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Towards better reporting standards of patients' characteristics in rehabilitation trials: applying a new conceptual framework to current standards

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Abstract

Background and aim: The reporting of clinical studies in rehabilitation has been criticized in several aspects, including the reporting of patient characteristics. This paper aims to contribute to the improvement of the reporting of patient characteristics in rehabilitation trials. Specifically, we want to determine the type of information that should be reported in rehabilitation trials that is specific to rehabilitation patients, and how this information is captured by current reporting standards.

Methods: In the first step, we made a conceptual analysis of characteristics of rehabilitation patients by addressing the specifics of the field of medical rehabilitation, including the definition of rehabilitation and a description of its beneficiaries. In the second step we compared this reference framework to the current reporting standards, especially the CONSORT statement and its extensions, as well as standards for the reporting of clinical guidelines (AGREE, RIGHT).

Results: Patients included in rehabilitation interventions should be distinguished by specific information. From a clinical perspective, patients dealt with in rehabilitation comprise broader diagnostic groups compared to other clinical settings. Information on comorbidities should be added in the description of the patients. Also, a description of baseline characteristics of patients should always include functioning characteristics of the patients, including information on relevant context factors, i.e. environmental and personal factors. The CONSORT statement aims to provide patient characteristic to enable transferability of results to users. It is represented in terms of selection (inclusion/exclusion) criteria and the description of the resulting samples. Extensions of the CONSORT statement specified that information on socioeconomic variables should be added, and the selection of patient characteristics to be reported at baseline should be based on the selection of outcome variables. Also, all relevant prognostic variables should be

reported. Only one CONSORT extension asks explicitly to include comorbid conditions. The reporting standards on guidelines demand a more comprehensive characterisation of patients, specific to the rehabilitation area.

Conclusion: Present reporting standards can only partly address relevant issues pertinent to medical rehabilitation. The present analysis provides a conceptual and empirical framework for the development of reporting standards on patient characteristics in rehabilitation trials.

Keywords: reporting standards, CONSORT, rehabilitation, Patient characteristics

Background and aim

A central aim of Cochrane Rehabilitation is to improve the uptake of evidence from systematic reviews of clinical trials in rehabilitation practice.[1] Stakeholders in rehabilitation practice need to know whether the results of a study or review can be transferred to their own practice field. Transferability of results depends both on the quality of the conduct of the study as well as on the quality and comprehensiveness of reporting of results. The need for better quality of reporting in rehabilitation trials is the starting point of this work. The quality of reporting can inform the appraisal whether study results are generalizable and transferable to real-life clinical practice. In rehabilitation, one important topic of trial reporting is patient characteristics and will be the focus of this paper.

In their paper on methodological challenges of rehabilitation research, Wade et al. (2010) [2] draw attention to special considerations related to patient characteristics in rehabilitation research in comparison to other clinical research. According to them, the selection of patients for rehabilitation is based on clinical problems stemming from an individual spectrum of clinical, physical, and psychosocial circumstances influencing activities and participation rather than on specific diseases. While non-rehabilitation biomedically oriented clinical studies generally aim at homogeneous disease-specific samples, rehabilitation studies usually broaden their study sample to groups that share a common medical problem, e.g. patients after stroke (independent of the specific type of stroke or reason for the stroke), or patients experiencing spasticity (independent of primary diagnosis).

Malmivaara (2019)[3] lists information that should be reported as baseline data in randomized controlled trials (RCTs) in order to be able to make claims on the generalizability of the study results based on the benchmarking approach. This list of key characteristics includes clinically

