

## ONLINE CONTENT

# Quality of reporting Randomized Controlled Trials (RCTs) in the nursing literature: Application of the Consolidated Standards of Reporting Trials (CONSORT)

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In the era of evidence-based practice (EBP), Randomized Controlled Trials (RCTs) may provide the best evidence of the efficacy of nursing interventions and yet the quality of RCT reporting in nursing literature has not been evaluated. The purposes of this study were to apply the Consolidated Standards of Reporting Trials (CONSORT) statement to published reports of nursing science, examine how adequately the published reports adhere to the statement, and examine the effect

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of the adoption of CONSORT on the quality of the RCT published reports. One hundred RCTs from 2002-2005 were identified from 4 nursing journals. Articles were randomly assigned to 4 reviewers and the quality of the published reports was evaluated using a modified CONSORT checklist. There was no difference between the 4 journals in the quality of the published reports of RCTs based on the modified CONSORT checklist employed ( $F = 1.27, P = .29$ ). The quality of reporting of RCTs improved significantly in the only journal, *Nursing Research*, to adopt the CONSORT statement during the study period ( $t = -2.70, P = .01$ ). Adoption of CONSORT is recommended as it may lead to an overall improvement in quality of reporting of RCTs in nursing journals. The profession may also wish to explore the use or development of standards similar to CONSORT but ones more appropriate for the types of research typical of that published by nurse scientists.

The term evidence-based practice (EBP) was popularized in the early 1990's and can be defined as a problem-solving approach to the delivery of care that integrates the best available scientific evidence from well-designed studies, clinicians' expertise, and patients' preferences and values.<sup>1-3</sup> Efforts to incorporate the best available scientific evidence from well-designed studies, clinicians' expertise, and patients' preferences and values into practice<sup>4-6</sup> have been tedious at best and strategies need to be developed to hasten the translation of evidence into clinical practice.<sup>7</sup> Furthermore, rigorously conducted study findings and sound clinical evidence is critical for transforming nursing practice, education, and health policy.<sup>8</sup>

The National Institutes of Health (NIH) defines

translational research as the process of applying ideas, insights, and discoveries generated through scientific inquiry to the treatment or prevention of human disease.<sup>9</sup> Elias A. Zerhouni, the NIH director, has suggested that translational research is a way to increase the speed with which evidence is incorporated into practice. To increase the speed of translation of research findings into practice, both the provider and the scientist are compelled to develop strategies for disseminating findings and incorporating evidence into practice, hence changing health care delivery and patient care.<sup>10</sup>

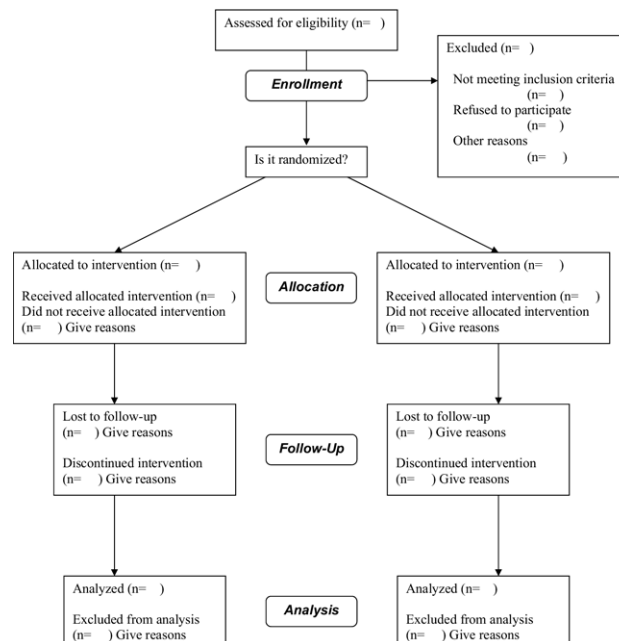
Just what evidence should be translated into practice? The US Preventive Services Task Force rated the quality of evidence as follows: Level I (evidence obtained from at least one properly designed RCT), II-1 (evidence obtained from well-designed controlled trials without randomization), II-2 (evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group), II-3 (evidence obtained from multiple time series with or without the intervention or dramatic results in uncontrolled trials), and III (opinion of respected authority based on clinical experience, descriptive studies or reports of expert committees).<sup>11</sup> Thus, much of the evidence that guides health care providers should come from RCTs and very little evidence should come from the opinion of authorities.

The rationale for relying heavily on data from RCTs is that these studies provide evidence supporting cause and effect which is invaluable to establish the efficacy of interventions, including those used predominately by nurses.<sup>3,12</sup> Further, RCTs control human and environmental bias and improve the internal validity of the study by employing random assignment of participants to groups and manipulation of the independent variable (intervention). Blinding, which is often used in RCTs can also help to eliminate bias.<sup>13,14</sup> Thus, studies that do little to eliminate bias may lead to faulty conclusions and present inherent risks to the validity and usefulness of the results.<sup>15-17</sup>

For nurse scientists to adequately evaluate and apply the results of RCTs, the report of the RCT must provide detailed information about the design, how random assignment was accomplished, blinding, data management, analyses, and interpretation. In other words, rigorously conducted and clearly written reports about RCTs can have a powerful impact on EBP, hence health care delivery and patient care.<sup>18</sup>

## THE CONSORT STATEMENT

In an effort to improve the reporting of RCTs, a group of methodologists and journal editors developed the Consolidated Standards of Reporting Trials (CONSORT) statement. The CONSORT statement, first published in 1996 and revised in 2001<sup>19-22</sup> is comprised of 22 guidelines in the form of a checklist and flowchart. The checklist can assist the scientists in writing a clear and comprehensive report of their RCT while the flowchart can



**Figure 1.** CONSORT flowchart (Data Source: <http://www.consort-statement.org/Downloads/flowchart.doc>)

help the scientist and readers track participants/subjects through the RCT (see Figure 1). The statement has been adopted by over 80 medical journals including *The Journal of the American Medical Association (JAMA)*, *The New England Journal of Medicine*, and *British Medical Journal (BMJ)*, and has been translated into 11 different languages (<http://www.consort-statement.org/Translation/translation.htm>). At least 2 nursing journals: *Nursing Research* and *Research in Nursing and Health* have recently adopted the CONSORT statement and flowchart.

Since the CONSORT statement was developed, the effect of the adoption and use of the statement on the quality of the reporting of RCTs has been evaluated by some disciplines using various approaches.<sup>23-25</sup> The studies usually included the frequencies of reporting specific CONSORT items in the published RCTs and some measure of a change in the quality of reporting after adoption of the CONSORT statement.

In studies related to cerebral palsy and obstetric anesthesia, only 52% and 65% of CONSORT items were included in the published reports.<sup>26,27</sup> In a study related to fracture care, > 75% of the trials met less than half of the CONSORT guidelines.<sup>23</sup> A study by Moher compared the mean numbers of CONSORT items that were included in a published RCT before and after the use of the CONSORT statement in 3 major medical journals including *BMJ*, *JAMA* and *The Lancet*.<sup>24</sup> The average frequency of reporting CONSORT items in the published RCTs significantly improved from 59% (23.4 items of their 40-item modified checklist) to 68% after adopting the CONSORT statement.<sup>24</sup>

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