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Letter to Editor

Reporting Randomized Controlled Trials in Rehabilitation Research

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Dear Editor

When people consider Randomized Controlled Trials (RCTs), they tend to focus on design issues, which is understandable. RCTs are an essential component of the arsenal of research designs and are the only research design whereby the true relationship between cause and effect can be discerned. Therefore, if we wish to know whether a new drug or rehabilitation technique works better than another, is safe, and economically feasible, a randomized controlled trial is the only way to answer the question. There are several variations on the basic design. At the top of the hierarchy is the double-blind RCT [1]. Still, it is also possible to have single-blind [2]—common in therapies where blinding of participants is difficult—and to conduct pragmatic [3] and non-inferiority trials [4]. However, even the best-designed clinical trial will be wasted if it is not reported properly and has not met some essential requirements for reporting. Most leading international publishers and journals will only publish RCTs if they are properly reported.

RCTs in rehabilitation studies encounter some questions which should be considered before starting and then reporting them. These questions are: What variables are we measuring?, What is the treatment? What is the dose of the medicine? Are the patients aware of whether they are being treated? Is the therapist aware of whether the patient is in the treatment group? How much effect do concomitant and possibly confounding features have? How much impact do individual patient factors have on the outcome? How much effect do external factors such as the family have on the outcome? How much effect do other team members have? and How much effect does the environment have on the outcome? [5]. Since RCTs are potent tools in research, researchers of rehabilitation science should recognize the limitations of RCTs and try to reduce them as much as possible.

The accepted international standards for reporting RCTs are the CONSORT (Consolidated Standards of Reporting Trials) [6] guidelines, which are incorporated into the EQUATOR (Enhancing the Quality and Transparency of Health Research) guidelines. Under the main CONSORT guidelines, there is a series of extensions concerned with specific types of trial designs, for

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example, pragmatic and non-inferiority trials and many others, including testing Chinese herbal medicines [7] and herbal medicines generally. The main features of the CONSORT guidelines are the checklists—with specific variations for the various designs—and the CONSORT flowcharts, with which most people will be familiar from reading reports of RCTs.

Trial registration

The CONSORT checklist contains 25 items with subquestions. Ironically, the final item includes two of the most critical questions, which, if not responded to in the affirmative mode, will preclude publication in a reputable international academic journal. The two questions refer, respectively, to trial registration and availability of the protocol for the study. Ideally, both should be available at the same place: a recognized trials registration site. These requirements are advocated under the +AllTrails(https://www.alltrials.net/) campaign, to which all major academic publishers are signatories. The motto of +AllTrials is 'All Trials Registered | All Results Reported'. The reason is to avoid the 'bottom drawer phenomenon,' which can lead to publication bias in systematic reviews when only trials considered favorable to the aims of the research or a pharmaceutical company are published, and the unfavorable ones are ignored. Internationally, the most commonly used trials registration site are ClinicalTrials.gov (https://clinicaltrials.gov/) in the United States but other regions such as the European Union (the EU Clinical Trials Register; https://www.clinicaltrialsregister.eu/), and in Iran, the IRCT (https://www.irct.ir/; Iranian Registry of Clinical Trials) are available too. Therefore, before starting a clinical trial, it should be registered publicly and this should be recorded accurately in the CONSORT checklist.

Writing up a trial

The CONSORT checklist is, essentially, a guide to structuring an article reporting an RCT and includes all the usual aspects of organization of a manuscript: Title, Abstract, Introduction, Methods, Results, and Discussion. However, what is more important is that under each of these broad headings, the checklist tells you what the expected content should be. For example, under the "Methods" section, you must describe the design, the participants, the interventions, the outcomes, and all other aspects of the methods. When writing up an RCT article, it is sensible to have the CONSORT checklist open and to indicate on the form the precise pages of the manuscript where you have addressed the checklist items.

In addition to the checklist, the other essential feature to complete is the CONSORT flowchart. For this purpose, you need to keep a meticulous track of the potential and actual participants in your study, how many left the study (and why), and how many completed the study. When presenting your flowchart, ensure that you can add up all participants from the bottom to the top of the flowchart. It is a common error and easy for reviewers to check that all the participants are not accounted for.

Additional features of RCTs in rehabilitation studies should also be considered. Non-pharmacologic treatments (NPTs), especially rehabilitation, cover a wide range of interventions. Hence, methodological issues due to the complexity of the intervention strategies, the role of care providers, the proficiency of the related center, and the difficulties of blinding participants and therapists in rehabilitation should always be considered. In 2017, CONSORT updated their guidelines for NPTs where some items of the CONSORT checklist were modified [8].

2. Conclusion

The CONSORT guidelines have revolutionized and standardized the presentation and publication of RCTs and variants of RCTs. They ensure that information in articles reporting RCTs is standardized and easier to find and use, for example, in systematic reviews. The basic guidelines are essential to consult if you are writing up an RCT for publication and, as they do gradually evolve, it is worth consulting the most recent versions. For RCTs in rehabilitation, CONSORT NPTs guidelines should be considered.

Ethical Considerations

Compliance with ethical guidelines

There were no ethical considerations to be considered in this research.

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Authors' contributions

Both authors equally contributed to preparing this article.

Conflict of interest

The authors declared no conflict of interest.

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