important data relevant to the particular disorder/ disease (e.g., age, gender, severity by outcome variables), the general health/risk status, comorbid conditions, behavioral factors (e.g., lifestyle factors), environmental factors (e.g., work conditions), issues related to inequity (e.g., socioeconomic status) and other potential predictors, confounders, and effect modifiers (p. 37). He conducted an analysis based on RCTs published in the most prominent medical journals, i.e. the British Medical Journal, the Journal of the American Medical Association, the Lancet, and the New England Journal of Medicine. Malmivaara found that while reporting of demographic- and disorder-specific clinical data is extensive in RCTs, other clinically important information was often lacking. For example, only four out of ten studies reported functioning or quality of life information. Less than half of the publications reported on comorbidities, and less than half of the studies reported on at least one behavioral factor. Environmental factors were reported in two thirds or less and inequity issues in one fourth or less of the studies. Reporting on environmental factors, comorbidities, behavioral factors and functioning could be regarded as important to rehabilitation practice, as rehabilitation patients are often approached from the bio-psycho-social-environmental perspective and interventions are planned and performed accordingly. An analysis of six major journals in rheumatology on adherence to CONSORT statement regarding information on patient recruitment showed that not even 10% of the trials include socioeconomic information on the patients or their educational status.[4]

A more encouraging view on the completeness of patient characteristics in clinical trials in the rehabilitation field can be inferred from the results of a study by Negrini et al. (2019)[5]on clinical replicability of RCTs in rehabilitation. They define clinical replicability as ‘‘the accurate description in published reports of clinical studies of all details needed to apply the intervention in everyday clinical practice’’ (p. 109). The description of participants’ features was on one hand

rated by clinical experts as moderate to poor in 44% of the reviewed studies. On the other hand, this feature was one of the best fulfilled compared to other criteria, such as the description of the intervention. This might be the result of the CONSORT statement's need to provide a comprehensive table with patient characteristics in all RCTs.[6]

Efforts such as the CONSORT statement have been created to improve the reporting of all trials. However, some specific characteristics, specific to rehabilitation have been missed; including in the area of patients' characteristics. Therefore, the general motivation of this paper is to contribute to the improvement of the reporting of patient characteristics in rehabilitation trials to improve the overall clinical replicability and transferability of the results to the clinical settings. We aim to outline the core characteristics of rehabilitation patients as the basis for developing a framework that would enable a more standardized reporting of patient characteristics in rehabilitation trials.

We will do that by addressing the following questions:

1. What kind of information should be reported in rehabilitation trials that is *specific* to rehabilitation patients?

2. How much of this information is currently captured by existing reporting standards?

Methods

The answer to the first question has been based on a conceptual analysis. The main author (TM) identified specific characteristics of rehabilitation patients by addressing peculiarities of the field of rehabilitation, referring to a definition of rehabilitation and a description of the clients or

beneficiaries of rehabilitation. This part of the analysis was mainly inspired by the work done to develop a conceptual description of rehabilitation endorsed by different international organisations of physical and rehabilitation medicine, and a conceptual description of rehabilitation services involving the first author of this paper.[7,8] On these grounds, the central characteristics of rehabilitation patients that should be reported in a rehabilitation trial have been delineated. A first draft of this conceptual analysis has been presented and discussed at the Cochrane Rehabilitation Methodology Meeting in Kobe (Japan), 8th June 2019. A second draft of the conceptual analysis resulting on the conceptual framework presented in this paper, has been written and submitted to the co-authors for comments, including the first draft of the whole paper. The last version of the paper, with the final reference framework, has been prepared by the authors and submitted to revision by other participants to the Kobe Meeting before submission.

The answer to the second question is based on a search of current reporting guidelines and disease-specific reporting standards. In doing so, we referred to the websites of the equator network (www.equator-network.org) and the CONSORT statement (www.consort-statement.org). We selected the CONSORT based reporting standards and a selection of relevant extensions: EXT-NPT (non-pharmacological treatments), EXT-SPI (social and psychological interventions), EXT-cluster rct, EXT-pragmatic trials, and EXT-N-of-1-trials. The selection was based on its appraised relevance for the reporting of rehabilitation trials to inform our analysis. We have analyzed these extensions with regard to reporting of patient characteristics, including if they provide advice on how to deal with functioning and comorbidity information. We also analyzed two reporting guidelines of clinical guidelines, AGREE and RIGHT as we have found a higher level of sensitivity for information on comorbidity in clinical guidelines.[9] We related

these standards to the results of our analysis of our first question of what should be reported in a rehabilitation trial from a conceptual view. The comparison between the results of our conceptual framework and current reporting standards allowed us to identify patient characteristics that are missing in these current standards and that should be integrated into a specific rehabilitation reporting standard.

