

ORIGINAL REPORT

DEVELOPMENT OF A MINIMUM REPORTING SET OF CONTEXTUAL FACTORS FOR REHABILITATION STUDIES: A DELPHI STUDY

Boya NUGRAHA, MS, PhD¹, Grace ENGEN, MSC², Cecilie ROE, MD, PhD^{2,3,4}, Marit KIRKEVOLD, RN, EDD, PhD², Helene L. SOBERG, PT, PhD², Nada ANDELIC, MD, PhD^{2,3} and Christoph GUTENBRUNNER, MD, PhD¹

From the ¹Department of Rehabilitation Medicine, Hannover Medical School, 30625-Hannover, Germany, ²Research Centre for Habilitation and Rehabilitation Models and Services (CHARM), Institute of Health and Society, Faculty of Medicine, ³Department of Physical Medicine and Rehabilitation and ⁴Institute of Clinical Medicine, Faculty of Medicine, University of Oslo, Oslo, Norway

Objective: To identify the most important categories of the International Classification of Service Organization in Rehabilitation (ICSO-R 2.0) for a minimum reporting data set.

Methods: A 2-step Delphi survey was used. Rehabilitation experts from all world regions including physicians, nurses, neuropsychologists, physiotherapists, and others, were invited to participate. In the first round, all participants were asked to rate the categories and subcategories of the ICSO-R 2.0 with the following criteria: Being relevant for study outcomes; Being distinctive among different rehabilitation settings; Being feasible to use and reported by objective figures or other clear characterization. All categories that were rated relevant, distinctive and feasible by more than 60% of respondents from the first round were included in the second round.

Results: The most important and relevant factors for the minimum reporting set in rehabilitation services regarding the provider were: human resources, context, technical resources, quality assurance and management, location of provider, and ownership. Regarding the service delivery, the most important and relevant factors were: target group, rehabilitation team, aspect of time and intensity, setting, location of service delivery, modes of referral, facility and reporting and documentation.

Conclusion: Several categories were identified, and reduction in these through discussions and iterative voting at workshops and consensus conferences is needed before finalizing the reporting set.

Key words: rehabilitation; health service; clinical trial; Delphi study; contextual factor; International Classification System for Service Organization in Health-Related Rehabilitation.

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Correspondence address: Boya Nugraha, Rehabilitation Medicine, Hannover Medical School, DE-30625 Hannover, Germany. E-mail: boya.nugraha@gmail.com

LAY ABSTRACT

A goal of this Delphi study was to identify the most important parameters of the International Classification of Service Organization in Rehabilitation (ICSO-R 2.0), to characterize rehabilitation services and identify important missing categories needed in a minimum reporting set. The most important and relevant factors for developing a minimum reporting set regarding the provider were: human resources, context, technical resources, quality assurance and management, location of provider, and ownership. Regarding service delivery the most important and relevant factors were: target group, rehabilitation team, aspect of time and intensity, setting, location of service delivery, modes of referral, facility and reporting and documentation. These factors should be discussed further, and a final set should be developed in workshops through discussion and iterative voting.

Rehabilitation has emerged as an important health strategy in different healthcare settings, and a health intervention for different health conditions. There is consensus that rehabilitation is needed not only for post-surgical care, congenital diseases, for people living in cancer, in palliative care, and treatment of non-communicable diseases, but also for sequelae of severe injuries, diseases (e.g. metabolic syndrome, stroke, etc.) and infectious diseases, including COVID-19 (both acute and long-term care) (1, 2). The implementation of rehabilitation interventions, such as other health strategies and health interventions, should be evidence based; in other words, they should be based on the results of clinical trials.

Clinical trials in rehabilitation have emerged during the last 3 decades, due to its relevance for almost every health condition, such as cancer (3–6), stroke (7–10), traumatic brain injury and other neurological disorders (11–13), COVID-19 (14–16), musculoskeletal pain (17, 18), and diabetes (19). Studies on rehabilitation services have been performed in different care settings, including hospitals and community (20). However, many studies

using similar rehabilitation interventions have shown different outcomes (21). One of the reasons could be due to external factors, such as the context of the studies (20, 22); for example, the studies assessing rehabilitation services in the university hospital may show different outcomes than those performed in the other care settings (21). For example, a comprehensive follow-up rehabilitation programme after inpatient rehabilitation for women with breast cancer (23) has shown a higher drop-out rate in the intervention group compared with the control group. Questioning the reasons directly to the participants, it is clear that some participants did not feel ill enough to be treated in a university hospital and others faced stigmatism from family and neighbourhood if continuously going to tertiary care hospital. Therefore, the dropout rate could be minimized if the study was delivered in the community or at home (23). This issue refers to the ICSO-R 2.0 location of service delivery and setting. Another study aiming at evaluating barriers and facilitators in utilizing rehabilitation services in South Africa (24) has shown that contextual factors, such as location of service delivery, facility, mode of referral, and health profession, can be barriers or facilitators of the process of accessing rehabilitation services and its outcomes.

