

Minimum Sample Size Requirements for a Validation Study of The Schizophrenia Quality of Life Scale-Revision 4 (SQLS-R4)

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Received: 05.02.2018; **Accepted:** 22.06.2018; **Available Online Date:** 09.10.2018
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Cite this article as: Martin C.R & Larkin D. Minimum Sample Size Requirements for a Validation Study of The Schizophrenia Quality of Life Scale-Revision 4 (SQLS-R4). J Basic Clin Health Sci 2018; 2:76-81. <https://doi.org/10.30621/jbachs.2018.411>

Abstract

Purpose: The Schizophrenia Quality of Life Scale-Revision 4 (SQLS-R4) is a widely used self-report quality of life measure used in a broad range of clinical contexts, from primary research to clinical trials. International use of the measure has led to translated versions validated for local context. Most translation and validation studies of the SQLS-R4 have been conducted with modest N, at the threshold of acceptability of even the most liberal recommendations for validation studies. Given the comparatively large number of items in the SQLS-R4 (N=33), low N studies could potentially be underpowered limiting validity and reliability. Using sample sizes from published studies as a baseline, the current investigation sought to determine a minimum sample size for an SQLS-R4 translation/validation study.

Methods: A model specification based on the two-factor structure of the SQLS-R4 was constructed to calculate an acceptable model fit based on the sample size used in most SQLS-R4 translation/validation studies (N=100). A series of Monte Carlo simulations was then conducted to determine the sample size required to offer a good fit to data for an adequately powered study.

Results: The series of simulations conducted suggests that a minimum sample size for an adequately powered validation/translation study of the SQLS-R4 to provide a good fit to data is N=160.

Conclusion: Sample size determination of SQLS-R4 validation/translation studies should be informed by the intrinsic measurement characteristics of the measure to ensure an adequately powered study.

Keywords: Schizophrenia Quality of Life-Revision 4 (SQLS-R4), simulation, sample size, questionnaire

INTRODUCTION

Quality of life measures are becoming increasingly important in therapeutic settings, informing clinical decisions, and guiding therapeutic interventions (1-3). This is particularly important for patients with chronic conditions, such as schizophrenia (4). Schizophrenia is generally defined by abnormalities in one or more of the following domains, delusions, hallucinations, disorganised thinking, grossly disorganised or abnormal motor behaviour and negative symptoms (5). In the therapeutic pathway, healthcare professionals are becoming acutely aware of the need to measure the patient's quality of life (QoL) (6). QoL is defined as the individual's perception on their position in life, set within the context of culture and value their system, including their goals, expectations, standards and concerns (7), which could be used to form long-term goals for medical interventions, for example, Adelufosi et al. (4).

For mainly practical purposes, there are a limited number of QoL measures used with a schizophrenia population. There are generic measures specifically designed for non-clinical populations exploring global concerns that are not necessarily unique to a schizophrenic population. On the other hand, specific measures such as the schizophrenic quality of life scale revision 4 (SQLS-R4, 6), has been identified as a particularly useful measure for understanding how symptoms of schizophrenia effect the patient's QoL (3, 8, 9). The SQLS-R4 is a self-report measure comprising 33 items from which two domains of QoL, psychosocial feelings (22 items, e.g. 'worry about the future') and cognition and vitality (11 items, e.g. 'lack energy') are derived. The items are scored on a 5-point frequency-response Likert scale ("never", "rarely", "sometimes", "often", "always"). A total score of both domains can also be calculated and individual domain and total scores are standardized by scoring algorithm to a 0 -100 scale. Higher SQLS-R4 scores indicate comparatively lower QoL

