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Reporting GUideline for Intervention DEscription in Rehabilitation (GUIDE-Rehab): a tool to open the 'black box' of rehabilitation complex interventions

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Abstract

In 2023, the World Health Assembly adopted a resolution to strengthen rehabilitation within health systems, calling for rehabilitation research. Within health, the term rehabilitation has multiple meanings, including a core strategy, a sector, a service and an intervention. The latter has been defined as complex and characterised as a 'black box', similar to complex interventions in other fields. The existing reporting guidelines are not sufficiently effective in describing interventions within the rehabilitation field.

We developed the GUideline for Intervention DEscription in Rehabilitation (GUIDE-Rehab) to address these challenges.

According to the Enhancing the QUAlity and Transparency Of health Research Network, we followed a Delphi process with multiple Consensus Meetings and piloting and used ACcurate COnsensus Reporting Document for reporting. The background research involved 21 papers. We based GUIDE-Rehab on the Rehabilitation Treatment Specification System, developed over 15 years of research to improve rehabilitation description; the definition of rehabilitation for research purposes; and the Template for Intervention Description and Replication reporting guideline. 68 representatives from global rehabilitation stakeholders (scientific societies, journals, evidence and methods groups), including individuals with lived experience of disability, from 26 countries across all continents and economies, participated. The piloting involved 17 chief editors, 7 research groups and participants from 10 scientific meetings.

The complete version comprises 16 items, while the version for uncontrolled studies includes 13. The short version (10 items for text, 6 for appendix) helps reduce the manuscripts' length. The GUIDE-Rehab graphical illustration (nine items) facilitates the intervention description. GUIDE-Rehab will assist in the reporting of interventions in rehabilitation to enhance clinical research and support clinical implementation.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Reporting guidelines are vital for enhancing the clarity and thoroughness of research publications. The definition of rehabilitation for research purposes describes it as a complex intervention, providing an explanation of the described 'black box' concept. Current intervention descriptions, such as Template for Intervention Description and Replication (TIDIeR), fail to fully reflect the complexity of rehabilitation, and the clinical reproducibility of randomised controlled trials has been shown to be low.

WHAT THIS STUDY ADDS

⇒ This study developed GUideline for Intervention DEscription in Rehabilitation (GUIDE-Rehab), a consensus-based reporting guideline for the intervention rehabilitation, created through an extensive multistakeholder process in accordance with the Enhancing the QUAlity and Transparency Of health Research guidelines. It provides a structured and comprehensive framework to improve transparency, reproducibility and comparability of rehabilitation research. The guideline incorporates diverse professional and patient perspectives to ensure relevance and usability.

Introduction

The term 'rehabilitation' is used in fields ranging from architecture to correctional facilities to

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ GUIDE-Rehab offers researchers, clinicians, journal editors and policymakers a valuable tool to enhance the reporting quality of rehabilitation research, potentially improving evidence synthesis and its application in practice. Future studies can check its validity and compare to the recently published TIDIeR-rehabilitation.

health, where it can refer to various aspects: (1) one of the five core strategies for achieving and maintaining population health, alongside promotion, prevention, treatment and palliation[1]; (2) an essential service for universal health coverage[2]; (3) a field that encompasses multiple rehabilitation professionals, including physical and rehabilitation medicine physicians and other medical specialists[3]; and (4) a specific intervention.[4]

In recent years, the importance of rehabilitation in healthcare systems has increased significantly due to population ageing and the rising prevalence of non-communicable and chronic diseases, resulting in a substantial growth in rehabilitation needs.[5] In May 2023, the 76th World Health Assembly unanimously adopted a resolution to strengthen rehabilitation in health systems,[6] following the WHO 'Rehabilitation 2030: A Call for Action' initiative.[7] This resolution mandated the scaling up of evidence-based rehabilitation services globally and recommended improving the quality of rehabilitation research. When considering rehabilitation as a health intervention, Cochrane Rehabilitation identified several issues with existing definitions.[8–12] Therefore, it engaged key global stakeholders in formulating a definition of rehabilitation for clinical research purposes.[4]