These types of factors are not reported in most clinical trials, and, if they are, they are most often not counted as relevant or confounding factors for the outcomes (20).

Evidence-based decision-making in medicine, including in rehabilitation, should be supported by 3 factors: clinical judgement, relevant scientific evidence, and patients' values, goals and preferences. Gutenbrunner & Nugraha (25) have proposed additional factors to be considered in evidence-based decision-making, which are called health system and service organization factors. The proposed factor can be formulated by using the International Classification of Service Organization in Rehabilitation (ICSO-R; (26)). Recently, Gutenbrunner et al. (27) published the second version of the ICSO-R (ICSO-R 2.0). The ICSO-R 2.0 was used as the framework for screening the external factors that had been reported in rehabilitation studies, in a systematic review by Andelic et al. (20) and Roe et al. (21).

Following these publications, the need to develop a consensus on which external factors, based on ICSO-R 2.0, are important and relevant for reporting in rehabilitation studies emerged. Therefore, a Delphi study was conducted for this purpose (22). The main aim was to identify the most important parameter categories of ICSO-R 2.0, to characterize rehabilitation services. This Delphi study was one of studies of a larger project to develop a minimum reporting set for rehabilitation studies.

METHODS

ICSO-R 2.0 was used as the framework to identify the most important external factors for rehabilitation trials (27). ICSO-R 2.0 consists of 2 dimensions and 23 categories (see Box 1).

All the dimension, categories and sub-categories, including their definitions, and inclusion and exclusion criteria of the ICSO-R 2.0, were gathered into the online data collection platform Nettskjema (University Information Technology Center (USIT), University of Oslo, Norway).

Recruitment and participants in the Delphi study

The 2-step Delphi-exercise was performed by experts with a background in clinical rehabilitation as well as in rehabilitation research. The experts had different professional backgrounds, came from all world regions, and worked in different rehabilitation settings. Prior to inviting the experts in the rehabilitation field, international organizations, such as the International Society of Physical and Rehabilitation Medicine (ISPRM), World Physiotherapy, World Federation of Occupational Therapy (WFOT), International Society of Prosthetics and Orthotics (ISPO), International Federation of Social Work (IFSW), World Association of Speech and Language Pathology (WASLP), International Council of Nurse (ICN) and International Neuropsychology Society (INS), were asked to nominate experts to participate in the study. In addition, experts from different regions of the world were also identified by our group. Finally, the invitation for the Delphi study was sent to 96 experts for both the first and the second round.

Box 1. Brief list of International Classification of Service Organization in Rehabilitation (ICSO-R) 2.0 – dimension, categories and subcategories (25):

1. Provider	2.3.2 Functioning groups
1.1 Context	2.3.3 Other target groups
1.2 Ownership	2.4 Mode of referral
1.3 Location of provider	2.5 Location of service delivery
1.4 Governance/leadership	2.5.1 Location characteristics
1.4.1 Mission	2.5.2 Catchment area
1.4.2 Vision	2.6 Facility
1.4.3 Involvement in governance and management	2.7 Setting
1.5 Quality assurance and management	2.7.1 Levels of care
1.6 Human resources	2.7.2 Mode of service delivery
1.7 Technical resources	2.7.3 Phase of healthcare
1.8 Funding of provider	2.8 Integration of care
1.8.1 Source of money	2.9 Patient-centeredness
1.8.2 Criteria of funding	2.10 Aspect of time and intensity
1.9 Other categories of provider	2.11 Rehabilitation team
	2.11.1 Professions, competencies
	2.11.2 Interaction approaches
	2.12 Reporting and documentation
2. Service delivery	2.13 Funding of service delivery
2.1 Health strategies	2.13.1 Source of money
2.2 Service goals	2.13.2 Criteria of payment
2.3 Target groups	2.14 Other categories of service delivery
2.3.1 Health condition groups	

Delphi – first round

An invitation e-mail, containing a URL link to the survey, was sent to the identified potential participants, followed by 1 email reminder (2 weeks after the initial invitation). The first round of the survey was performed from 4 May to 1 June 2020;

All participants were asked to rate (as yes/no/cannot decide) the dimensions, categories and sub-categories of the ICSO-R 2.0, along with the following criteria:

- being *relevant* for study outcomes;
- being *distinctive* among different (and typical) rehabilitation settings;
- being *feasible* to use and ideally can be reported by objective figures (numerical scales, assessment tools) or other clear characterization.

All the categories that had been rated relevant, distinctive and feasible by more than 60% of the respondents from the first round were included in the second round. This resulted in 6 out of 9 categories at the provider and 8 out of 14 categories at the service delivery of the ICSO-R 2.0.

Delphi – second round

The second-round survey was performed from 26 October to 18 November 2020. In this round the 6 categories from the provider and the 8 categories from the service delivery should be ranked. Each category for the provider could be ranked only once (on a scale of 1–6, with 1 being the most important; and 6 the least important to be included in the minimum reporting set for rehabilitation studies). Similarly, the selected 8 categories for service delivery had to be ranked by the participants (on a scale of 1–8; with 1 being the most important; and 8 the least important to be included in the minimum reporting set for rehabilitation studies).

