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Title: **Reliability and acceptability of the Multiple Sclerosis Quality of Life-29 questionnaire in an English speaking cohort**

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Abstract

We assessed internal consistency, validity, reliability and agreement of MSQoL-29 ; a shorter version of MSQoL-54 used for assessing Quality of life of people with Multiple sclerosis.

100 participants were recruited and 91 completed the study. Internal consistency of MSQoL-29 was good . Intraclass correlation coefficients were strongly positive between MSQoL -54 and MSQoL -29 and between the MSQoL-29 done 4 to 8 weeks apart . On Bland-Altman plots, the MSQoL-29 scores of 95% of participants done 4 to 8 weeks apart were within the limits of agreement. Time to complete MSQoL-29 was 12.5 minutes shorter than for MSQOL-54 .

MSQoL-29 has good internal consistency, validity and test-retest reliability and was quicker to complete.

Introduction:

Persons with multiple sclerosis (PwMS) have lower Health Related Quality of Life (HRQoL) compared to people living with long term conditions like Parkinson's disease, epilepsy and diabetes mellitus^{2,3}.⁴ MSQoL-54 is a MS-specific HRQoL instrument validated in many languages⁵. Based on responses for each of the 54 questions, the scores are linearly transformed into two composite scores, the Physical Health Composite (PHC) and Mental Health Composite (MHC); the values of each range from 0 to 100, with higher scores indicative of a higher HRQoL⁶. Using confirmatory factor analysis and Rasch modelling Rosato et al devised a shortened version with 29 questions called MSQoL-29⁷. The aim of this study is to assess the validity, reliability, internal consistency and acceptability of MSQoL-29 in an English speaking cohort.

Participants and methods

We conducted this study at a regional MS centre in United Kingdom. The study received ethical approval from the York Research Ethics Committee. Inclusion criteria were 1) diagnosis of MS according to the 2010 revision of McDonald's criteria⁸ 2) ability to read and understand written English, 3) consent to participate in the trial, 4) able to attend two appointments 4 to 8 weeks apart. Patients with cognitive issues that would impair understanding of the questionnaires were excluded from the trial.

At initial visit the participants completed both MSQoL-54 and MSQoL-29 and a feedback form. The order of administration of the two questionnaires was randomised (online random number generator) so that half of the participants completed the MSQoL-29 first and the others completed the MSQoL-54 first. The time taken to complete the questionnaires was recorded. After 4 to 8 weeks participants with relapses or significant health problems requiring hospitalisation or an appointment with doctor were excluded. Others completed MSQoL-29. .

Statistical analyses: Statistical analyses were performed using SPSS version 22.0 for Windows and version 23.0 for Macintosh. All tests were two sided and significance was accepted at 5% ($\alpha=0.05$). Internal consistency was assessed using Cronbach's alpha⁹. Intraclass Correlation Coefficients (ICC) were used to assess the validity of MSQoL-29 by looking at its correlations with MSQoL-54. The test retest reliability was assessed calculating ICC between MSQoL-29 administered 4-8 weeks apart¹⁰. Bland-Altman plots were used to assess the agreement between MSQoL 54 and 29^{12,13}. The limits of agreement (LOAs) were taken as 2 SD of the mean of MSQoL 29 and 54¹³. The agreement between the two MSQoL-29 scores were also assessed using Bland-Altman plots and limits of agreement (LOAs) were taken as 2 SD of the mean of MSQoL 29 for visits 1 and 2. Feedback responses were analysed as frequencies.

Results:

A total of 100 participants were recruited and 91 completed both visits. Socio-demographic and clinical characteristics of participants are shown in Table 1.

Table 1: Sociodemographic and clinical characteristics of the participants

None of the patients scored minimum or maximum in PHC or MHC during any of the assessments. The mean time to complete MSQoL-54 was 19.79 +6.93 minutes and MSQoL-29 was 7.22 +2.94 minutes. Participants took 12.5 minutes less to complete MSQoL-29. (paired t test $t=-12.148$, $p= 0.0001$). The Cronbach's alpha for MSQoL-29 PHC was 0.875 and MSQoL-29 MHC was 0.914 suggestive of good internal consistency¹⁰. The ICC between MSQoL 54 and MSQoL-29 were : PHC-0.914 (CI 0.872 – 0.942), MHC-0.875 (CI- 0.814 to 0.916). The ICC between two MSQoL-29 scores done 4 to 8 weeks apart were: PHC- 0.970 , CI- 0.955 -0.980 and MHC - 0.937, CI- 0.904 -0.958.

