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A proposal for an Italian minimum data set assessment protocol for robot-assisted rehabilitation: a Delphi study

M. FRANCESCHINI [1], R. COLOMBO [2], F. POSTERARO [3, 4], P. SALE [1]

[1]*Department of Neurorehabilitation IRCCS San Raffaele-Pisana, Rome, Italy*
[2]*Service of Bioengineering "Salvatore Maugeri" Foundation, IRCCS, Pavia, Italy*
[3]*Laboratory of Rehabilitation Bioengineering Auxilium Vitae Rehabilitation Center, Volterra, Pisa, Italy*
[4]*Rehabilitation Department, Versilia Hospital-AUSL12 Camaiore, Lucca, Italy*

Background. **At present there is no agreement on a common evaluation protocol to assess improvement in stroke patients after robotic therapy.**
Aim. **The aim of this study was to identify a Minimum Data Set Assessment Protocol, using an agreement-based survey.**
Design. **A Delphi survey.**
Setting. **This study was conceived by the Italian Robotic Neurorehabilitation Research Group (IRNRG), an Italian group involved in the clinical application of robot-assisted rehabilitation devices**
Population. **Stroke subjects.**
Methods. **A 3-round Delphi survey was carried out through the electronic submission of questionnaires to a panel of experts identified in fourteen rehabilitation centers. For each generated item, experts were asked to rate questions on a 5 point Likert Scale.**
Results. **After the 1st round the questionnaire was filled out by 43 (84.3%) out of 51 experts invited to participate in the study. In the 2nd and 3rd rounds we explored the specific evaluation tools for each of the ICF domains identified in the 1st round. The experts identified the following assessment tools for the upper limb: the Ashworth Scale, the Fugl-Meyer assessment scale, the Frenchay Arm Test, the Medical Research Council scale, the Motricity Index, Frenchay Activities Index and Modified Barthel Index; and for the lower limb: the Ashworth Scale, the Motricity Index, the 10 meter walking Test, the 6 minutes walking Test, the Functional Ambulatory Classification, the Timed Up and Go Test, the Walking Handicap Scale, the Borg Rating of Perceived Exertion, the Heart Rate, the Medical Research Council Scale, the Tinetti Balance Scale and the Modified Barthel Index.**
Conclusion. **The Delphi survey presented in this study allows the identification of a shared assessment protocol to be applied in clinical practice and research for the evaluation of the real improvement related to robot-assisted rehabilitation of the upper and lower limb in patients after stroke.**
Clinical Rehabilitation Impact. **Clinicians and researchers could use the results of this study to obtain a common language in robotic rehabilitation assessments**

KEY WORDS: Outcome Assessment (Health Care) - Therapy - Delphi Technique - Stroke - Rehabilitation.

Corresponding author: M. Franceschini, Department of Neurorehabilitation - IRCCS San Raffaele- Pisana, Rome, Italy.
E-mail: marco.franceschini@sanraffaele.it

Life expectancy in developed and developing countries is rising sharply and people are exposed to risk factors for heart and vascular diseases for longer periods.[1] Stroke is a leading cause of adults' disability and the consequent motor impairment restricts function in arm and leg movements and mobility of people surviving the acute phase.[2, 3] Conventional rehabilitation programs have been proven to be effective in improving walking and arm functions; however, they often involve great consumption of health care resources.[4-6]

Recently, innovative technologies and strategies

such as robotics have been proposed to overcome this difficulty and improve motor outcome and the quality of life of stroke survivors.[5, 6]

Although their effectiveness has been analyzed and proven in several literature review papers, studies involving a large number of subjects are at present still missing.[5, 7-10]

The main difficulty to this purpose is represented by the fact that the different devices proposed for robot therapy, both for clinical and home settings, are characterized by different types of assistance, mechanical design, control strategy and have been applied in different fields and pathologies.[6] This makes pooling data of different studies very difficult and allows comparison across studies for systematic review purposes. Moreover, knowledge on how different patients improve their motor impairment is still incomplete. In particular, to what extent patients can benefit from robot-assisted training and how long robotic treatment should be continued still remain open questions.[11]

