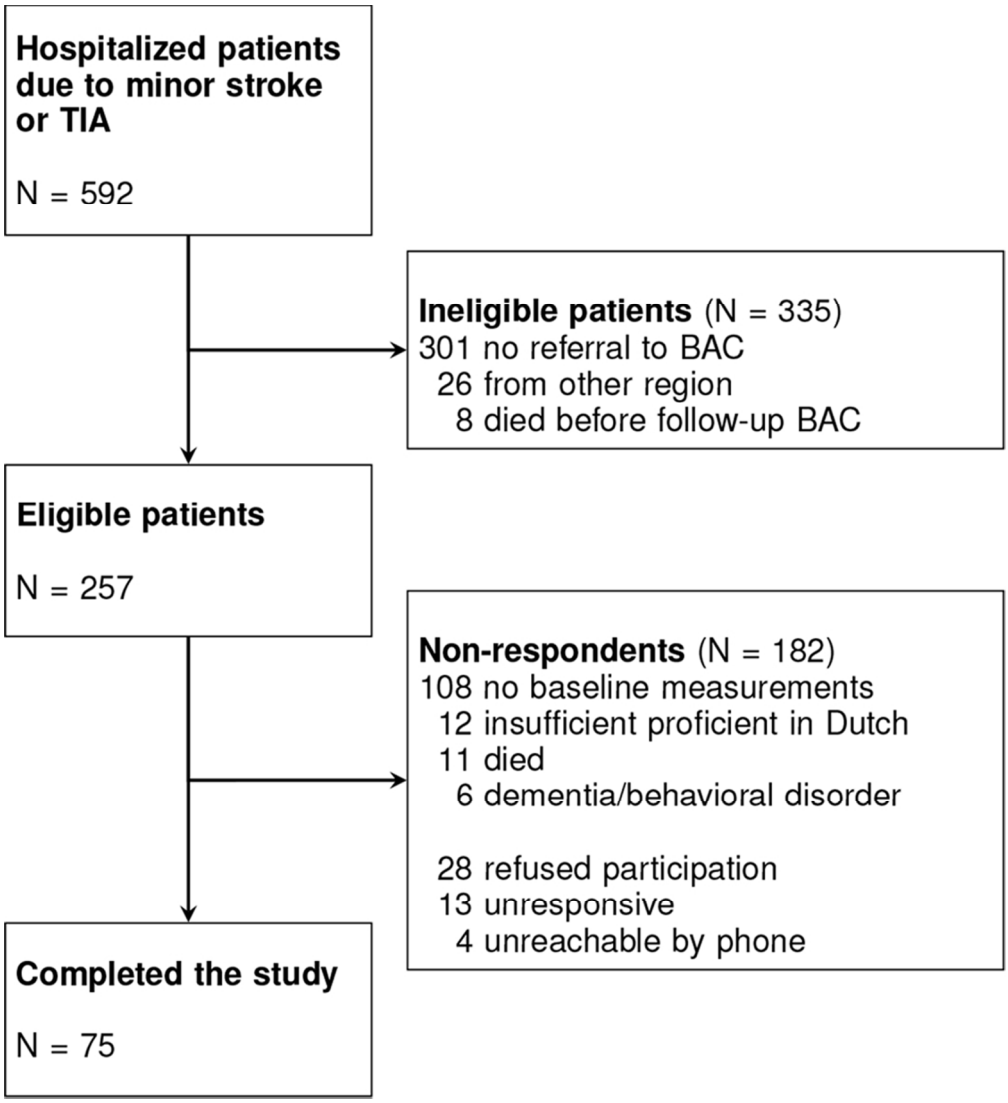

Figure 1. Flow chart of the study population

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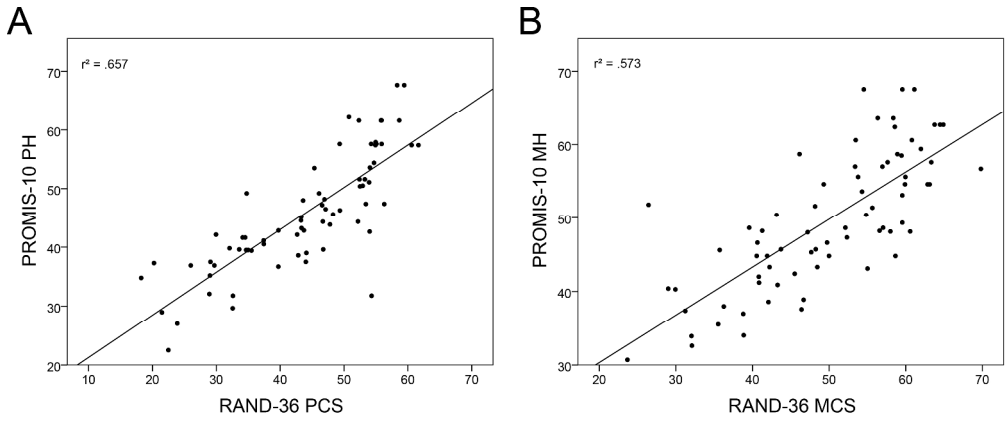

Figure 2. Scatterplots of PROMIS-10 and RAND-36 physical (A) and mental health scores (B).

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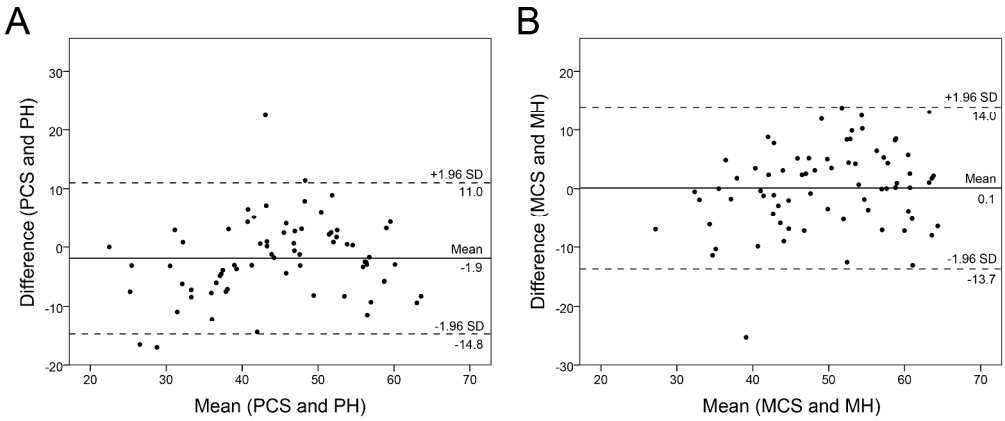

Figure 3. Bland-Altman plots of PROMIS-10 and RAND-36 physical (A) and mental health scores (B).

