

In search of solutions for evidence generation in rehabilitation: the second Cochrane Rehabilitation Methodology Meeting

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Abstract

The availability of evidence to support rehabilitation has been a long-standing challenge. We believe that now is the time to start a systematic process of improvement. For this reason, Cochrane rehabilitation is producing an effort to improve the methodology used to generate evidence. Two Cochrane Rehabilitation Methodology Meetings (CRMM) have been performed (Paris, France, July 2018; Kobe, Japan, June 2019) and 2 others programmed (Milan, Italy, February 2020; Orlando, USA, March 2020). All material discussed during CRMMs is published. In this issue we have the papers from the Kobe CRMM about blinding, current reporting standards for population and comparison groups, and the protocol of the RCT Rehabilitation Checklists (RCTRACK) project.

The articles published in this issue aim to help the rehabilitation scientific community to move forward, to improve the process of generating evidence in rehabilitation, and to strengthen our field as presented to the general scientific community. To accomplish these goals we need to clearly describe our methods and our approach to future rehabilitation research. Not all fields of study can apply the same methodology in science, but each field must define its research methodology and demonstrate the characteristics that make it a specific field of inquiry.

Keywords: Evidence; rehabilitation; Methodology

The availability of evidence to support rehabilitation has been a long-standing challenge. We believe that now is the time to start a systematic process of improvement¹. Cochrane rehabilitation was launched in December 2016 with this specific aim to create a bridge between the world of Cochrane and the field of rehabilitation^{2,3}. Since the very beginning, this knowledge translation work⁴ has been interpreted in terms of dissemination^{5,6} but also as an effort to improve the methodology used to generate evidence⁵⁻⁸. After a first period of investigations to understand the importance of various issues related to the generation of evidence in rehabilitation⁷ we decided to organize the Cochrane Rehabilitation Methodology Meetings (CRMM)⁸.

The first CRMM took place in July 2018 in Paris, France thanks to the work of William Leveck with the collaboration of Thorsten Meyer, Antti Malmivaara and Stefano Negrini. That meeting was supported by a “Catalyst: Seeding” grant from the Royal Society Te Apārangi of New Zealand⁸. As a result of a 2-day meeting and multiple discussions, a series of papers underlining the complexity of the field of rehabilitation and its representation in rehabilitation research were written and published in a special Issue of the European Journal of Physical and Rehabilitation Medicine⁸⁻¹⁹. Rehabilitation is a very individualized, person-centered, multi-modal and interactive approach^{9,10}. This description is, however, in conflict with the demands for homogeneity and standardization in primary studies and particularly in systematic reviews. Those papers from the Paris meeting explored a series of issues including the “real-world impact” of rehabilitation reviews¹¹, the “human risk of bias”¹², the problems in Cochrane Reviews on rehabilitation with the inclusion of information on participants’ comorbidities¹³, the use of well described control groups¹⁴, the description of interventions¹⁵, and the potential of using the ICF in research^{16,17}. Finally, two topics specific to Cochrane were added to the discussion, including the prioritization of the production of systematic reviews¹⁸ and the overview of reviews¹⁹. Two other studies resulting from the same CRMM have been completed, namely a study on the replicability of rehabilitation trials in practice (REREP)²⁰ and a scoping review on methodological issues in rehabilitation medicine research²¹.

All the above-mentioned studies attracted the attention of the rehabilitation community, and the International Society of Physical and Rehabilitation Medicine (ISPRM) decided to support the CRMM meetings. They also constituted the basis for the second CRMM that was organized by Thorsten Meyer, Stefano Negrini and Antti Malmivaara and took place in June 2019 in Kobe, Japan prior to the 13th World Congress of ISPRM. The topics discussed in that meeting are reported in this Special Section of the American Journal of Physical Medicine and Rehabilitation, and included blinding^{22,23}, description of population²⁴ and comparison groups²⁵, and the proposal of a new reporting guidelines for rehabilitation trials²⁶.

Blinding is often difficult in rehabilitation, if not impossible or even not indicated. The problem of blinding relates to the question of when to do it but also to the consequences of blinding on the outcomes. Malmivaara et al.²² conducted a systematic review to assess whether blinding vs non-blinding have been analyzed conceptually and showed the absence of specific formal studies. This raises a big issue particularly (but not only) in all rehabilitation RCTs dealing with the effectiveness of multimodal interventions. In most of the cases, the absence of double blinding should not be considered a negative when assessing the possible risk of bias. Armijo-Olivo et al.²³ performed a systematic review to identify the association between different types of blinding and treatment effects. The authors found seven studies that showed mixed associations with no consistent pattern. Therefore, the question of whether blinding is needed or not in rehabilitation studies has been identified as an important issue^{21,22} and has not been conceptually studied²². In addition, we do not really know the consequences of different blinding approaches²³.

Two other articles in this issue focus on the current reporting standards suggestions for RCTs (i.e., CONSORT) regarding two other typical problems of rehabilitation: the description of the population²⁴ and the comparison groups²⁵. Meyer et al.²⁴ performed a conceptual analysis of characteristics of rehabilitation patients that should systematically be reported including comorbidities, level of functioning, and context (environmental and personal) factors. They found

that present reporting standards address these issues only partially. Levack et al.²⁵ recommended the development of additional standards, particularly about usual care and the selection of control, and the need to report the rationale for the chosen comparison.

The last paper of the series is the protocol of a project that we expect to be highly relevant for the future of research in rehabilitation: the RCT Rehabilitation Checklists (RCTRACK)²⁶. This paper summarizes the preliminary studies that clearly showed the need to improve the quality of conduct and reporting of RCTs in rehabilitation: a scoping review²¹, the REREP study²⁰, studies of reporting and conduct instruments²⁷⁻²⁹, and the first CRMM⁸⁻¹⁹. The methodology and all the phases of RCTRACK, the first reporting guideline totally devoted to rehabilitation, are then reported.

The third CRMM will be held in February 2020 in Milan, Italy and will be the beginning of a new project of Cochrane Rehabilitation that intends to identify a rehabilitation definition that will be useful for research purposes. It will be a Consensus Conference where experts will work and propose a definition that will then be submitted to a Delphi Process for approval by the rehabilitation worldwide community. The fourth meeting of the CRMM will take place in March 2020, in Orlando, USA, before the 14th World Congress of ISPRM and will be dedicated to the RCTRACK project presented in this issue²⁶.

The articles published in this issue aim to help the rehabilitation scientific community to move forward, to improve the process of generating evidence in rehabilitation, and to strengthen our field as presented to the general scientific community. To accomplish these goals we need to clearly describe our methods and our approach to future rehabilitation research. Not all fields of study can apply the same methodology in science, but each field must define its research methodology and demonstrate the characteristics that make it a specific field of inquiry.

Cochrane Rehabilitation Methodology Meeting participants included: Chiara Arienti (Ita), Susan Armijo-Olivo (Can), Julia Patrick Engkasan (Mys), Walter R. Frontera (PR), Frane Grubisic (Cro), Allen Heinemann (USA), Carlotte Kiekens (Bel), William Levack (Nzl), Wendy

Machalicheck (USA), Antti Malmivaara (Fin), Thorsten Meyer (Ger), Stefano Negrini (Ita), Aydan Oral (Tur), Melissa Selb (Che), Gerold Stucki (Che), Will Taylor (Nzl), John Whyte (USA).

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