Results

1. What kind of information should be reported in rehabilitation trials that is specific to rehabilitation patients?

To answer this question, we relate to rehabilitation from a health-related perspective, i.e. health-related or medical rehabilitation. In doing so, we are aware that there are other fields of rehabilitation, including educational, vocational, or social rehabilitation that have developed other standards and practices. Health-related or medical rehabilitation is linked to the medical sphere and has to relate (not to simply take over) its logic and ways of thinking. This enables to pinpoint similarities and differences. It is important to note, however, that aspects of educational, vocational or social rehabilitation should always be integrated in a comprehensive rehabilitation approach and that rehabilitation should not be seen as a mere medical endeavor. From this perspective we have to answer the question, what makes the field of rehabilitation special in comparison to other medical fields?

First, rehabilitation has been conceptualized as one out of four (or five, respectively) health strategies (promotive, preventive, curative, rehabilitative and supportive) that are central to health interventions.[10,11] This conceptualization anchors rehabilitation by its primary aim: to

maintain or optimize functioning using the International Classification of Functioning, Disability and Health (ICF[12]) as a standard reference system for the assessment and reporting of functioning.[13,14] This understanding of rehabilitation as a health strategy has been taken up by different international organizations of physical and rehabilitation medicine (PRM)[7] and is represented in the definition of rehabilitation presented by WHO and the World Bank (2011)[15] in the World Report on Disability. There, rehabilitation is defined as „…a set of measures that assist individuals who experience, or are likely to experience, disability to achieve and maintain optimal functioning in interaction with their environment“[15(p. 96)] . This is complemented by the notion of functioning in the ICF that comprises aspects of body structures, body functions, activities (especially activities of daily living) and participation (i.e. involvement in major life activities and in society). To fully capture the lived experience of persons with a health condition or disability, these aspects of functioning have to be viewed from their dynamic interaction with the environment. This interaction is a mean feature of the ICF model of functioning that depicts functioning and its opposite side of the continuum, i.e. disability, only in interaction with contextual factors, including environmental and personal factors, and the health condition.[12]

Second, rehabilitation patients are usually characterized by multiple health problems comprising comorbidities, multimorbidity, and/or congenital conditions[9,16], which are increasing with age.[17] Wade et al. (2010)[2] emphasized that medical literature is usually inclined toward presenting studies with bio-medically homogenous groups. In contrast, an early notion from the 1980s deemed research in the field of rehabilitation as impossible, arguing that "each patient is different" (p. 699) referring to the problem of the vast heterogeneity of patients forcing researchers to consider a huge number of confounding variables. Fortunately, rehabilitation research has evolved despite this demur. Still, rehabilitation has to deal with broader clinical

conditions compared to biomedical research. Also, additional personal factors or important environmental factors of the patients have to be taken into account. The multi-dimensionality of rehabilitation, especially from the standpoint of the ICF, is reflected in the multidimensional characteristics of the beneficiaries of rehabilitation. They tend to present with a complex health situation requiring the expertise of an interprofessional team.[7,8,13]

Third, patients should not be regarded as mere recipients of interventions, but as main co-producers of rehabilitation interventions and services (so-called prosumers, cf. Meyer et al. 2014[8]). The intervention and the service itself can only be realized when the patient and the professionals work together on a common (explicit or implicit) intervention or service goal. Therefore, the patients' characteristics that have a strong impact on this interaction need to be determined. For example, information of the patient's motivation or readiness for change are an important feature of rehabilitation and are strongly linked to rehabilitation goal-setting.[18].