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2	"Design: Observational cohort study."
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2	"PROMIS-10 was found to strongly correlate with the RAND-36. Paper-and-pencil assessment was found to have a higher correlation than telephone assessment. This study provides support for the use of the Dutch PROMIS-10 in assessing health status in patients after TIA and minor stroke."
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported		"… previous studies in TIA and minor stroke patients found high prevalence of dysfunction across all domains of health, of which cognitive and emotional problems were most notable [3-6]. These symptoms may be overlooked with conventional clinical measures such as the neurological examination or the Barthel Index, but can be a major contributor to an impaired

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				performance of activities of daily living and a diminished quality of life (QoL)"
Objectives	3	State specific objectives, including any prespecified hypotheses	4	"… to investigate the construct validity and reliability of the Dutch PROMIS-10 in TIA and minor stroke patients in the Netherlands. We also aim to evaluate different assessment methods of the PROMIS-10: on paper (filled in by the patient) assessment versus assessment through the telephone."
Methods				
Study design	4	Present key elements of study design early in the paper	4	"… single-centre observational cohort study …"
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4	"… at OLVG Oost hospital. Between January 2016 and January 2017 medical records of patients diagnosed with a TIA or minor stroke one year ago were screened for eligibility …" "Eligible patients were approached by telephone for study participation. (…) study materials were sent by mail; study information, consent form, PROMIS-10, RAND-36 (…), and a short form for obtaining socio-demographic

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				data. PROMIS-10 was assessed on paper from January 1 to July 31, 2016 and by telephone from August 1, 2016 to January 31, 2017. On paper assessments of the PROMIS-10 and RAND-36 were completed by the patients at home on their own or with help of a proxy. Telephone assessments of the PROMIS-10 were carried out by reading out the exact questions and marking the given answers. Clinical data were extracted from medical records."
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4	"Eligibility included a clinical diagnosis of TIA or minor stroke followed by discharge without inpatient rehabilitation treatment. (…) TIA and minor stroke were defined as (…) symptoms of stroke on admission that fully resolves within 24 hours and three days, respectively." "Exclusion criteria were: age below 18 years, persistent neurological symptoms three days post-stroke, insufficient proficiency in Dutch, dementia or any behavioural disorder …"

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		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	n/a	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4, 5	"PROMIS-10 (…) Physical health (PH) and mental health (MH) T-scores" "RAND-36 (…) physical (PCS) and mental (MCS) component score." "marital status, level of education ((…) low (primary school), average (secondary school low or medium level), and high (highest level secondary school, and/or college degree, and/or university degree) [20], living arrangement, and work status." "… clinical diagnosis of TIA or minor stroke followed by discharge without inpatient rehabilitation treatment. MRI is not part of the standard diagnostic work-up of stroke but was performed whenever other causes than ischemia could not be ruled out. For this study TIA and minor stroke were defined as acute neurological deficits

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				with symptoms of stroke on admission that fully resolves within 24 hours and three days, respectively."
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4	"Clinical data were extracted from medical records." "On paper assessments of the PROMIS-10 and RAND-36 were completed by the patients at home on their own or with help of a proxy. Telephone assessments of the PROMIS-10 were carried out by reading out the exact questions and marking the given answers."
Bias	9	Describe any efforts to address potential sources of bias	4, 5	"Between January 2016 and January 2017 medical records of patients diagnosed with a TIA or minor stroke one year ago were screened for eligibility" "Eligibility included a clinical diagnosis of TIA or minor stroke followed by discharge without inpatient rehabilitation treatment. (…) TIA and minor stroke were defined as (…) symptoms of stroke on admission that fully resolves within 24 hours and three days, respectively."

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				"If during the re-evaluation residual or new symptoms are present or suspected, patients are referred to the Beroerte Adviescentrum (…) patients who were not referred to the BAC or did not complete baseline measurements were deemed ineligible." "On paper assessments of the PROMIS-10 and RAND-36 were completed by the patients at home on their own or with help of a proxy. Telephone assessments of the PROMIS-10 were carried out by reading out the exact questions and marking the given answers. Clinical data were extracted from medical records." "Socio-demographic data collected were: marital status, level of education (…),living arrangement, and work status."
Study size	10	Explain how the study size was arrived at	4	"Between January 2016 and January 2017 medical records of patients diagnosed with a TIA or minor stroke one year ago were screened for eligibility"

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Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5	"Numerical variables were summarized by the mean ± SD, and frequencies and percentages were used for binary and categorical variables."
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5, 6	"… correlation between PROMIS-10 and RAND-36 was assessed by calculating Pearson's correlation coefficient (r), with a bias corrected and accelerated bootstrapping (BCa) method providing 95% confidence intervals. Agreement between PROMIS-10 and RAND-36 was assessed by constructing Bland-Altman plots with horizontal lines representing 95% limits of agreement (LOA) (mean difference ±1.96 SD). (…)For the internal consistency of the PROMIS-10, reliability analysis was used to calculate Cronbach's αs for both physical (4 items) and mental (4 items) subscales. A cut-off point of ≥ .70 was chosen for indication of good reliability (α) and correlation (r) [21]. A p-value of < .05 was considered to be statistically significant.
		(*b*) Describe any methods used to examine subgroups and interactions	5, 6	"Differences in patient characteristics were assessed using the independent samples *t*-test and χ^2 test."

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				"An independent samples t-test was performed for assessing differences between assessment methods of the PROMIS-10. "
		(*c*) Explain how missing data were addressed	6	"… two had missing values in the physical total score, and one in both physical and mental total score of the PROMIS-10, another patient had missing values in both component scores of the RAND-36."
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n/a	n/a
		(*e*) Describe any sensitivity analyses	n/a	n/a
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6	"… 592 patients were identified who were diagnosed with a TIA or minor stroke one year prior to the assessment (…) 301 patients were not referred to BAC for follow-up care, 26 patients originated from a different region or country, and 8 died before BAC follow-up. Of the remaining 257 eligible patients, 182 were non-respondents (108 had no baseline measurements, 12 were insufficient proficient in Dutch, 11 died before follow-up at one year

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				post-stroke, 6 had dementia or a behavioural disorder, 28 refused participation, 13 were not responsive after initial consent, and 4 were not reachable by phone) and 75 patients were included for the study …"
		(b) Give reasons for non-participation at each stage	6	"… 301 patients were not referred to BAC for follow-up care, 26 patients originated from a different region or country, and 8 died before BAC follow-up. " "… 108 had no baseline measurements, 12 were insufficient proficient in Dutch, 11 died before follow-up at one year post-stroke, 6 had dementia or a behavioural disorder, 28 refused participation, 13 were not responsive after initial consent, and 4 were not reachable by phone…"
		(c) Consider use of a flow diagram	6	"Figure 1. Flow chart of the study population"
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6	"Of the 75 included patients, mean age was 68.9 ± 11.2 years, 51 (68.0%) were male, 60 (80.0%) had their first-ever ischemic event, 49 (65.3%) had the diagnosis minor stroke and 26 (34.7%) TIA. The ischemic event was located in the

