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Clinimetric scales; 2.7 Measuring quality of life: Indicator or causal items; 2.8 Developing and testing questionnaires; 2.8.1 Specify the research question and define the target population; 2.8.2 Identify concepts; 2.8.3 Create instrument; 2.8.4 Assess measurement properties; 2.8.5 Modify instrument; 2.9 Further reading
3 Choosing a quality of life measure for your studySummary; 3.1 Introduction; 3.2 How to choose between instruments; 3.3 Appropriateness; 3.4 Acceptability; 3.5 Feasibility; 3.6 Validity; 3.6.1 Tests for criterion validity; 3.6.2 Tests for face and content validity; 3.6.3 Tests for construct validity; 3.7 Reliability; 3.7.1 Repeatability reliability; 3.7.2 Graphical methods for assessing reliability between two repeated measurements; 3.7.3 Internal reliability or internal consistency reliability; 3.8 Responsiveness; 3.8.1 Floor and ceiling effects; 3.9 Precision; 3.10 Interpretability
3.11 Finding quality of life instruments4 Design and sample size issues: How many subjects do I need for my study?; Summary; 4.1 Introduction; 4.2 Significance tests, P-values and power; 4.3 Sample sizes for comparison of two independent groups; 4.3.1 Normally distributed continuous data - comparing two means; 4.3.2 Transformations; 4.3.3 Comparing two groups with continuous data using non-parametric methods; 4.3.4 Dichotomous categorical data - comparing two proportions; 4.3.5 Ordered categorical (ordinal) data; 4.4 Choice of sample size method with quality of life outcomes; 4.5 Paired data
4.5.1 Paired continuous data - comparison of means4.5.2 Paired binary data - comparison of proportions; 4.6 Equivalence/non-inferiority studies; 4.6.1 Continuous data - comparing the equivalence of two means; 4.6.2 Binary data - comparing the equivalence of two proportions; 4.7 Unknown standard deviation and effect size; 4.7.1 Tips on obtaining the standard deviation; 4.8 Cluster randomized controlled trials; 4.9 Non-response; 4.10 Unequal groups; 4.11 Multiple outcomes/endpoints; 4.12 Three or more groups; 4.13 What if we are doing a survey, not a clinical trial?
4.13.1 Sample sizes for surveys

Sommario/riassunto

An essential, up-to-date guide to the design of studies and selection of the correct QoL instruments for observational studies and clinical trials. Quality of Life (QoL) outcomes or Person/Patient Reported Outcome Measures (PROMs) are now frequently being used in randomised controlled trials (RCTs) and observational studies. This book provides a practical guide to the design, analysis and interpretation of studies that use such outcomes. QoL outcomes tend to generate data with discrete, bounded and skewed distributions. Many investigators are concerned about the appropriateness o