

Master thesis

Determination of the minimal important change in the quality of life in people with aphasia.

A clinimetric study of the evaluation of the SAQOL-39NLg.

Name:	Anne den Broeder
Student number:	5828015
Course:	Afstudeeronderzoek
Version:	Final version
Date:	27-06-2019
Word count:	English summary: 279 words Nederlandse samenvatting: 290 words Text: 3563 words
Reference style:	Vancouver superscript Reference style
Supervisor:	Dr. Lizet van Ewijk and Nicole van der Wal MA.
Place of internship:	HU university of applied sciences Utrecht
Lecturer:	Dr. Rob Zwitserlood
Education:	Clinical Language, Speech and Hearing Sciences, program in Clinical Health Sciences, Faculty of Medicine, Utrecht University, The Netherlands
Journal:	Aphasiology
Checklist used:	STROBE Statement

Abstract

Background: Aphasia influences the ability to communicate and can influence quality of life (QoL). To measure QoL in people with aphasia (PWA), the stroke and aphasia quality of life scale (SAQOL-39NLg) was developed. The SAQOL-39NLg is divided into three domains. All psychometric properties of the SAQOL-39NLg have been determined, except for the minimal important change, which indicates the experienced change in QoL according to PWA. Therefore, the interpretability of test-retest results on the SAQOL-39NLg is limited.

Aim: Determining the Minimal Important Change (MIC) in terms of clinical relevance of test-retest results on the SAQOL-39NLg, in people with chronic aphasia post stroke.

Methods and procedures: This study involved a prospective clinimetric design, in which on two points in time data of the SAQOL-39NLg in PWA (n=35) were collected by an anchor-based approach of the MIC. Participants assessed their change in QoL since the previous measurement by responding to anchor questions, using six-point Likert scales. The results of the two measurements and the anchor questions were used to calculate MIC for improvement and deterioration in QoL.

Outcomes and results: The MIC for improvement on the SAQOL-39NLg in general is 0.09 points, for the domain 'physical' 0.03, for 'communication' 0.43, and for the psychosocial domain -0.35. The MIC for deterioration on the SAQOL-39NLg in general was -0.22, for the domain 'physical' -0.21, for 'communication' -0.07, and for the psychosocial domain -0.22 points.

Conclusions: This study provides scores of the clinical relevance of the SAQOL-39NLg for improvement and deterioration in QoL as experienced by PWA. These scores enhance the interpretability of the SAQOL-39NLg, which could be added to the guideline of this questionnaire.

Keywords: Aphasia, Quality of life, SAQOL39-NL, Minimal important change.

Nederlandse samenvatting

Achtergrond: Afasie beïnvloedt de mogelijkheden om te communiceren en daarbij de kwaliteit van leven. Om kwaliteit van leven bij personen met afasie (PMA) te meten, is de stroke and aphasia quality of life scale (SAQOL-39NLg) ontwikkeld, welke al gebruikt wordt in de Nederlandse gezondheidszorg. De SAQOL-39NLg bestaat uit 39 vragen, verdeeld over drie domeinen. Alle psychometrische eigenschappen van de SAQOL-39NLg zijn onderzocht,

A.W. den Broeder; 5828015; final version; 27-06-2019

Clinical relevance of the SAQOL-39NLg

met uitzondering van het minimale klinisch relevante verschil. Daardoor is de interpreteerbaarheid van test-hertest resultaten van de SAQOL-39NLg beperkt.

Doel: Achterhalen van het minimale klinisch relevante verschil (MIC) van test-hertest resultaten van de SAQOL-39NLg voor personen met chronische afasie.

Methode: Het studie design was prospectief en klinimetrisch, waarbij data van de SAQOL-39NLg op twee momenten bij PMA in de chronische fase (n=35) werd verzameld. Participanten beoordeelden bij het tweede afname moment hun verandering in kwaliteit van leven sinds het vorige afname moment, door vier ankervragen te beantwoorden op een 6-punts Likert schaal. De resultaten van de SAQOL-39NLg en de antwoorden op de ankervragen zijn gebruikt om de MIC te berekenen voor verbetering of verslechtering in kwaliteit van leven.

Resultaten: De MIC voor verbetering op de SAQOL-39NLg in het algemeen is 0,09 punten, voor het domein fysiek 0,03, voor communicatie 0,43, en voor het psychosociale domein – 0,35. De MIC voor verslechtering op de SAQOL-39NLg in het algemeen is –0,22, voor het fysieke domein –0,21, voor het domein communicatie –0,07 en voor het psychosociale domein –0,22.

Conclusie: Deze studie voorziet van scores van de klinische relevantie van de SAQOL-39NLg voor verbetering en verslechtering in kwaliteit van leven, ervaren door PMA. Deze scores vergroten de interpreteerbaarheid van de SAQOL-39NLg, en kunnen worden toegevoegd aan de handleiding van de vragenlijst.

Trefwoorden: Afasie, kwaliteit van leven, SAQOL39-NLg, minimaal klinisch relevant verschil.

Introduction

Aphasia is a language impairment, which is caused by a brain injury such as a stroke. Aphasia changes the production and/or comprehension of language and it can affect the ability to write or read.¹ Aphasia extremely disturbs the ability to communicate, which makes it hard for people with aphasia (PWA) to participate in social activities.²⁻⁴ Social support such as friendship and feeling integrated within the social society is severely affected by

aphasia.^{2,3,5} Between 62% and 70% of PWA develop a depression.⁶ This makes aphasia one of the largest factors of a descending Health Related Quality of Life (HRQL).⁷

Speech-language therapists (SLTs) diagnose and treat aphasia at all periods of recovery after stroke. Traditionally, SLTs were used to focus on the functional improvement of aphasia. According to the International Classification of Functioning (ICF), the therapy approach has changed.⁸ Therapy now also focusses on barriers in activities, and participation in the community. Thereby, the HRQL has become an important outcome in rehabilitation after stroke.^{9,10} One of the advantages of using HRQL is that it enables the SLT to have a holistic view on the PWA as a person, rather than just focussing on functional impairments. HRQL can be used as an evaluation of the impact of aphasia in daily life.¹¹

HRQL is typically measured by Patient Reported Outcome Measures (PROM). To examine the HRQL of PWA, Hilari and Byng¹² developed an aphasia adapted version of the Stroke Specific Quality of Life scale (SS-QOL): the Stroke and Aphasia Quality of Life scale (SAQOL-39).^{12,13} This is the only tool to measure HRQL of stroke patients with or without aphasia.¹⁴ Van Ewijk et al.¹⁵ translated the SAQOL-39 into a Dutch-language version, which is currently used in the generic stroke population in the Netherlands.

