Reviewer's report

Title: Sample size calculations for skewed distributions

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Reviewer: Stephen John Walters

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The paper should emphasise the use of the proposed sample size method for count outcomes such as:
number of visits to a GP in a year; number of children in a family;
number of epileptic fits in a year etc
which are frequently summarised with the mean number per time period; but a based on a discrete non-negative integer outcome.

Numerous papers have highlighted the robustness of "standard" statistical methods of analysis such as the t-test and linear regression; to departures from the assumptions that the outcome follows a Normal distribution for sample sizes as low as 20 or 30 per groups.


Does the sample size estimation method also depend on how the outcome data are summarised? E.g. mean or proportion or a rate or time to an event? And what is an appropriate comparative summary measure e.g. difference in means; difference in proportions, relative risk, hazard ratio etc?

Why for data that follows a Normal distribution would one not use the standard sample size formulae for comparing two means?

Why for a binary outcome, would one not use the standard sample size formula for comparing two proportions.

See ....


David Machin, Michael J. Campbell, Say-Beng Tan, Sze-Huey Tan
Sample Size Tables for Clinical Studies John Wiley & Sons, 26 Aug 2011 - Medical - 264 pages


Can the authors give us examples of outcome data that follows a gamma or poisson or negative binomial distribution? It would also be helpful to see examples of the different shapes of these distributions. Perhaps they could be shown graphically?

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Can the authors provide more detail on the example? What is the outcome? How is it distributed? What is an appropriate summary measure for the data? What is an appropriate comparative summary measure for the data?

The motivating example needs to be given more prominence and occur earlier in the paper.

Page 11 Minor point - power depends on the sample size and the size of the alternative hypothesis. What is the alternative hypothesis?

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Is it a problem if we over estimate the sample size? Particularly when one allows for attrition and missing data and the fact that many studies do not recruit to their target sample size. See

Sully BG, Julious SA & Nicholl J (2013) A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded by two UK funding agencies.. Trials, 14, 166.

McDonald AM, Knight RC, Campbell MK, Entwistle VA, Grant AM, Cook JA, Elbourne DR, Francis D, Garcia J, Roberts I, Snowdon C: What influences recruitment to randomised controlled trials?

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests: None