A possible solution could be the implementation of many studies with a standardized assessment protocol. Two recent literature reviews analyzed the outcome measures and evaluation tools that have been applied to assess the effectiveness of robot training.[12, 13] Their findings show that both in clinical practice and research there is a lack of agreement on the outcome measures that should be used to assess changes due to the technology-assisted rehabilitation intervention. In general, more emphasis was given to measuring the changes at the impairment level (using kinematic assessment or clinical rating scales) rather than those in daily living functional activities.[12] Furthermore, the most commonly used scales for the lower limb evaluated only the basic components of walking.[13]

Both these review works concluded that future studies should also include instrumental evaluation and the criteria for scale selection should be based on the ICF framework, psychometric properties and patient characteristics.

The selection of a minimum data set of evaluation tools to be used in common clinical practice should be considered a fundamental prerequisite for an extensive clinical application of robotic devices; consequently a specific method is required for its shared definition.

The Delphi methodology is a technique that was proposed to obtain agreement in controversial issues and has been adopted in medical, nursing and health services research.[14, 15] It consists in questioning a panel of experts on specific matters and issues. The information regarding the topic under assessment is generally provided to each expert through specific questionnaires. On the basis of the obtained responses the questions, eventually with some modification or integration, are resubmitted to the expert panel in successive rounds until agreement is reached. The Delphi methodology is defined as a multi-stage process where each stage builds on the results of the previous one.[14] Hence, this methodology seems the most appropriate technique to obtain agreement in the definition of a standardized assessment protocol.

Aim of the present study was to identify the outcome measures and evaluation tools to establish a minimum data set assessment protocol to be used in common clinical practice, in order to evaluate the changes obtained by means of robot-assisted rehabilitation of the upper and lower limbs. The proposed evaluation protocol has the aim to allow homogeneous data collection from different clinical settings, thus encouraging discussion between practitioners and sharing of clinical results even outside a specific research context.

Materials and methods

This study was conceived by the Italian Robotic Neurorehabilitation Research Group (IRNRG), an Italian group of "stakeholders" involved in the clinical application of robot-assisted rehabilitation devices. The study was conducted using the well-established Delphi technique methodology, in accordance with the research guidelines and recommendations recently proposed by literature.[16, 17] The study was approved by the committee on research ethics at the institution in which the research was conducted and any informed consent from human subjects was obtained as required.

A steering committee composed of four members was formed during a periodical meeting of the IRNRG. The committee included two clinical neurologists with documented experience in robot-assisted rehabilitation, a physiatrist with experience in neurorehabilitation research and the Delphi methodology and a bioengineer with documented experience in the development and clinical application of ro-

botic rehabilitation devices. The steering committee had the following responsibilities: 1) to define and contact for acceptance the clinical institutions which were involved in the survey. Most of them were the affiliation organizations of the people attending the meeting in which the steering committee was set-up; 2) to sketch out the questions to be asked during the survey; 3) to discuss the outcomes of each round of the survey; 4) to decide on the number of rounds of the survey; 5) to decide on the percentage of accord in order to define the level of agreement. The committee preliminarily met once before start of the study and again before each Delphi round, but did not participate in the survey.

Delphi participants

The participants were selected in each of the institutions which provided formal subscription to the study, besides including one or more of the following categories: Bioengineers, Neurologists, Occupational Therapists, Physiatrists and Physiotherapists (defined as the experts from now on). Inclusion criteria for experts were: 1) to have a proven track record in professional practice; 2) to have at least 2 years of experience in assessing and treating stroke survivors and/or experience in the clinical application of robotic devices for the rehabilitation of the upper and lower limbs; and 3) to be currently employed and demonstrate continuing professional interests. For each institution, the steering committee identified a person called the "team leader" who was in charge of recruiting other experts who possessed the requirements reported above. Due to the specific clinical aim of this survey, the recruitment criteria explicitly required the participation of professionals who were actually daily involved in the rehabilitation of patients, thus excluding people who had only a short specific research experience.

