

Original article

Transparency of outcome reporting and trial registration of randomized controlled trials in top psychosomatic and behavioral health journals: A systematic review

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Received 10 August 2010; received in revised form 21 September 2010; accepted 28 September 2010

Abstract

Objective: The most reliable evidence for evaluating healthcare interventions comes from well-designed and conducted randomized controlled trials (RCTs). The extent to which published RCTs reflect the efficacy of interventions, however, depends on the completeness and accuracy of published results. The Consolidated Standards of Reporting Trials statement, initially developed in 1996, provides guidelines intended to improve the transparency of published RCT reports. A policy of the International Committee of Medical Journal Editors, initiated in 2005, requires clinical trials published in member journals to be registered in publicly accessible registries prior to patient enrollment. The objective of this study was to assess the clarity of outcome reporting, proportion of registered trials, and adequacy of outcome registration in RCTs published in top behavioral health journals. **Methods:** Eligible studies were primary or secondary reports of RCTs published in

Annals of Behavioral Medicine, Health Psychology, Journal of Psychosomatic Research, and Psychosomatic Medicine from January 2008 to September 2009. Data were extracted for each study on adequacy of outcome reporting and registration. **Results:** Of 63 articles reviewed, only 25 (39.7%) had adequately declared primary or secondary outcomes, whereas 38 (60.3%) had multiple primary outcomes or did not define outcomes. Only 13 studies (20.6%) were registered. Only 1 study registered sufficiently precise outcome information to compare with published outcomes, and registered and published outcomes were discrepant in that study. **Conclusion:** Greater attention to outcome reporting and trial registration by researchers, peer reviewers, and journal editors will increase the likelihood that effective behavioral health interventions are readily identified and made available to patients.

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Keywords: Methods; Review; Systematic; Randomized controlled trials at topic; Behavioral medicine; Psychosomatic medicine

Introduction

Evidence-based approaches are increasingly emphasized in practice guidelines and healthcare policy [1–3], and psychological and behavioral treatments supported by

strong evidence are more likely to be evaluated positively and implemented in clinical practice than at any time previously [4]. The most reliable evidence for determining the efficacy of interventions comes from well-designed and conducted randomized controlled trials (RCTs) [5,6], and high-quality RCTs are prioritized in clinical guideline development [6]. The extent to which published RCTs accurately reflect the efficacy of interventions, however, depends on the completeness and transparency of reports of results [5,7,8].

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A single primary outcome variable is generally identified prior to beginning a trial to answer the main question addressed by the trial. Other secondary outcome variables are typically specified, as well [5,9]. In some cases, more than one primary outcome may be specified with appropriate statistical adjustment. However, this is not typically recommended due to the complexity of interpreting potentially contradictory results. All outcome definitions should specify a priori the measure and time point of interest.

Study publication bias occurs when the decision to publish or not publish study data depends on the results [10–12], and numerous studies have shown that published studies are significantly more likely to have positive results than nonpublished studies [10,13–18]. Within-study selective outcome reporting, on the other hand, relates to published studies and refers to the selection of outcomes to report based on statistical significance, including the prioritization of time points for analysis, selective reporting of a subset of measures, and data-driven selection or switching of primary outcomes compared with prestudy protocols [10,19,20]. Comparisons of study protocols and published results have shown that significant outcomes are more likely to be reported than nonsignificant outcomes and that nonsignificant prespecified primary outcomes are sometimes replaced with statistically significant secondary outcomes that are identified as “primary” in published reports [10,20–27].

Two important initiatives have emphasized the need to improve the transparency and completeness of RCT outcome specification and reporting: the Consolidated Standards of Reporting Trials (CONSORT) statement [28–30] and the International Committee of Medical Journal Editors (ICMJE) registration requirements for RCTs [31]. CONSORT, which has been endorsed by most major medical journals and international editorial groups [31], provides a checklist of items that should be reported by RCT authors and used by peer reviewers, editors, and research consumers to critically review and interpret trial results [5]. CONSORT specifies that authors of RCTs should report fully defined prespecified primary and secondary outcome measures, including how and when they were assessed, and discourages multiple primary outcomes [30]. ICMJE trial registration policy [32] requires adequate pretrial registration, including a priori specification of all primary and secondary trial outcomes with time of measurement, for all trials intended to affect clinical practice that began recruiting on or after July 1, 2005. Trials that were ongoing as of July 1, 2005, were required to have registered by September 13, 2005 [32]. Examples of publicly accessible registries include ClinicalTrials.gov [33], the International Standard Randomized Controlled Trial Number Register (ISRCTN) [34], and region-specific registries, all of which can be accessed through the World Health Organization registry search portal [35].

The objective of this study was to assess the degree to which RCTs designed to improve health that were published

in top psychosomatic and behavioral health journals (*Annals of Behavioral Medicine*, *Health Psychology*, *Journal of Psychosomatic Research*, and *Psychosomatic Medicine*) adequately registered and reported trial outcomes. Its specific objectives were to (1) determine the proportion of recently published RCTs that clearly and appropriately declared outcomes as primary or secondary and (2) assess the degree to which RCT outcomes were registered adequately, as well as whether there were discrepancies between registered and published outcomes.

Methods

Article selection

We searched PubMed on October 31, 2009, to identify RCTs published between January 2008 and October 2009 in *Annals of Behavioral Medicine*, *Health Psychology*, *Journal of Psychosomatic Research*, or *Psychosomatic Medicine* [36] using the search limit of study type (“randomized controlled trial”). We also conducted a hand search of the titles/abstracts of all published articles in the four journals, searching for the words “random,” “randomized,” and “randomly” to identify potentially eligible RCTs not identified in the PubMed search.

Based on the definition used in a recent study of RCT registration in high-impact medical journal publications [37], we included studies if they reported data from an RCT, defined as a comparative study with random assignment of participants, of an intervention intended to improve health. Studies that randomized participants into experimental conditions not intended to improve health (e.g., laughter vs. mental stress conditions to assess arterial stiffness) or that primarily assessed intervention feasibility were excluded. Secondary analyses that reported on trial outcomes, including subgroup analyses, were included. Secondary analyses that tested mediational processes, used RCT data for cross-sectional analyses, or only analyzed control or treatment group data were excluded. Two reviewers assessed articles for eligibility, and disagreements were resolved by consensus.

Data extraction and classification

Two investigators independently extracted and entered relevant data into a standardized Excel spreadsheet. Discrepancies were resolved by consensus.

Objective 1: Clearly and adequately declared outcomes in published articles

Published articles were classified as reporting (1) primary, (2) multiple primary, (3) secondary, or (4) undefined outcomes.

An article was classified as reporting a primary outcome if a single outcome was clearly and consistently defined as primary throughout the article or, alternatively, if a single primary outcome could be determined from the power

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