

Reviewer Comments:

Reviewer #1: Abstract: The abstract provides a good over view of the study and it is relatively clear and organized.

1. Problem Statement: Authors present a clear description of the nature of the problem regarding the use (or lack of use) of the ITT in RCTs. I suggest on P. 2 for lines 3-5 that authors include a reference regarding their statements about RCTs and ITT approach being seen as "gold standards." The authors indicate little is known in nursing RCTs about ITT approach use and this leads to potential unidentified bias present in nursing RCTs. This problem is significant and relevant to nursing.

2. Background Literature: The authors present a rather good and extensive review of the literature regarding ITT approach use in medical studies and indicate that there is a lack of reviews for nursing studies. On p. 5, first paragraph, the authors should clarify whether these are reports involving "medical studies" or "nursing studies." They do provide some existing evidence that the problem is likely to be present in the nursing literature and there is a need to examine nursing RCTs to determine the extent of the actual use of ITT approaches. As a part of the significance of the problem, I believe the authors need to indicate that this review would serve to increase attention of nursing researchers, reviewers for nursing research journals, editors of nursing research journals and readers of nursing research to the problem by presenting the current state of the use of ITT in nursing RCTs.

3. Framework and Purpose: As part of the background literature, the authors discuss the logic and rationale behind RCT's and ITT and include clear definitions of terms important to understanding the concepts being studied. The purposes identified seem to flow from the problem statement and background discussion. The background discussion also covers most of the methodologic and study characteristics they address in the identified purposes.

4. Design and Methods : Authors clearly indicate this was a study involving a review of nursing RCTs. The sample and sample selection process is clearly stated and includes a table of journals and # of RCTs found (Table 1). It might be helpful to include impact factor value of each journal as well in this table. It is important that authors included a hand-search for the RCTs as it adds credibility to the accuracy for the number of RCTs they found in their search. The flow chart in Figure 1 is also important to assist the reader in understanding final sample size. Data collection procedures were clearly discussed for the variables extracted. Coding categories were clearly presented by the variables extracted and Tables 2 & 3 were helpful for the reader in examining RCT study characteristics and ITT use.

5. Data Analysis: The descriptive statistics were appropriate for the data presented. The 95% confidence intervals were also suitable for the important indicators. The regression analysis was done to examine explanatory variables which were those examined in the medical RCT's reviews and thus seemed appropriate to examine in the regression

equation.

6. Results: The results presented were well organized based on the purposes of the study and had headings matching those purposes. Tables 1-3 were helpful for following the written presentation. It seems that it would be possible to include less written descriptions of some sample characteristics which are also given in Table 2. I found Figure 2 a little confusing to follow the legend for what represents what. I would suggest providing a table with the numerical information and possibly including some of the other data that was presented in writing under attrition.

7. Discussion & Limitations: The discussion is quite relevant to the results presented although authors do not provide many comparisons of results presented in background literature review. The conclusions presented appear to be consistent with the findings. Authors refer back to the CONSORT guidelines in pointing out significance of their findings related to outcomes reported in nursing RCTs and refer to the literature regarding potential for biased estimates of treatment effectiveness in nursing RCTs. The authors discuss limitations of their study regarding representativeness of the sample of nursing RCT's given that nurse researchers also publish in journals outside of nursing.

8. Organization & Style: The overall style of the manuscript is helpful as it is clearly written for researchers who are involved in RCTs as well as those readers who do not have this background and experience. The study was well organized overall and presented a format that clearly followed from their original stated purposes for the review.

9. Summary: The problem addressed in this study is significant. The background information and results from the study are important to nursing researchers involved in RTCs as well as those who are not. The information is also important to nurses who wish their practice to be evidence-based. In addition it is informative for reviewers of nursing research manuscripts and nursing research journal editors in their efforts to adequately evaluate nursing studies submitted for publication.

Reviewer #2: This manuscript addresses an important and timely topic that is of interest to the nursing and medical communities. In the present study, the authors conducted a systematic review on the use of the intention-to-treat principle in nursing clinical trials. The manuscript is exceptionally well written. The review appears to have been appropriately conducted and the data correctly summarized and presented. The synthesis results are relatively clear-cut and ideas flow logically and coherently. The findings provide insights for designing methodologically strong nursing clinical trials to establish solid evidence-based nursing science. The authors are to be congratulated on their efforts.

CHECKLIST FOR STYLE

ABSTRACT -- Only 2-3 keywords are required, please delete 5

REFERENCES --

After the 6th author's name and initial, use et al. to indicate the remaining authors of the article (e.g., Altman; Artinian; Smith).

Please provide the page # for the quote by Higgins & Green (2008).

Is Polit (2010) an in-press item? Please explain.