

Information Commonly Unreported in Intervention Effectiveness Studies

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In 2008, the CONSORT statement for nonpharmacological treatments (e.g., rehabilitation, psychotherapy, surgery; Boutron, Moher, Altman, Schulz, & Ravaud, 2008) was created as an extension of the original and revised CONSORT statements for intervention effectiveness reporting (Altman et al., 2001; Moher, Schulz, & Altman, 2001). The CONSORT statement for nonpharmacological studies was developed to address specific variables that could have an impact on treatment effect and are often unreported in published intervention effectiveness studies. In this editorial, we outline some of the most critical factors that are commonly missing from intervention effectiveness manuscript submissions received by the *American Journal of Occupational Therapy (AJOT)*. For the complete CONSORT 2008 checklist of essential items for nonpharmacological treatments, see Boutron et al. (2008). See also the reporting standards for occupational therapy intervention effectiveness studies recommended by *AJOT* (Gutman, 2010) and Figure 1.

Title

Titles help indexers categorize articles so that they can be easily accessed. If essential information is missing from the title, the article may never be accessed by interested researchers, policymakers, health insurers, practitioners, and consumers. Critical elements to include in titles to fully represent the type of research study completed are participant allocation and treatment design (e.g., randomized controlled study, two-group controlled study), intervention (and comparison treatment, if studied), and sample. An example of such a title is “Virtual Reality

Versus Computer-Based Cognitive Therapy for Adults With Traumatic Brain Injury: A Pilot Randomized Controlled Study.”

Abstract

Although *AJOT* article abstracts are limited to 150 words or less, key elements that must be reported are frequently left out. Because the abstract is the most commonly read section of an article, authors should provide information needed to assess the study’s internal and external validity. At a minimum, they should include sample size, recruitment procedure, and experimental and control interventions (e.g., “20 participants recruited from a convenience sample participated in the fall prevention intervention”). If space allows, authors should also report the type of professionals providing the intervention, the setting in which the intervention was carried out, and blinding procedures (i.e., whether participants and therapists were blinded to group assignment, whether outcomes were assessed by a blinded researcher).

Purpose Statement and Research Question

The last paragraph of the introduction should explain the study’s purpose and state the specific research questions. These questions should be used to guide the presentation of data in the Results and Discussion sections. Although *AJOT* submissions commonly provide the purpose of studies, the actual research questions are frequently unreported.

