

ARTICLE ONLINE FIRST

This provisional PDF corresponds to the article as it appeared upon acceptance.

A copyedited and fully formatted version will be made available soon.

The final version may contain major or minor changes.

Current evidence from the Randomised Controlled Trials Rehabilitation Checklist (RCTRACK) reporting guideline project

Stefano NEGRINI, Leighton CHAN, Giorgio FERRIERO, Walter FRONTERA, Allen
HEINEMANN

European Journal of Physical and Rehabilitation Medicine 2020 Oct 13

DOI: 10.23736/S1973-9087.20.06635-6

Article type: Editorial

© 2020 EDIZIONI MINERVA MEDICA

Article first published online: October 13, 2020

Manuscript accepted: October 9, 2020

Manuscript received: October 5, 2020

Subscription: Information about subscribing to Minerva Medica journals is online at:

<http://www.minervamedica.it/en/how-to-order-journals.php>

Reprints and permissions: For information about reprints and permissions send an email to:

journals.dept@minervamedica.it - journals2.dept@minervamedica.it - journals6.dept@minervamedica.it

Current evidence from the Randomised Controlled Trials Rehabilitation Checklist (RCTRACK) reporting guideline project

Stefano NEGRINI ^{1,2*}, Leighton CHAN ³, Giorgio FERRIERO ^{4,5}, Walter FRONTERA ^{6,7}, Allen HEINEMANN ⁸

1. Department of Biomedical, Surgical and Dental Sciences, University “La Statale”, Milan, Italy
2. IRCCS Istituto Ortopedico Galeazzi, Milan, Italy
3. Department of Rehabilitation Medicine, Clinical Center, National Institutes of Health, Bethesda, MD, USA
4. Physical and Rehabilitation Medicine Unit, Scientific Institute of Tradate, Istituti Clinici Scientifici Maugeri IRCCS, Tradate, Italy
5. Department of Biotechnology and Life Sciences, University of Insubria, Varese, Italy
6. Department of Physical Medicine, Rehabilitation, and Sports Medicine, University of Puerto Rico School of Medicine, San Juan, Puerto Rico
7. Department of Physiology, University of Puerto Rico School of Medicine, San Juan, Puerto Rico
8. Department of Physical Medicine and Rehabilitation, Feinberg School of Medicine, Northwestern University, and Shirley Ryan AbilityLab, Chicago, IL, USA

*Corresponding author

Prof. Stefano Negrini

Department of Biomedical, Surgical and Dental Sciences, University “La Statale”, Milan, Italy

E-mail: stefano.negrini@unimi.it

The quality of the reporting of clinical trials in rehabilitation has been improving but it should be enhanced further. This editorial introduces a collaborative effort by the American Journal of Physical Medicine and Rehabilitation (AJPM&R), the Archives of Physical Medicine and Rehabilitation (ArPM&R), and the European Journal of Physical and Rehabilitation Medicine (EJPRM) aimed at promoting the development of new reporting guidelines for Randomised Controlled Trials (RCTs) in rehabilitation using the RCTRACK (RCTs RehAbilitation CheckList) initiative of Cochrane Rehabilitation (1). These journals are publishing three complimentary thematic Special Sections with the papers produced during the 4th Cochrane Rehabilitation Methodology Meeting held in Orlando, FL, USA in March 2020. These papers summarize the literature background of the RCTRACK guidelines, that are now in the last stages of production.

Cochrane Rehabilitation, founded in 2016 (2), is the international body applying evidence knowledge translation activities to the field of rehabilitation. It serves as a bridge between Cochrane and rehabilitation stakeholders (3). In addition to activities aimed at disseminating all the Cochrane evidence in the field (4-6), Cochrane Rehabilitation has also started to work on methodological issues with the goal of improving the generation of scientific evidence in rehabilitation (7). The main activity to accomplish this goal has been a series of methodological meetings (8-10) that allow a group of experts to focus on the major issues faced by rehabilitation researchers. As a result, the RCTRACK project was started (1) with the aim of developing a reporting guideline specific to rehabilitation. The 4th Cochrane Rehabilitation Methodology Meeting was the second Consensus Meeting of the RCTRACK project. The starting point was the results of the first meeting held in 2019 (7-10) and was divided into 7 Technical Working Groups (1). The work of these groups was presented and discussed over 2 days, thanks to funding support from the International Society of Physical and Rehabilitation Medicine (ISPRM). The 3 collaborating journals are publishing the papers that resulted from that meeting in special sections divided by topics.