The Consolidated Standards of Reporting Trials statement has demonstrated the value of reporting guidelines for enhancing both reporting and conduct of research across several health areas.[13] The Template for Intervention Description and Replication (TIDieR)[14] was published to improve the reporting of interventions. Unfortunately, rehabilitation studies continue to be poorly reported[15–17] and only a minority are clinically replicable.[18] The term 'black box' is frequently used to illustrate the general lack of detail in describing interventions in rehabilitation.[19–21] The Cochrane Rehabilitation definition, based on the Population, Intervention, Comparison, Outcome (PICO) framework and the WHO International Classification of Functioning, Disability and Health, opens new perspectives on reporting of rehabilitation studies.[4] The definition states that rehabilitation is a multimodal (implementation of multiple interventions at the same time—eg, it can include at the same time the interventions exercise therapy, education, cognitive behavioural treatment all mixed up to achieve a complex intervention), person-oriented (requiring multiple outcomes), collaborative (involving multiple people, including physicians, therapists, patient and family/caregivers) process (changing over time and in different settings) that targets a person's capacity (body structures, functions, activities/participation) and/or contextual factors to optimise functioning in people with health conditions who are experiencing or are likely to experience disability.[4] Accordingly, rehabilitation can be recognised as a complex intervention, as defined by Skivington *et al*:[22] 'An intervention might be considered complex because of properties of the intervention itself, such as the number of components involved; the range of behaviours targeted; expertise and skills required by those delivering and receiving the intervention; the number of groups, settings, or levels targeted; or the permitted level of flexibility of the intervention or its components.' In this sense, unpacking the 'black box' presents a challenge that rehabilitation shares with other health fields requiring complex interventions.[23 24] The above definition avoids the classical circular argument that 'rehabilitation is what rehabilitation professionals do',[25] indicating that not everything conducted in the rehabilitation field is necessarily the intervention 'rehabilitation' (eg, manipulations). Further examples and explanations can be found in the original paper.[4]

The need for and importance of developing an improved guideline for studies meeting the rehabilitation definition[4] emerged from the work of Cochrane Rehabilitation through its Methodological Meetings[26–28] and the annual meetings with the Advisory Board,[29] constituted by relevant global rehabilitation stakeholders. The rehabilitation community agreed that this was a top priority,[30] as confirmed by the recently published extension of TIDIeR.[31] This extension follows the 'classical' TIDIeR approach, with a greater focus on simple than complex interventions. Over the last 15 years, the Rehabilitation Treatment Specification System (RTSS), actively disseminated by the American Congress of Rehabilitation Medicine, has been developed to specifically unveil the 'black box' of rehabilitation as a complex intervention.[32 33] The RTSS approach requires defining an intervention by dividing it into its separable components and identifying, for each, the known or hypothesised active ingredients and the target they directly impact. The RTSS expands and details the 'Why' TIDIeR category, and makes the 'What', 'Who', 'How' and 'Where' categories only derivatives to achieve the 'Why'. In this theory-based approach, the intervention trial is an empirical comparison but also tests the underlying intervention theory ('Why').

Aim and scope

This manuscript reports on the development of GUideline for Intervention DEscription in Rehabilitation (GUIDE-Rehab), a checklist designed to accurately report intervention studies of rehabilitation as a complex intervention. GUIDE-Rehab seeks to ensure that the known or hypothesised active ingredients responsible for functional changes are clearly articulated and that, in complex interventions, ingredients are linked to the measurable changes they induce. GUIDE-Rehab applies to the reporting of intervention details in all types of rehabilitation intervention research, from randomised controlled trials to case reports through observational, controlled and uncontrolled studies. It can be used in conjunction with any reporting guideline suitable for the study design employed. Some of the items required by GUIDE-Rehab are in line with recent guidance documents, like the recommendations for the development, implementation, and reporting of control interventions in efficacy and mechanistic trials of physical, psychological, and self-management therapies(CoPPS Statement)[34] and the Guidance for intervention fidelity in non-drug, non-surgical trials.[35]

Development of the GUIDE-Rehab reporting guideline

All details of the methods are reported in online supplemental material 1 following the ACCORD (ACcurate COnsensus Reporting Document) guideline.[36] GUIDE-Rehab is part of the Randomised Controlled Trials in Rehabilitation Checklist (RCTRACK) project.[30] We adhered to the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) Network guidance[37] and registered the project.[38] The 68 volunteer panellists, who declared no conflict of interest and came from 26 countries across all continents and economies, included key global rehabilitation stakeholders,

experts in evidence-based medicine and methodology, developers of previous guidelines[39–42] and individuals with lived experience of disability (online supplemental material 2).