Who are the users or beneficiaries of health-related rehabilitation? While rehabilitation professionals often deal with specific groups of patients in practice, we have to be aware of the different target groups of rehabilitation in order to be able to develop standards. There is an array of different target groups. These groups are not always exclusively disjunct, but can be distinguished with regard to the main origin of the disability and to the stage of the health condition. These groups comprise

- persons with a congenital condition, a developmental, in childhood acutely acquired or progressive condition, who need to optimize different aspects of functioning during growth or in specific life phases. This requires a therapeutic action not only on the impaired body structure/function, but also on the others that cannot develop properly due to the interaction with the impairment, resulting in an increased disability. Rehabilitation

for this group of people would be considered habilitation, since they would not be returning to a previous health state but rather optimizing existing functioning (cf. to the United Nations Convention on the Rights of Persons with Disabilities[19]) e.g. muscular dystrophy, dysmelia, spina bifida.

- patients with limitations in functioning following an acute event (injury or onset of illness) e.g., traumatic brain injury, cardiac event.
- patients with a chronic health condition and (risk of) substantial limitations or deterioration in functioning, e.g. chronic low back pain, type 2 diabetes mellitus, schizophrenia, rheumatoid arthritis, multiple sclerosis
- elderly patients with multimorbidity who need to maintain a level of functioning (esp. independent living)

In addition, primary or family caregivers might also be included in this list, since they are often an important resource to improve a patient's level of functioning, and they are directly affected by the level of well-being of the respective patient.[20] The beneficiaries of rehabilitation often seek rehabilitation services to address problems in self-care, mobility, performing everyday activities in the household, at work or school as well as psychosocial difficulties in addition to the impairments of body functions and structures inherent in the beneficiary's medical condition[13] – all issues represented in the ICF.[12] Taken together, it has become clear that patients in medical rehabilitation are characterized both by a clinical condition that is often complex and a state of functional limitations that constitute the ultimate aims of rehabilitation interventions. The bio-psycho-socio (and further environmental) model of rehabilitation (cf. WHO 2001[12], Wade et al. 2004[21]) complements with a patient view that is not restricted to a specific pathology.

This patient view rather has to relate to different – interacting – characteristics of the patient including his frequently observed additional morbidities, functional limitations and capacities as well as social characteristics and the immediate environment of the person.

Which disease-related characteristics should be reported?

Medicine is still the dominant professional category in health care. It is organized within disciplines. These disciplines constitute not only chairs at medical universities, departments and approaches to medical education; they are also the drivers of scientific organisations and research approaches. Some areas of medicine have long been targeted to improve the quality of reporting. Implicit or explicit standards have been developed as to which information should be reported as patient characteristics in clinical trials, e.g. in the areas of cardiology or psychiatry. In the area of psychiatry, for example, with the emergence of the concept of negative symptoms in schizophrenia in the 1980s and 1990s, it has become a standard to report both on the level of positive and negative symptoms in clinical studies in this patient group. In diabetes, no study could be published without the inclusion of central physiological information, such as Hb1c-score, blood pressure or previous cardiac events. In the area of rehabilitation, some scientific organisations have also published standards to be reported in clinical studies to foster comparability of results. For example, table 1 displays some reporting standards regarding patients' characteristics in studies including patients with spinal cord injury (Table 1). All these efforts to improve reporting highlight the importance of providing specific information related to the subjects that could affect decision making and transferability of results in clinical practice.

Table 1 (reporting standards for patient characteristics in clinical spinal cord injury (SCI) research)[22]

A specific issue in the reporting of information in clinical studies relates to comorbidities of the diseases in question. As mentioned above, comorbidities are a central characteristic of patients in rehabilitation. It could be shown that knowledge of comorbidities is relevant for clinical decision making, because a co-occurrence of diseases may alter a person's experience of illness and affect the clinical acts of diagnosis, prognosis, and treatment. Comorbidity and multimorbidity are expected to be more likely to raise patients' baseline risks without treatment, lower patients' responsiveness to treatment, and raise patients' vulnerability to adverse effects of therapy.[23]

There is currently a strong need for more empirical research on the impact of comorbidity and multimorbidity on the course of illness and health in terms of functioning. In a review of evidence on comorbidities, Gijsena et al. (2001)[23] showed that this evidence stems mostly from cardiovascular diseases, cancer, musculoskeletal diseases and diabetes. Gijsena et al. (2001)[23] found only a few studies on causes of comorbidity or comorbidity patterns. Comorbidity is associated with higher risk of mortality, especially in diseases that affect systems essential for maintaining physiological homeostasis. Comorbid mental disorders have been significantly associated with functional status or quality of life. Also, comorbidity has been consistently related to different indicators of health care utilization.[24]