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				left hemisphere in 30 (40.0%) patients, 23 (30.7%) in the right hemisphere, and 22 (29.3%) were vertebrobasilar."
		(b) Indicate number of participants with missing data for each variable of interest	6	"… two had missing values in the physical total score, and one in both physical and mental total score of the PROMIS-10, another patient had missing values in both component scores of the RAND-36."
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	7	"Days between onset and follow-up, mean (*SD*)"
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	6	"Mean (SD) scores for the PROMIS-10 were 45.8 (9.9) for PH, and 49.6 (9.1) for MH. Scores for the RAND-36 were 43.7 (11.4) for PCS, and 49.9 (10.7) for MCS."
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		
		Cross-sectional study—Report numbers of outcome events or summary measures		
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8	"PROMIS-10 and RAND-36 physical and mental scores correlated significantly, r = .81, BCa CI [.69, .88], p < .001, and r = .76, BCa CI [.64, .85], p < .001, respectively …"
		(*b*) Report category boundaries when continuous variables were categorized	5	"… level of education (assessed on the Dutch 7-point scale 'schaal van Verhage', and afterwards stratified into three groups: low (primary school), average (secondary school

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			low or medium level), and high (highest level secondary school, and/or college degree, and/or university degree) [20], …"
	(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a	n/a

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Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11, 12	"… mental health was found to be similar when comparing gender." "However, when taking diagnosis into account, physical and mental scores between the two groups did not significantly differ for both PROMIS-10 and RAND-36."
Discussion				
Key results	18	Summarise key results with reference to study objectives	10, 11	"… overall strong correlation between the PROMIS-10 and the RAND-36. QoL attributed to physical health was found to have a higher correlation than QoL attributed to mental health." "… we compared two assessment methods of the PROMIS-10. Both physical and mental health assessed by telephone, although slightly inferior to on-paper assessment, was found to have a strong correlation with on-paper assessed RAND-36."
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12, 13	"… small sample size …" "… mean (*SD*) of 9.4 (14.7) days between assessment of RAND-36 on paper and assessment of PROMIS-10 by telephone …"

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				"… no information regarding test-retest reliability of PROMIS-10 as is was only assessed at one time point." "… confounding factors such as individual personality traits, extent of social support, socio-economic status and ethnicity was not accounted for in this study, while these factors undoubtedly impact self-reported quality of life."
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13	"… support for the use of the Dutch version of the PROMIS-10 in patients after minor stroke or TIA in the Netherlands. Despite satisfactory validity of telephone assessment, careful interpretation is advised, especially when addressing mental health status. Additional data and further research with the PROMIS-10 in stroke patients is desirable for establishing more firm results."
Generalisability	21	Discuss the generalisability (external validity) of the study results	12	"The generalizability of our results is reduced due to our small sample size." "Timing of measurement of health status in stroke should also be taken into account. We assessed the PROMIS-10 at one year post-

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				stroke…"
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14	"This research is funded by the Foundation Teaching Hospital OLVG, Amsterdam."

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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BMJ Open

Validity of the PROMIS-10 Global Health assessed by telephone and on paper in minor stroke and transient ischemic attack in the Netherlands

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Title

Validity of the PROMIS-10 Global Health assessed by telephone and on paper in minor stroke and transient ischemic attack in the Netherlands

Running title

PROMIS-10 in minor stroke and transient ischemic attack

Authors

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Abstract

Objectives: Dysfunction after transient ischemic attack (TIA) and minor stroke is often underestimated by clinical measures. Patient-reported outcome measures used in value-based healthcare may help detecting these problems. The PROMIS-10 Global Health is a concise patient-centered outcome measuring tool proposed for assessing health status in stroke patients. This study aims to address the validity of the Dutch PROMIS-10 in stroke patients in the Netherlands and also aims to compare telephone versus on-paper assessment.

Design: Observational cohort study.

Setting: Single-centre hospital in the Netherlands.

Participants: 75 patients who were diagnosed with TIA or minor stroke and discharged without rehabilitation treatment one year ago (between December 2014 and January 2016) completed the study.

Primary and secondary outcome measures

PROMIS-10 physical and mental health scores assessed one year post-stroke on paper (n = 37) and by telephone (n = 38) was compared to RAND-36 physical and mental component scores assessed on paper.

Results: PROMIS-10 and RAND-36 correlated significantly in physical health, r = .81, 95% CI [.69, .88], and mental health, r = .76, 95% CI [.64, .85]. Paper-and-pencil assessed correlations were r = .87 and .79 for physical and mental health, respectively. Telephone assessed correlations were r = .76 and .73 for physical and mental health, respectively. Internal consistency analysis indicated high reliabilities for both health components of the PROMIS-10, all Cronbach's αs > .70.

Conclusions: The Dutch PROMIS-10 was found to strongly correlate with the RAND-36. Paper-and-pencil assessment was found to have a higher correlation than telephone assessment. This study provides support for the use of the Dutch PROMIS-10 in assessing health status in patients after TIA and minor stroke.

Strengths and limitations of this study

- This is the first study that addresses the PROMIS-10 as measuring tool for health status in TIA and minor stroke patients in the Netherlands.
- Subjects were very similarly distributed in terms of clinical and socioeconomic factors between different comparator groups.
- Generalizability of the study results is reduced due to a relatively small sample size.

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- There was a time window between assessment of paper-based RAND-36 and telephone-based PROMIS-10.
- PROMIS-10 was assessed at one time point only; this study provides no insight on test-retest reliability of the PROMIS-10.

Keywords: quality of life, patient-reported outcomes, stroke, transient ischemic attack

Introduction

Following a stroke many patients experience persistent deficits and reduced functional independence [1], while full recovery is assumed in TIA and minor stroke patients who are discharged to home without further rehabilitation treatment [2]. However, previous studies in TIA and minor stroke patients found high prevalence of dysfunction across all domains of health, of which cognitive and emotional problems were most notable [3-6]. These symptoms may be overlooked with conventional clinical measures such as the neurological examination or the Barthel Index, but can be a major contributor to an impaired performance of activities of daily living and a diminished quality of life (QoL) [2,7-9]. This emphasizes the importance of patient-reported outcomes (PROs), which measure health status reported directly from the patient [10]. Measuring PROs is also an essential principal in the emerging value-based healthcare [11]. As such, health measurement is shifting from process measurement towards outcome measurement to improve quality while reducing costs [12]. This initiated the proposal of a Stroke Standard Set for measuring health in stroke by the International Consortium for Health Outcomes Measurement (ICHOM) [13]. The expert group recommends the Patient Reported Outcomes Measurement Information System 10-Question Short Form (PROMIS-10 Global Health) for assessing health status after stroke [14]. The PROMIS-10 has been translated into Dutch by the Dutch-Flemish PROMIS group (http://www.dutchflemishpromis.nl), but has not yet been validated or compared with existing validated instruments in stroke patients [15].

Aims

This study aims to investigate the construct validity and reliability of the Dutch PROMIS-10 in TIA and minor stroke patients in the Netherlands. We also aim to evaluate different assessment methods of the PROMIS-10: on paper (filled in by the patient) assessment versus assessment through the telephone. As telephone assessment might be more feasible in the population of stroke patients, which mainly consists of elderly patients.