(6). The SQLS-R4 has been designed to be short (10-15 minutes to complete), with robust psychometric properties, solid factor structure, and internal reliability (6, 10-12). The psychometric stability of the SQLS-R4 only pertains to the original study and would not necessarily apply to the development of translated or adapted versions of the SQLS-R4. The measure would be required to undergo analysis to assess its psychometric stability anew. An accepted and robust method of accomplishing this is through using confirmatory factor analysis (CFA), which represents a special case of structural equation modelling (13). An essential methodological concern with the use of CFA for psychometric appraisal of factor structure is the issue of sample size. Sample size concerns also apply to other forms of factor analysis for example exploratory factor analysis (EFA). It is of grave methodological disquiet that sophisticated statistical analysis such as CFA, EFA and structural equation modelling based methods, often rely on sample size calculations that are based on standard practice rather than embedded in theory. Therefore, the number of participants is often disproportionate to the number of items in the measure ranging from 3 to 10 and greater (14, 15). With studies recommending minimum samples sizes that are limited in their scope, and arguably under powered for example 50, de Winter, Dodou (16), Jung and Lee (17), 100, Kline (18), 150, Hutcheson and Sofroniou (19) and 200, Gorsuch (20). Small sample sizes are not uncommon see for example Crothers and Dorrian (21). Using samples sizes that are based on practice rather than theory or 'rule of thumb' are exposed to a number of methodological limitations, for example, they may not be sensitive to the factor structure, or whether the model has just one or multiple factors. Also, the model may be insensitive to the relationship between factors and the relationship of items to factors in terms of anticipated factor loadings. Rather than relying on 'rule of thumb' Muthén and Muthén (22) have proposed an approach that is contextually sensitive to determine a sample size for CFA for an adequately powered study. The model needs to be based on an established factor structure, where the relationships between factors, and between items are known, if these conditions are met a Monte Carlo simulation can be conducted based on established sample size determination conventions (23, 24), such as power (0.80) and alpha ($p = 0.05$). Monte Carlo simulation require that data

are generated from a population with hypothesized parameter values. The following criteria are examined: parameter estimate bias, standard error bias, and coverage. In order to undertake a Monte Carlo simulation several features need to be considered, the choice of model and the population values for each parameter of the model must be selected. For the current simulation both parameters were drawn from data derived from the SQLS-R4. Estimates from previous studies, are generally the most appropriate values in the Monte Carlo simulation (22). In translating, adapting, and/or validating a study using the SQLS-R4 it would be beneficial to determine the minimum sample size, to inform the viability, exactitude, and realities of conducting such studies. This will also safeguard the study by conferring confidence in the findings that the study is adequately powered, and the sample size is based on empirical observations, and not the 'rule of thumb'. In many regards the rule of thumb refers to a process whereby researchers will follow samples sizes that have been established in previous studies without determining the most appropriate sample size for their own study. In addition, determining the most appropriate minimum sample size based on the two-factor SQLS-R4 model, would benefit the body of validation studies which have been conducted, across the globe. It is also incumbent upon the research team to adequately power translation/adaptation/validation studies of the SQLS-R4, so that patients who volunteer for such studies are not misrepresented in the findings. It is also incumbent upon the research team to find the most appropriate number of patients to take part in order to satisfy the study aims and objectives.

To date most translation/adaptation/validation studies have used just 100 patients, presumably based on the 'rule of thumb' sample size established by Martin and Allan (6) see for example Su, Yang (3), Kuo, Chen-Sea (8) Kuo, Ma (25). However, selection of such a modest sample size may be problematic particularly in terms of the relatively large number of items ($N=33$) within the measure which would violate other minimum sample size criteria such as number of participants to number of items ratio (26). Table 1 summaries the SQLS-R4 translation/adaptation/validation studies emphasizing the limited sample size.

Table 1. Summary of SQLS-R4 translation/adaptation/validation studies.

Authors	Publication DOI	Primary diagnosis	Mean length of time of diagnosis	Gender Male/Female	Mean Age years (SD)	Sample Size
Chia-Ting Su et al.	10.1155/2017/5328101	Schizophrenia	26.6 ± 8.1 years	66/34	49.2(7.87)	100
Chou, Chia-Yeh et al.	10.1016/j.psychres.2014.12.059	Schizophrenia	undefined	29/12	37.9(7.36)	41
Martin and Allan	10.1080/13548500500407383	Schizophrenia	24.64 years SD. 7.99 (mean age of first diagnosis)	74/26	40.7(11.43)	100
Nur AkmarTaha et al.	10.1016/j.vhri.2012.03.006	Schizophrenia	11.42 ± 8.02 years	110/112	37.7 (10.13)	222
Kuo et al	10.3109/13651500902919376	Schizophrenia	12.52 ± 7.47 years	75/25	36.9 (8.82)	100
Kuo, Chen-Sea et al	10.1007/s11136-007-9262-9	Schizophrenia	12.52 ± 7.47 years	75/25	36.9 (8.82)	100
Isjanovski et al.	10.3889/oamjms.2016.015	Schizophrenia	18.1 ± 9.4 years	42/19	47.4 (8.9)	61

