Technical Note

Validation study can be a separate study design

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Abstract

Psychometrics has a very important role and with the increase in the number of cross-cultural research projects, there is a need to adapt health status measures. In validation study, there are different scientific steps during translation, cultural adaptation, sample size estimation and assessing reliability and validity with distinct statistical analysis. Author aimed to opine to use validation study as a separate study design rather than the current trend of assigning cross-sectional study design.

KEY WORDS: Validation study, cross-sectional study, psychometrics

Introduction

Psychometrics has a very important role in public health, psychiatry, primary health care and many other fields even in health promotional strategy for measuring the attitude.[1] With the increase in the number of multinational and multicultural research projects, the need to adapt health status measures for use in other than the source language has also grown rapidly[2] for the assessment of health outcomes as well as to take further actions based on the research. Currently, most of the researchers are mentioning cross-sectional study as the study design during the validation studies. Steps in validation study comprise standard translation and cultural adaptation, reliability testing in different forms by statistical markers and validity testing in different forms with distinctive statistical analysis. Author raises some distinctive characteristics of scale validation that may demand a separate study design for the validation studies.

Translation and Cultural Adaptation

Cross-cultural adaptation follows a very scientific procedure, which follows translation of scale from original to expected language by two or more different translators among them one person is informed regarding the process and other one person is totally disguised regarding the process. Then the two versions are compiled and back translated into the original language by two different persons. This back translated versions are compiled and submitted for expert committee approval, which is composed by following guidelines. Expert committee observations are accepted to ensure semantic, idiomatic, experiential and conceptual equivalence. Pretesting is done with the suggested questionnaire with 30–40 people and further changes are accepted based on the pretesting and final version of questionnaire is prepared by following the scientific steps.[2]

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Sample Size Estimation

Sample size estimation follows a different scientific method based on either item sample ratio or statistical procedure that is specifically different from other study designs. Regarding Exploratory Factor Analysis (EFA) basis of sample size estimation, recommendations to ensure the sample size ranges from 100 to 250 while other recommendations mentioned to ensure a sample size >300 to ensure good statistical estimation. The item sample ratio and sample size estimation process lacks any definitive ratio. Researchers use minimum 2 to maximum 20 people per item to estimate the sample size that is assumed arbitrarily. Some authors use Kaiser–Meyer–Olkin (KMO) sampling adequacy test to ensure the adequate sample size.[1,3,4]

Reliability Assessment

Reliability is measured in the form of internal consistency based on Cronbach's alpha having a level af bove ≥0.70; test–retest reliability by comparing the data obtained by interviewing the subjects after a certain period of time, arbitrary

2 weeks, with statistical markers; and inter-rater reliability by comparing the data obtained by interviewing the subjects by another interviewer with statistical markers.[1,3]

Validity Assessment

Validity is assessed in different forms: face validity during translation and adaptation process, content validity during translation and adaptation process, criterion validity by comparing with the gold standard measures, construct validity by factor analysis, convergent validity by comparing with similar instruments, divergent validity by comparing with different instruments, concurrent validity, predictive validity, and known group validity by specific statistical process. All the validity forms follow very distinctive scientific method and significantly different from other study design.[1–3]

Why Different

In every step of the validation study, there is a different scientific established pathway that is being used day to day as well as established, practiced and contradictory to the basic cross-sectional design. Based on the above mentioned considerations, author aimed to focus on scientific debate to ascertain the validation study as a different study design rather than cross sectional design.

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