Several studies determined the psychometric properties of the SAQOL-39 and the Dutch SAQOL-39NLg following the COSMIN checklist (Consensus-based Standards for the selection of health status Measurement INstruments).^{16,17} The COSMIN criteria consist of four topics, divided into ten features which can be used to assess whether an instrument meets the standard for good methodological quality. These topics are reliability, validity, responsiveness, and interpretability.

In previous studies, almost all components of the validity of the SAQOL-39NLg were determined.^{15,18} The construct validity was established by Van Ewijk et al.¹⁵, who made a cross-cultural translation of the SAQOL-39g. The questionnaire showed an excellent test-retest reliability, good overall reliability, internal consistency, and validity, and adequate responsiveness to change.^{15,18} The content validity is currently under research.

Responsiveness to change is determined by using Standardised Response Mean (SRM) scores.¹⁸ De Vet et al.¹⁶ states that the SRM only provides information about the magnitude of the change and not about the validity of the change. Additionally, the smallest detectable change (SDC) is determined, which shows the changes falling outside the measurement error.^{19,20} However, an SDC on QoL may be statistically significant in studies with a large population, but do not necessarily have to be experienced as meaningful change according to PWA.²¹⁻²³ Yet, information about the validity of change and therefore the clinical relevance is lacking in the SS-QOL, the SAQOL-39, and the SAQOL-39NLg. Consequently, the questionnaire cannot be fully interpreted.

To accomplish all COSMIN criteria, the interpretability in terms of clinical relevance has to be determined by establishing the validity of the change. To assess the validity of change, the minimal important change (MIC) has to be calculated. The MIC indicates whether improvements in test-retest results are relevant for the patients or the clinicians. Therefore, the results of the MIC are of great value in clinical practice.¹⁶

To summarize, the statistical significance from the SAQOL-39NLg is established, but to interpret these scores to a clinically relevant outcome, the MIC according to PWA has to be determined. Therefore, the objective of the present study is to determine the MIC of test-retest results on the SAQOL-39NLg in PWA, in terms of clinical relevance.

Method

Recruitment and study population

PWA caused by stroke were recruited through SLTs working in healthcare organizations connected to a Dutch organization called *Hersenz*. This organization focuses on treatment of persons with acquired brain injury. There are thirteen aphasia centers located all over the Netherlands connected to *Hersenz*. SLTs working for this organization are specialized in working with people who have chronic aphasia. SLTs of *Hersenz* were asked to approach the PWA they are working with for participation in this study. After the PWA agreed to participate, they received a patient information form (Appendix A). Only adult patients in the chronic phase of aphasia and of whom the SAQOL-39NLg was carried out at least once, were included. PWA were excluded if informed consent was not possible due to cognitive impairments and in case of primary progressive aphasia, or severe depression. *Hersenz* provides the option for their patients to give permission for always sharing their data for the purpose of medical research. In case the participants have not already given this permission, they had to sign an informed consent form (Appendix B).

Measurements

In the present study, the SAQOL-39NLg was used. The SAQOL-39NLg consists of 39 questions, subdivided into three domains: physical (16 items), psychosocial (16 items), and communication (7 items). Each question can be scored by PWA on a 5-point scale using two response formats ranging from 1 (could not do it at all) to 5 (no problems at all); and 1 (definitely yes) to 5 (definitely no). Across all questions, a mean score of the SAQOL-39NLg

in total and for each separate domain can be calculated which is minimally 1 and maximally 5. In the end, a higher score indicates a better QoL after experiencing a stroke.¹⁹ Smallest detectable change (SDC) scores have previously been calculated, therefore statistical significant change in SAQOL-39NLg scores can be calculated. The SDC for the SAQOL-39NLg in total is 0.64, for the domain 'physical' 0.72, for 'communication' 1.61 and for the domain 'psychosocial' the SDC is 1.00.¹⁹

Additionally, four anchor questions were asked.

1. How much has your quality of life in general changed since the last measurement of the SAQOL-39NLg?
2. How much has your quality of life in physical activities changed since the last measurement of the SAQOL-39NLg?
3. How much has your quality of life in communication abilities changed since the last measurement of the SAQOL-39NLg?
4. How much has your quality of life in cognition, emotions, and behavior changed since the last measurement of the SAQOL-39NLg?

Appendix C shows the anchor questions in Dutch with visual support for the participants who completed the SAQOL-39NLg hardcopy.

The anchor question had to be rated on a six-point Likert scale. This scale was used by respondents to rate items at a level of agreement on a particular statement¹⁶. The response options based on de Vet et al.²⁰ were: completely recovered (1), much improved (2), slightly improved (3), no change (4), slightly worse (5), much worse (6).

Study procedure

This study involved a prospective, clinimetric design. Data of two time points in PWA post stroke were analyzed. *Hersenz* works with a protocol which states that the SAQOL-39NLg has to be carried out every six months. In the period from January until April 2019, all SLTs working at *Hersenz* were asked by e-mail to administer a registration of the SAQOL-39NLg. This was done by as many PWA as possible, who already completed the SAQOL-39NLg at least once.

Of all included PWA, baseline characteristics were collected. The selection of the baseline questions was based on Van Ewijk et al.¹⁵ In this study, only the most relevant characteristics were showed, which are: age, gender, aetiology and time post onset. Subsequently, data of the SAQOL-39NLg was collected with a minimum interval of two months between the current and previous measurement. Data collection was performed by the SLTs who treat the PWA. When necessary, any supported conversation techniques to aid understanding was allowed.

The measurements were in attendance of the SLT. All data were shared anonymously between SLT and the researcher, by coding all participants names with client ID's.