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Methods

Study design

This single-centre observational cohort study was part of a concurrent quality of life study at OLVG Oost hospital. Between January 2016 and January 2017 medical records of patients diagnosed with a TIA or minor stroke one year ago were screened for eligibility, as Mierlo et al. (2016) reported improvement of quality of life occurring the most in the first six months and up to one year after stroke [16]. Eligible patients were approached by telephone for study participation. Following verbal consent to study participation, study materials were sent by mail; study information, consent form, PROMIS-10, RAND-36 (a health-related quality of life measure), and a short form for obtaining socio-demographic data. PROMIS-10 was assessed on paper from January 1 to July 31, 2016 and by telephone from August 1, 2016 to January 31, 2017. On paper assessments of the PROMIS-10 and RAND-36 were completed by the patients at home on their own or with help of a proxy. Telephone assessments of the PROMIS-10 were carried out by reading out the exact questions and marking the given answers. Clinical data were extracted from medical records. Full ethical approval was given by the Medical Research Ethics Committees United (MEC-U), Nieuwegein. Informed consent was obtained from all individual participants included in the study. Clinical data (age, gender, diagnosis, stroke localization and incidence) of non-participating and excluded eligible patients were recorded in a non-identifiable manner without requiring consent.

Subjects

Eligibility included a clinical diagnosis of TIA or minor stroke followed by discharge without inpatient rehabilitation treatment. MRI is not part of the standard diagnostic work-up of stroke but was performed whenever other causes than ischemia could not be ruled out. For this study TIA and minor stroke were defined as acute neurological deficits with symptoms of stroke on admission that fully resolves within 24 hours and three days, respectively.

As standard practice TIA and stroke patients discharged to home are re-evaluated shortly after discharge by a specialized stroke nurse. If during the re-evaluation residual or new symptoms are present or suspected, patients are referred to the Beroerte Adviescentrum (BAC, 'Stroke Advice Centre'), a central body that coordinates and effectuates outpatient care for stroke patients. As the BAC measures baseline health status, which is an inclusion

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criterion for the concurrent QoL study, patients who were not referred to the BAC or did not complete baseline measurements were deemed ineligible.

Exclusion criteria were: age below 18 years, persistent neurological symptoms three days post-stroke, insufficient proficiency in Dutch, dementia or any behavioural disorder that may compromise study participation.

Measures

The PROMIS-10 is a 10-item measure for self-reported QoL, physical health, and mental health. It has been shown to be reliable, precise and comparable to legacy instruments [17]. Physical health (PH) and mental health (MH) T-scores can be calculated through an online scoring service provided by Assessment Center (www.assessmentcenter.net/ac_scoringservice). The T-score distributions are standardized with mean (*SD*) of 50 (10) for the United States' (US) general population, where higher scores indicate better outcome. In this study a Dutch version of the PROMIS-10 was used [15]. As standardized scores for the Netherlands are unavailable, T-scores were calculated using the US population standard scores.

The RAND-36 (identical to the SF-36) is a widely used QoL measure, comprising of 36 items covering a wide range of health domains [18]. Two component scores can be derived: physical (PCS) and mental (MCS) component score. PCS and MCS are standardized with mean (*SD*) of 50 (10), with higher scores reflecting better outcome. The RAND-36 has been translated and validated into multiple languages, including Dutch [19]. In this study the Dutch RAND-36 version 2 was used. However, PCS and MCS were calculated using US-standardized weights for a more equal comparison to the PROMIS-10, which was calculated similarly.

Socio-demographic data collected were: marital status, level of education (assessed on the Dutch 7-point scale 'schaal van Verhage', and afterwards stratified into three groups: low (primary school), average (secondary school low or medium level), and high (highest level secondary school, and/or college degree, and/or university degree) [20], living arrangement, and work status.

Data analysis

Numerical variables were summarized by the mean ± *SD*, and frequencies and percentages were used for binary and categorical variables. Differences in patient characteristics were assessed using the independent samples *t*-test and χ^2 test for continuous and categorical variables, respectively. For assessing construct validity, correlation between

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PROMIS-10 and RAND-36 was assessed by calculating Pearson's correlation coefficient (*r*), with a bias corrected and accelerated bootstrapping (BCa) method providing 95% confidence intervals. Agreement between PROMIS-10 and RAND-36 was assessed by constructing Bland-Altman plots with horizontal lines representing the mean difference and 95% limits of agreement (LOA) (mean difference ±1.96 SD) [21]. An independent samples *t*-test was performed for assessing differences between assessment methods of the PROMIS-10. For the internal consistency of the PROMIS-10, reliability analysis was used to calculate Cronbach's αs for both physical (4 items) and mental (4 items) subscales. A cut-off point of ≥ .70 was chosen for indication of good reliability (α) and correlation (*r*) [22]. A *p*-value of < .05 was considered to be statistically significant. All statistical analysis was performed using IBM SPSS version 22.

Patient and public involvement

The development of the research question was based on earlier research on patients' experience of our care after a TIA or minor stroke. Many patients had hidden signs and symptoms that were not recognized by doctors at first sight. We are now developing 'Value-based healthcare' with help of patient related outcome measures like the one that is investigated in this study, to be able to detect these hidden signs and symptoms. In the informed consent form we stated that after the end of the study we will send a letter to the participants to inform them about the results of the study.

Results

A total of 592 patients were identified who were diagnosed with a TIA or minor stroke one year prior to the assessment (from December 2014 to January 2016). Following re-evaluation by their physician, 301 patients were not referred to BAC for follow-up care, 26 patients originated from a different region or country, and 8 died before BAC follow-up. Of the remaining 257 eligible patients, 182 were non-respondents (108 had no baseline measurements, 12 were insufficient proficient in Dutch, 11 died before follow-up at one year post-stroke, 6 had dementia or a behavioural disorder, 28 refused participation, 13 were not responsive after initial consent, and 4 were not reachable by phone) and 75 patients were included for the study (see figure 1).

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Figure 1. Flow chart of the study population

[insert figure 1.]

Of the 75 included patients, mean age was 68.9 ± 11.2 years, 51 (68.0%) were male, 60 (80.0%) had their first-ever ischemic event, 49 (65.3%) had the diagnosis minor stroke and 26 (34.7%) TIA. The ischemic event was located in the left hemisphere in 30 (40.0%) patients, 23 (30.7%) in the right hemisphere, and 22 (29.3%) were vertebrobasilar. There were no statistically significant differences between the study population and the non-respondents. Mean (*SD*) scores for the PROMIS-10 were 45.8 (9.9) for PH, and 49.6 (9.1) for MH. Scores for the RAND-36 were 43.7 (11.4) for PCS, and 49.9 (10.7) for MCS.

In 37 patients the PROMIS-10 and RAND-36 were assessed on paper; two had missing values in the physical total score, and one in both physical and mental total score of the PROMIS-10, another patient had missing values in both component scores of the RAND-36. These 37 patients formed the 'paper-and-pencil group'. 38 patients completed the PROMIS-10 by telephone (and the RAND-36 on paper), these patients formed the 'telephone group'. Patient characteristics of both groups are summarized in table 1. No statistically significant differences were observed between the two groups.