The preparatory research included 14 papers from the first[43] and second[27] Cochrane Rehabilitation Methodological Meetings, and 7 RCTRACK preparatory papers.[28] GUIDE-Rehab is based on the RTSS,[32 33 44] one of the RCTRACK preparatory papers specifically focused on intervention reporting,[15] the definition of rehabilitation for research purposes[4] and the TIDieR guideline.[14] The procedure included a kick-off Consensus Meeting, a Delphi process and three piloting procedures: editorial (17 chief editors), clinical research (7 teams) and general rehabilitation audience (10 meetings). The Delphi included only one round because the predefined 90% agreement threshold was reached immediately, and a restitution of the final GUIDE-Rehab was conducted for final comments and acceptance.

The GUIDE-Rehab intended audiences include people involved in research at all levels. We did not have any direct funding or endorsing organisations. Cochrane Rehabilitation promoted and cohordinated the whole process, and the Cochrane Rehabilitation Advisory Board participants officially represented their global organisations or journals.

The GUIDE-Rehab reporting guideline

Table 1 reports the items of GUIDE-Rehab (16 items): 1 item for the abstract/introduction, 12 items for the methods section (8 for the intervention, 3 for the comparator and 1 for background treatment), 1 for the results and 2 for the discussion sections.

To enhance implementation, we developed two additional versions and a graphical illustration. The short version (10 items) provides all the items that must be reported in manuscripts, while the other 6 items must be included in an online supplemental appendix. The 13 items for the uncontrolled studies version are designed for studies without a comparison group. The GUIDE-Rehab graphical illustration of the intervention (nine items) (figure 1) visually summarises the intervention under investigation; it can be used in research, clinics and education.

The complete GUIDE-Rehab document (online supplemental appendix 1) includes an introduction, the scope, a description of the items with complete examples, guidance on how to use the guideline and a glossary of terms.

Discussion

GUIDE-Rehab is specific to rehabilitation but is underpinned by a theory-based approach developed by the RTSS over more than a decade:[32 33 44] the RTSS requires that an intervention be defined with respect to its known or hypothesised active ingredients and the target they directly impact, such that any intervention trial is also a test of the underlying intervention theory. Treatments specified according to the RTSS have two key features: (1) the requirement to divide the intervention (which in rehabilitation is almost always complex) into its multiple components according to the measurable target, and for each component the active ingredients to achieve that target and the mechanisms connecting them (together, an intervention theory); (2) the need to explicitly address the ingredients that promote patient engagement in the necessary treatment activities. Since practicing clinicians can rarely implement an intervention as published,[18] this structure provides them with a logical basis for determining what can and cannot be altered to achieve specific outcomes and what is required to ensure patient engagement. And since intervention materials and devices are often merely delivery vehicles for active ingredients, the treatment theory points to their essential features. For researchers, the structure promotes explicit testing of treatment theories that cross individual treatments. It helps clarify the direct versus downstream indirect outcomes of the intervention and identifies which targets have been measured by the study's outcome measures. It clarifies the degree of overlap in treated targets between two intervention protocols and, for similar targets, allows a comparison of the ingredients used to treat them.

As TIDIeR is the current reference standard for non-pharmacological studies, including rehabilitation, we provide a direct comparison in table 2. While TIDieR requires more relevant details than previous guidelines about the kinds of interventions in the rehabilitation field, it does not provide any explicit filter for determining what is 'relevant'. Our primary concern is to offer a solution that describes the complexity of rehabilitation,[4] often referred to as a 'black box'. Thus, GUIDE-Rehab operationalises 'relevant details' as those that identify separable intervention components and clearly identify the known or hypothesised active ingredients and measurable direct targets of each.