Additionally, during the second measurements of the SAQOL-39NLg, four anchor questions were asked, which indicate the experienced difference since the last measurement of the SAQOL-39NLg according to the PWA. An anchor-based method to measure the MIC is an often-used approach, in which patients can rate the magnitude of the perceived change in one question, which provides the best measure from an individual perspective.^{20,22} The first anchor question was asked before starting T2. Every anchor question was asked prior to the corresponding domain of the SAQOL-39NLg.

The questionnaire was completed in a quiet place, by an SLT. The SLT at T2 did not have to be the same SLT at T1.

Statistical analysis

Data were analyzed using IBM SPSS Statistics, version 24.²⁴ For all the missing values on the SAQOL-39NLg, the average score of the questions was taken per participant. Data was presented in frequencies of the responds on each anchor question, for each domain of the SAQOL-39NLg. The mean scores in total and for each domain on both examinations of the SAQOL-39NLg were calculated, and additionally, the mean change scores between T1 and T2 were computed.

For each domain, the results of the anchor question were divided into three groups: patients who experienced improvement (anchor<4), patients who were not importantly changed (anchor=4), and patients who experienced deterioration (anchor>4). Since it is not possible to establish the MIC for these three groups at the same time, de Vet et al.¹⁶ recommends to calculate the MIC two times, dichotomized for improvement in comparison to no change at all, and dichotomized for deterioration in comparison to no change at all. Then ROC (Receiver Operating Characteristics) curves are generated with the mean differences between T1 and T2 on the SAQOL-39NLg as dependent variable, and dichotomized results of the anchor questions divided in the groups as described above, as the independent variable. Consequently, eight ROC-curves were plotted: for each anchor question an ROC-curve both for improvement, and for deterioration. In these graphs, coordinates were determined for the score with the highest sensitivity and lowest 1-specificity (the top left corner of the graph). These coordinates indicated the minimal important change in QoL according to PWA, expressed in SAQOL-39NLg scores. Finally, the MIC scores were compared with the SDC scores of the SAQOL-39NLg, which had already been determined.¹⁹

Ethical issues

This study was conducted according to the principles of the Declaration of Helsinki (version 2008) and in accordance with the General Data Protection Regulation in Dutch Algemene Verordening Gegevensbescherming (AVG).²⁵ All participants included in this study have signed informed consent forms or gave permission to *Hersenz* for sharing their data for the purpose of medical research. Previous research on the psychometric properties of the SAQOL-39NLg was examined and considered exempt by the METC of University Medical Center Utrecht (number of METC protocol: 16-628/C).

Results

Participants

Seven SLTs employed by *Hersenz* collected data at two SAQOL-39NLg measurement moments, of which three SLTs carried out the SAQOL-39NLg hardcopy. Three SLTs carried out the SAQOL-39NLg within the digital system BergOp, in which the questionnaire and the anchor questions were implemented. One SLT completed T1 of the questionnaire in BergOp in combination with a hardcopy version of T2. In total 35 participants (PWA) were included in this study. Of these, 25 were male and 10 were female, with ages ranging from 44 to 83 years ($M=64.3$, $SD=10.4$), and time post onset at the moment of T2 ranging from 12 months to 199 months ($M=40.6$; $SD=34.6$). The most relevant characteristics of the participants are presented in Table 1.

[Table 1]

The mean scores of this study on the SAQOL-39NLg in total and for each domain on T1 and T2 with calculated differences in scores between T2 and T1, are presented in Table 2.

[Table 2]

Minimal important change total score SAQOL-39NLg

Table 3 illustrates the mean change scores between T2 and T1 and frequencies of all anchor outcomes for the SAQOL-39NLg in general.

[Table 3]

The clinical improvement MIC for the SAQOL-39NLg in total was 0.09 points. The clinical deterioration MIC for the SAQOL-39NLg in total was -0.22 points. The plotted ROC-curves revealing these results, can be found in figure 1 and 2.

[Figure 1]

[Figure 2]

Minimal important change physical domain SAQOL-39NLg

Table 4 illustrates the mean change scores between T2 and T1 and frequencies of all anchor outcomes for the domain 'physical' on the SAQOL-39NLg.

[Table 4]

The clinical improvement MIC for the SAQOL-39NLg on the domain 'physical' was 0.03 points. The clinical deterioration MIC of the domain 'physical' was -0.21 points. The plotted ROC-curves revealing these results, can be found in figure 3 and 4.

[Figure 3]

[Figure 4]

Minimal important change communication domain SAQOL-39NLg

Table 5 illustrates the mean change scores between T2 and T1 and frequencies of all anchor outcomes for the domain 'communication' of the SAQOL-39NLg.

[Table 5]

The clinical improvement MIC for the SAQOL-39NLg on the domain 'communication' was 0.43 points. The clinical deterioration MIC of the domain 'communication' was -0.07 points. The plotted ROC-curves revealing these results, can be found in figure 5 and 6.

[Figure 5]

[Figure 6]

Minimal important change psychosocial domain SAQOL-39NLg

Table 6 illustrates the mean change scores between T2 and T1 and frequencies of all anchor outcomes for the domain 'psychosocial' of the SAQOL-39NLg.

[Table 6]

The clinical improvement MIC for the SAQOL-39NLg on the domain 'psychosocial' was -0.35 points. The clinical deterioration MIC of the domain 'psychosocial' was -0.17 points. The plotted ROC-curves revealing these results, can be found in figure 7 and 8.

[Figure 7]

[Figure 8]

An overview of all MIC scores presented with the SDC scores that have already been investigated, can be found in Table 7.

[Table 7]

Discussion

The aim of this study is to determine the minimal important change in terms of clinical relevance of test-retest results in QoL in PWA, measured with the SAQOL-39NLg. An anchor based method was used, in which 35 PWA assessed their change in QoL on a six-point scale, since the previous measurement of the SAQOL-39NLg.