Study procedure

The survey was carried out through the electronic submission of questionnaires delivered to the identified team leaders. The questionnaires for each round of this study were designed by the steering committee on the basis of the preliminary discussions carried out in the two IRNRG meetings preceding the committee establishment.

The questionnaire included the questions and the possible answers; in addition, for each question a specific free text field was available in order to allow the inclusion of brief suggestions, clarifications and other comments.

The first questionnaire included instructions for the respondents providing exact information on the purpose of the study, what they were asked to do, how much time they were expected to contribute and what use would have been made of the provided information. In order to guarantee anonymous responses, the steering committee required that each institution participating in the study returned the filled questionnaires to a data collection administrator who had the task to insert the answers in a specific anonymized database and stimulate feedback if the questionnaires weren't returned after the established deadline. Essentially the data collection administrator associated a computer-generated random ID to each "expert" participant and used it to fill in the database and manage possible clarification queries between experts and the principal investigator. Each questionnaire took about 20 minutes or less to complete, depending on the round. Each time the collection administrator declared the round complete, the principal investigator analyzed and summarized the results and then submitted a report to the other members of the steering committee. Except for the first round, the questions for subsequent rounds were based on the responses of the previous round. Four weeks were given to the experts to respond in each round. A specific reminder alert was sent to participants one week before the round deadline. For each generated item, experts were asked to rate on a 5 point Likert Scale (1=strong disagreement, 2=moderate disagreement, 3=agreement with reservation, 4=agreement with minor reservation, 5=strong agreement) whether they believed the item should be selected.[18] The first rounds started in January 2013 and the survey was concluded in mid-January 2014.

Survey round 1

In the first round, 5 questions considering mainly general issues on assessment and robot therapy were included. Specifically, the first item judged the importance of implementing a common assessment protocol to evaluate the effectiveness of robotic intervention. In other words we measured the level of agreement toward a shared data collection in order

to obtain data with an homogeneous and significant sample size. The second item explored which advantages the experts expected from a common evaluation protocol. In particular, it assessed if this would improve their clinical activity, allow comparison of changes due to robotic intervention, and be useful mainly for research purposes or both for research and clinical practice. The third item assessed which International Classification of Functioning, Disability and Health (ICF) domains should be considered in the minimum data set. Here we explored the possibility that only some domains could be considered really important to be evaluated during daily clinical activity, with the fourth item asking which ICF domains should be explored by a set of evaluation tools. The fifth item assessed if the minimum data set should include detailed evaluation of high level functions such as cognitive functions, aphasia and neglect or rather just a global evaluation of the patient's ability to follow instructions and execute the requested motor tasks.

Survey round 2

On the basis of the results of round 1, the steering committee formulated the questionnaire for the Delphi round 2. The questionnaire included a list of clinical evaluation tools divided in upper and lower limb sections. Each section was in turn divided into groups of evaluation tools referred to the ICF assessment domains selected in the previous round.

The experts did this task being conscious that there is no automatic translation of scores from existing tools into ICF categories and qualifiers.[19] Each group of tools was built considering the review of literature analyzing those that are most commonly used for the evaluation of patients who undergo robot-assisted rehabilitation [12, 13] and recent work on assessment of participation after stroke.[20, 21]

Survey round 3

After the analysis of the Delphi survey round 2, those outcome measures that could not reach agreement but obtained a score very close to it (from 66 to 80%) were included in survey round 3 with the instruction to make a clear choice when two or more of them provided similar information. Moreover, round 3 included specific items addressing questions or clarifications detailed by the experts in the note fields of the previous round.

Data analysis

A quantitative and qualitative analysis was completed on the responses of the three Delphi rounds. Quantitative analysis for each item was performed in order to determine the number and percentages of experts who gave a certain answer (agreement/disagreement). Subsequently, these results were compared with the defined levels of conformity. In particular, the steering committee specified that in order to obtain a positive agreement toward an item statement, the sum of the results of levels 3, 4 and 5 of the Likert Scale had to be ≥80%. Conversely, to result in a negative agreement the sum of levels 1 and 2 had to be ≥66%. No agreement was considered reached when the results were lower than the two threshold values reported above. In the first round, when agreement was reached on an item, these elements could be used to compose new questions on related subjects. In round 2, when negative agreement was reached on an outcome measure, that measure was excluded in the following round.