The mean value of each category (based on the rankings by the participants) was computed to obtain the

final ranking/priority for both the provider and service delivery of the minimum reporting set for rehabilitation studies.

RESULTS

First round

Participants. Thirty-two out of 96 of the invitees (33%) responded to the survey. The participants were from different regions, but most were Europeans (25%), South and South-East Asians (21.9%), followed by Central and East Asia (18.8%), North America (12.5%), and Middle and South America (9.4%). Middle East, Africa and Oceania represented 12.4% of respondents.

The participants in this survey had diverse professions: physical and rehabilitation medicine (PRM) physicians 68.8%; physiotherapists (PT) 9.4%; neuropsychologist 3.1%; neurologist 3.1%; speech and language therapist (SLT) 3.15%; and others (rehabilitation-related public health workers, prosthetist and orthotist, rehabilitation engineer, health economist) 12.5%.

Provider. Table I shows the result from the first round of Delphi survey on the Provider of the ICSO-R 2.0. All of the categories and subcategories domains of the ICSO-R 2.0 were selected by all participants. The domains that had been selected as being relevant, distinctive and feasible by $\geq 60\%$ of participants would proceed to the second round (see bold text in Table I). The 7 domains for the provider are: context (1.1), ownership (1.2), location of provider (1.3), quality assurance and management (1.4), human resources (1.6), and technical resources (1.7). The overview of all the results including the domains (categories and subcategories) that were rated as being not relevant, not distinctive, not feasible, and “cannot decide” are shown in Table SI.

Service delivery. Table II shows the result from the first round of the Delphi survey on the service delivery

Table I. Results from the first round of the Delphi survey on the Provider of the International Classification of Service Organization in Rehabilitation (ICSO-R 2.0)

ICSO-R 2.0 categories, subcategories	% Being Relevant	% Being Distinctive	% Being Feasible
1.1 Context	75.0	84.4	71.9
1.2 Ownership	71.9	87.5	62.5
1.3 Location of Provider	78.1	81.2	75.0
1.4 Governance/leadership	68.8	65.6	43.8
1.4.1 Mission	62.5	59.4	43.8
1.4.2 Vision	65.6	59.4	37.5
1.4.3 Involvement in governance and management	65.6	62.5	31.2
1.5 Quality assurance and management	81.2	71.9	62.5
1.6 Human resources	84.4	93.8	87.5
1.7 Technical resources	84.4	90.6	84.4
1.8 Funding of provider	71.9	75	59.4
1.8.1 Source of money	68.8	71.9	59.4
1.8.2 Criteria of spending	56.2	68.8	43.8
1.9 Other categories of provider	–	–	–

Categories that were selected as being relevant, distinctive, and feasible by more than 60% of participants are in **bold**.

Table II. Results from the first round of the Delphi survey at the Service Delivery of International Classification of Service Organization in Rehabilitation (ICSO-R 2.0)

ICSO-R 2.0 categories, subcategories	% Being Relevant	% Being Distinctive	% Being Feasible
2.1 Health strategies	81.2	78.1	56.2
2.2 Service goal(s)	84.4	90.6	59.4
2.3 Target group(s)	87.5	84.4	84.4
2.3.1 Health condition groups	87.5	90.6	81.2
2.3.2 Functioning groups	87.5	78.1	75.0
2.3.3 Other target groups	65.6	71.9	53.1
2.4 Modes of referral	75.0	87.5	65.6
2.5 Location of service delivery	87.5	81.2	65.6
2.5.1 Location characteristics	78.1	78.1	59.4
2.5.2 Catchment area	65.6	75	59.4
2.6 Facility	68.8	81.2	62.5
2.7 Setting	93.8	90.6	62.5
2.7.1 Levels of care	87.5	96.9	78.1
2.7.2 Mode of service delivery	93.8	87.5	84.4
2.7.3 Phase of health care	90.6	87.5	68.8
2.8 Integration of care	71.9	71.9	40.6
2.9 Patient-centredness	81.2	71.9	43.8
2.10 Aspect of time and intensity	90.6	78.1	71.9
2.11 Rehabilitation team	90.6	90.6	84.4
2.11.1 Professions, competencies	93.8	90.6	81.2
2.11.2 Interaction approaches	81.2	81.2	37.5
2.12 Reporting and documentation	81.2	81.2	62.5
2.13 Funding of service delivery	68.8	81.2	59.4
2.13.1 Source of money	62.5	75.0	50.0
2.13.2 Criteria of payment	56.2	75.0	50.0
2.14 Other categories of service delivery	-	-	-

Categories that were selected as being relevant, distinctive, and feasible by more than 60% of participants are in **bold**.