In this study, none of the PWA experienced complete recovery or much worsening of their QoL. Also, for each domain, many people have chosen for much improved or slightly worsened QoL. Most people were more neutral by answering that their QoL was slightly improved or not changed at all. All included participants were in the chronic phase of their aphasia. Chronic aphasia is expected to be the most stable phase without strong worsening or improvement of the abilities.²⁶

Results of this study showed that PWA experienced a meaningful improvement when their mean score increased with 0.09 points on the SAQOL-39NLg, compared to the previous measurement. For the domain physical an improvement of 0.03 points was found to be clinically relevant, for the domain communication 0.43 points, and for the psychosocial domain the MIC is -0.35 points. The MIC was also calculated for experienced deterioration of the QoL. For the QoL in general a deterioration of -0.22 points was clinically relevant, for the domain physical the MIC for deterioration was -0.21 points, for the domain communication -0.07 points, and for the psychosocial domain the MIC for deterioration was -0.22 points. These scores demonstrate the minimal scores needed to experience change in QoL, according to PWA, which enhances the interpretability of the SAQOL-39NLg, expressed in clinical relevance.

The expectation of this study was that a statistically significant change in PROM scores do not necessarily have to be meaningful for PWA.^{20,21} Van Ewijk et al.¹⁹ previously investigated

the smallest detectable change (SDC) scores, which represent cut-off points for a statistically significant change in test-retest scores. Remarkably, the SDC for the SAQOL-39NLg in general and for each separate domain, are larger than the MIC scores for improvement in general and for each domain. This means that if PWA have a change score smaller than the SDC, and thus there is a high risk of measurement error ($\geq 95\%$), the change can still be meaningful for the PWA.^{22,23} This result also suggests that if PWA have a significant change score on the SAQOL-39NLg, the SLT can assume that the results are also clinically relevant for the PWA.^{22,23} The reason for a smaller MIC in comparison to the SDC could be, that for PWA in the chronic phase less functional improvement is expected and consequently they could feel more content with small improvements.²⁶ An explanation of the interpretation of change when the MIC is smaller than SDC is visualized in Figure 9.

[Figure 9]

Hilari³ found that people with stroke and aphasia report a lower QoL than people with stroke, but without aphasia. In the present study the domain 'communication' shows remarkably higher MIC for improvement than for the other domains, and the MIC for deterioration is clearly the smallest of all domains. This indicates it is harder for PWA to experience an increased QoL in communication than for the other domains, and also the QoL in communication deteriorates earlier compared to the other domains.

Results show that the MIC scores for the psychosocial domain are negative both for the group that showed deterioration in QoL and for the group that showed improvement in QoL. We presume this result is unreliable, since it would indicate that PWA still experience an improvement in the QoL when scoring -0,35 or better on the SAQOL-39NLg, compared to the previous measurement. The ROC curve showed an unexpected vertical line, representing a minimal variation in sensitivity. This unusual score could be caused by the terms in the anchor question: 'cognition, emotions, and behavior' which are not commonly used terms for every participant. The SLT had the choice to explain these terms, however, presumably every SLT explained these terms differently. Another reason for this negative MIC could be that PWA possibly experience improvement in their psychosocial wellbeing, but that the reasons for that improvement do not occur in the questions of the SAQOL-39NLg. Nevertheless, this score cannot be used in clinical practice. Interpreting a negative number as improvement in QoL does not seem to be reliable. Therefore, further research on the MIC for the domain psychosocial on the SAQOL-39NLg is needed. For now, it is important in clinical practice to ask PWA if they recognize themselves in the scores after the measurements.

There are some limitations to this study. Firstly, the aim was to collect data from 50 participants.¹⁶ However, some speech therapists who initially agreed to contribute to this study were unable to participate due to a lack of time, reorganizations, or they had not administered the SAQOL-39NLg earlier in their patients. For these reasons, the aim to include 50 participants was not achieved. However, still a number of 35 PWA did participate in this study. Because of the heterogeneity of the group, the results are expected to be representative and generalizable for other PWA in the chronic phase (>6 months post stroke).

Secondly, the anchor questions were divided into six-point scale, based on de Vet et al.²⁷ Three response options indicated the grade of improvement, one response option indicated no change at all, and two response options indicated the grade of deterioration. This means that less options can be chosen for deterioration, than for improvement. Consequently, the random chance that a participant records deterioration of QoL is smaller. However, the results showed that no one described their QoL as much worse. For that reason the expectation is that an additional option in the response format of the anchor questions for deterioration would not show significant differences.

Furthermore, due to a lack of time, requirements of the moments of measurement could not be specified in advance of this study. This means measurement for T1 but also for T2 could possibly happen for example 6 months after stroke and as well at 150 months after stroke. Then again, this results in better variation and thus generalizability of the results. Nevertheless, a recommendation for further research is to use agreed times post-stroke to fill in the SAQOL-39NLg twice. To ensure there was enough time for the QoL to change, a minimum interval of two months between T1 and T2 was established. No maximum number of months was established.

At last, during measurement of the SAQOL-39NLg, the SLT was sitting next to the PWA. This could lead to bias because the PWA may have responded socially acceptable, after all the effort the SLT did for the PWA in the treatment period before T2. Nevertheless, the SLT was needed during the measurements, to provide explanation of questions the PWA did not understand.

In conclusion, this study provides MIC scores for improvement and deterioration in QoL in accordance to PWA, measured with the SAQOL39NLg. It is important for SLTs to notice that PWA experience a meaningful change in QoL sooner than statistical significance is achieved. Additionally, these results show that an increasing QoL in communication is harder to achieve for PWA than increasing QoL on physical or psychosocial domain. These MIC

scores enhance the interpretability of the SAQOL-39NLg, which can be used in the guideline of this questionnaire. However, the MIC scores on psychosocial domain do not seem to be reliable, therefore more research is needed with another formulated anchor question specified for the psychosocial domain. To enhance the generalizability, it would be of additional value to combine this data with supplemented data of more participants.