Calculations were performed using the Microsoft Excel spreadsheet (Microsoft, Redmond, WA, Usa).

Results

Fourteen rehabilitation centers were involved in the study. After the 1st round the questionnaire was filled out by 43 (84.3%) out of 51 experts invited to participate in the study. The distribution of participants had the following representation: 13.95% bioengineers, 16.28% neurologists, 11.63% occupational therapists, 34.88% physiatrists and 23.26% physiotherapists. In the 2nd and 3rd rounds we obtained 100% of answers.

The general information collected during the 1st round evidenced that the majority of participants (88.37%) was in favor of a minimum data set assessment protocol to evaluate patients treated with robots. Specifically, they believed that it could be useful to improve and compare daily clinical activity (93.02% and 86.05% respectively). Almost all the responses (95.35%) were in favor of the use of the ICF framework to select the domains to be evaluated. The Body Functions (93.02%), Activities (90.70%) and Participation (86.05%) were the selected domains. The assessment of personal factors and of en-

TABLE I.—*Statements/questions and results of Round 1.*

	Agreed (%)	Disagreed (%)
Use of a common assessment protocol to evaluate the effectiveness of robotic rehabilitation (pre- and post-treatment) is very important.	88.37*	11.63
Do you think that a common assessment protocol could be useful for:		
improving daily clinical activities?	93.02*	6.98
comparing results during daily clinical activities?	86.05*	13.95
research activity purposes?	67.44*	32.56
research and clinical activity purposes?	72.09*	27.91
A common assessment protocol should be based on the ICF domains.	95.35*	4.65
Which of the ICF domains do you believe could be relevant for your daily practice?		
Body function	93.02*	6.98
Activities	90.70*	9.30
Participation	86.05*	13.95
Personal factors	18.60	81.40*
Environmental factors	16.30	83.70*
The common assessment protocol should include a rating scale for evaluation of cognitive function.	93.02*	6.98

*Values over threshold.

TABLE II.—*Questions and responses obtained in Round 2 for the evaluation of upper limb disabilities. *Values over threshold.*

	Agreed (%)	Disagreed (%)
Which of the following assessment tools do you recommend should be included in the protocol for evaluation of body function in individuals after stroke with upper limb disabilities?		
Ashworth Scale	95.35*	4.65
Dynamometer	27.91	72.09*
Electromyography	30.23	69.77*
Fugl-Meyer scale	93.02*	6.98
Kinematic Analysis	34.88	65.12
Medical Research Council Scale	95.35*	4.65
Motricity Index	95.35*	4.65
Nottingham Sensory Assessment	32.56	67.44*
Range of Motion	60.47	39.53
Visual Analogue Scale for pain	81.40*	18.60
Which of the following assessment tools do you recommend should be included in the protocol for evaluation of activities in individuals after stroke with upper limb disabilities?		
Action Research Arm Test	41.86	58.14
Arm Motor Ability Test	20.93	79.07*
Barthel Index	83.72*	16.28
Box and Block Test	55.81	44.19
Chedoke-McMaster Stroke Assessment	20.93	79.07*
French Index Activity	83.72*	16.28
Frenchay Arm Test	81.40*	18.60
Functional Independence Measure	27.91	72.09*
Functional Independence Measure motor subscale	32.56	67.44*
Abilhand	20.93	79.07*
Nine-Hole Peg Test	62.79	37.21
Rivermead Motor Assessment	32.56	67.44*
Which of the following assessment tools do you recommend should be included in the protocol for evaluation of participation in individuals after stroke with upper limb disabilities?		
EuroQol Quality of Life Scale	46.51	53.49
Numerical Rating Scale	44.19	55.81
Stroke Impact Scale	41.86	58.14
The Short Form (36) Health Survey	39.53	60.47

vironmental factors was considered useful but time consuming to be used in daily practice. A number of 93.02% of experts requested the inclusion of the evaluation of cognitive functions (Table I).