Table III. Ranking of categories from the Delphi survey regarding the provider of the International Classification of Service Organization in Rehabilitation (ICSO-R 2.0)

Categories	Rank	Mean rank value (by participants)
1.6 Human resources <i>Spectrum of staff/personnel (different types of health professionals, administrative staff, technical staff, researcher, and other personnel) within the provider.</i> <i>Inclusions:</i> full-time-equivalents of staff, affiliated and supportive staff, regular volunteers. <i>Exclusions:</i> retired personnel, volunteers not involved on a regular basis, family or informal caregivers, competencies of the rehabilitation team (2.11).	1	2.3
1.1 Context <i>Context describes whether the provider is independent or embedded in a parent or larger organization and how the context is organized.</i> <i>Inclusions:</i> Independent unit, hospital, university, community, network of organizations, or another umbrella organization. <i>Exclusions:</i> Ownership (1.2), location of provider (1.3).	2	2.8
1.7 Technical resources <i>Equipment and infrastructure available for service delivery.</i> <i>Inclusions:</i> Diagnostic, therapeutic and assistive devices, data processing and communication devices, and other affiliated technical resources; reporting and documentation platform. <i>Exclusions:</i> Facility (2.6).	3	3.4
1.5 Quality assurance and management <i>Activities and programmes, promoted by the owner or provider, intended to assure or improve the quality of service delivery.</i> <i>Inclusions:</i> Assessment or evaluation of the quality of service delivery, identification of problems or shortcomings in service delivery, designing activities to overcome these deficiencies, and follow-up monitoring to ensure effectiveness of corrective steps; any systematic way to pursue quality assurance activities (internal and external), including accreditation/certification, audit; appointed quality manager; single interventions with the explicit aim to improve structure/process/outcome quality. <i>Exclusions:</i> Any non-systematic (i.e. occasional, non-planned) approach.	4	3.6
1.3 Location of provider <i>Place where the provider is located.</i> <i>Inclusions:</i> Place of legal registration of the provider (city, country). <i>Exclusions:</i> Location of service delivery (2.5).	5	4.4
1.2 Ownership <i>Legal and contextual characteristics of the owning entity.</i> <i>Inclusions:</i> Public body (e.g. government, administration), private non-profit organization (e.g. non-governmental organization (NGO), charity organization), private for-profit organization (owned by shareholders or private investor/s), or combination of owning entities (public-private partnership). <i>Exclusions:</i> Governance /leadership (1.4), mission (1.4.1), vision (1.4.2), involvement in governance and management (1.4.3), facility (2.6), setting (2.7).	6	4.5

of the ICSO-R 2.0. All of the category and subcategory domains of the ICSO-R 2.0 were selected by all participants. The domains that were selected as being relevant, distinctive and feasible by equal or more than 60% of the participants were included in the second round (see bold text and numbers). The 8 domains for the categories are: target group (2.3), modes of referral (2.4), location of service delivery (2.5), facility (2.6), setting (2.7), aspect of time and intensity (2.10), rehabilitation team (2.11), and reporting and documentation (2.12). The overview of all the results, including the domains (categories and subcategories) that were rated as *not* being relevant, not distinctive and not feasible; and “cannot decide” are shown in Table SII.

Second round

In the second round, the survey was sent to 96 invitees. Thirty-two people responded in the second round (33%). However, 7 responses were excluded, as the

respondents had not ranked the variables properly (same ranking was given to 2 or more categories). Therefore, only 25 responses were valid and were used to calculate the mean values of the rankings. As shown in Table III, the rankings/priorities were defined based on the mean value of the rankings given by the respondents for each category. From the calculations, the order of importance from the most to the least is as follows for the provider: human resources (1.6), context (1.1), technical resources (1.7), quality assurance and management (1.5), location of provider (1.3) and ownership (1.2).

Table IV shows the rankings for service delivery. Based on the mean rank values, the order of importance from the most to the least is as follows: target group (2.6), rehabilitation team (2.11), aspect of time and intensity (2.10), setting (2.7), location of service delivery (2.5), modes of referral (2.4), facility (2.6), and reporting and documentation (2.12).

Table IV. Ranking of categories from the second round of the Delphi survey regarding service delivery

