

Methodological quality and reporting of randomised controlled trials published in Indian medical journals

Dear Editor,

We read with interest the article by Misra *et al.*^[1] who conducted a community-based randomised trial to explore the effect of vitamin D supplementation on development of diabetes among women with prediabetes living in a rural area of North India. Findings from this trial may impact on the decision-making whether to use vitamin D or not to prevent the incidence of diabetes among prediabetic women. Although methodological and reporting guidance are available^[2] to the trial's authors, there are several methodological drawbacks (unclear on randomised control trial [RCT] design, sample size estimation, method of randomisation, statistical analysis, and adherence to consolidated standards of reporting trials [CONSORT]) that limit the acceptability of results from this trial. Therefore, we would like to discuss the quality of conduct and reporting of RCTs published in Indian medical journals.

A recent article by Goenka *et al.*^[3] assessed the quality of RCTs published in Indian medical journals and reported serious deficiencies in the methodology and result sections in most RCTs. They found only 57% RCTs adhered to the CONSORT 2010 reporting guidelines, 8.3% reported trial design, 20.2% reported method of randomisation and 40% reported sample size calculation. Most of the trials only reported interventions, allocation concealment, blinding and statistical methods domains. They also identified several reasons for poor methodology and reporting, which mainly included ignorance of the authors, lack of training on the nuances of doing a clinical trial and poor review by reviewers and journal editors. Similar findings are also reported by several other authors who assessed the quality of RCTs published by Indian authors. Juneja *et al.*^[4] assessed the quality of RCTs published between 2012 and 2015 in a teaching tertiary care hospital and reported non-adherence and suboptimal reporting in the methods and results sections. Hariohm *et al.*^[5] assessed the quality of RCTs published between 2000 and 2013 by Indian physiotherapists and reported substantial scope for improvement in conducting and reporting trials. Satpute *et al.*^[6] assessed the statistical methods reported in RCTs published between 2013 and 2014 in five high-impact pharmacology journals. Findings from this review showed inconsistencies and non-adherence to the statistical components of the CONSORT statement, especially with respect to sample size calculation.

Medical research is an evolving dynamic field that impacts on individuals' health and healthcare system in general. RCTs play a major role in evidence gathering, as these are usually considered to be the gold standard for evaluating the safety and efficacy of a treatment. CONSORT guidelines were first established in 1996 and further updated in 2001 and 2010 to enhance the quality and standardise reporting of RCTs. Several design-specific extensions (such as extension for cluster RCTs) are also available to guide trial authors for better design and reporting. The CONSORT 2010 statement^[2] includes a 25-item checklist that provides guidance for reporting RCTs on different domains of design, conduct and its presentation. The CONSORT 2010 statement is freely available at the CONSORT website (www.consort-statement.org). We believe that potential trial authors will understand the importance of methodology and reporting when conducting and presenting their findings in a journal article.

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Conflicts of interest

There are no conflicts of interest.

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