The recently published TIDIeR extension for rehabilitation[31] represents a similar step forward for rehabilitation reporting over the original TIDieR, in referring to active ingredients and theory. But different parts of a complex intervention are built on different theories, which link specific bundles of ingredients to specific targets. Without that information, which GUIDE-Rehab requires, clinicians must choose to implement all or none of the intervention, and researchers, similarly, must compare entire intervention protocols. Moreover, GUIDE-Rehab's requirement to highlight the ingredients that support engagement in treatment allows evaluation of two different reasons for treatment failure (failure to adequately perform the intervention vs good performance of an ineffective intervention). GUIDE-Rehab and the TIDieR extension also differ in adherence to the current EQUATOR guidelines, representation of the entire rehabilitation community and piloting.

GUIDE-Rehab also introduces the concept of background treatment, defined as 'all interventions provided to all study participants (intervention and comparison) which are common to both groups'. The notion of a stand-alone intervention or an adjunct to other therapies is well-known, with the distinction typically proposed in systematic reviews.[45] Often, in rehabilitation, it is unethical to include a control group receiving 'no intervention' (eg, confining a patient to bed after a stroke to evaluate the effectiveness of active rehabilitation or not instructing a patient who cannot walk on how to use a wheelchair to assess the effectiveness of mobility training programmes). Thus, new interventions are frequently studied as add-ons to other interventions (background treatment), thereby becoming an integral part of the rehabilitation process.[4] Researchers rarely describe the additional interventions that all participants might receive, and they provide even less detail about potential interactions between this background treatment and either the experimental intervention or its comparator.

Moreover, like the comparator in some observational studies, the background treatment may be reported as 'usual care'. In rehabilitation, there is little well-defined standard practice,[46 47] rendering 'usual care' unspecified. We used the term background 'treatment' and not 'intervention', because multiple interventions could constitute it; similarly, we insist on 'background treatment' instead of 'usual care' because we want authors to understand the need to describe it without using the meaningless term 'usual care'; finally, it is highly probable (and should be reported) that the background treatment, interacting with the studied intervention, becomes part of the overall rehabilitation programme.

The background treatment can alter the effects of an experimental intervention by: (1) swamping the effects of the

Table 1 The GUIDE-Rehab reporting guideline. All items are numbered consecutively. The short form and the uncontrolled studies versions exclude some items according to what reported in the footnotes. For further details and explanations, see online supplemental appendix 1. All the items of GUIDE-Rehab focus only on the description of the intervention. These items should be integrated into the appropriate reporting guideline for specific study designs

Number	Item
Abstract and Introduction section	
1	Intervention type In the abstract, introduction and, if possible, in the title, identification of the studied intervention as one of the following types: rehabilitation programme, intervention for rehabilitation.
Material and Methods section	
2	Intervention theory Brief description (or reference) of the theory/theories on which the studied intervention is based.
3	Intervention targets Description of the different targets of the studied intervention.
4	Intervention components Description of the intervention components used to address each intervention target.
5°	Components theory Description of the rationale for how the intervention components would change each intervention target.
6°	Intervention ingredients and quantity Description of the intervention ingredients concerning each of the following attributes (where they are relevant to the intervention theory): materials, procedures, personnel, mode of delivery, context and team factors. Description of the quantity of the intervention ingredients in units relevant to their hypothesised mechanisms of action.
7°	Tailoring If tailored, description of the participant assessments involved in determining the amount of each tailored intervention ingredient and how the assessment will determine the quantity of that ingredient. Provide an algorithm, if available.
8°	Quantity changes If the ingredient quantities in the intervention change over time, description of the participant assessment or measurement that triggers the progression and the algorithm that specifies the change in ingredients.
9°	Treatment fidelity (a) optimisation and (b) assessment Description of what is done to ensure the delivery of ingredients intrinsic to the intervention's effects. If relevant, a description of necessary instructional and motivational ingredients needed to achieve fidelity. Description of how you measured the delivery of ingredients intrinsic to the intervention's effects and necessary instructional and motivational ingredients needed to achieve fidelity (if relevant).
10*	Comparator rationale Description of the rationale for the selection of the comparator.
11*	Comparator description Description of the comparison intervention, following items one to nine, focusing on the ingredients that may overlap with those in the experimental intervention.
12*	Sham comparator If the comparison is a sham, description of which intervention ingredients are excluded.
13	Background treatment Description of background treatment(s) focusing particularly on their active ingredients or ingredients that may interact with intervention ingredients.
Results section	
14	Modifications and fidelity If the study intervention was modified during the study, a description of the changes concerning the categories relevant to the original intervention components and the rationale for the modification. Description of the findings related to treatment fidelity assessment.
Discussion section	
15	Comparator, background treatment and daily activities Value and meaning of results according to the chosen comparator. Possible interactions of the background treatment(s) with the intervention and the comparator. Description of other daily activities autonomously performed by participants that could change the effect of one or more intervention components.
16°	Implementation For approaches nearing the point of clinical adoption, discuss possible factors influencing implementation (barriers and facilitators).