References

1. Bastiaanse R. Afasie. Bohn Stafleu van Loghum; 2010.
2. Cruice, Madeline, et al. "Measuring quality of life: Comparing family members' and friends' ratings with those of their aphasic partners." *Aphasiology* 19.2 (2005): 111-129.
3. Hilari, Katerina. "The impact of stroke: are people with aphasia different to those without?." *Disability and rehabilitation* 33.3 (2011): 211-218.
4. Hilari, Katerina, and Sarah Northcott. "Social support in people with chronic aphasia." *Aphasiology* 20.1 (2006): 17-36
5. van Ewijk, Lizet, et al. "Measuring quality of life in Dutch people with aphasia: development and psychometric evaluation of the SAQOL-39NL." *Aphasiology* 31.2 (2017): 189-200.
6. Kauhanen, M-L., et al. "Aphasia, depression, and non-verbal cognitive impairment in ischaemic stroke." *Cerebrovascular Diseases* 10.6 (2000): 455-461.
7. Lam, Jonathan MC, and Walter P. Wodchis. "The relationship of 60 disease diagnoses and 15 conditions to preference-based health-related quality of life in Ontario hospital-based long-term care residents." *Medical care* (2010): 380-387.
8. World Health Organization (WHO), Nederlandse vertaling van de 'International Classification of Functioning, Disability and Health'. Bohn Stafleu Van Loghum; 2001.
9. Teasell, Robert, et al. "The next revolution in stroke care." *Expert review of neurotherapeutics* 14.11 (2014): 1307-1314.
10. Lee, Hyejin, et al. "Community integration and quality of life in aphasia after stroke." *Yonsei medical journal* 56.6 (2015): 1694-1702.
11. Bullinger, M., et al. "Developing and evaluating cross-cultural instruments from minimum requirements to optimal models." *Quality of life Research* 2.6 (1993): 451-459.
12. Hilari, Katerina, and Sally Byng. "Measuring quality of life in people with aphasia: the Stroke Specific Quality of Life Scale." *International journal of language & communication disorders* 36.sup1 (2001): 86-91.
13. Williams, Linda S., et al. "Measuring quality of life in a way that is meaningful to stroke patients." *Neurology* 53.8 (1999): 1839-1839.
14. Hilari, Katerina. *Assessing health-related quality of life in people with aphasia*. Diss. City University London, 2002.
15. van Ewijk, Lizet, et al. "Measuring quality of life in Dutch people with aphasia: development and psychometric evaluation of the SAQOL-39NL." *Aphasiology* 31.2 (2017): 189-200.
16. de Vet, Henrica CW, et al. *Measurement in medicine*. Cambridge University Press, 2011.
17. Hiemstra, Laurie A., et al. "Concurrent validation of the Banff Patella Instability Instrument

- to the Norwich Patellar Instability Score and the Kujala Score in patients with patellofemoral instability." *Orthopaedic Journal of Sports Medicine* 4.5 (2016): 2325967116646085.
18. Van Ewijk, Lizet, et al. "Psychometric properties of the Dutch SAQOL-39NL in a generic stroke population." *Topics in stroke rehabilitation* 26.2 (2019): 101-105.
 19. Van Ewijk, Lizet, Van Versteegde, Lotte, Raven-Takken, Evelijn, & Ter Wal, Nicole. *The stroke and aphasia quality of life scale, generic stroke version SAQOL-39NLg, handleiding*. 2017.
 20. de Vet, Henrica C., et al. "Minimal changes in health status questionnaires: distinction between minimally detectable change and minimally important change." *Health and quality of life outcomes* 4.1 (2006): 54.
 21. Lydick, E., and R. S. Epstein. "Interpretation of quality of life changes." *Quality of life Research* 2.3 (1993): 221-226.
 22. Terwee, Caroline B., et al. "Linking measurement error to minimal important change of patient-reported outcomes." *Journal of clinical epidemiology* 62.10 (2009): 1062-1067.
 23. van Kampen, Derk A., et al. "Determination and comparison of the smallest detectable change (SDC) and the minimal important change (MIC) of four-shoulder patient-reported outcome measures (PROMs)." *Journal of orthopaedic surgery and research* 8.1 (2013): 40.
 24. Corp, I. B. M. "IBM SPSS statistics for windows, version 24.0." Armonk, NY: IBM Corp (2016).
 25. World Medical Association. "Declaration of Helsinki. Ethical principles for medical research involving human subjects." <http://www.wma.net/e/policy/b3.htm> (2008).
 26. van Wessel, S., et al. "Logopedische Richtlijn'Diagnostiek en behandeling van afasie bij volwassenen'." (2015).
 27. De Vet, Henrica CW, et al. "Minimally important change determined by a visual method integrating an anchor-based and a distribution-based approach." *Quality of life research* 16.1 (2007): 131.
 28. de Vet, Henrica CW, and Caroline B. Terwee. "The minimal detectable change should not replace the minimal important difference." *Journal of clinical epidemiology* 63.7 (2010): 804.

Tables and figures

Table 1: Baseline characteristics

Participants (35)

Age in years, mean (SD) [range]	64.3 (10.4)	[44-83]
Time post onset in months, mean (SD) [range] (n=33)	40.6 (34.6)	[12-199]
	N	Percentage %
Gender		
Female	10	28.6
Male	25	71.4
Aetiology		
Infarction	27	77.1
Hemorrhagic	3	8.6
Other	2	5.7
Unknown	3	8.6

Table 2: mean scores SAQOL-39NLg T1 and T2

Domains	Mean SAQOL-39NLg T1 (sd)	Mean SAQOL-39NLg T2 (sd)	Change in mean scores
<i>Physical</i>	4.07 (0.65)	4.15 (0.69)	+0.08
<i>Communication</i>	2.73 (0.79)	3.09 (0,74)	+0.36
<i>Psychosocial</i>	3.55 (0.77)	3.67 (0.72)	+0.12
<i>Total</i>	3.61 (0.58)	3.76 (0.57)	+0.16

Table 3: Mean change score of the SAQOL-39NLg total according to the anchor

Anchor outcome	N (%)	Mean change scores (sd)
Completely recovered (1)	0 (0)	X
Much improved (2)	7 (20)	0.39 (0.52)
Slightly improved (3)	15 (42.9)	0.17 (0.45)
No change (4)	10 (28.6)	0.06 (0.46)
Slightly worse (5)	3 (8.6)	-0.24 (0.45)
Much worse (6)	0 (0)	X
Total	35 (100)	0.15 (0.48)

