ACRM
AMERICAN CONGRESS OF REHABILITATION MEDICINE

Archives of Physical Medicine and Rehabilitation

journal homepage: www.archives-pmr.org

Archives of Physical Medicine and Rehabilitation 2015;96:702-14

REVIEW ARTICLE (META-ANALYSIS)

Randomized Controlled Trials in Adult Traumatic Brain Injury: A Review of Compliance to CONSORT Statement

Juan Lu, MD, MPH, PhD,[a] Kelli W. Gary, PhD, MPH, OTR/L,[b] Al Copolillo, PhD, OTR/L,[b] John Ward, MD, MHA,[c] Janet P. Niemeier, PhD,[d] Kate L. Lapane, PhD[e]

From the [a]Department of Family Medicine and Population Health, Division of Epidemiology, and Departments of [b]Occupational Therapy and [c]Neurosurgery, Virginia Commonwealth University, Richmond, VA; [d]Department of Physical Medicine and Rehabilitation, Carolinas Rehabilitation, Charlotte, NC; and [e]Department of Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, MA.

Abstract

Objective: To describe the extent to which adherence to Consolidated Standards of Reporting Trials (CONSORT) statement in randomized controlled trials (RCTs) in adult traumatic brain injury (TBI) has improved over time.

Data Sources: MEDLINE, PsycINFO, and CINAHL databases were searched from inception to September 2013.

Study Selection: Primary report of RCTs in adult TBI. The quality of reporting on CONSORT checklist items was examined and compared over time. Study selection was conducted by 2 researchers independently. Any disagreements were solved by discussion.

Data Extraction: Two reviewers independently conducted data extraction based on a set of structured data extraction forms. Data regarding the publication years, size, locations, participation centers, intervention types, intervention groups, and CONSORT checklist items were extracted from the including trials.

Data Synthesis: Of 105 trials reviewed, 38.1%, 5.7%, and 32.4% investigated drugs, surgical procedures, and rehabilitations as the intervention of interest, respectively. Among reports published between the 2 periods 2002 and 2010 (n=51) and 2011 and September 2013 (n=16), the median sample sizes were 99 and 118; 39.2% and 37.5% of all reports detailed implementation of the randomization process; 60.8% and 43.8% provided information on the method of allocation concealment; 56.9% and 31.3% stated how blinding was achieved; 15.7% and 43.8% reported information regarding trial registration; and only 2.0% and 6.3% stated where the full trial protocol could be accessed, all respectively.

Conclusions: Reporting of several important methodological aspects of RCTs conducted in adult TBI populations improved over the years; however, the quality of reporting remains below an acceptable level. The small sample sizes suggest that many RCTs are likely underpowered. Further improvement is recommended in designing and reporting RCTs.

Archives of Physical Medicine and Rehabilitation 2015;96:702-14

Well-designed and properly conducted randomized controlled trials (RCTs) provide the most reliable evidence in health interventions. This, in turn, leads to improvement in the prevention or treatment of disease.[1] Many RCTs have been conducted with adequate methodological rigor to advance scientific knowledge. The ability to evaluate and disseminate this knowledge directly rests on the transparent and thorough reporting of trial methodology and findings. The lack of adequate reporting influences readers' interpretation of the evidence and makes it more difficult to replicate the results for future research and follow recommended treatment options.[2,3] To alleviate this problem, guidelines have been created to assist researchers, peer reviewers, and journal editors in complete reporting of RCTs.

The Consolidated Standards of Reporting Trials (CONSORT) statement is a minimum set of evidence-based recommendations designed to improve the quality of reporting RCTs. It was initially published in 1996,[4] then revised twice subsequently in 2001 and 2010.[5,6] The revisions were each accompanied by a detailed explanation and elaboration document for the purpose of enhancing the use, understanding, and dissemination of the statement.[7,8] The CONSORT provides structured guidance to

Supported by the National Center for Advancing Translational Sciences (Clinical and Translational Science Award no. UL1TR000058).

Disclosures: none.

0003-9993/14/$36 - see front matter © 2015 by the American Congress of Rehabilitation Medicine
http://dx.doi.org/10.1016/j.apmr.2014.10.026

help researchers prepare reports of trial findings, facilitate complete and transparent reporting, and aid in critical appraisal and interpretation. The most current version of the statement includes a 25-item checklist and a flow diagram. The checklist provides standardized approaches to report the trial design, analysis, and interpretation, and the diagram gives instructions to display the progress of all participants throughout the trial.