Categories	Rank	Mean rank value (by participants)
2.3 Target group(s) <i>Groups of people with rehabilitation needs and their caregivers for which the service is delivered.</i> <i>Inclusions:</i> Patients with any or specific health condition(s), persons with any or specific impairment, activity limitations and/or participation restrictions, and other target group(s), such as age-related groups, formal or informal caregivers. <i>Exclusions:</i> Students, residents, researchers.	1	2.6
2.11 Rehabilitation team <i>Professions and competencies of rehabilitation team members; team structure and methods of team communication.</i> <i>Inclusions:</i> Health and health-related professionals delivering services to the users (patients), peer counsellors, and others, multi-professional team composition, interdisciplinary way of working, etc., patients as part of the rehabilitation team and team supervision, counselling, etc. <i>Exclusions:</i> Administrative staff, technical and maintenance staff (exception: rehabilitation engineers), cleaning staff.	2	2.7
2.10 Aspect of time and intensity <i>Time schedule of service provision and interventions.</i> <i>Inclusions:</i> Length of stay or treatment period, intermittent vs continuous treatments, duration of single treatments, number and duration of treatment sessions, and total duration of treatment, service hours. <i>Exclusions:</i> Any aspects of time related to service organization, such as years since funding of the organization, phase of healthcare (2.7.3).	3	4.3
2.7 Setting <i>Levels of care, mode of service delivery, and phase of healthcare under which rehabilitation interventions take place.</i> <i>Inclusions:</i> levels of care (2.7.1); mode of service delivery (2.7.2); phase of healthcare (2.7.3). <i>Exclusions:</i> Location of provider (1.3), location of service delivery (2.5).	4	4.4
2.5 Location of service delivery <i>Location characteristics of the place and the catchment area of service delivery.</i> <i>Inclusions:</i> Rural area, urban area, community, centralized, decentralized (affiliated services, home of users, e-communication networks). <i>Exclusions:</i> Address.	5	5.2
2.3 Modes of referral <i>How the user accesses the service.</i> <i>Inclusions:</i> Direct access (patients' self-referral), referral by health professionals, health services, or other persons or organizations. <i>Exclusions:</i> Criteria of payment (2.13.2) or other financial aspects of accessibility; facility (2.6) including physical accessibility; reservation/registration process.	6	5.4
2.5 Facility <i>Facilities of service delivery.</i> <i>Inclusions:</i> Building, and other aspects of facilities, such as laboratories, diagnostic and therapy rooms, beds, etc., catering and laundry services, physical accessibility. <i>Exclusions:</i> Location of provider (1.3), location of service delivery (2.5).	7	5.6
2.12 Reporting and documentation <i>Health and functioning parameters in individual patient records.</i> <i>Inclusions:</i> Content of patient records (including dimensions such as ICF domains with consideration of established clinical assessment schedules, ICD domains), reporting of outcomes, methods of documentation (e.g. electronic records, paper documents). <i>Exclusions:</i> Quality assurance and management (1.5), service goals (2.2), service organization related outcomes, such as economic data, working times, use of resources, etc.	8	5.8

ICF: International Classification of Functioning, Disability and Health; ICD: International Classification of Diseases.

DISCUSSION

The relevance and importance of developing a minimum reporting set for factors relevant to service organization for rehabilitation trials have been discussed earlier in our previous article (22). It has also set out a methodological approach and processes for that purpose. One of these is Delphi study, which is the present study. This study was performed to identify the most important categories of the ICSO-R 2.0 in order to characterize rehabilitation services and identify important missing categories needed in a minimum reporting set in rehabilitation studies. The results will be used as one of the parameters for a consensus meeting to develop a rehabilitation reporting set for rehabilitation studies. Previous studies have been reported as part of the projects (20), including the introduction to the project (22).

The response rate of the first round of the Delphi process was 33% (32/96). One of the barriers to obtaining higher response rates in this study could be the difficulty in understanding the ICSO-R 2.0, despite our having presented the definitions, inclusions and exclusions with surveys. This was compensated by supplementary explanations by the authors and 1 of the ICSO-R developers (BN) to the participants who needed clarification, either by email or by teleconference. As the current study was performed anonymously, it was not possible to identify who had responded on the first round. Therefore, the same set of invitees ($n=96$) were invited to participate in the second round without distinguishing the responders from the non-responders. Sixty percent was used as the cut-off point for consensus on the first round, which was in agreement with the suggested cut-off for the Delphi study (28).

Based on this result, some categories have been ranked. The first 3 from provider and first 4 from service delivery can be elaborated as follows:

- *Human resources (1.6) and rehabilitation team (2.11)*: From the results, it appears that the participants acknowledged the importance of workforce for rehabilitation studies. In the ICSO-R 2.0, workforce is described in both of the dimensions, provider and service delivery, under the category human resources (1.6) and rehabilitation team (2.11), respectively. For a rehabilitation minimum reporting set, the workforce should be defined more precisely as the personnel who are involved in screening, prescribing interventions or treatments in every treatment arm; otherwise, the scope will be too broad. If the term “human resources” (dimension of provider) should be used, it would also include administrative staff, technical staff, and others (27). Therefore, as a

proposal, the term “rehabilitation team involved in the study” can be used.

- *Context (1.1) and Setting (2.7)*: As mentioned above, the success and the results of the study can also be influenced by in which context and setting the study was conducted (29). In ICSO-R 2.0, context describes whether the provider is independent or embedded in a parent or larger organization and how the context is organized. It includes independent units, hospitals, universities, community settings, network of organizations, or other umbrella organizations. Meanwhile, it excludes ownership and location of provider.
- *Technical resources (1.7)*: Technical resources in the ICSO-R 2.0 include diagnostic, therapeutic and assistive devices, data processing and communication devices, and other affiliated technical resources; reporting and documentation platform. In clinical trials technical resources are critical, not only the utilized devices or tools, but also model/type/version can influence the results of the trials (30).
- *Target group(s) (2.3)*: Target groups in ICSO-R 2.0 are defined as “groups of people with rehabilitation needs and their caregivers for which the service is delivered, which include patients with any or specific health condition(s), persons with any or specific impairment, activity limitations and/or participation restrictions, and other target group(s), such as age-related groups, formal or informal caregivers”. It is obvious that target group(s) are the participants/objects of the study. The information of target group is also part of the Consolidated Standards of Reporting Trials (CONSORT) statement (31). However, in rehabilitation it is crucial to look at the target groups from the perspective of the underlying disease (International Classification of Diseases; ICD) and the status for functioning (International Classification of Functioning, Disability and Health; ICF).
- *Aspect of time and intensity (2.10)*: Aspect of time and intensity is defined as “time schedule of service provision and interventions. It includes length of stay or treatment period, intermittent vs continuous treatments, duration of single treatments, number and duration of treatment sessions, and total duration of treatment, service hours”. In clinical trials, aspect of time and intensity can refer to the dosage of the treatment (32). In a study of post-stroke rehabilitation, patients showed improved recovery after up to 24 sessions of locomotor training or strength and balance exercise. However, increasing beyond 24 sessions reduced the improvement in gait and walking speed (33). Therefore, the aspects of time and intensity must be carefully taken into account for clinical trials. Furthermore, it is also important to take these aspects into account as influencing factors for outcomes.