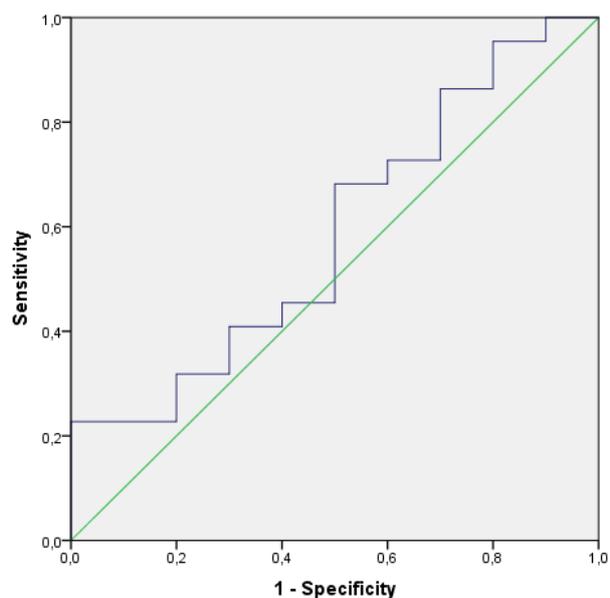


Figure 1: ROC curve of improvement in QoL on the SAQOL-39NLg in total

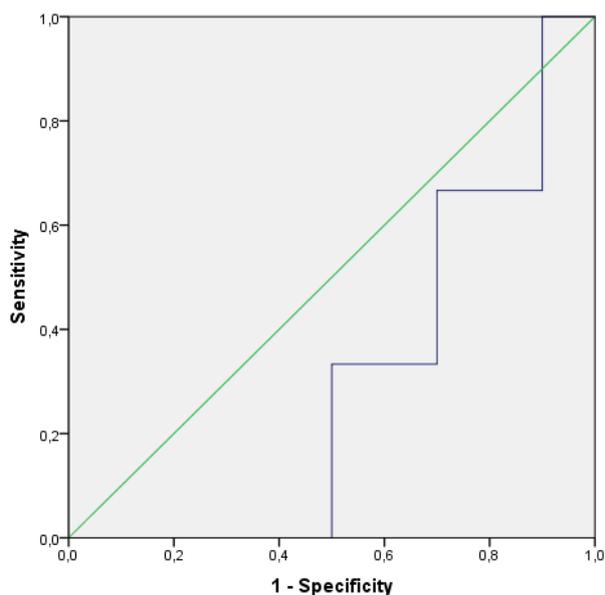


Figure 2: ROC curve of deterioration in QoL on the SAQOL-39NLg

Table 4: Mean change score of the SAQOL-39NLg domain: physical, according to the anchor

Anchor outcome	N (%)	Mean change scores (sd)
Completely recovered (1)	0 (0)	X
Much improved (2)	7 (20)	0.31 (0.66)
Slightly improved (3)	10 (28.6)	0.03 (0.32)
No change (4)	15 (42.9)	0.05 (0.49)
Slightly worse (5)	3 (8.6)	-0.13(0.23)
Much worse (6)	0 (0)	X
Total	35 (100)	0.08 (0.47)

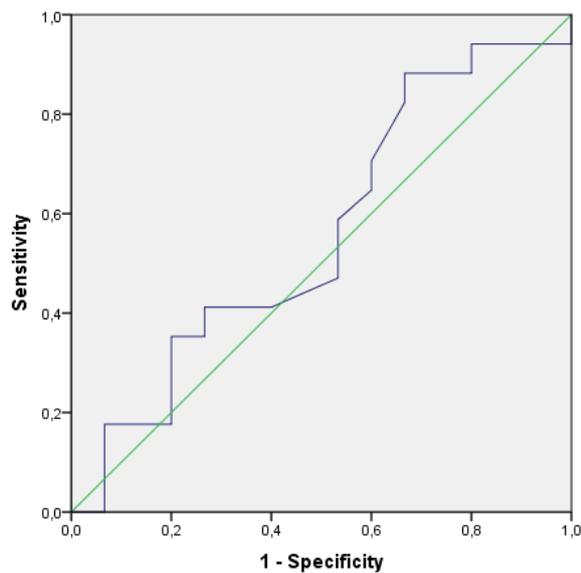


Figure 3: ROC curve of improvement in QoL on the domain 'physical'

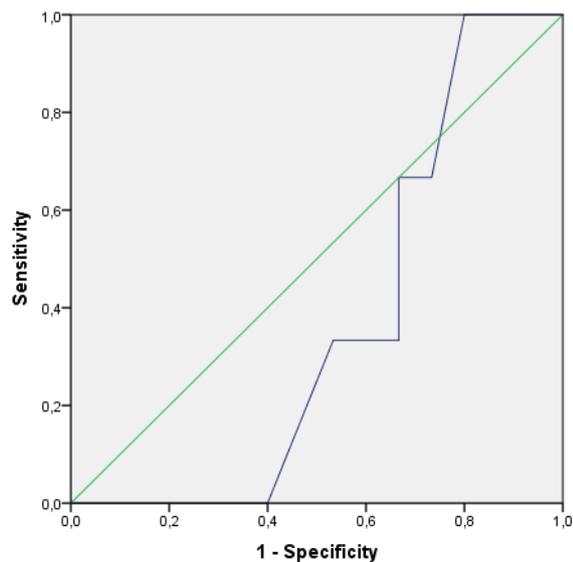


Figure 4: ROC curve of deterioration in QoL on the domain 'physical'

Table 5: Mean change score of the SAQOL_39NLg domain: communication, according to the anchor

Anchor outcome	N(%)	Mean change scores (sd)
Completely recovered (1)	0 (0)	X
Much improved (2)	7 (20)	0.39 (0.65)
Slightly improved (3)	17 (48.6)	0.46 (0.52)
No change (4)	8 (22.9)	0.26 (0.55)
Slightly worse (5)	3 (8.6)	0.05 (0.08)
Much worse (6)	0 (0)	X
Total	35 (100)	0.37 (0.53)