*Not included in the uncontrolled studies version because not applicable to studies without a comparison group.

°These items could be reported in the appendices if the short form version is applied.

GUIDE-Rehab, GUideline for Intervention DEscription in Rehabilitation; SF, short form; U, uncontrolled studies version.

intervention with overlapping active ingredients or blocking the effects of the intervention with incompatible ingredients, (2) modifying (either increasing or decreasing) patient engagement in the experimental intervention,[33] (3) altering the patient's expectations of the experimental treatment's impact[48] and/or (4) interacting differently with the experimental intervention and the comparator(s). Good reporting is the first step towards minimising these issues and advancing evidence-based rehabilitation.

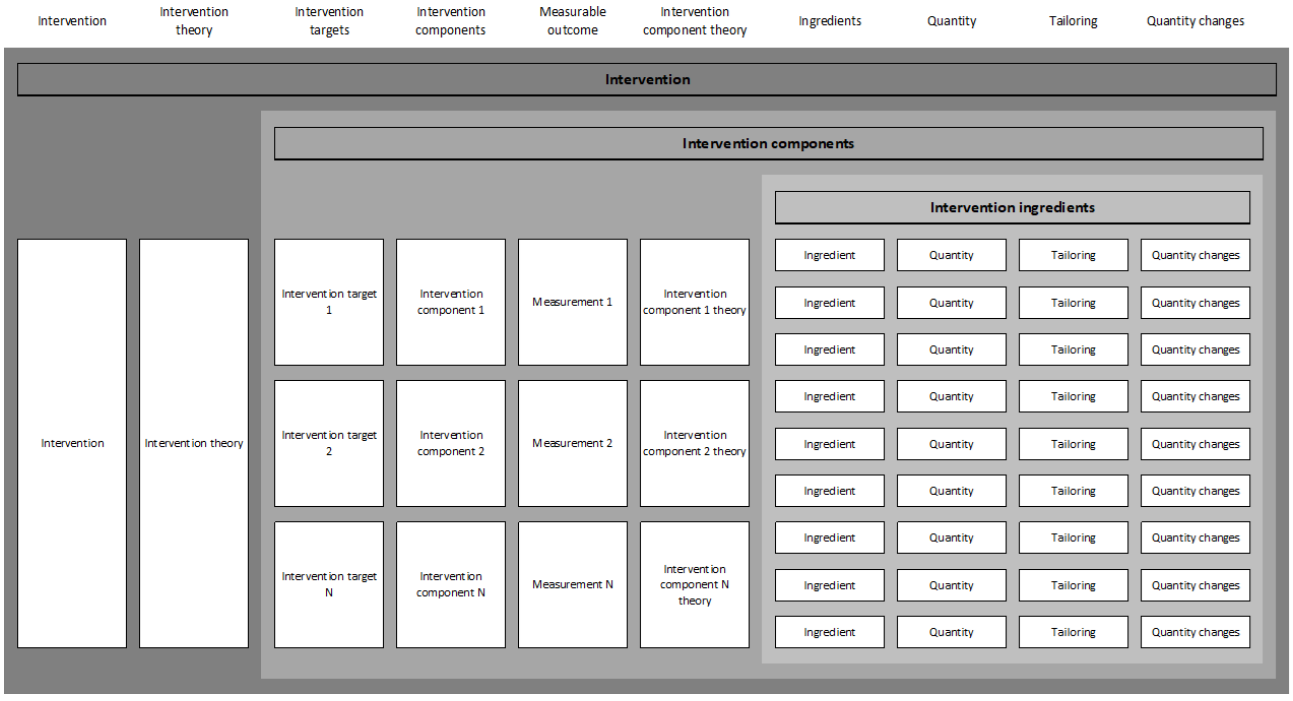

Figure 1 GUIDE-Rehab graphical illustration of the intervention according to the GUIDE-Rehab. The figure represents GUIDE-Rehab items as boxes, one within the other, moving from the largest (the intervention) to the intermediate (the components able to change one of the targets) to the smallest (the ingredients that compose the components). GUIDE-Rehab, GUideline for Intervention DEscription in Rehabilitation.