Method

The most compromised section of *AJOT* submissions is the Method section, which

<p>Title</p> <p>Intervention (and comparison treatment if studied)</p> <p>Sample</p> <p>Participant allocation and treatment design (e.g., randomized controlled study, two-group controlled study)</p> <p>Abstract</p> <p>Objectives: State study purpose.</p> <p>Method: Describe research design; intervention (include length and use of follow-up points); clinical population; sample size; participant allocation (recruitment procedures); type and number of interveners; setting; blinding of participants, therapists, and data collectors.</p> <p>Results: State primary findings (use statistical significance levels and effect sizes if appropriate).</p> <p>Conclusion: Describe implications of the findings for the population and profession.</p> <p>Introduction</p> <ul style="list-style-type: none"> • Describe background of problem. • Define all key concepts and constructs. • Summarize relevant research. • Identify gaps in previous research that show need for study. • Describe how study will contribute to profession's knowledge. • Provide purpose statement. • Provide specific research questions. <p>Method</p> <p>Research Design</p> <ul style="list-style-type: none"> • Describe study design. • State whether intention-to-treat analysis was used if design was a randomized controlled trial. • State that institutional review board approval and participant consent were obtained. <p>Participants</p> <ul style="list-style-type: none"> • Describe recruitment methods. • Describe inclusion and exclusion criteria. <p>Instruments</p> <ul style="list-style-type: none"> • List each instrument used to measure an outcome measure. • Describe the intended purpose and the population for which the instrument was developed. • Provide established levels of reliability and validity using numerical values. • Indicate type of data collected by the instrument. • Provide one or more references for each instrument. <p>Intervention</p> <p>Description</p> <ul style="list-style-type: none"> • State whether intervention is manualized (provide Web site address to access manual and training documents). • State intervention duration and intensity. • Indicate content of each session and delivery method. • Describe intervention tailoring for specific participants. • Indicate other interventions that participants received simultaneously. <p>Interveners</p> <ul style="list-style-type: none"> • Report type and number of interveners. • Report eligibility criteria used to select participating therapists. • State therapists' experience level. • Indicate whether therapists received training in intervention administration and what training consisted of. • State whether therapists were blinded to group assignment and how blinding was ensured. • State whether same or different therapists provided intervention to both treatment and control groups. 	<p>Fidelity</p> <ul style="list-style-type: none"> • Describe methods used to ensure that intervention was administered uniformly and in accordance with written protocol or manual. <p>Data Collection</p> <ul style="list-style-type: none"> • Describe how, when, and by whom each set of data was collected throughout study. • Indicate whether multiple data collectors were used. • State whether data collectors were blinded to group assignment. • Indicate whether data collectors were trained and how. • Report whether interrater reliability was established between multiple raters. • State whether data collectors were different from interveners. <p>Data Analysis</p> <ul style="list-style-type: none"> • Describe the statistical methods used to compare groups on primary and secondary outcomes. • Justify use of nontraditional statistical methods that are not congruent with established rules of parametric and nonparametric data analysis. • Provide citation for all statistical methods and briefly describe those that are not well established. • Indicate statistical software program used. <p>Results</p> <ul style="list-style-type: none"> • Provide description of participant flow through each study phase (also use flow diagram). • Describe participant demographics (age, gender, race and ethnicity, educational level, socioeconomic level). • Provide sample size justification and power analysis. • Describe whether treatment and control groups were equivalent on baseline measures. • Summarize findings on the basis of research questions. • When reporting statistical significance, report effect size in addition to <i>p</i> values. • Provide confidence intervals for the estimated effect. • Indicate how missing data were handled. • Report any adverse reactions to the intervention or comparison treatment. <p>Discussion</p> <ul style="list-style-type: none"> • Answer research questions on the basis of interpretation of findings. • Indicate whether findings are novel or support previous work. • Provide explanation for unexpected findings. • Explain how findings contribute to consensus regarding best practice. <p>Limitations</p> <ul style="list-style-type: none"> • Acknowledge limitations that may have biased results and reduced internal and external validity (e.g., nonadherence to treatment protocol, compromised blinding procedures, lack of intervention fidelity, differences among therapist skill levels). • Indicate whether power of sample size was sufficient to answer the research questions. <p>Future Research</p> <ul style="list-style-type: none"> • Indicate how future research can address the study's limitations. • Identify research questions that still need to be answered regarding the effectiveness and efficiency of the intervention.
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Figure 1. American Journal of Occupational Therapy—recommended intervention effectiveness manuscript headings.

often lacks sufficient detail to appraise and replicate the studies presented. We recommend using the following subheadings in the order in which they are presented: Research Design, Participants, Instruments (or Measures), Intervention, Data Collection, and Data Analysis. Commonly unreported data in these sections are discussed below. (Because most authors correctly address the Data Analysis section, it is not discussed in the sections that follow.)

Research Design

Including a Research Design section as the first subheading of the Method section is usually beneficial. Here, briefly describing the research design and stating that institutional review board approval and participant consent were obtained are important. Our experience has been that when this section is not provided in a manuscript, ascertaining this information elsewhere in the text is difficult. In many instances, the research design is never stated.

Participants

The Participants section should describe the inclusion and exclusion criteria, recruitment process, and setting. If randomization was used, the method used in the assignment sequence and concealment process should be made clear. Information regarding participant flow (e.g., number of participants assessed for eligibility, number enrolled, number assigned to specific intervention groups, number lost, final number included in analysis) should be provided in the first paragraph of the Results section, accompanied by a flow diagram (see Gutman, 2010). Similarly, participant demographics should also be provided in the first paragraph of the Results section rather than in the Participants section.