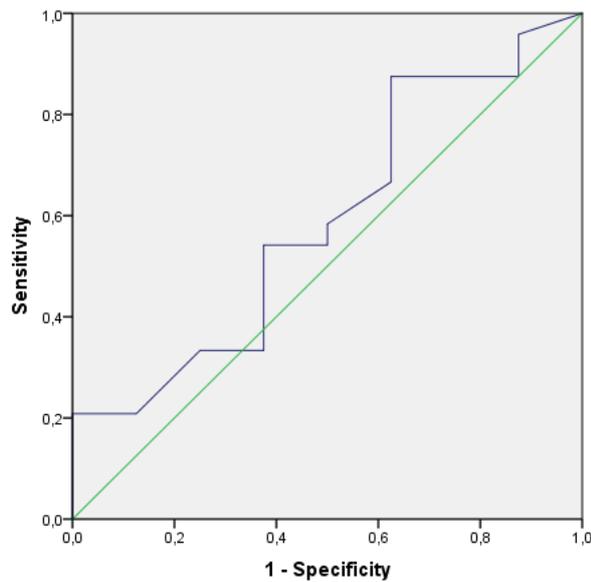


Figure 5: ROC curve of improvement in QoL on the domain 'communication'

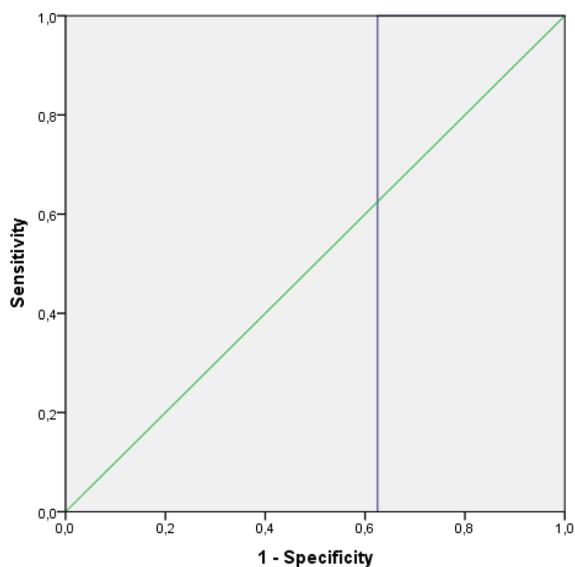


Figure 6: ROC curve of deterioration in QoL on the domain 'communication'

Table 6: Mean change score of the SAQOL_39NLg domain: psychosocial, according to the anchor

Anchor outcome	N (%)	Mean change scores (sd)
Completely recovered (1)	0 (0)	X
Much improved (2)	7 (20)	0.10 (1.28)
Slightly improved (3)	11 (31.4)	0.29 (0.85)
No change (4)	13 (37.1)	0.12 (0.63)
Slightly worse (5)	4 (11.4)	-0.27 (0.59)
Much worse (6)	0 (0)	X
Total	35 (35)	0.12 (0.83)

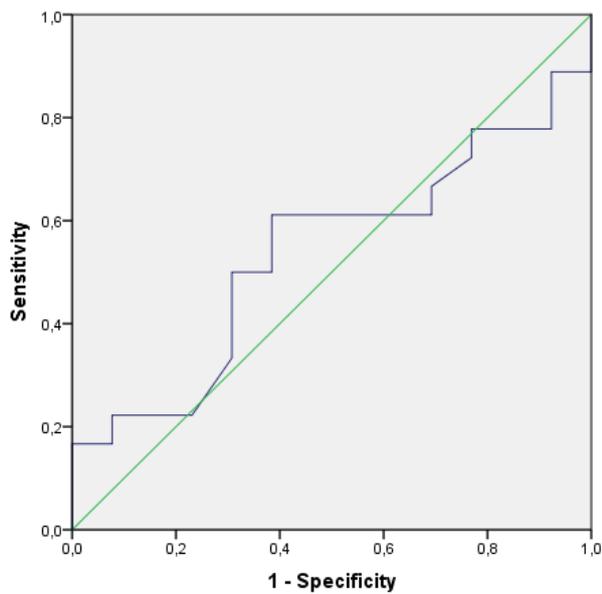


Figure 7: ROC curve of improvement in QoL on the domain 'psychosocial'

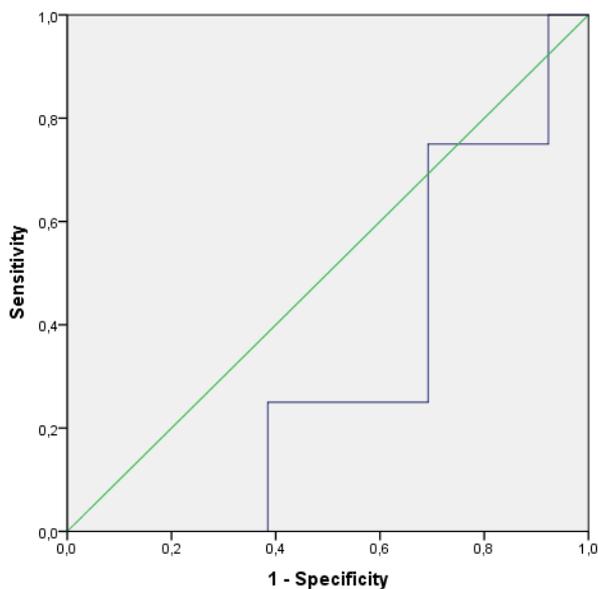


Figure 8: ROC curve of deterioration in QoL on the domain 'psychosocial'

Table 7: Overview MIC and SDC SAQOL-39NLg

Domain	MIC improvement	MIC deterioration	SDC
Physical	0.03	-0.21	0.72
Communication	0.43	-0.07	1.61
Psychosocial	-0.35	-0.17	1.00
Total	0.09	-0.22	0.64