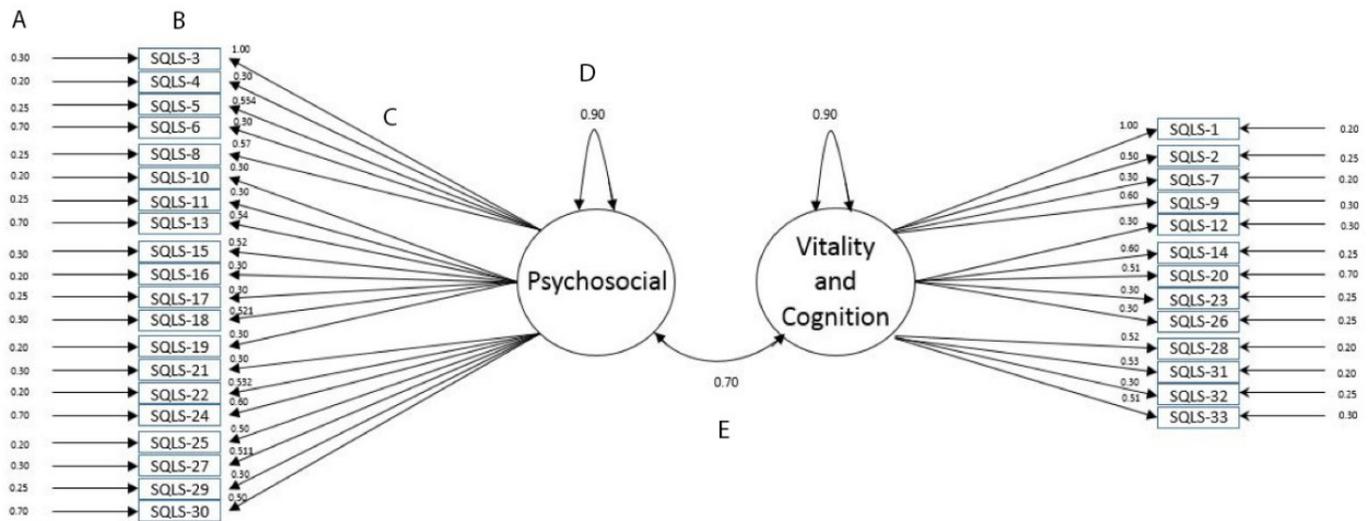


Figure 1. Two-Factor Model of the SQLS-R4 indicating key parameter values used in the model to produce through simulation a model for comparison fit index of .09 based on a sample size of N=100. The SQLS-R4 is a self-report measure comprising 33 items from which two domains of QoL, psychosocial feelings (22 items) and cognition and vitality (11 items) are derived. **A)** Is the measure of error in the item (each question in the SQLS-R4). **B)** Are individual questions that when combined measure either psychosocial feelings or cognition and vitality. **C)** Represents regression weights, linked by regression lines. **D)** Measure of model fit relative to other models or comparative fit index (CFI). CFI analyses the model fit by examining the discrepancy between the data and the hypothesized model, while adjusting for the issues of sample size inherent in the chi-squared test of model fit, and the normed fit index. A figure of 0.90 or larger is considered to indicate acceptable model fit. **E)** The figure of 0.70 is a measure of factor correlation.

OBJECTIVES

Using the rubric interpreted from previous SQLS-R4 studies that a sample size of N=100 is adequate to produce an acceptable fit to data, the current study sought to determine the minimum sample size required to offer a good fit to data within an adequately powered study using Monte Carlo simulation (22).

METHOD

Using the power analysis and sample size calculation approaches of Muthén and Muthén (22) and Beaujean (27), a model based on the SQLS-R4 was constructed with appropriately specified parameter values (please see Table 2), essentially, for the two-factor model (a model of the SQLS-R4), specifying the covariance between factors, item-factor loadings, residuals variances. The model constructed, used plausible parameter values gleaned from previous studies to generate a model that would produce a minimum acceptable fit to data by standard convention based on a sample size of N=100. This model would then be used to generate data through Monte Carlo approaches estimating the model parameters over N=10,000 simulated samples from which parameter estimates would be averaged across these samples. Consistent with convention, minimum power for each parameter was set at 0.80 (22). The model specification is shown in Figure 1.