Table 1. Patient characteristics between the study population (n = 75, divided in 'paper-and-pencil' and 'telephone' group) and non-respondents (n = 182)

Characteristic	Study population (*n* = 75)			Non-respondents (*n* = 182)	*p*-value
	'Paper-and-pencil' (*n* = 37)	'Telephone' (*n* = 38)	*p*-value		
Days between onset and follow-up, mean (*SD*)	374.8 (59.7)	375.7 (30.7)		n/a	
Age, y, mean (*SD*)	67.4 (9.9)	70.4 (12.2)	.258[a]	68.5 (12.2)	.810[a]
Gender			.160[b]		.053[b]
Female	9 (24.3)	15 (39.5)		82 (45.1)	
Male	28 (75.7)	23 (60.5)		100 (54.9)	
Diagnosis			.170[b]		.086[b]

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TIA	10 (27.0)	16 (42.1)		44 (24.2)	
Minor stroke	27 (73.0)	22 (57.9)		138 (75.8)	
Localization			.921[b]		.683[c]
Right hemisphere	12 (32.4)	11 (28.9)		51 (28.0)	
Left hemisphere	14 (37.8)	16 (42.1)		77 (42.3)	
Vertebrobasilar	11 (29.7)	11 (28.9)		47 (25.8)	
Ocular	0 (0.0)	0 (0.0)		3 (1.6)	
Other/unknown	0 (0.0)	0 (0.0)		4 (2.2)	
Stroke incidence			.729[b]		.469[b]
First ever	29 (78.4)	31 (81.6)		138 (75.8)	
Relapse	8 (21.6)	7 (18.4)		44 (24.2)	
Marital status			.999[c]		
Married	22 (59.5)	22 (57.9)		n/a	
Unmarried	13 (35.1)	14 (36.8)		n/a	
Widowed	2 (5.4)	2 (5.3)		n/a	
Education			.532[c]		
Low	5 (13.9)	3 (7.9)		n/a	
Average	16 (44.4)	21 (55.3)		n/a	
High	15 (41.7)	14 (36.8)		n/a	
Living arrangement			.925[b]		
Alone	15 (40.5)	15 (39.5)		n/a	
With spouse/relative(s)	22 (59.5)	23 (60.5)		n/a	
Current work status			.969[b]		
Back to work	8 (21.6)	8 (21.1)		n/a	
Not (fully) back to work	6 (16.2)	7 (18.4)		n/a	

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Retired	23 (62.2)	23 (60.5)		n/a	

Abbreviations: TIA = transient ischemic attack, n/a = not available. All data are expressed as n (%), except where specified. [a] *t*-test; [b] χ^2 test; [c] Fisher's Exact test.

Construct validity

PROMIS-10 and RAND-36 physical and mental scores correlated significantly, $r = .81$, BCa CI [.69, .88], $p < .001$, and $r = .76$, BCa CI [.64, .85], $p < .001$, respectively (see figure 2). Figure 3 shows the Bland-Altman plots for PROMIS-10 and RAND-36 physical and mental health. The mean difference between the measures were -1.9 and 0.1 for physical health and mental health, respectively. For both physical and mental health, the paired differences and averages were fairly evenly scattered within the upper and lower LOA.

Figure 2. Scatterplots of PROMIS-10 and RAND-36 physical (**A**) and mental health scores (**B**).

[Insert Figure 2.]

Figure 3. Bland-Altman plots of PROMIS-10 and RAND-36 physical (**A**) and mental health scores (**B**). The mean of both measures (x-axis) was plotted against their difference (y-axis). The continuous line represents the mean difference and the dashed lines represent the 95% limits of agreement.

[Insert Figure 3.]

When scores for the PROMIS-10 PH and MH were divided between 'paper-and-pencil' and 'telephone' groups, correlation between the PROMIS-10 and RAND-36 physical and mental health increased in the 'paper-and-pencil' group and decreased in the 'telephone' group. The results are summarized in table 2. Mean PH score was lower in the 'paper-and-pencil' group than in the 'telephone' group. This difference was not statistically significant. The mean MH score was also lower in the 'paper-and-pencil' group than in the 'telephone' group. This difference however, was statistically significant. Mean scores of the RAND-36 PCS and MCS were not statistically significantly different among the two groups based on assessment method of PROMIS-10. The results are summarized in table 3.

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Table 2. Bivariate correlations between PROMIS-10 and RAND-36

	RAND-36		
	PCS	MCS	*n*
PROMIS-10			
PH	.82* [.70, .90]	—	71
MH	—	.70* [.57, .82]	73
PROMIS-10 (paper-and-pencil)			
PH	.88* [.78, .93]	—	33
MH	—	.70* [.54, .84]	35
PROMIS-10 (telephone)			
PH	.77* [.54, 91]	—	38
MH	—	.70* [.50, .86]	38

***p < .01. BCa bootstrap 95% CIs reported in brackets. Abbreviations: PCS = physical component score, MCS = mental component score, PH = physical health, MH = mental health.**

Table 3. Independent samples t-tests comparing PROMIS-10 and RAND-36, between 'paper-and-pencil' and 'telephone' group

	'Paper-and-pencil'		'Telephone'				
	Mean (*SD*)	*n*	Mean (*SD*)	*n*	95% CI for mean difference	*t*-value (df)	*p*-value
PROMIS-10 PH	44.1 (10.1)	34	47.2 (9.5)	38	-7.67, 1.57	-1.32 (70)	.192

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PROMIS-10 MH	45.6 (8.5)	36	53.4 (8.0)	38	-11.57, -3.90	-4.02 (72)	.001
RAND-36 PCS	48.7 (12.2)	36	51.0 (11.8)	38	-7.86, 3.27	-0.82 (72)	.414
RAND-36 MCS	34.7 (8.4)	36	37.7 (7.6)	38	-6.64, 0.80	-1.56 (72)	.122

Abbreviations: PH = physical health, MH = mental health, PCS = physical component score, MCS = mental component score.

Internal consistency

The PROMIS-10 demonstrated high reliabilities for both PH, Cronbach's α = .79, and MH, Cronbach's α = .83. Similar αs were observed for the PROMIS-10 assessed by paper-and-pencil and telephone: α = .82 and .81 for PH and MH, respectively, in the 'paper-and-pencil' group; α = .77 and .80 for PH and MH, respectively, in the 'telephone' group.

Discussion

In this study we used the Dutch PROMIS-10 to assess QoL in patients at one year after TIA or minor stroke. Our results indicate an overall strong correlation between the PROMIS-10 and the RAND-36. QoL attributed to physical health was found to have a higher correlation than QoL attributed to mental health. This could be explained due to physical health tending to be more objective and less multidimensional in nature. Whereas mental health is generally more subjective and an exact cause is less easy to pinpoint, which makes mental health more prone to recall bias. Additionally, physical health tends to be more consistent over time, while mental health is more prone to fluctuations. As PROMIS-10 and RAND-36 measures self-reported health over a period in time, timing of assessment is more likely to affect mental health than physical health. Nonetheless, both correlations were within the range considered to be moderate to high. Bland-Altman plots demonstrated good agreement between PROMIS-10 and RAND-36. The average discrepancy between PROMIS-10 and RAND-36 was small and not clinically relevant. Visual inspection of Bland-Altman plots between PROMIS-10 and RAND-36 physical and mental health revealed no obvious trend or inconsistent variability.