There is evidence that systematic reviews lack information on comorbidities. In a review of the representation of comorbidities in Cochrane reviews on unspecific chronic low back pain, Meyer & Wulff (2019)[9] found that comorbidities were not considered systematically or even at all. The discussion of comorbidities appears more enhanced in the clinical guideline literature, since these guidelines have to deal with clinically relevant situations. A clear-cut need to address

comorbidities both in systematic reviews and clinical guidelines was stated. Co- or multimorbidities should be considered as part of the inclusion/exclusion criteria, in the data extraction from original studies, as well as in pre-specified subgroup analyses.[9] The problem of representation of comorbidities in systematic reviews could reflect the absence on comorbidity issues in the original trials or the use of comorbidities as a reason for exclusion of patients. In sum, rehabilitation patients are often characterized by comorbidities, problems related to these comorbidities should be addressed in rehabilitation practice and might be identified as relevant prognostic factors. Therefore, the way of dealing with comorbidities can be viewed as one of the central issues in rehabilitation, reporting of comorbidities should be a standard in rehabilitation trials, otherwise limiting generalizability and transferability of study results to real-life clinical practice.

Which functioning-related characteristics should be reported?

Patient functioning is regarded as the core concept that underpins research in rehabilitation.[13] Information on patient functioning can be useful in identifying which patient characteristics should be considered for evaluating, comparing and reporting rehabilitation interventions.[25] Specifically, patient characteristics can be operationalized as functioning outcomes to be examined and reported as part of the comparison of diverse interventions in rehabilitation studies using the ICF as a reference framework. Several examples were given by Stucki and colleagues in their conceptual paper to illustrate the use of the ICF for the comparative evaluation and standardized reporting of rehabilitation interventions.[24] One of those examples was the multicentre RCT conducted by McNeely and colleagues, in which the Lymph-ICF[26], an ICF-

based instrument, was used to assess quality of life as a primary outcome in their examination of the efficacy of night-time compression on arm lymphedema volume maintenance in breast cancer survivors.[27]

One challenge researchers face when reporting a study is deciding which ICF-based patient characteristics to include and report in rehabilitation studies. To facilitate this decision, researchers in rehabilitation can rely on established ICF sets, such as the ICF Generic-7 and -30 Sets and ICF Core Sets. The ICF Generic-7 Set (G-7) comprising of organ unspecific body functions (b130 Energy and drive functions, b152 Emotional functions, b280 Sensation of pain) and activities & participation categories (d230 Carrying out daily routine, d450 Walking, d455 Moving around, d850 Remunerative employment) is the minimal standard for the description of patient characteristics.[28] The ICF Generic-30 Set (G-30) is suggested for the reporting of patient characteristics in evaluating and comparing complex interventions. G-30 comprises of G-7 plus 6 additional body function and 17 additional activities and participation categories that are relevant in clinical settings.[29] Furthermore, the ICF Generic-30 Set plus the relevant ICF Core Set is suggested for the reporting of patient characteristics for rehabilitation interventions for specific patient populations. For this, clinical assessment schedules (CLAS), i.e. recommendation for what aspects of functioning to document, for whom and when, and the data collection tools to use, proposed for specific rehabilitation service types may be considered.[30] For example, the CLAS for the service type "specialized post-acute rehabilitation" for SCI patients would include G-30 plus the Brief ICF Core Set for SCI plus the minimal set of environmental factors accompanying the G-30.[28,29]

It becomes clear that a selection of relevant functional information for the reporting of patient characteristics has to relate to generic and disease-specific aspects of functioning as well as to the context of the rehabilitation setting (service).