Since the initial publication, the quality of clinical trial reporting has improved over the years in general[9,10] and in many medical specialties.[11-13] However, the quality of reporting is far from satisfactory, and incompleteness and inaccurate reporting of trial results compounded with poor methodological rigor remain a serious concern.[10,14-16]

Thus far, there are limited assessments of CONSORT compliance and improved reporting in RCTs in the traumatic brain injury (TBI) literature. We previously reported on 100 RCTs in adult TBI with the aims of synthesizing evidenced-based interventions and facilitating the effectiveness of interdisciplinary care.[17] The current review extends this previous work by (1) examining the extent that these reports of RCTs adhere to the CONSORT statement, and (2) assessing whether the quality of reports has improved over time.

Methods

Study sample

From our previous review,[17] we searched databases of MEDLINE, PsycINFO, and CINAHL to identify all primary reports of RCTs in adult TBI populations through June 29, 2011, using the search terms of "Traumatic Brain Injury or Brain Injury" plus "Randomized Controlled Trials or Randomised Controlled Trials." Hand searches against published reviews were also performed. Two authors independently assessed titles, abstracts, and full-text articles according to the eligibility criteria. We excluded trials with (1) exclusive pediatric samples; (2) acquired brain injury samples, unless the sample was predominantly TBI or the results were reported separately for the TBI sample and met the search criteria; (3) a sample size <20; (4) a focus on specific symptoms after TBI (eg, elbow contractures, seizures); (5) a focus on safety and pharmacokinetics solely; or (6) non-English languages. As a result, the review selected 100 eligible studies, including 93 published RCT reports and 7 studies with unpublished results.[18]

For this review, we updated the initial research and further included 12 published RCT reports up to September 2013. After excluding 7 studies with unpublished results from the previous review, this review included a total of 105 RCT reports in adult TBI populations.

Data extraction

Data extraction was carried out by 3 authors (J.L., A.C., K.W.G.). For each article, at least 2 authors independently extracted data. To ensure the quality and consistency of the data extraction, the process started with practice on the first 10 reports reviewed, from which authors extracted data based on a set of structured data extraction forms and discussed all discrepancies. Most differences were due to differing interpretations of the data extraction form; thus the form was modified and the exercise repeated using another 10 articles until agreement was reached for all data items listed on the form. After the agreement on the data extraction form, the same authors continued the process of data extraction and resolving discrepancies for the remaining reports. The overall rater agreement on the assessment of checklist items is 96%.

List of abbreviations:

CI	**confidence interval**
CONSORT	**Consolidated Standards of Reporting Trials**
RCT	**randomized controlled trial**
RR	**relative risk**
TBI	**traumatic brain injury**

CONSORT compliance

We used the 2010 CONSORT reporting guideline[6,8] to evaluate the studies. From the original 25 items, this study evaluated the items that can be assessed and compared objectively across trials. The methodological items include the use of the term "randomized trial" in the title, location of data collection, predefined primary outcome, sample size estimation, method of randomization sequence generation, allocation concealment and implementation, who was blind and how blinding was achieved, publication of a participant flow diagram, period of recruitment, period of follow-up, as well as the attrition due to loss to follow-up, and intention-to-treat analysis. Since more than half the trial reports in this review were published before CONSORT revision in 2001,[5,7] table 1 provides methodological items and definitions used to assess reporting of RCTs, and comparisons of these items in CONSORT versions 2001 and 2010. The definitions were mainly adopted from Hopewell et al[10] with some revision. In addition, the information regarding the status of trial registration, accessibility of the full protocol, and funding resources (ie, reported as solely industry, part industry or nonindustry, or not reported) was also assessed.

Other data extraction

We also extracted data on the trial publication years, size, locations (ie, United States or non-United States trials), participation centers (ie, single or multicenter), intervention types (ie, drug intervention, rehabilitation, or others), and intervention groups (ie, 2 or $\geq$3 groups).

Statistical analysis

We summarized the data descriptively. The numbers and proportions of the methodological items were reported by the publication years. The years were grouped into 3 periods: trial reports published (1) before the CONSORT 2001 revision, (2) after the 2001 revision but before the 2010 revision, and (3) after the 2010 revision. The descriptive summary statistics were used to compare the quality of RCT reports published between the periods. Risk ratios and associated 95% confidence intervals (CIs) were calculated and used to quantify changes in reporting between the publication periods. Forest plots were used to illustrate the methodological compliance between the publication years. SAS version 9.4[a] was used for all analyses.

Results

Study selections

A total of 105 RCT reports were included in the current review. Figure 1 shows the article identification process.