The articles published in the ArPM&R focus on general issues under the title of “*Current issues with methodology and reporting guidelines in rehabilitation from the RCTRACK project*”. These papers discuss contemporary methodological problems in our field and how reporting guidelines address them. Arienti et al. (11) discuss the main methodological issues in rehabilitation trials identified through a scoping review. In 71 studies the main issues were the application of randomized-controlled trial design (32%), definition of core outcome sets (28%), intervention description (22%), methodological (conducting) and reporting quality (21%), clinical practice applicability (14%), blinding assessor (10%), randomization methods or allocation concealment (8%), and participant descriptions and recruitment (8%). Dijkers’ article (12; not presented in the meeting) includes an overview of 56 reviews (3,454 primary studies) and found that in rehabilitation intervention papers, TIDieR checklist items 1 (‘name’) and 2 (‘why’) are generally reported adequately, while this is not true for most other items that can be as low as 10% for item 10 (‘modifications’). Comparators are reported even more poorly. Finally, Armijo-Olivo et al. (13) updated their previous paper (14) on tools and items to evaluate the risk of bias and reporting of RCTs in rehabilitation, and found a lack of agreement on a core set of items in our field.

EJPRM articles report the statistical issues in a special section titled “*Problems with statistics in rehabilitation from the RCTRACK project*”. These papers provide an overview of the main statistical issues and suggest solutions specific to our field. Kumbhare et al. (15) report a systematic review of 99 non-pharmacological rehabilitation RCTs and found that one in five did not properly and adequately report the sample size calculation methods, two in five the randomization procedures, and one in five had at least one mismatch in statistical analyses. Armijo-Olivo et al. produced two complimentary papers (16,17) on attrition, missing data, and compliance related biases. They found lack of specificity of items in reporting and conduct guidelines (16), while missing data and compliance-related biases influence treatment effect estimates in rehabilitation trials (17). Meyer et al. (18) provided a conceptual and empirical framework for the development of reporting standards on patient characteristics in rehabilitation trials, discussing the type of information specific to

rehabilitation patients that should be reported (e.g. comorbidities, functioning characteristics including relevant context factors). They also found that reporting standards only partly address these pressing issues.

Finally, AJPM&R is publishing articles addressing practical issues and outcomes, in a special section titled *“Problems with reporting of treatment and outcomes in rehabilitation from the RCTRACK project”*. These articles provide an overview of specific problems of rehabilitation interventions that require precise methodological answers. Arienti et al. (19) found in a systematic review that 45% of 97 RCTs did not use all PICO (Population, Intervention, Comparison, Outcome) elements to frame the research question. Whyte et al. (20) reported a scoping review of 156 guidelines and identified specific themes related to treatment reporting and evaluated these themes against TIDieR criteria. They concluded that, even if rehabilitation is a diverse field, a clear description of a treatment’s separable components, along with distinct treatment theories for each, can improve reporting of relevant information. Wang et al. (21) studied the reporting criteria of outcome measures in rehabilitation RCTs. After a complex 4-phases study, they propose four criteria: description of the outcome construct, justification of the chosen outcome according to ICF and psychometric properties of the measurement tool, description and justification of the timing of outcome measurement, and complete and unselective reporting.

Overall, these 3 special sections provide a comprehensive overview of the problems in the reporting of RCTs in rehabilitation as presented during the 4th Cochrane Rehabilitation Methodology Meeting. Together with the articles on the new definition of rehabilitation for scientific research purposes (10, 22-26), these studies offer the scientific background of the RCTRACK project and guidelines. During the RCTRACK Consensus Meeting, the first draft of 2 guidelines was prepared. Together with the originally conceived RCTRACK (1) a second guideline on rehabilitation interventions can be used with all study designs and not only RCTs. The two guidelines may be used in conjunction when reporting RCTs. Both drafts are under revision and further development through Delphi rounds by the RCTRACK Executive Committee and the RCTRACK Advisory Committee (1).

The main RCTRACK guideline could be named CONSORT-Rehabilitation extension and may become official if there is agreement with the CONSORT group. It will include the classical CONSORT guideline items, with other items relevant to rehabilitation research questions, PICO (Participants, Interventions, Comparison, Outcomes), statistics, and results. The new RCTRACK reporting guideline on rehabilitation interventions (treatment) builds on TIDieR to produce a new and specific framework for our field. Its name is now under discussion. It will contain items grouped in 3 dimensions: treatment, comparison and “background treatment”. About the last dimension, many rehabilitation interventions are proposed as adjunctive treatments to so-called “usual care” therapies (background treatment), that unfortunately are seldom well described, even if they can highly influence the efficacy of the studied interventions (22).

The AJPM&R, ArPM&R, and EJPRM support the development of these reporting guidelines for rehabilitation research by the Cochrane Rehabilitation RCTRACK initiative (1). This initiative is aligned with those promoted previously by rehabilitation journals on reporting guidelines (27) and trials registration (28). We strongly believe these efforts serve to improve the quality of science in our field.