2. How is the description of patient characteristics represented in current reporting standards?

CONSORT statement

In the CONSORT statement items number 4a and b relate to what CONSORT calls "participants"[6] (no page numbers). In item 4a, eligibility criteria for participants, the authors expect a comprehensive description of these criteria. The reasoning refers to external validity issues in terms of generalisability, since the reader should be supported to help interpret the study to judge to whom the results of the study might apply.[31] Item 4b is only indirectly related to the participants, as it asks for information on the setting and location where the data was collected. In addition, item number 15 asks for a table showing baseline *demographic* and *clinical* characteristics for each group, also with the aim to support appraisal of transferability of results. These baseline data should include outcomes that can be measured at the start of the trial.[30] The CONSORT statement provides no further specification of clinical characteristics. As long as the criteria are explicitly defined on how the groups are set up and different characteristics are equally distributed among the groups, there are no further requirements toward the reporting of patients' characteristics (see table 2).

***TABLE 2 here: Patient characteristics in CONSORT statement and extensions (item 4a and 15) ***

CONSORT extensions

The CONSORT extension on nonpharmacological treatments was set up to address treatments such as surgery, psychotherapy, education, devices, and explicitly also rehabilitation[32(p. 40)]. Extensions were made for the CONSORT items 4a and 15. However, they relate to broaden the description to care providers or centers and do not add new requirements for patient characteristics within these items. Still, in item number 5 on interventions new requirements were added. Item 5a asks, when applicable, for the description of the procedure for tailoring the intervention to the individual participant. Item 5d asks for details of whether and how adherence of participants to interventions was assessed or enhanced. Both items, however, do not relate to baseline or other relevant characteristics of the patients.

The CONSORT extension on social and psychological interventions also added issues for items 4a and 15. In 4a, a similar proposal was made to include information on the eligibility criteria for the settings and those delivering the interventions[32], therefore adding nothing more on the level of patient characteristics. In item 15 (baseline data), the SPI extension explicitly asks for information on socioeconomic variables and other inequalities, if applicable. In the comments, the authors emphasize that the baseline data table should include all pre-intervention data on trial outcomes as well as data on potential prognostic variables.[33] Patients are also referred to in a new item number 26, stakeholder involvement. Item 26a should document any involvement of the intervention developer, which could include patient groups, in the design, conduct, analysis, or reporting of the trial, or other stakeholder involvement in trial design conduct, or analyses (26b). Also, in 26c incentives offered as part of the trial should be documented.[32]

The CONSORT extension for reporting N-of-1 trials (CENT) from 2015, item 4a has been modified. Authors are asked to report "diagnosis or disorder, diagnostic criteria, comorbid

conditions, and concurrent therapies"[34(p. 4)]. The explanation of this extension reads that this information should support the reader regarding the transferability of the results ("…help readers gauge to which populations and subpopulations the findings of trial are applicable" [35(p. 6)]).

In the CONSORT extension for improving the reporting of pragmatic trials, there is an explicit request to be comprehensive in the reporting of the eligibility criteria of the patients to be able to gauge the degree to which the study includes "typical participants"[36 (p. 4)]. In the explanation for the addendum the authors refer to the problem that in efficacy trials too strict inclusion and exclusion criteria, including comorbidities, are used which reduce the generalizability of results. No further addition has been made regarding patient characteristics.

Standards for reporting of clinical practice guidelines (AGREE, RIGHT)

The AGREE checklist (Appraisal of Guidelines, Research and Evaluation) was developed primarily as a tool to assess the methodological quality of practice guidelines.[37] Therefore, it has direct implications for the reporting of the guidelines and its content on patient characteristics. Here it can be shown that the expected information is more comprehensive compared to the CONSORT statement or its extensions. The AGREE checklist asks for the definition of the target population, including sex and age, and if relevant the following information: clinical condition, severity or stage of disease, comorbidities as well as excluded populations (www.agreetrust.org). No further criteria are mentioned.

In the RIGHT statement (Essential Reporting Items for Practice Guidelines in Healthcare) item 7 refers to the target population of the respective guideline. In 7a, authors are asked to describe the primary population that is the target of the guideline. In 7b, any subgroups that are given special consideration should be made explicit.[38] There is another item 5, brief description of the health

problem(s), that asks for general information on the basic epidemiology of the problem, including the "prevalence/incidence, morbidity, mortality, and burden (including financial) resulting from the problem" (p. 130).[37] No further criteria for information on patient characteristics are mentioned in the statement.