The results of this study are relevant to the development of reporting criteria for clinical trials concerning factors related to service organization (22). This is based on the grounded hypothesis that rehabilitation outcomes may be influenced by factors such as the service location, structure and profile of rehabilitation team, technical resources and other factors related to service organization (6, 24, 34–38). Such factors can be seen as contextual factors in service delivery, which is in line with the comprehensive World Health Organization (WHO) model of functioning and health (39). It may also reflect the extension of the Sackett's model of evidence-based decision-making in medicine, for which, in the context of health-related rehabilitation, a fourth factor has been proposed (25).

In a systematic review of clinical rehabilitation trials of disorders of the nervous system, Roe et al. (12) reported that contextual factors related to service provision and delivery were scarcely described. Using the ICSO-R framework, Andelic et al. (20) investigated the reporting of categories of service organization in rehabilitation outcome studies, and demonstrated that this framework of classification is feasible for the systematic reporting of contextual factors in rehabilitation services at the meso level. However, in another systematic review (personal communication with Cecilie Roe). Identified only a few studies that systematically investigated the influence of characteristics pertaining to service organization on rehabilitation outcomes. It was shown that rehabilitation outcomes could be influenced by the setting (particularly, the mode of service delivery), aspect of time, intensity and rehabilitation team.

In order to document the quality of controlled trials in medicine, the use of standards for reporting potentially influential factors is a precondition to include studies in meta-analysis. One of the best known is the statement of Consolidated Standards of Reporting Trials (CONSORT) (31). Factors related to service organization are not included in this reference list or in its specifications. However, the Template for Intervention Description and Replication (TIDieR) checklist and guide for interventional studies (40) included 4 dimensions related to the organization of services. The questions are: “who provided” (“for each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given”), “how” (“describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group”), “where” (“describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features”),

“when and how much” (“describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose”). Last, but not least, Cochrane rehabilitation is developing an extension for the CONSORT statement, in order to provide standards of reporting appropriate for rehabilitation intervention and, in particular, for multidimensional interventions typically used for rehabilitation, which is called the Randomized Controlled Trials Rehabilitation Checklist (RCTRACK) (41).

The strength of this study is its inclusion of a diverse group of participants, both geographically and in terms of their expertise in the field of rehabilitation. This diversity has enriched the findings and reduced the influence of bias on the results. Despite the fact that all types of rehabilitation professionals were identified and invited to participate in this study, an occupational therapist (OT) was not represented in the first round of the survey. In the second round, the participants were not asked to provide information regarding their profession and work location. ICSO-R 2.0 was used as the framework for selection, as it has been developed to describe rehabilitation service organization and systematically report the external factors or settings associated with rehabilitation interventions and studies.

A reporting set of service organization may be useful for the development of a feasible method to characterize the service organization surrounding rehabilitation studies and the management of practical issues in the field of rehabilitation. The results of this study may contribute to the development of such a minimum reporting set. However, additional steps are necessary. The identified categories should be discussed and prioritized in multi-professional working groups, including using the methodological approach that has been developed in the ICF Core-Set projects (42). One important criterion will be the question of whether standardized methods are available to assess the respective category (so-called value-sets) (27). Last, but not least, testing of feasibility, validity and reliability should be performed. Furthermore, the resulting set of categories should be aligned with commonly used standards, such as the CONSORT (31) or RCTRACK approach (41).

Study limitations

As aforementioned, some participants might have difficulty understanding the ICSO-R 2.0. However, the authors responded promptly to questions posed by the participants by email and teleconference. Although all types of rehabilitation professionals had been identified and invited to participate in this study, no OTs, psychologists or general practitioners responded.

CONCLUSION

This study determined the most important and relevant factors for developing a minimum reporting set in rehabilitation. Regarding the provider, these factors are: human resources, context, technical resources, quality assurance and management, location of provider, and ownership; and, regarding service delivery, the factors are: target group, rehabilitation team, aspect of time and intensity, setting, location of service delivery, modes of referral, facility and reporting and documentation. These factors should be discussed in multi-professional workshops in which consensus can be reached through iterative voting, in order to arrive at a feasible and suitable final reporting set.