Table 2 Comparison between the GUIDE-Rehab and the TIDieR reporting guideline

GUIDE-Rehab	TIDiER
Abstract and Introduction section	
Intervention type	–
Material and Methods section	
Intervention theory	Why
Intervention targets	Why
Intervention components	How
Components theory	Why
Intervention ingredients and quantity	3–4. What – 5. Who provided – 7. Where – 8. When and how much
Tailoring	Tailoring
Quantity changes	Tailoring – 10. Modifications
Treatment fidelity (a) optimisation and (b) assessment	How – 9. Tailoring
Comparator rationale	Why
Comparator description	3–4. What – 5. Who provided – 6. How – 7. Where – 8. When and how much – 9. Tailoring – 10. Modifications
Sham comparator	
Background treatment	
Results section	
Modifications and fidelity	Modifications – 12. How well
Discussion section	
Comparator, background treatment and daily activities	–
Implementation	–
–	Brief name

GUIDE-Rehab, GUideline for Intervention DEscription in Rehabilitation; TIDieR, Template for Intervention Description and Replication.

GUIDE-Rehab recognises that a researcher may not have access to the same level of detail about background interventions (or even the main comparators in observational studies) as about their experimental intervention but guides them to focus on background intervention ingredients that may overlap or interact with the active ingredients of the study intervention.

Our paper has several strengths. We followed the EQUATOR[37] and reported using the ACCORD[36 44] guidelines. The individuals involved in the development and piloting of GUIDE-Rehab come from diverse regions, backgrounds, rehabilitation professions and stakeholder groups, with cross-sectional input from all specialist domains. There was a diverse mix of clinicians and researchers, including many methodologists and editors of rehabilitation journals. We had good participation and a strong, swift agreement, likely due to the extensive preparation phase and the previous RTSS work. We piloted GUIDE-Rehab with multiple end-users. We describe different versions and a graphical representation to provide authors and editors with flexibility in their implementation.

The main limitations of our work included the lack of anonymity and the limited number of Delphi rounds. Also, the participation was incomplete, even if it can be considered good (80%). These limitations were partly softened by the long preparation, the well-developed kick-off Consensus Meeting and the final panellists' acceptance. Moreover, although the Delphi round specific to GUIDE-Rehab was only one, it was the fourth in a series, with the first three focused on RCTRACK. Another limitation was some unresolved dissent, but this was accepted due to the criticisms raised: disagreement with the rehabilitation definition, which was foundational to the study and not part of it, and the process followed, which we could not change in the end. Finally, the definition of background treatment could be confused with 'usual' or 'standard' care, which we, in fact, directly suggest avoiding. We added specific sentences in GUIDE-Rehab on this aspect.

End-users found GUIDE-Rehab time-consuming, complex and challenging to complete. However, they also deemed it logical and useful. Like any reporting guideline, it is less burdensome if the items are considered in the design and analysis of the study rather than merely during publication. Using GUIDE-Rehab will require effort to learn, similar to other reporting guidelines, but we believe users and the field will ultimately find it worthwhile. Our group will actively disseminate materials to the rehabilitation community to facilitate uptake.

Conclusions

We developed GUIDE-Rehab to 'unpack the black box' of the complex intervention rehabilitation. It operationalises years of research on the RTSS approach and the rehabilitation definition for research purposes. GUIDE-Rehab shares with the recent TIDieR extension an increased focus on theory and active ingredients. However, there are important differences, and future research shall (1) explore the experiences in research and in interpreting the literature reported using them, and (2) identify their most impactful items. Another possible evolution in research is implementing the GUIDE-Rehab theory-based approach to other complex interventions outside rehabilitation.

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