Quality criteria for simulated data

Using Muthén and Muthén (22) criteria that indices of relative parameter estimate bias (RPEB) and relative parameter standard error bias (RPSEB) be used to determine simulation quality,

acceptable RPEB and RPSEB values of ≤ 0.10 for all parameters was specified as threshold values for simulation quality. RPSEB values of ≤ 0.05 for parameters of major interest has been suggested Muthén and Muthén (22). Coverage is an important index of simulation quality and refers to the percentage of simulation replications where the parameter value sits within the 95% confidence interval (CI). Coverage is determined to be acceptable within the range of 0.91 to 0.98 (22). A conventional type 1 error rate of 0.05 was specified. Conventional threshold values for confirmatory factor analysis fit indices were used to specify the baseline (N=100) and determine the criteria for a good fit model. Using the unitary index of the comparative fit index (CFI), (28), to specify the acceptable fit (29) baseline model (~ 0.90) and the good fitting model (≥ 0.95) (30), other accepted indices of model fit were also calculated for a given sample size including, the root mean squared error of approximation (RMSEA), (13) and the squared root mean residual (SRMR), (30). RMSEA values of ≤ 0.08 are indicative of acceptable fit (31) and RMSEA values (< 0.05) indicate good fit (32). SRMR values of < 0.08 indicate acceptable fit (30). A χ^2 statistic was also calculated. 10,000 replications were run for each simulation and two simulations for each model was run to allow consistency to be evaluated. A unique random number seed was used to set each simulation. Each simulation was specified by an incremental rise (N=10 and N=5) in sample size from baseline (N=100) until a sample size consistent with a good fit to data (CFI=0.95) was observed. Statistical analysis was conducted using the R programming language (33) and the specialist R structural equation modelling packages Lavaan (34) and Simsem (35).

RESULTS

Monte Carlo simulation findings for each sample size are summarised in Table 2, Comparative Fit Index (CFI) is a measure of model fit relative to other models. Root Mean Squared Error of Approximation (RMSEA) is used as a measure of the differences between values (sample and population values) predicted by a model or an estimator and the values actually observed. Standardised Root Mean Residual (SRMR) is the square root of the discrepancy between the sample covariance matrix and the model covariance matrix. Relative Parameter Estimate Bias (RPEB) and Relative Parameter Standard Error Bias (RPSEB) being indicators of the parameters anticipated value and an estimated true value. Evaluation of simulation quality, model fit and statistical power as a function of sample size indicates that a good fit to data would be found with a minimum sample size of N=160.

DISCUSSION

This current study represents the first investigation, to the authors knowledge, to explore the sample size requirements that would inform a translation/adaptation and/or validation for the schizophrenic quality of life scale revision 4 (SQLS-R4, 6). Moreover, the study itself, represents an important milestone for future endeavours in translation/adaptation and/or validation of the SQLS-R4 by setting a minimum sample size, to ensure that future studies have adequate power. Therefore, the model

parameters specified for the simulations represent an exemplar in being identical to the measurement characteristics and structure of the SQLS-R4. Noteworthy is that this approach not only represents a departure from 'rule of thumb' used in many studies but in addition it also demonstrates an innovative within the simulation literature where Monte Carlo models are often based on a simplified model approximation (for example, item-factor loadings specified as identical across the model). Pivotal in this explanation is dependent upon the availability of original model specification derived from original data and the use of simulation approaches to an applied research question.

There are very real practical constraints when conducting clinical research, often studies are limited in terms of sample size because of very pragmatic and reasonable difficulties in acquiring adequate number of patients or participants. This however, could be argued is not an adequate justification for underpowered studies, but it is not surprising that many validation studies are conducted with sample sizes between N=100 – N=200 and generally, these sample sizes are justified on the basis of 'rule of thumb' recommendations, and not on sufficient access to a specific population. This raises a methodological conundrum, where research groups are often caught performing a balancing act between resource accessibility and scientific plausibility. A limited literature search discloses numerous published EFA and CFA studies with sample sizes within the 'rule of thumb' range acknowledge but qualify their sample size as an accepted limitation. However, it could be argued that a

Table 2. Monte Carlo simulation for model sample sizes ranging from N=100 to N=160. CFI: Comparative Fit Index; RMSEA: Root Mean Squared Error of Approximation; SRMR: Standardised Root Mean Residual; RPEB: Relative Parameter Estimate Bias; RPSEB: Relative Parameter Standard Error Bias; RPEB and RPSEB criteria for acceptability ≤ 0.05, Acceptable coverage range 0.918-0.954.