Subsequently, we compared two assessment methods of the PROMIS-10. Both physical and mental health assessed by telephone, although slightly inferior to on-paper assessment, was found to have a strong correlation with on-paper assessed RAND-36. No studies were found that addressed the validity of telephone assessment of the PROMIS-10. Two studies however, evaluated telephone assessment of other PROMIS measures

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[23,24]. In line with our results, both studies provide support for telephone assessment. One of the studies compared telephone to self-administered assessment; aside from small mode effects most likely related to study design, no apparent differences were reported as was found in our study [24]. In our study we suspect that lack of visual support when choosing a score within a range might have been contributing to a lower correlation. Other noted caveats in telephone assessment in our study were hesitation, choosing scores in between, and the tendency to substantiate choices during assessment.

When comparing PROMIS-10 and RAND-36 scores between the 'paper-and-pencil' and 'telephone' group, it is notable that scores of the on paper assessed RAND-36 were similar in both physical and mental health, whereas PROMIS-10 mental health scores were significantly higher (i.e. better) in the 'telephone' group compared to the 'paper-and-pencil' group. This relatively small difference is most likely attributable to the small sample size. However, we also speculate that patients could be inclined to appear better, answer more socially desirable, and are less inclined to open up about mental problems in a direct telephone interview as opposed to on-paper assessment. This speculation can be supported by findings by Perkins et al. (1998) and Erhart et al. (2009), who reported statistical significant differences for mental health components in favour of telephone assessment, compared to self-administration by mail [25,26].

Other possible causes for the difference between our PROMIS-10 'telephone' and 'paper-and-pencil' group could be due to differences in diagnosis (TIA of minor stroke) or gender. However, subgroup analysis revealed no significant differences for both physical and mental health scores between the two groups for both PROMIS-10 and RAND-36. The remaining patient characteristics obtained in this study were nearly identically distributed among both groups and are therefore unlikely to have confounded the results.

Limitations

The generalizability of our results is reduced due to our small sample size. Moreover, our study population does not cover the full range of stroke patients. Aside from exclusion of major stroke, as our target population were TIA and minor stroke patients, a large number of patients were not included as referral to the BAC based on symptoms was not indicated. Nonetheless, these relatively mildly affected patients still represent part of our target population. The same applies to patients who were excluded due to an insufficient proficiency in Dutch. In contrast to

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generalizability, these limitations should barely affect our results, as patient characteristics were similar among the included patients and the non-respondents.

Noteworthy is the mean (*SD*) of 12.5 (7.6) days between assessment of RAND-36 on paper and assessment of PROMIS-10 by telephone in our 'telephone' group. On the other hand, on paper assessment of the PROMIS-10 is (assumed to be) completed on the same day. Health status might change over these few days. Moreover, three items of PROMIS-10 are concerned with the past seven days (fatigue, emotional problems, and pain).

Timing of measurement of health status in stroke should also be taken into account. We assessed the PROMIS-10 at one year post-stroke, in contrast to the 3 months post-stroke proposed by the ICHOM consensus group [13]. In our current study one year post-stroke was chosen based on the results of Mierlo et al. (2016), who reported improvement of quality of life occurring up to one year after stroke, with most changes occurring within the first six months [16]. Another limitation is that there is no information regarding test-retest reliability of PROMIS-10 as is was only assessed at one time point.

Lastly, possible confounding factors such as individual personality traits, extent of social support, socio-economic status and ethnicity was not accounted for in this study, while these factors undoubtedly impact self-reported quality of life.

Conclusions

This study provides support for the use of the Dutch version of the PROMIS-10 in patients after minor stroke or TIA in the Netherlands. Despite satisfactory validity of telephone assessment, careful interpretation is advised, especially when addressing mental health status. Additional data and further research with the PROMIS-10 in stroke patients is desirable for establishing more firm results.

Contributorship statement

K.H. Lam and V.I.H. Kwa state that the following criteria for contributorship, in accordance to the ICMJE criteria for authorship, are met:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

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- Drafting the work or revising it critically for important intellectual content; AND

- Final approval of the version to be published; AND

- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work the authors have done, all authors are able to identify which co-authors are responsible for specific other parts of the work. In addition, the authors have confidence in the integrity of the contributions of our co-authors.

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Competing interests

The authors declare that they have no competing interests.

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Data sharing statement

Individual participant data collected during the study that underlie the results reported in the manuscript, after deidentification (text, tables and figures), will be available for data sharing. The data will be available immediately after publication and ends 36 months after publication. The data will be available to investigators whose proposed use of the data has been approved by an independent review committee. Up to 36 months after publication, the data can be requested and accessed electronically.

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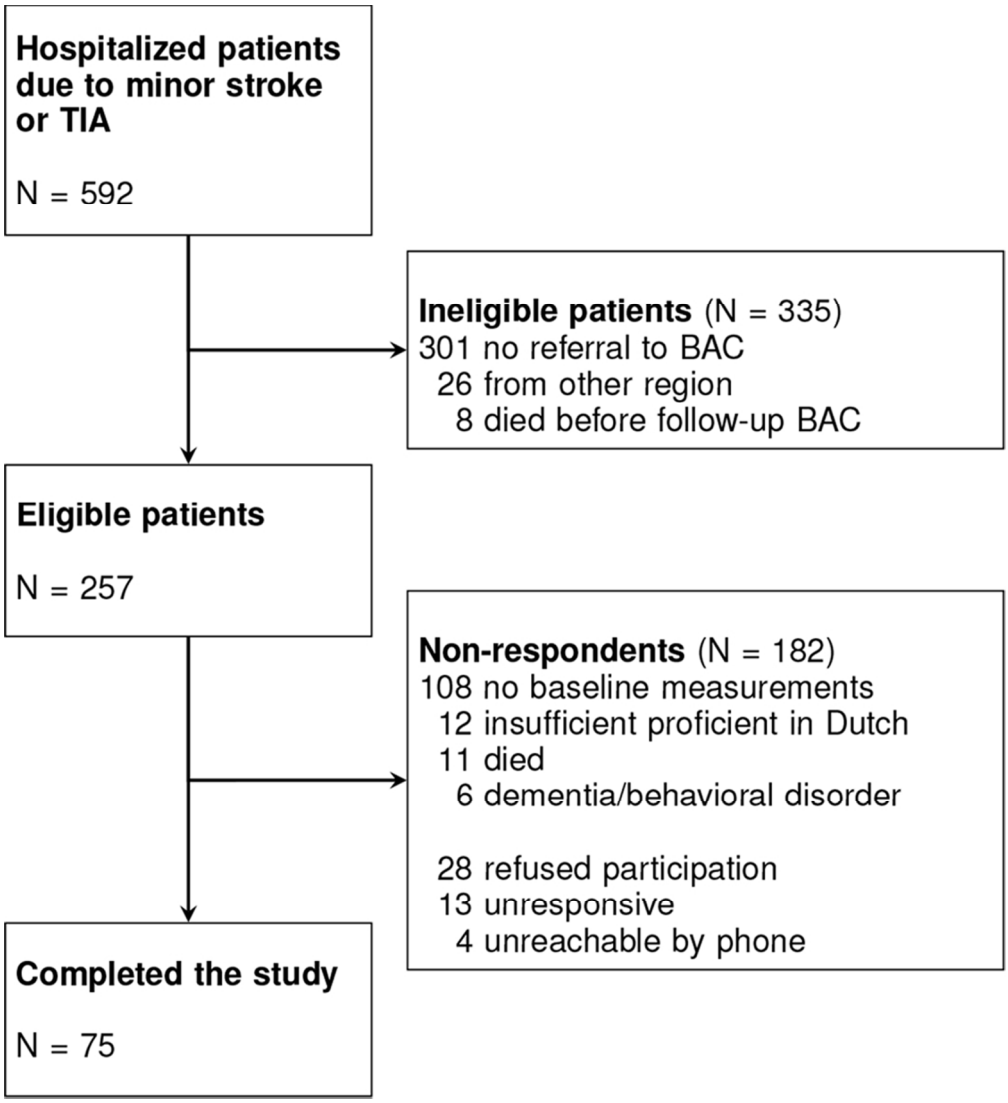

