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Bias in experimental nursing research: Strategies to improve the quality and explanatory power of nursing science

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ABSTRACT

In a guest editorial in this journal, Rahm Hallberg [Rahm Hallberg, I., 2006. Challenges for future nursing research: providing evidence for health-care practice. International Journal of Nursing Studies 43, 923–927] called for research which has greater explanatory power to determine the effectiveness of nursing interventions. In this paper we critique the suggestion made by the evidence-based nursing movement that randomisation *per se* is the principal route to better quality nursing research. In contrast, we evaluate the new CONSORT criteria for pragmatic RCTs, which assess the quality of strategies to reduce selection, performance, attrition and detection biases, allowing many different types of comparative studies to be covered by application of the checklist. We propose that randomisation alone is a necessary but insufficient strategy and that nursing researchers rise to Rahm Hallberg's challenge by adopting the extended criteria to assist in the critical appraisal, design and reporting of all experimental research in nursing.

What is already known about the topic?

- Recent years there have been an increased numbers of calls for an improved quality in nursing research as well as for research with greater explanatory power to determine the effectiveness of nursing interventions.
- Evidence-based nursing journals suggest raising the quality of nursing research through the adoption of the Randomised Controlled Trials.
- Since 2001 researchers have been encouraged to use the CONSORT criteria to report Randomised Controlled Trials.

What this paper adds

- The 2001 CONSORT criteria contains only three items directly related to randomisation and the elimination of selection bias.
- The removal or elimination of performance, attrition and detection bias is independent of randomisation.
- The recently extended CONSORT statement for pragmatic trials (2008) can be used to assure the quality of design and reporting for any experimental study in nursing.

1. Introduction

Over the last 5 years there have been a number of calls to improve the quality of nursing research in terms of both the designs applied and the rigour of their individual application. For example, in a recent guest editorial in this journal, Rahm Hallberg (2006) has called for research which has greater explanatory power to determine the effectiveness of nursing interventions. She defined this as research which is less descriptive, involves more experimentation and is generalisable outside the specific research environment into routine nursing situations. Secondly, whilst Rahm Hallberg has also called for better quality nursing research, this issue has been more stridently articulated by the evidence-based nursing

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movement and associated researchers (DiCenso et al., 1998; Torgerson and Torgerson, 2001). The principal route to better quality espoused by this movement is the Randomised Controlled Trial (RCT) where randomisation is regarded as the main driver of trial quality (Thompson, 2004; Torgerson and Torgerson, 2001).

These two issues of generalisability and quality are separate but closely related. Rahm Hallberg's (2006) call for clinically relevant research echoes serious concerns from those that manage, deliver and receive health care, that much research is so highly specialised that the patients, the interventions being tested and the randomised controlled research methods used produce results which are of little relevance for the real world (Wolff, 2001; Lindsay, 2004; Van Meijel et al., 2004; Tharayan and Adhikary, 2007; Zwarenstein et al., 2008). Rahm Hallberg (2006) reflects these views but also airs concerns about the current methodological state of nursing research by calling for research which is more *generalisable* outside the specific environment under study. She urges a move from description to explanation. Unlike some critics of clinical trials in nursing (e.g. Lindsay, 2004), she does not call for fewer RCTs in nursing, but for research designs which are likely to produce results where the findings are both robust and *externally valid*, and thus of more use to those that plan, manage, deliver and receive nursing care.

More vociferous calls for an increase in the number of nursing RCTs *per se* come from evidence-based nursing researchers (e.g. Cullum, 2000; DiCenso et al., 1998) who argue that randomised controlled designs are the gold standard in terms of measuring cause and effect, and suggest that the quality of randomisation and allocation concealment should be the primary criteria when appraising study quality (Cullum, 2000). Despite the fact that systematic reviews of RCTs almost always identify significant numbers of trials which are of very poor quality (Moher et al., 2001a,b; Wood et al., 2008), nursing trials being no exception (Lindsay, 2004), proponents of RCTs in nursing call increasingly for more of the same. However, at least part of the reason for the quality gap might be the difficulties in designing RCTs which fulfil the dual criteria of being both a high quality rigorous test and being of relevance to nursing care.

Some objectors to randomised trials in nursing argue that one cannot 'standardise' either patients or nursing interventions to the extent seen in, for example, drug trials or other tightly defined medical interventions (Lindsay, 2004). Rahm Hallberg's (2006) arguments address this objection head on by challenging researchers to conduct trials which both establish the effectiveness of nursing interventions and demonstrate their usefulness to practising nurses, rather than to retreat into research which is either too localised or so tightly restricted as to render it of limited value to other nurses. This balance of validity, both internal (elimination of confounding variables) and external (generalisability to routine clinical environments) (Rothwell, 2006a,b) is at the heart of the research design dilemmas faced by nurses working to improve the evidence base of nursing (Box 1).

One type of RCT which attempts to address this balance is the 'pragmatic RCT', described by Schwartz and Lellouch (1967) as an attitude to the research design that takes into account choices that capitalise on the applicability of the trial's result to the usual care setting and which rely on outcomes of importance for that setting whilst tested in a wide range of participants. Others regard explanatory and pragmatic trials to lie on a continuum. At one end of the continuum lie trials with a highly explanatory focus concerned with whether an intervention works at all and undertaken in ideal environments with highly selected patients whilst at the other end are pragmatic trials where the focus is on intervention effectiveness in 'normal' environments with a group of patients as near to those seen in usual health care environments as possible (Tunis et al., 2003; Zwarenstein et al., 2008).

Although nursing researchers such as Thompson (2004) recommend the pragmatic RCT for nursing research, these trials may involve the sacrifice of internal validity for increased external validity. As a consequence they may be appraised as of poorer quality than a controlled trial with high internal validity. One example of a critical appraisal tool that is likely to rate trials which focus on external validity as of poor quality is the checklist accompanying the Consolidated Standards of Reporting Trials – CONSORT – (Berg et al., 1996; Altman et al., 2001; Moher et al., 2001a,b), commonly used in peer reviews of RCT reports. For example, trials where blinding of participants and clinicians to experimental and control treatments occurs are regarded by the CONSORT criteria to be of higher quality, despite the difficulty of blinding patients and nurses to procedures which are observably different. As a consequence many nursing trials are likely to receive low ratings of quality. Recently, however, the CONSORT group has published a revision or *extension* of the CONSORT guidelines to include pragmatic RCTs (Zwarenstein et al., 2008). This may allow specific quality criteria to be applied to pragmatic trials in nursing, removing the disadvantage

Box 1. Overview of concepts.

Validity[a]	
External	The result must be relevant to a definable group of patients in a particular clinical setting i.e. being able to generalise to the population at large.
Internal	Study design and conduct must eliminate the possibility of bias, i.e. being able to eliminate confounding variables within the study itself.
Randomised Controlled Trials[b]	
Pragmatic	Trial designed to help chose between options of care.
Explorative	Trial designed to test causal research hypothesis.
Bias[c]	
Selection	Systematic differences in groups being compared.
Performance	Systematic differences in care provided to groups being compared apart from the intervention under evaluation.
Attrition	Systematic differences in withdrawals from different groups.
Detection	Systematic differences in outcome assessments between groups.

[a] Brewer (2000).
[b] Schwartz and Lellouch (1967).
[c] Shadish et al. (2002).