The Bland Altman plots of agreement for MHC and PHC scores of MSQoL-54 and MSQoL-29 and two MSQoL-29 scores showed that that 95% of observations were between the LOA.

Of the 91 participants 51(52.6%) indicated they had no preference between MSQoL-54 and MSQoL-29 and 40(47.4%0 preferred MSQoL-29. The participants found MSQoL-54 'long', or 'time consuming' . Two participants were concerned about removal of the bladder and bowel dysfunction question in MSQoL-29. Three participants did not like the questions regarding sexual function, .

Discussion

The study evaluated the internal consistency, validity and reliability of MSQoL-29 for the first time in an English speaking cohort of PwMS. The feedback from the participants indicated that MSQoL-29 was an acceptable tool. Our data show that MSQoL is preferred by the patient and is quicker to complete than MSQoL-54.

The internal consistency of MSQoL-29 for both PHC and MHC was excellent and good respectively. ¹⁴⁻¹⁶ As observed by Rosato *et al.* in the Italian speaking population, we noted a strong correlation between scores of MSQoL-54 and MSQoL-29. ⁸ Our data showed that reliability of MSQoL-29 is as good as that of MSQoL-54 ^{7,15}.The MSQoL-29 is as valid and reliable a tool to evaluate QoL in PwMS as MSQoL-54.

When two different methods are measuring the same outcome, it is expected that there would be a moderate correlation based on the simple fact that the outcome being measured is the same. Bland-Altman plot is a more thorough method of analysis, where results from individual participants can be scrutinised. ^{12,13} In the Bland-Altman plot, the overall agreement between MSQoL 54 and MSQoL-29 and MSQoL-29 done 4-8 weeks apart appears good. There is considerable variation between scores in certain participants. There are no studies on any HRQoL instruments using Bland-Altman plot.

Further studies are required to ascertain whether wide limits of agreement are likely to be clinically relevant.

Both MSQoL 54 and MSQoL-29 did not show ceiling or floor effect. Differences in the mean time to complete the two instruments were significantly shorter for MSQoL-29. Ten minutes has been cited as the length of time fully compatible with clinical practice.¹⁸ The mean time required to complete MSQoL-29 was 7.22 +2.94 minutes; 12.5 minutes less than the time to complete MSQoL-54. In view of the comparable validity and reliability and shorter completion time MSQoL-29 would likely be more appropriate tool in clinical practice .

Limitations

Almost all participants had RRMS and EDSS score of 4.5 to 7.0. Future research on MSQoL-29 need to include a more diverse sample of PwMS. The MSQoL- 29 was not validated against any other QoL measures.

Conclusion

Ours was the first study to investigate the validity and reliability of MSQoL-29 in a large English speaking cohort. This study showed that MSQoL-29 is an internally consistent, valid and reliable instrument to measure QoL in PwMS. It could be completed at less than 10 minutes. Further research evaluating the Bland-Altman agreement of HRQoL instruments is required.

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Table 1: Sociodemographic and clinical characteristics of the participants

| | |
|---|--------------------------------|
| Variables | |
| Age, mean years | 42.8 (SD-9.179, range-20 -67) |
| Gender | |
| Men | 30 |
| Women | 70 |
| Education | |
| School | 40 |
| Vocationally trained | 18 |
| University | 42 |
| Living arrangements | |
| Alone | 32 |
| With partner, family or carer | 78 |
| Care needs | |
| Nil | 54 |
| Requires assistance | 46 |
| Type of MS | |
| Relapsing-remitting | 98 |
| Secondary progressive | 2 |
| Duration since MS diagnosis, mean years | 5.5 (SD-7.15, Range-0.5 -30)) |
| EDSS score | |
| 4.5 | 32 |
| 5.0 | 13 |
| 5.5 | 4 |
| 6.0 | 31 |
| 6.5 | 11 |
| 7 | 9 |