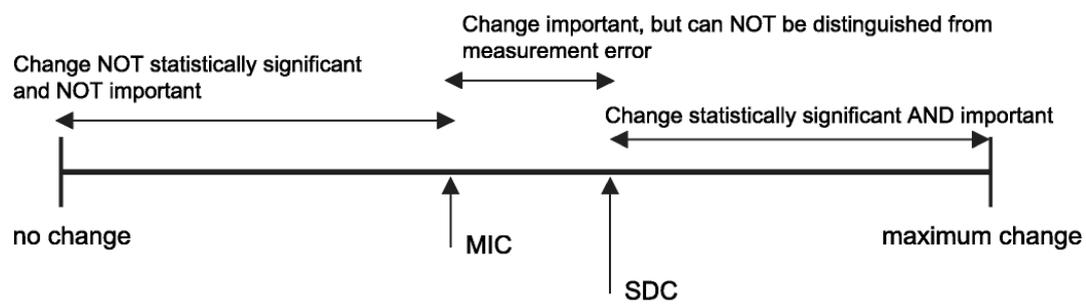


Figure 9: Interpretation of change when the MIC is smaller than SDC.²⁸

Appendices

Appendix A: Patient information form

Geachte heer/mevrouw,

U wordt vriendelijk gevraagd om mee te doen aan het **afstudeeronderzoek** van student Anne den Broeder. Anne doet onderzoek naar **de kwaliteit van leven met afasie**. Dit kan gemeten worden met de **vragenlijst**: SAQOL-39NLg. Meedoen is geheel vrijwillig. Lees deze informatiebrief rustig door.

Vraag uw logopedist om uitleg als er onduidelijkheden zijn.

Onderwerp van het onderzoek

Een beroerte verandert vaak de **kwaliteit van leven**. Er is een **vragenlijst** ontwikkeld **voor mensen met afasie**. Daarmee kunnen personen met afasie **zelf aangeven** wat voor kwaliteit van leven zij ervaren. Wij willen weten of uw kwaliteit van leven veranderd is.

Doel van het onderzoek

Met dit onderzoek meten wij of de **kwaliteit van leven** bij mensen met afasie **veranderd** is gedurende de tijd. Daarnaast willen wij weten of **u zelf vindt** dat uw kwaliteit van leven veranderd is.

Uitvoering van het onderzoek

Dit onderzoek wordt gedaan door dr. Lizet van Ewijk (onderzoeker Hogeschool Utrecht), Nicole ter Wal (onderzoeker Hogeschool Utrecht) en Anne den Broeder (student logopediewetenschap). Wij hebben uw gegevens verkregen van uw logopedist werkzaam bij Hersenz.

Wij verwachten van u dat u **eenmalig een vragenlijst invult** met uw logopedist of samen met de student die dit onderzoek uitvoert, Anne den Broeder.

Mogelijke voordelen van meedoen:

- U helpt met het **vergroten van kennis van logopedisten** over de kwaliteit van leven bij mensen met afasie.
- Deze kennis kan gebruikt worden bij het invullen van **programma's van het afasiecentrum**.
- Deze kennis kan ook aanleiding zijn voor **vervolgonderzoek**.

A.W. den Broeder; 5828015; final version; 27-06-2019

Clinical relevance of the SAQOL-39NLg

Mogelijke nadelen van meedoen:

- Het invullen van de vragenlijst kost ongeveer **45 minuten tijd**.
- De vragenlijst kan **confronterend** zijn wanneer u moeilijkheden in uw kwaliteit van leven ervaart.

Vrijwillige deelname

Deelname aan het onderzoek is geheel vrijwillig. **U mag altijd stoppen**. U hoeft geen reden op te geven.

Gebruik en bewaren van uw gegevens

Uw gegevens zullen gebruikt worden in de scriptie van Anne den Broeder. Uw gegevens zijn dan **anoniem**. Alleen de onderzoekers en uw logopedist weten uw naam.

Appendix B: Form for informed consent

Ondertekening toestemmingsformulier

Wanneer u mee wilt doen aan dit onderzoek, kunt u **schriftelijke toestemming** geven op het toestemmingsformulier. Hiermee geeft u aan dat u de informatie heeft begrepen en instemt met deelname aan het onderzoek.

Wanneer u **nog tijd nodig** heeft **om er over na te denken**, kunt u dit aangeven bij uw logopedist.

Het handtekeningblad wordt door de onderzoekers bewaard. U krijgt een tweede exemplaar van deze toestemmingsverklaring.

Heeft u vragen?

Vragen kunt u stellen aan uw logopedist, of contact opnemen met onderzoekers via het volgende mailadres:

a.w.denbroeder@students.uu.nl

Contactpersonen

- Anne den Broeder
- Uw behandelend logopedist

Bij voorbaat dank voor uw medewerking

Toestemmingsformulier deelnemer

Onderzoek: *De klinische relevantie van de SAQOL-39NL*

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn voldoende beantwoord.

- Ik weet dat meedoen vrijwillig is en dat ik altijd mag stoppen. Ik hoef dan geen reden te geven.

- Ik weet dat sommige mensen mijn gegevens kunnen inzien. Die mensen staan vermeld in deze informatiebrief.

- Ik weet dat mijn gegevens op de Hogeschool Utrecht bewaard worden zoals bij wet beschreven.

- Ik wil:
 - wel** meedoen aan dit onderzoek

 - niet** meedoen aan dit onderzoek.

Naam deelnemer:

Handtekening:

Datum : __ / __ / __

Appendix C: anchor questions hardcopy

Allereerste vraag vóór de uitleg van de vragenlijst:

In hoeverre is uw kwaliteit van leven veranderd sinds het vorige testmoment?

					
Helemaal hersteld	Veel beter geworden	Een beetje beter geworden	Niet veranderd	Een beetje slechter geworden	Veel slechter geworden

Vraag vóór vraag 1:

In hoeverre is het uitvoeren van lichamelijke activiteiten veranderd sinds het vorige testmoment?

					
Helemaal hersteld	Veel beter geworden	Een beetje beter geworden	Niet veranderd	Een beetje slechter geworden	Veel slechter geworden

Vraag vóór start communicatief domein (tussen vraag 16 en 17):

In hoeverre is de communicatie veranderd sinds het vorige testmoment?

					
Helemaal hersteld	Veel beter geworden	Een beetje beter geworden	Niet veranderd	Een beetje slechter geworden	Veel slechter geworden

Vraag vóór start psychosociaal domein (tussen vraag 21 en 22):

In hoeverre is de cognitie, zijn de emoties en is het gedrag veranderd sinds het vorige testmoment?

					
Helemaal hersteld	Veel beter geworden	Een beetje beter geworden	Niet veranderd	Een beetje slechter geworden	Veel slechter geworden