Discussion

This paper aims to contribute to the improvement of the reporting of patient characteristics in rehabilitation trials. In a first step, we wanted to identify the kind of information that should be reported in rehabilitation trials that is *specific* to rehabilitation patients. In a second step, we analyzed current reporting standards to see what kind of patient information data is called for by them.

We have come to the conclusion that rehabilitation patients should be characterized by specific information. From a clinical perspective, patients dealt with in rehabilitation comprise broader diagnostic groups compared to biomedical trials which often restrict their studies to specific clinical conditions within (sub-)categories of diseases. This is related to the task of rehabilitation, to deal with problems resulting from a disease and only indirectly with the disease itself. It has also been stated that information on comorbidities, which typically characterizes rehabilitation patients, should be added. Also, outcome in rehabilitation is always related to functioning in terms of the ICF. Therefore, a description of baseline characteristics of patients should always include functioning characteristics of the patients. According to the ICF model this should include also information on relevant context factors, i.e. environmental and personal factors. Taken clinical and functional information together, it becomes clear that the multidimensional

problems that make patients approach or apply for rehabilitation services should be represented in the description of patient characteristics in clinical studies.

What kind of information is required at present in clinical trials or clinical guidelines? Our analysis of the CONSORT statement and a selection of relevant extensions found some general possible connecting points. First of all, the reporting of patient characteristics in the CONSORT statement aims to provide information on transferability of results to users, which is in line with the motivation for this paper. Patient information is represented in terms of selection (inclusion/exclusion) criteria on the one hand, and the description of the resulting samples on the other hand. No specific information on what to report is given. Extensions of the CONSORT statement specified that information on socioeconomic variables should be added. Also, the selection of patient characteristics to be reported at baseline should be based on the selection of outcome variables –which in rehabilitation are always related to functioning information. In addition, all relevant prognostic variables should be reported. In rehabilitation trials this means that those variables with prognostic value for the level of functioning of the patients should be included. These prognostic variables can stem from all the different ICF categories represented in the ICF model of functioning, including environmental factors, personal factors and the health condition. As part of the contextual factors, one CONSORT extension explicitly asks for information on socioeconomic variables and other inequalities, if applicable. Only one statement, the N-of-1 trials (CENT) from 2015, asks to include comorbid conditions. Another one, the extension for pragmatic trials, makes an explicit request to be comprehensive in the reporting of the eligibility criteria of the patients to be able to gauge the degree to which the study includes "typical participants". This, in their explanations, should include information on comorbidities. The reporting standards on guidelines are a bit more specific in this regard: the AGREE

statement explicitly asks for the clinical condition, severity or stage of disease, and for comorbidities. In the RIGHT statement, information on subgroups should be made explicit (which could comprise a comorbid condition). Also, information on the burden of the problem should be reported – albeit in terms of a brief description of the health problem(s) the guideline is aiming at.

We have to conclude that the present reporting standards are only partly able to represent the needs of rehabilitation trials. While the issue of comorbidity has been picked up by a few standards, there is no indication for the necessity of a comprehensive, multidimensional characterisation of patients, both clinically and – especially – with regard to functioning. In the end, as already stated, generalizability of results heavily depends on this point. Recently, the American College of Rheumatology has developed recommendations for patient-reported Functional Status Assessment Measures for use in routine clinical practice in patients with rheumatoid arthritis.[39] These types of recommendations could also inform the development of standards for reporting patients' characteristics in rehabilitation, as they translate directly into practice needs.

The results of this paper show that it seems quite worthwhile to develop specific reporting standards for patient characteristics in rehabilitation trials. However, we have to be aware that – as so often – the best might be the enemy of the good. The number of information should be limited in order to be manageable for those who conduct rehabilitation trials. Setting standards works best if we find good agreement in the research community, keep the effort of assessment to a certain minimum, and to really focus on the most important issues. As with the ICF core sets, it might be reasonable to argue for a minimum core set of patient characteristics to be reported, and a regular core set, the indication for both might differ by study type or journal. It

would be quite useful, though, to agree on (comparable) methods to assess the respective patient information. Besides indication, there might be information on patient characteristics that is specific to different rehabilitation setting, such as acute inward rehabilitation clinics or community-based rehabilitation institutions, but such an analysis has still to be undertaken.

