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REVIEW ARTICLE

On the Reporting of Experimental and Control Therapies in Stroke Rehabilitation Trials: A Systematic Review

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Abstract

Objective: To use the *C*entralized *O*pen-*A*ccess *R*ehabilitation database for *S*troke to explore reporting of both experimental and control interventions in randomized controlled trials for stroke rehabilitation (including upper and lower extremity therapies).

Data Sources: The Centralized Open-Access Rehabilitation database for Stroke was created from a search of MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Cumulative Index of Nursing and Allied Health from the earliest available date to May 31, 2014.

Study Selection: A total of 2892 titles were reduced to 514 that were screened by full text. This screening left 215 randomized controlled trials in the database (489 independent groups representing 12,847 patients).

Data Extraction: Using a mixture of qualitative and quantitative methods, we performed a text-based analysis of how the procedures of experimental and control therapies were described. Experimental and control groups were rated by 2 independent coders according to the Template for Intervention Description and Replication criteria.

Data Synthesis: Linear mixed-effects regression with a random effect of study (groups nested within studies) showed that experimental groups had statistically more words in their procedures (mean, 271.8 words) than did control groups (mean, 154.8 words) ($P<.001$). Experimental groups had statistically more references in their procedures (mean, 1.60 references) than did control groups (mean, .82 references) ($P<.001$). Experimental groups also scored significantly higher on the total Template for Intervention Description and Replication checklist (mean score, 7.43 points) than did control groups (mean score, 5.23 points) ($P<.001$).

Conclusions: Control treatments in stroke motor rehabilitation trials are underdescribed relative to experimental treatments. These poor descriptions are especially problematic for "conventional" therapy control groups. Poor reporting is a threat to the internal validity and generalizability of clinical trial results. We recommend authors use preregistered protocols and established reporting criteria to improve transparency.

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A thorough and complete reporting of methods in clinical trials is essential not only for reproducibility of research but also for the clinical interpretation and implementation of experimental methods. Despite a general understanding of the necessity of reporting, there is significant research[1-3] suggesting that reporting in clinical trials is poor. To address this problem, stakeholders have developed numerous checklists and guidelines to improve the reporting of biomedical research.[4-6] Despite these guidelines, a problematic outcome of this research is the finding that reporting of nonpharmaceutical interventions is worse than the reporting of pharmaceutical interventions (which are, in themselves, also poorly reported).[2,3] This difference is in some ways understandable

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because the dose, timing, frequency, and pathway of treatment are easier to define in pharmaceutical trials where active ingredients are directly measurable. However, the mere recognition of this difference does not negate the problems that poor reporting poses to rehabilitation medicine. In physical and occupational therapy interventions, for instance, the active ingredient(s) and dosage of therapy are often not clear, dose-response curves are not easily quantified, and treatments are highly variable.[7,8]

Accurate and complete reporting is especially critical in *control* groups for several reasons. First, complete reporting for control groups establishes the internal validity of experimental findings (ie, interpreting a difference between experimental and control groups is contingent on the adequacy of the control). Second, complete reporting is required for comparing interventions across experiments. For instance, the difference between therapy A and control A might be contrasted with the difference between therapy B and control B. If reporting is poor, perceived differences in the efficacy of experimental treatments might actually reflect differences in control treatments. In a pharmaceutical intervention, control groups might receive identically administered placebos. In rehabilitation trials, however, control groups might be described as "conventional" therapy but, despite the same name, differ significantly in their frequency, intensity, timing, and type of therapy.[8]

The ambiguous use of the term "conventional" therapy creates considerable confusion in the literature. If all the details were adequately reported, readers could understand and contrast what occurred in different "conventional" therapies. However, previous researchers[9,10] have noted that this is not the case and many critical details of therapy are often missing, referred to as the "black box" of therapy. Although this lack of detail has been noted, it has not been quantified or formally analyzed. Thus, a first step toward addressing the underreporting of methodological details is to quantify the problem in the field of stroke rehabilitation.

In the present analysis, our objectives were (1) to characterize the reporting of important methodological details in both experimental and control arms of stroke rehabilitation trials across different types of participants, interventions, and outcomes; (2) to assess potential differences in reporting for experimental vs control groups; (3) to identify potential areas of weakness in reporting, which need to be addressed by collective action by research stakeholders (eg, authors, reviewers, editors, publishers); and finally (4) to repeat objectives 1 to 3 specifically in those interventions reported as conventional therapy. Focusing on this subset of interventions is an essential first step in eliminating the "black box" of therapy, illustrating the variation and ambiguity in interventions that are described as "conventional" therapy.

The present analysis is part of the systematic review we conducted to construct the *C*entralized *O*pen-*A*ccess *R*ehabilitation database for *S*troke (SCOAR),[8,11] which includes data from randomized controlled trials (RCTs) for upper and lower extremity therapies in adults with stroke. From SCOAR, we analyzed existing variables describing the type, frequency, duration, and overall dose of therapy. In addition, independent coders extracted descriptions of the experimental and control therapies from the RCTs and assessed all groups separately according to the Template for Intervention Description and Replication (TIDieR) checklist.[5] TIDieR is a 12-point checklist that assigns points on the basis of the criteria described in table 1. Although the TIDieR checklist has previously been used to describe physical and occupational therapy interventions,[12-14] this analysis represents the first attempt to use the TIDieR checklist to describe experimental and control therapies separately.

List of abbreviations:

PEDro	**Physiotherapy Evidence Database**
RCT	**randomized controlled trial**
SCOAR	**Centralized Open-Access Rehabilitation database for Stroke**
TIDieR	**Template for Intervention Description and Replication**

Methods

Selection of studies

The present analysis is part of SCOAR; thus, all RCTs met the same eligibility criteria as that of the systematic review[8] (for a full list of the included RCTs, see supplemental appendix S1, available online only at http://www.archives-pmr.org/). SCOAR was constructed from a systematic search of MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Cumulative Index of Nursing and Allied Health from the earliest available date to May 2014 that identified 215 independent studies that focused on motor rehabilitation in adults with stroke, totaling 489 independent therapy groups. The summary statistics for these groups represent 12,847 patients in total. Details of the systematic review and construction of the database have been presented previously[8] (see also PROSPERO Registration No.: CRD42014009010). The PICO criteria[15] for the review were as follows:

1. *Population:* Human adults with motor impairment as a result of stroke (regardless of etiology or prior stroke).
2. *Intervention:* Any physical or occupational therapy intervention that required active movement on the part of the participant.
3. *Control:* All studies had to be RCTs, and studies were required to explicitly state random assignment to groups. For our analysis, we coded groups as "control" if they were identified as controls by the original authors. Alternatively, if a group received "conventional," "routine," "standard," or "usual" care without being specifically named as control, it was assumed that this was a control condition.
4. *Outcomes:* Only validated assessments of impairment or functional motor capacity that were administered by a clinician were extracted as outcomes (this excludes self-report measures, neuroimaging/-physiological measures, and study-specific kinematic/kinetic measures).

Extraction of therapy descriptions

To describe how therapy was delivered, we used extant variables in SCOAR (to represent time in therapy), created a therapy description coding template (to extract additional information on how therapy was delivered), and calculated word and reference counts (to estimate the amount of space in the article devoted to therapy descriptions). These measures are described below.

We used a number of methodological variables in SCOAR that were relevant to our descriptive analysis. These variables were as follows: (1) whether the therapy was experimental or control;