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REFERENCES

- World Health Organization. Recommendations: rehabilitation in health systems 2017; Geneva: WHO; 2017.
- Cieza A, Causey K, Kamenov K, Hanson SW, Chatterji S, Vos T. Global estimates of the need for rehabilitation based on the Global Burden of Disease study 2019: a systematic analysis for the Global Burden of Disease Study 2019. *Lancet* 2021; 396: 2006–2017.
- Kroz M, Reif M, Glinz A, Berger B, Nikolaou A, Zerm R, et al. Impact of a combined multimodal-aerobic and multimodal intervention compared to standard aerobic treatment in breast cancer survivors with chronic cancer-related fatigue – results of a three-armed pragmatic trial in a comprehensive cohort design. *BMC Cancer* 2017; 17: 166.
- Anwar SL, Adistyawan G, Wulaningsih W, Gutenbrunner C, Nugraha B. Rehabilitation for cancer survivors: how we can reduce the healthcare service inequality in low- and middle-income countries. *Am J Phys Med Rehabil* 2018; 97: 764–771.
- Anwar SL, Adistyawan G, Wulaningsih W, Erlangga Z, Gutenbrunner C, Nugraha B. Cancer rehabilitation: closing the gap in low- and middle-income countries. *Eur J Phys Rehabil Med* 2019; 55: 536–538.
- Gutenbrunner C VK, Rambow-Bertram P, Laux B, Gehrke A. Reasons for non-participation in rehabilitative measures in an outpatient setting of women with treated breast cancer – a retrospective analysis. *Int J Rehab Res* 2004; 27: 60.
- Yeh IL, Holst-Wolf J, Elangovan N, Cuppone AV, Lakshminarayan K, Capello L, et al. Effects of a robot-aided somatosensory training on proprioception and motor function in stroke survivors. *J Neuroeng Rehabil* 2021; 18: 77.
- Bigoni M, Cimolin V, Vismara L, Tarantino AG, Baudo S, Trotti C, et al. Retraining selective trunk muscle activity: a key to more successful rehabilitation outcomes for hemiparetic stroke patients. *NeuroRehabilitation* 2021; 49: 87–94.
- Rethnam V, Langhorne P, Churilov L, Hayward KS, Herisson F, Poletto SR, et al. Early mobilisation post-stroke: a systematic review and meta-analysis of individual participant data. *Disability Rehabil* 2020 Jul 16;1-8.
- Omar NH, Mohd Nordin NA, Chai SC, Abdul Aziz AF. Functionality among stroke survivors with upper limb impairment attending community-based rehabilitation. *The Med J Malaysia* 2020; 75: 146–151.
- Fure SC, Howe EI, Andelic N, Brunborg C, Sveen U, Roe C, et al. Cognitive and vocational rehabilitation after mild-to-moderate traumatic brain injury: a randomised controlled trial. *Ann Phys Rehabil Med* 2021: 101538.
- Roe C, Tverdal C, Howe EI, Tenovuo O, Azouvi P, Andelic N. Randomized controlled trials of rehabilitation services in the post-acute phase of moderate and severe traumatic brain injury – a systematic review. *Frontiers Neurol* 2019; 10: 557.
- Widyadharma IP LN, Dharmatika IMP, Gayathridayawasi, Indrayani IAS, Nugraha B. Industrial revolution 4.0 in neurorehabilitation: the implementation of virtual reality for neurological disorders. *MNJ* 2021; 7: 1–5.
- Gutenbrunner C, Stokes EK, Dreinhofer K, Monsbakken J, Clarke S, Cote P, et al. Why Rehabilitation must have priority during and after the COVID-19-pandemic: a position statement of the Global Rehabilitation Alliance. *J Rehabil Med* 2020; 52: jrm00081.
- Nugraha B WL, Laswati H, Kusumastuti P, Tulaar ABM, Gutenbrunner C. COVID-19 pandemic in Indonesia: situation and challenges of rehabilitation medicine in Indonesia. *Act Med Indo* 2020; 52: 299–305.
- Gutenbrunner C, Nugraha B, Martin LT. Phase-adapted Rehabilitation for acute corona virus disease-19 (COVID-19) patients and patient with long-term sequelae of COVID-19. *Am J Phys Med Rehabil* 2021; 100: 533–538.
- Nugraha B, Karst M, Engeli S, Gutenbrunner C. Brain-derived neurotrophic factor and exercise in fibromyalgia syndrome patients: a mini review. *Rheumatol Int* 2012; 32: 2593–2599.
- Wellburn S, Ryan CG, Coxon A, Dickson AJ, Dickson DJ, Fatoye F, et al. Long-term improvements following a residential combined physical and psychological programme for chronic low back pain. *BMJ Open Qual* 2021; 10.
- Keers JC, Bouma J, Links TP, ter Maaten JC, Gans RO, Wolfenbuttel BH, et al. One-year follow-up effects of diabetes rehabilitation for patients with prolonged self-management difficulties. *Patient Educ Couns* 2006; 60: 16–23.
- Andelic N, Lu J, Gutenbrunner C, Nugraha B, Gormley M, Soberg HL, et al. Description of health-related rehabilitation service provision and delivery in randomized controlled trials: a topic review. *J Rehabil Med* 2020; 52: jrm00093.
- Roe C, Kirkevoold M, Andelic N, Soberg HL, Sveen U, Bautz-Holter E, et al. The challenges of describing rehabilitation services: a discussion paper. *J Rehabil Med*. 2018; 50: 151–158.
- Nugraha B, Andelic N, Soberg HL, Engen G, Kirkevoold M, Roe C, et al. Towards standardized reporting of service organization in rehabilitation for clinical trials. *J Rehabil Med* 2021; 53: jrm00207
- Gutenbrunner C VK R-BP, Laux B, Gehrke A. Reasons for non-participation in rehabilitative measures in an outpatient setting of women with treated breast cancer – a retrospective analysis. *Int J Rehab Res* 2004; 27: 60.
- Naidoo U, Ennion L. Barriers and facilitators to utilisation of rehabilitation services amongst persons with lower-limb amputations in a rural community in South Africa. *Prosthet Orthot Int* 2019; 43: 95–103.
- Gutenbrunner C, Nugraha B. Decision-making in evidence-based practice in rehabilitation medicine: proposing a fourth factor. *Am J Phys Med Rehabil* 2020; 99: 436–440.
- Gutenbrunner C, Bickenbach J, Kiekens C, Meyer T, Skempes D, Nugraha B, et al. ISPRM discussion paper: proposing dimensions for an International Classification System for Service Organization in Health-related Rehabilitation. *J Rehabil Med* 2015; 47: 809–815.
- Gutenbrunner C, Nugraha B, Gimigliano F, Meyer T, Kiekens C. International Classification of Service Organization in Rehabilitation: an updated set of categories (ICSO-R 2.0). *J Rehabil Med* 2020; 52: jrm00004.
- Keeney S, Hasson F, McKenna H. Consulting the oracle: ten lessons from using the Delphi technique in nursing research. *J Adv Nurs* 2006; 53: 205–212.
- Nugraha B, Andelic N, Soberg HL, Engen G, Kirkevoold M, Roe C, et al. Towards standardized reporting of service organization in rehabilitation for clinical trials. *J Rehabil Med* 2021; 53: jrm00207.
- Nugraha B, Ghashang SK, Hamdan I, Gutenbrunner C. Effect of Ramadan fasting on fatigue, mood, sleepiness,