Figure 1. Flow chart of the study population

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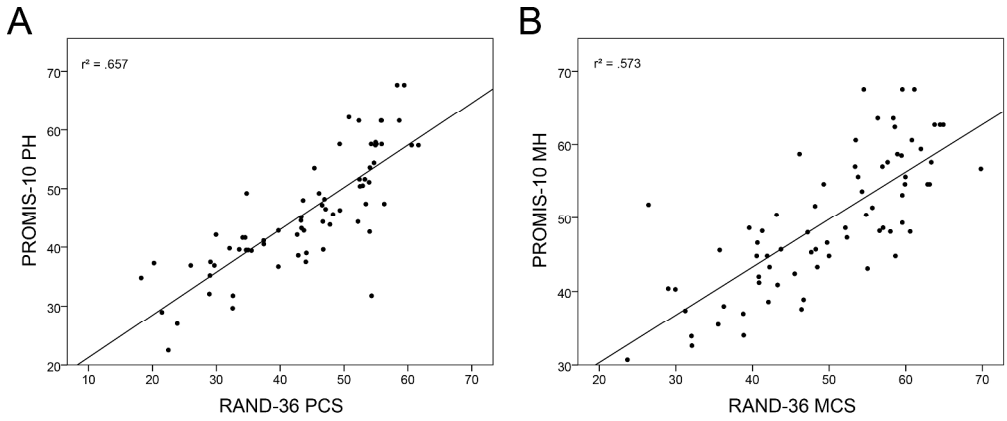

Figure 2. Scatterplots of PROMIS-10 and RAND-36 physical (A) and mental health scores (B).

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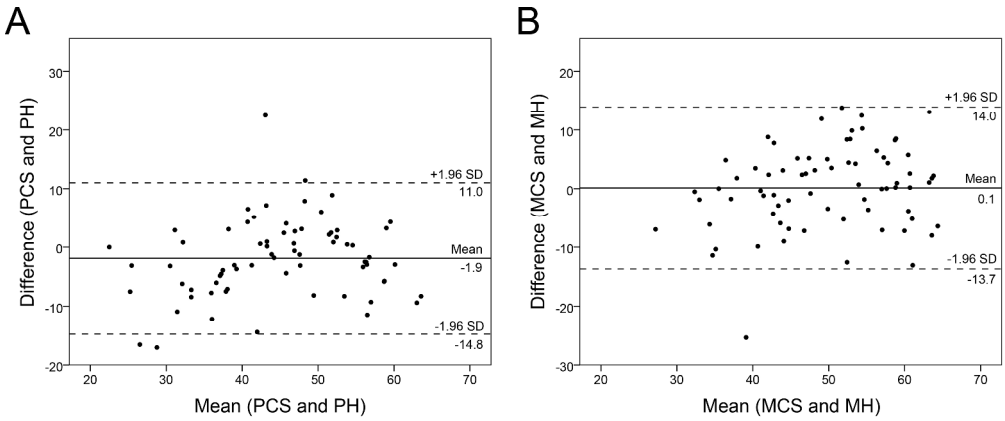

Figure 3. Bland-Altman plots of PROMIS-10 and RAND-36 physical (A) and mental health scores (B).

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2	"Design: Observational cohort study."
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2	"PROMIS-10 was found to strongly correlate with the RAND-36. Paper-and-pencil assessment was found to have a higher correlation than telephone assessment. This study provides support for the use of the Dutch PROMIS-10 in assessing health status in patients after TIA and minor stroke."
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported		"… previous studies in TIA and minor stroke patients found high prevalence of dysfunction across all domains of health, of which cognitive and emotional problems were most notable [3-6]. These symptoms may be overlooked with conventional clinical measures such as the neurological examination or the Barthel Index, but can be a major contributor to an impaired

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				performance of activities of daily living and a diminished quality of life (QoL)"
Objectives	3	State specific objectives, including any prespecified hypotheses	4	"… to investigate the construct validity and reliability of the Dutch PROMIS-10 in TIA and minor stroke patients in the Netherlands. We also aim to evaluate different assessment methods of the PROMIS-10: on paper (filled in by the patient) assessment versus assessment through the telephone."
Methods				
Study design	4	Present key elements of study design early in the paper	4	"… single-centre observational cohort study …"
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4	"… at OLVG Oost hospital. Between January 2016 and January 2017 medical records of patients diagnosed with a TIA or minor stroke one year ago were screened for eligibility …" "Eligible patients were approached by telephone for study participation. (…) study materials were sent by mail; study information, consent form, PROMIS-10, RAND-36 (…), and a short form for obtaining socio-demographic

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				data. PROMIS-10 was assessed on paper from January 1 to July 31, 2016 and by telephone from August 1, 2016 to January 31, 2017. On paper assessments of the PROMIS-10 and RAND-36 were completed by the patients at home on their own or with help of a proxy. Telephone assessments of the PROMIS-10 were carried out by reading out the exact questions and marking the given answers. Clinical data were extracted from medical records."
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4	"Eligibility included a clinical diagnosis of TIA or minor stroke followed by discharge without inpatient rehabilitation treatment. (…) TIA and minor stroke were defined as (…) symptoms of stroke on admission that fully resolves within 24 hours and three days, respectively." "Exclusion criteria were: age below 18 years, persistent neurological symptoms three days post-stroke, insufficient proficiency in Dutch, dementia or any behavioural disorder …"

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		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	n/a	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4, 5	"PROMIS-10 (…) Physical health (PH) and mental health (MH) T-scores" "RAND-36 (…) physical (PCS) and mental (MCS) component score." "marital status, level of education ((…) low (primary school), average (secondary school low or medium level), and high (highest level secondary school, and/or college degree, and/or university degree) [20], living arrangement, and work status." "… clinical diagnosis of TIA or minor stroke followed by discharge without inpatient rehabilitation treatment. MRI is not part of the standard diagnostic work-up of stroke but was performed whenever other causes than ischemia could not be ruled out. For this study TIA and minor stroke were defined as acute neurological deficits

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				with symptoms of stroke on admission that fully resolves within 24 hours and three days, respectively."
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4	"Clinical data were extracted from medical records." "On paper assessments of the PROMIS-10 and RAND-36 were completed by the patients at home on their own or with help of a proxy. Telephone assessments of the PROMIS-10 were carried out by reading out the exact questions and marking the given answers."
Bias	9	Describe any efforts to address potential sources of bias	4, 5	"Between January 2016 and January 2017 medical records of patients diagnosed with a TIA or minor stroke one year ago were screened for eligibility" "Eligibility included a clinical diagnosis of TIA or minor stroke followed by discharge without inpatient rehabilitation treatment. (…) TIA and minor stroke were defined as (…) symptoms of stroke on admission that fully resolves within 24 hours and three days, respectively."