Instruments

The Instruments section should describe each assessment used to measure an outcome variable. The instrument's intended purpose, population for which it was developed, type of data collected (e.g., self-report, Likert, total score), and established psychometric properties should be clearly stated. Reporting precise numerical values

established for specific types of reliability and validity rather than imprecise modifiers such as *good*, *moderate*, or *high* is necessary. Reporting these values is particularly important for readers who may be unfamiliar with the instruments and need the values to appraise their rigor.

Intervention

Another section commonly underreported in *AJOT* submissions is the Intervention section. A thorough description of all interventions, procedures for and amount of contact in control conditions, type and number of interveners, and blinding of therapists is critical for study appraisal, comparison with other studies, replication, and inclusion in systematic reviews and meta-analyses.

Intervention Description. Key elements of the intervention should be concisely described. Whether the intervention is manualized should be clearly stated, and authors should provide a Web site address (or contact information) to enable readers to access the manual and training documents. Intervention elements that must be precisely stated in the manuscript text are intervention duration and intensity (i.e., number and length of sessions, length of intervention over time), the content of each session and the delivery method (i.e., individual sessions vs. group treatment), and how the intervention was tailored for specific participants with comorbid conditions or unique clinical characteristics. Indicating whether the participants simultaneously received other services whose impact on study variables could not be controlled is also critical.

Interveners. Information about the professionals who provided the intervention is frequently unreported in *AJOT* submissions. Authors should report the type and number of professionals who provided intervention, the eligibility criteria used to select therapists, the experience level of the participating therapists, whether therapists received training in intervention administration (and what that training consisted of), and whether therapists were blinded to group assignment. Describing this information for therapists providing intervention to the experimental and control groups is necessary, and indicating whether

the same therapists provided intervention to both the experimental and control groups is critical. If therapists provided treatment to both groups, authors must indicate whether blinding of therapists to group assignment was achieved and how blinding was ensured.

Intervention Fidelity. Also frequently left out of *AJOT* submissions is information about intervention fidelity—the procedures used to ensure that the intervention was administered uniformly and in accordance with written manuals, particularly when multiple therapists were used. Methods to ensure intervention fidelity often include videotaping or audiotaping therapy sessions for later analysis, holding group supervision sessions in which therapists and principal investigators discuss sessions to ensure that therapy is being administered as intended, and using checklists completed by therapists and observing investigators to ensure that key elements were addressed in each session.

Data Collection

The section most frequently missing from the Methods section is the Data Collection section. This section should detail how, when, and by whom each set of data was collected. It is essential to tell readers who collected the data and whether multiple data collectors were used, whether data collectors were blinded to group assignment, whether data collectors were trained, whether interrater reliability was established between raters, and whether data collectors were different from those who provided intervention. Without this key information, readers cannot assess the possibility of bias or whether compromised data collection procedures affected the results.

Results

As stated earlier, the Results section should begin with a brief description of participant flow, which should be precisely illustrated in a detailed flowchart. Participant demographics should also be provided in the Results section, or the reader should be referred to a table providing them. In accordance with minimal reporting standards, age, gender, race–ethnicity, and educational and socioeconomic level should be

reported. After this first paragraph, the organization of the Results section should be guided by the order of the research questions listed in the purpose statement.

Discussion

In addition to an interpretation of findings, the Discussion section should examine findings with regard to the type of control or comparison treatment used and the influence of compromised blinding procedures, lack of intervention fidelity, and different therapist skill levels. If specific clinical implications beyond the findings can be derived, this information should be placed under a separate subheading. The Discussion section should include a brief subsection with a bulleted list summarizing

the implications of the research for occupational therapy practice. This new requirement went into effect with the current issue of *AJOT*. Additional subheadings in the Discussion section should include Limitations and Future Research. ▲

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