and health-related quality of life of healthy young men in summer time in Germany: a prospective controlled study. *Appetite* 2017; 111: 38–45.

31. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Ann Intern Med* 2010; 152: 726–732.
32. Jette AM. The importance of dose of a rehabilitation intervention. *Phys Ther* 2017; 97: 1043.
33. Rose DK, Nadeau SE, Wu SS, Tilson JK, Dobkin BH, Pei Q, et al. Locomotor training and strength and balance exercises for walking recovery after stroke: response to number of training sessions. *Phys Ther* 2017; 97: 1066–1074.
34. Andelic N, Bautz-Holter E, Ronning P, Olafsen K, Sigurdottir S, Schanke AK, et al. Does an early onset and continuous chain of rehabilitation improve the long-term functional outcome of patients with severe traumatic brain injury? *J Neurotrauma* 2012; 29: 66–74.
35. Doig E, Fleming J, Kuipers P, Cornwell PL. Comparison of rehabilitation outcomes in day hospital and home settings for people with acquired brain injury – a systematic review. *Disabil Rehabil* 2010; 32: 2061–2077.
36. Rose H, Ashford S, Singer B, Turner-Stokes L. Patient engagement and satisfaction with goal setting in rehabilitation: impact on outcome. *Int J Stroke* 2015; 10: 20–21.
37. Longley V, Peters S, Swarbrick C, Bowen A. What factors affect clinical decision-making about access to stroke rehabilitation? A systematic review. *Clin Rehabil* 2019; 33: 304–316.
38. Al-Rashaida M L-PJ, Amayra I, Lázaro E, Martínez O, Berrocoso S, García M, Pérez M. Factors affecting the satisfaction of people with disabilities in relation to vocational rehabilitation programs: a literature review. *J Vocat Rehabil* 2018; 49: 97–115.
39. World Health Organization. International Classification of Functioning, Disability and Health: ICF. Geneva: WHO; 2001.
40. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014; 348: g1687.
41. Negrini S, Armijo-Olivo S, Patrini M, Frontera WR, Heineemann AW, Machalicek W, et al. The randomized controlled trials rehabilitation checklist: methodology of development of a reporting guideline specific to rehabilitation. *Am J Phys Med Rehabil* 2020; 99: 210–215.
42. Selb M, Escorpizo R, Kostanjsek N, Stucki G, Ustun B, Cieza A. A guide on how to develop an International Classification of Functioning, Disability and Health Core Set. *Eur J Phys Rehabil Med* 2015; 51: 105–117.