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				"If during the re-evaluation residual or new symptoms are present or suspected, patients are referred to the Beroerte Adviescentrum (…) patients who were not referred to the BAC or did not complete baseline measurements were deemed ineligible." "On paper assessments of the PROMIS-10 and RAND-36 were completed by the patients at home on their own or with help of a proxy. Telephone assessments of the PROMIS-10 were carried out by reading out the exact questions and marking the given answers. Clinical data were extracted from medical records." "Socio-demographic data collected were: marital status, level of education (…),living arrangement, and work status."
Study size	10	Explain how the study size was arrived at	4	"Between January 2016 and January 2017 medical records of patients diagnosed with a TIA or minor stroke one year ago were screened for eligibility"

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Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5	"Numerical variables were summarized by the mean ± SD, and frequencies and percentages were used for binary and categorical variables."
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5, 6	"… correlation between PROMIS-10 and RAND-36 was assessed by calculating Pearson's correlation coefficient (r), with a bias corrected and accelerated bootstrapping (BCa) method providing 95% confidence intervals. Agreement between PROMIS-10 and RAND-36 was assessed by constructing Bland-Altman plots with horizontal lines representing 95% limits of agreement (LOA) (mean difference ±1.96 SD). (…)For the internal consistency of the PROMIS-10, reliability analysis was used to calculate Cronbach's αs for both physical (4 items) and mental (4 items) subscales. A cut-off point of ≥ .70 was chosen for indication of good reliability (α) and correlation (r) [21]. A p-value of < .05 was considered to be statistically significant.
		(*b*) Describe any methods used to examine subgroups and interactions	5, 6	"Differences in patient characteristics were assessed using the independent samples *t*-test and χ^2 test."

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				"An independent samples t-test was performed for assessing differences between assessment methods of the PROMIS-10. "
		(*c*) Explain how missing data were addressed	6	"… two had missing values in the physical total score, and one in both physical and mental total score of the PROMIS-10, another patient had missing values in both component scores of the RAND-36."
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n/a	n/a
		(*e*) Describe any sensitivity analyses	n/a	n/a
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6	"… 592 patients were identified who were diagnosed with a TIA or minor stroke one year prior to the assessment (…) 301 patients were not referred to BAC for follow-up care, 26 patients originated from a different region or country, and 8 died before BAC follow-up. Of the remaining 257 eligible patients, 182 were non-respondents (108 had no baseline measurements, 12 were insufficient proficient in Dutch, 11 died before follow-up at one year

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				post-stroke, 6 had dementia or a behavioural disorder, 28 refused participation, 13 were not responsive after initial consent, and 4 were not reachable by phone) and 75 patients were included for the study …"
		(b) Give reasons for non-participation at each stage	6	"… 301 patients were not referred to BAC for follow-up care, 26 patients originated from a different region or country, and 8 died before BAC follow-up. " "… 108 had no baseline measurements, 12 were insufficient proficient in Dutch, 11 died before follow-up at one year post-stroke, 6 had dementia or a behavioural disorder, 28 refused participation, 13 were not responsive after initial consent, and 4 were not reachable by phone…"
		(c) Consider use of a flow diagram	6	"Figure 1. Flow chart of the study population"
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6	"Of the 75 included patients, mean age was 68.9 ± 11.2 years, 51 (68.0%) were male, 60 (80.0%) had their first-ever ischemic event, 49 (65.3%) had the diagnosis minor stroke and 26 (34.7%) TIA. The ischemic event was located in the

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				left hemisphere in 30 (40.0%) patients, 23 (30.7%) in the right hemisphere, and 22 (29.3%) were vertebrobasilar."
		(b) Indicate number of participants with missing data for each variable of interest	6	"… two had missing values in the physical total score, and one in both physical and mental total score of the PROMIS-10, another patient had missing values in both component scores of the RAND-36."
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	7	"Days between onset and follow-up, mean (*SD*)"
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	6	"Mean (SD) scores for the PROMIS-10 were 45.8 (9.9) for PH, and 49.6 (9.1) for MH. Scores for the RAND-36 were 43.7 (11.4) for PCS, and 49.9 (10.7) for MCS."
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		
		Cross-sectional study—Report numbers of outcome events or summary measures		
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8	"PROMIS-10 and RAND-36 physical and mental scores correlated significantly, r = .81, BCa CI [.69, .88], p < .001, and r = .76, BCa CI [.64, .85], p < .001, respectively …"
		(*b*) Report category boundaries when continuous variables were categorized	5	"… level of education (assessed on the Dutch 7-point scale 'schaal van Verhage', and afterwards stratified into three groups: low (primary school), average (secondary school

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			low or medium level), and high (highest level secondary school, and/or college degree, and/or university degree) [20], …"
	(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a	n/a

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Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11, 12	"… mental health was found to be similar when comparing gender." "However, when taking diagnosis into account, physical and mental scores between the two groups did not significantly differ for both PROMIS-10 and RAND-36."
Discussion				
Key results	18	Summarise key results with reference to study objectives	10, 11	"… overall strong correlation between the PROMIS-10 and the RAND-36. QoL attributed to physical health was found to have a higher correlation than QoL attributed to mental health." "… we compared two assessment methods of the PROMIS-10. Both physical and mental health assessed by telephone, although slightly inferior to on-paper assessment, was found to have a strong correlation with on-paper assessed RAND-36."
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12, 13	"… small sample size …" "… mean (*SD*) of 9.4 (14.7) days between assessment of RAND-36 on paper and assessment of PROMIS-10 by telephone …"

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				"… no information regarding test-retest reliability of PROMIS-10 as is was only assessed at one time point." "… confounding factors such as individual personality traits, extent of social support, socio-economic status and ethnicity was not accounted for in this study, while these factors undoubtedly impact self-reported quality of life."
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13	"… support for the use of the Dutch version of the PROMIS-10 in patients after minor stroke or TIA in the Netherlands. Despite satisfactory validity of telephone assessment, careful interpretation is advised, especially when addressing mental health status. Additional data and further research with the PROMIS-10 in stroke patients is desirable for establishing more firm results."
Generalisability	21	Discuss the generalisability (external validity) of the study results	12	"The generalizability of our results is reduced due to our small sample size." "Timing of measurement of health status in stroke should also be taken into account. We assessed the PROMIS-10 at one year post-

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				stroke…"
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14	"This research is funded by the Foundation Teaching Hospital OLVG, Amsterdam."

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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