References

1. Negrini S, Armijo-Olivo S, Patrini M, Frontera WR, Heinemann AW, Machalicek W, Whyte J, Arienti C; RCTTRACK Promoters. The Randomized Controlled Trials Rehabilitation Checklist: Methodology of Development of a Reporting Guideline Specific to Rehabilitation. *Am J Phys Med Rehabil.* 2020 Mar;99(3):210-215. doi: 10.1097/PHM.0000000000001370.
2. Negrini S, Arienti C, Gimigliano F, Grubišić F, Howe T, Ilieva E, Levack W, Malmivaara A, Meyer T, Patrick Engkasan J, Rathore FA, Kiekens C. Cochrane Rehabilitation: Organization and Functioning. *Am J Phys Med Rehabil.* 2018 Jan;97(1):68-71. doi: 10.1097/PHM.0000000000000832.
3. Negrini S, Gimigliano F, Arienti C, Kiekens C. Knowledge Translation: The Bridging Function of Cochrane Rehabilitation. *Arch Phys Med Rehabil.* 2018 Jun;99(6):1242-1245. doi: 10.1016/j.apmr.2017.11.002. Epub 2017 Dec 12.
4. Negrini S, Arienti C, Pollet J, Engkasan JP, Gimigliano F, Grubisic F, Howe T, Ilieva E, Levack W, Malmivaara A, Meyer T, Oral A, Rathore F, Kiekens C. Cochrane Rehabilitation: report of the first year of work. *Eur J Phys Rehabil Med.* 2018 Jun;54(3):463-465. doi: 10.23736/S1973-9087.18.05317-0.
5. Negrini S, Arienti C, Engkasan JP, Gimigliano F, Grubisic F, Howe T, Ilieva E, Lazzarini SG, Levack WM, Malmivaara A, Meyer T, Oral A, Patrini M, Pollet J, Rathore FA, Kiekens C. Cochrane Rehabilitation: 2018 annual report. *Eur J Phys Rehabil Med.* 2019 Apr;55(2):314-318. doi: 10.23736/S1973-9087.19.05785-X. Epub 2019 Apr 1.
6. Arienti C, Kiekens C, Bettinsoli R, Engkasan JP, Gimigliano F, Grubisic F, Howe T, Ilieva E, Lazzarini SG, Levack WM, Malmivaara A, Meyer T, Oral A, Patrini M, Pollet J, Rathore FA, Negrini S. Cochrane Rehabilitation: 2019 annual report. *Eur J Phys Rehabil Med.* 2020 Feb;56(1):120-125. doi: 10.23736/S1973-9087.20.06188-2.
7. Levack WM, Meyer T, Negrini S, Malmivaara A. Cochrane Rehabilitation Methodology Committee: an international survey of priorities for future work. *Eur J Phys Rehabil Med.* 2017 Oct;53(5):814-817. doi: 10.23736/S1973-9087.17.04958-9.
8. Levack WM, Malmivaara A, Meyer T, Negrini S. Methodological problems in rehabilitation research. Report from a cochrane rehabilitation methodology meeting. *Eur J Phys Rehabil Med.* 2019 Jun;55(3):319-321. doi: 10.23736/S1973-9087.19.05811-8. Epub 2019 Apr 15.
9. Negrini S, Meyer Psy T, Arienti C, Malmivaara A, Frontera WR; Cochrane Rehabilitation Methodology Meeting participants. In Search of Solutions for Evidence Generation in Rehabilitation: The Second Cochrane Rehabilitation Methodology Meeting. *Am J Phys Med Rehabil.* 2020 Mar;99(3):181-182. doi: 10.1097/PHM.0000000000001374.
10. Negrini S, Meyer T, Arienti C, Kiekens C, Pollock A, Selb M, Stucki G; 3rd Cochrane Rehabilitation Methodology Meeting participants. The 3rd Cochrane Rehabilitation Methodology Meeting: "Rehabilitation definition for scientific research purposes". *Eur J Phys Rehabil Med.* 2020 Sep 16. doi: 10.23736/S1973-9087.20.06574-0. Epub ahead of print.
11. Arienti C, Armijo-Olivo S, Minozzi S, Tjosvold L, Lazzarini SG, Patrini M, Negrini S. The challenges of real-world evidence to improve global health: all the methodological issues of research in rehabilitation. *Arch Phys Med Rehabil.* 2021 (submitted)
12. Dijkers MPJM. An overview of studies using the Template for Intervention Description and Replication (TIDieR) as a measure of trial intervention reporting quality. *Arch Phys Med Rehabil.* 2021 (accepted)
13. Armijo-Olivo S, Patrini M, de Oliveira Souza AI, Dennett L, Dahchi M. Tools to assess the Risk of bias and Reporting Quality of Randomized Controlled Trials in Rehabilitation. *Arch Phys Med Rehabil.* 2021 (submitted)
14. Armijo-Olivo S, Fuentes CJ, Ospina M, Saltaji H, Hartling L. Inconsistency in the Items Included in Tools Used in General Health Research and Physical Therapy to Evaluate the Methodological Quality of Randomized Controlled Trials: A Descriptive Analysis. *BMC Medical Research Methodology* 2013;13(116):1-19.