Model	N	Cycle	χ ²	CFI	RMSEA	SRMR	Coverage	RPEB	RPSEB	Power
SQLS-R4 two-factor	100	1	638.796	0.896	0.054	0.072	0.918-0.950	0.001-0.023	0.003-0.037	0.902-1
	100	2	636.851	0.897	0.054	0.071	0.920-0.951	0.001-0.022	0.001-0.040	0.898-1
	110	1	627.552	0.911	0.050	0.068	0.922-0.949	0.001-0.021	0.003-0.035	0.925-1
	110	2	627.815	0.911	0.050	0.068	0.918-0.951	0.001-0.022	0.004-0.036	0.928-1
	120	1	619.191	0.923	0.046	0.065	0.923-0.952	0.001-0.020	0.001-0.030	0.943-1
	120	2	619.510	0.923	0.046	0.065	0.923-0.950	0.001-0.020	0.001-0.031	0.940-1
	130	1	612.765	0.932	0.043	0.062	0.925-0.951	0.001-0.018	0.001-0.030	0.957-1
	130	2	612.699	0.932	0.043	0.062	0.925-0.952	0.001-0.019	0.001-0.031	0.960-1
	140	1	607.435	0.940	0.040	0.060	0.927-0.952	0.001-0.017	0.001-0.031	0.967-1
	140	2	608.402	0.939	0.041	0.060	0.928-0.950	0.001-0.017	0.001-0.027	0.966-1
	150	1	602.413	0.946	0.038	0.058	0.926-0.952	0.001-0.017	0.001-0.031	0.979-1
	150	2	603.619	0.946	0.038	0.058	0.928-0.952	0.001-0.016	0.001-0.029	0.976-1
	155	1	600.012	0.949	0.037	0.057	0.927-0.951	0.001-0.016	0.001-0.024	0.977-1
	155	2	600.884	0.948	0.037	0.057	0.925-0.953	0.001-0.016	0.001-0.028	0.979-1
	160	1	599.937	0.950	0.037	0.056	0.927-0.952	0.001-0.015	0.001-0.021	0.985-1
	160	2	599.510	0.950	0.037	0.056	0.929-0.954	0.001-0.015	0.001-0.027	0.984-1
	160 R	1	598.113	0.951	0.036	0.056	0.929-0.952	0.001-0.015	0.002-0.026	0.983-1
	160 R	2	599.905	0.951	0.037	0.056	0.927-0.951	0.001-0.014	0.001-0.038	0.980-1

tailored sample size estimation for a specific measure, in relation to this study the SQLS-R4, would enthuse confidence within the research team, in terms of justifiable sample size from the outset. This would inform the requirement to secure adequate resources, and access to the desired population, and would inform the feasibility of the proposed investigation. Furthermore, adherence to an empirically-derived and instrument-specific sample size estimation may offer useful evidence in the write up of the study that sample size was indeed both sufficient and appropriate.

A limitation of the current study is that the sample size estimations derived by simulations conducted are specific to the SQLS-R4, as such the sample size estimation is not appropriate to use as an estimation of sample size for other instruments, therefore is not transferable. It should be noted that there are at least two elements that impact on sample size selection for a CFA model are non-normal data and missing data (22). We would argue that research groups should consider these elements in relation to future SQLS-R4 studies and indeed, any planned validation study. We would advocate, that whenever possible, the complete data set should be used within the analysis, with the smallest number of missing data points (<5%). It must be acknowledged however, that the 'rule of thumb' sample size established by Martin and Allan (6) and utilised by other studies (3, 8, 25) used an estimated sample size that was much too small, thus lacking in power. This underlines the importance of conducting simulations such as the Monte Carlo simulation to determine the sample size required to offer a good fit to data for an adequately powered study.

CONCLUSION

The current simulation used a series of Monte Carlo simulations to determine the sample size required to offer a good fit to data for an adequately powered study for the SQLS-R4. This analysis revealed that a minimum sample size of N=160 is required. We therefore recommend that future validation studies on the SQLS-R4 subscribe to this as a minimum sample size in order to avoid type 1 error. We emphasise that a N=160 is the minimum sample size, and that studies which use larger samples sizes increase the power and precision.

Traditionally studies employing EFA and CFA have customarily used the 'rule of thumb' to estimate the minimum sample size, however, this technique is insensitive to the gradations and characteristics of the instrument under investigation. We therefore advocate that before a study commences and irrespective of the particular instrument being considered for a validation, some planning and provision must be given over to sample size requirements, and to not just to rely on 'rule of thumb'. The current study also draws attention to the rather perplexing limitations in the promotion of small N for validation studies using EFA, CFA and SEM.

Ethics Committee Approval: Not Applicable

Informed Consent: Not Applicable

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - CM, DL; Design - CM; Supervision - CM, DL; Data Collection and/ or Processing - CM; Analysis and/or Interpretation - CM; Literature Search - DL; Writing - CM, DL; Critical Reviews - CM, DL

Conflict of Interest: The authors declare that there are no conflicts of interest.

Financial Disclosure: This study has received no financial support

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