The present analysis might be limited by different points. Regarding the definition of rehabilitation, we resorted to one – although widely respected and referenced – definition of rehabilitation as a health strategy.[7,15] It would be quite interesting to integrate also the thinking of further types of rehabilitation, i.e. social, educational and occupational rehabilitation explicitly. Also, we did not strive for a complete recognition of reporting standards; therefore the selection of reporting standards might have overlooked developments that have been made in more distal fields of inquiry, e.g. in standards for the reporting of herbal interventions, or Traditional Chinese Medicine. Our focus on the CONSORT statements and therefore the RCTs might have precluded further developments in non-RCT research.

The present analysis, however, should be well suited enough to provide a conceptual and empirical background for the development of reporting standards on patient characteristics in rehabilitation trials. For the further development of reporting standards for rehabilitation trials, the interested reader should refer to the paper of Negrini et al. (2020) in this issue on the RCTRACK project. Here, it should be made clear to the users on what to report or not. Future research and work should also focus on developing specific standards by condition, e.g. the development of a set of core prognostic factors that should be reported for each condition.

Conclusions

The current reporting of patient related issues regarding general and disease specific health status, comorbid conditions, and patients' behavioural, environmental and equity related factors is often lacking in randomized controlled trials in biomedical and in rehabilitation studies. The current recommendations for uniform reporting of patient characteristics in RCTs and in clinical guidelines emphasize reporting of the PICO (patient, intervention, comparator, outcome). Complexity of participants in rehabilitation trials call for a more in-depth description of the patients' characteristics. Our suggestion is that a comprehensive description of patient characteristics in rehabilitation trials would be the recommendation for all researchers when planning a RCT, and that reasons for omitting any of the important baseline characteristics of patients should be provided in the RCT protocol.

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Table 1: Publication standards for patient characteristics in spinal cord injury (SCI) research

From a clinical study perspective, Tuszynski et al. (2007)[1] discussed a number of patient characteristics that have prognostic value for medical SCI interventions and should either serve as inclusion/exclusion criteria, variables that should be taken into consideration to compare or match intervention and control group, or as relevant prognostic factors / confounders.

These criteria include

- age and gender
- ASIA grade: Classification of the American Spinal Injury Association, that describe the completeness of a spinal cord injury ranging from level A (no motor or sensory function at the level of S4–S5 sacral segments) to level E (normal motory and sensory function)
- SCI levels of injury (cervical, thoracic, lumbar)
- time point post-injury / stage: acute, subacute, chronic
- lesion characteristics (location, size, associated, edema, parenchymal sparing, extent of haemorrhage, number of involved spinal segments)
- concomitant brain injuries
- cause of SCI, including type of trauma
- comorbidities, including diabetes, hypertension, autoimmune disease, psychiatric illness
- medication (e.g. use of high-dose methylprednisolone) and other treatment factors

Table 2: Patient characteristics in CONSORT statement and extensions (item 4a and 15) (references in the main text)

Standards	Participants (CONSORT Item 4a)	Baseline data (CONSORT item 15)
CONSORT	Eligibility criteria for participants	A table showing baseline demographic and clinical characteristics for each group
CONSORT extension on nonpharmacological treatments	When applicable, eligibility criteria for centers and for care providers	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group
CONSORT extension on social and psychological interventions	When applicable, eligibility criteria for settings and those delivering the interventions	Include socioeconomic variables where applicable
CONSORT extension for reporting N-of-1 trials	Diagnosis or disorder, diagnostic criteria, comorbid conditions, and concurrent therapies.	(no extensions)
CONSORT extension for improving the reporting of pragmatic trials	Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (eg, nurses), institutions (eg, hospitals), communities (or localities eg, towns) and settings of care (eg, different healthcare financing systems)	(no extensions)

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