15. Amiri M, Kumbhare D. Randomized controlled trials in non-pharmacological rehabilitation research: a scoping review of the reporting of sample size calculation, randomization procedure, and statistical analyses. *Eur J Phys Rehabil Med*. 2020 Sep 16. doi: 10.23736/S1973-9087.20.06451-5. Epub ahead of print.
16. Armijo-Olivo S, Machalicek W, de Oliveira Souza AI, Dennett L, Ballenberger N. Improving reporting of attrition, missing data, and compliance related biases in randomized controlled trials of rehabilitation Interventions. *Eur J Phys Rehabil Med* 2020 (submitted)
17. Armijo-Olivo S, Machalicek W, Dennett L, Ballenberger N. Attrition, missing data, and compliance related biases in randomized controlled trials of rehabilitation interventions: Towards improving reporting and conduct . *Eur J Phys Rehabil Med* 2020 (submitted)
18. Meyer T et al. Reporting of patients' characteristics in rehabilitation trials: an analysis of publications in major clinical rehabilitation journals. *Eur J Phys Rehabil Med* 2020 (submitted)
19. Arienti C, Lazzarini SG, Patrini M, Pulijak L, Pollock A, Negrini S. The structure of research question in rehabilitation randomized controlled clinical trials: a systematic review *Am J Phys Med Rehabil*. 2020 (submitted)
20. Wang D, Taylor-Vaisey A, Negrini S, Côté P. Criteria to evaluate the quality of outcome reporting in RCTs of rehabilitation interventions. *Am J Phys Med Rehabil*. 2020 Sep 21. doi: 10.1097/PHM.0000000000001601. Epub ahead of print.
21. Whyte J, Dijkers M, Fasoli SE, Ferraro M, Katz LW, Norton S, Parent E, Pinto SM, Sisto SA, Van Stan JH, Wengerd L. Recommendations for Reporting on Rehabilitation Interventions. *Am J Phys Med Rehabil*. 2020 Sep 2. doi: 10.1097/PHM.0000000000001581. Epub ahead of print.
22. Negrini S, Arienti C, Kiekens C. Usual care: the big but unmanaged problem of rehabilitation evidence. *Lancet*. 2020 Feb 1;395(10221):337. doi: 10.1016/S0140-6736(19)32553-X.
23. Negrini S, Arienti C, Kükükeveci A, Lazzarini SG, Patrini M, Kiekens C. Current rehabilitation definitions do not allow correct classification of Cochrane systematic reviews. An overview of cochrane reviews. *Eur J Phys Rehabil Med*. 2020 Sep 16. doi: 10.23736/S1973-9087.20.06585-5. Epub ahead of print.
24. Levack WM, Rathore FA, Negrini S. Expert opinions leave space for uncertainty when defining rehabilitation interventions: analysis of difficult decisions regarding categorization of rehabilitation reviews in the Cochrane library. *Eur J Phys Rehabil Med*. 2020 Sep 29. doi: 10.23736/S1973-9087.20.06615-0. Epub ahead of print.
25. Meyer T, Kiekens C, Selb M, Posthumus E, Negrini S. Toward a new definition of rehabilitation for research purposes: a comparative analysis of current definitions. *Eur J Phys Rehabil Med*. 2020 Sep 29. doi: 10.23736/S1973-9087.20.06610-1. Epub ahead of print.
26. Arienti C, Patrini M, Pollock A, Lazzarini S, Oral A, Negrini S. A comparison and synthesis of rehabilitation definitions used by consumers (google), major stakeholders (survey) and researchers (Cochrane systematic reviews). A terminological analysis. *Eur J Phys Rehabil Med* (in publication)
27. Chan L, Heinemann AW, Roberts J. Elevating the quality of disability and rehabilitation research: mandatory use of the reporting guidelines. *Arch Phys Med Rehabil*. 2014 Mar;95(3):415-7. doi: 10.1016/j.apmr.2013.12.010.
28. Chan L, Heinemann AW. Clinical Trial Registration: The Time Has Come.... *Arch Phys Med Rehabil*. 2015 Dec;96(12):2093. doi: 10.1016/j.apmr.2015.09.005.