In the second round we explored the specific evaluation systems for each domain identified in the first round in patients after stroke. The results obtained after this round are reported in Tables II, III, as well as a detailed list of the tools for the evaluation included in the questionnaire.

Furthermore, the experts expressed the need of obtaining more clarifications with respect to some approved items. In particular, which specific version of Fugl Meyer, Ashworth and Barthel Index Scale should be used. The analysis of the results of participation for the upper limb section in round 2 showed no agreement for all the proposed assessments. In round 3 they were re-submitted to obtain a confirmation of these results. For the cognitive measurement of patients the following assessments were proposed in round 2: Mini Mental State Examination (MMSE),[22] Aachen Aphasia Test,[23] Barrage Test for the neglect [24] and clinical evaluation. Only the clinical evaluation reached the agreement with 83.72%. In addition, the experts identified the need to assess the patient's acceptability of robotic therapy by means of a specific scale.

The third round answered the questions reported above. The original version of the Fugl Meyer Scale (0-66 score range),[25] the Modified Ashworth Scale (MAS), with score ranging from 0 (no increase in muscle tone) to 4 (affected part rigid in flexion or

TABLE III.—*Questions and responses obtained in Round 2 for the evaluation of lower limb disabilities. *Values over threshold.*

		Agreed (%)	Disagreed (%)
Which of the following assessment tools do you recommend should be included in the protocol for evaluation of body function in individuals after stroke with lower limb disabilities?			
	Ashworth Scale	97.67*	2.33
	Electromyography	25.58	74.42*
	Fugl-Meyer scale	44.19	55.81
	Medical Research Council Scale	58.14	41.86
	Motricity Index	100*	0.00
	Range Of Motion	55.81	44.19
	Rivermead Motor Assessment	41.86	58.14
	Visual Analogue Scale for pain	60.47	39.53
Which of the following assessment tools do you recommend should be included in the protocol for evaluation of activities in individuals after stroke with lower limb disabilities?			
	10-meter walking Test	93.02*	6.98
	2-min walking Test	18.60	81.40*
	6-min walking Test	90.70*	9.30
	10-min walking Test	27.91	72.09*
	Barthel Index	81.40*	18.60
	Berg Balance Scale	46.51	53.49
	Borg Rating of Perceived Exertion	86.05*	13.95
	Heart Rate	81.40*	18.60
	Functional Ambulatory Classification	90.70*	9.30
	Functional Independence Measure	30.23	69.77*
	Functional Independence Measure motor subscale	32.56	67.44*
	Gait Analysis	30.23	69.77*
	Timed Up and Go Test	93.02*	6.98
	Tinetti scale	86.05*	13.95
Which of the following assessment tools do you recommend should be included in the protocol for evaluation of participation in individuals after stroke with lower limb disabilities?			
	EuroQol Quality of Life Scale	51.16	48.84
	Numerical Rating Scale	39.53	60.47
	Stroke Impact Scale	41.86	58.14
	The Short Form (36) Health Survey	41.86	58.14
	Walking Handicap Scale	93.02*	6.98

extension) [26] and the Modified Barthel Index [27] were selected by the panel of experts to be included in the minimum data set assessment protocol. During round 3 the steering committee proposed the assessment of the patient's acceptability of robot therapy through one of the following choices: 1) Numerical Visual Analogue Score;[28] 2) NASA Task Load Index;[29] 3) Intrinsic motivation inventory;[30, 31] 83.72% of participants expressed agreement on the use of the NASA Task Load Index.[29] For the upper limb, with reference to the participation and/or quality of life, the result of round 3 confirmed the one of round 2. At the end of the third round we observed that the experts agreed on the following tools:

— Upper limb. The Ashworth Scale,[26] the Fugl-Meyer assessment Scale,[25] the Frenchay Arm Test,[32] the Medical Research Council Scale,[33] the Motricity Index,[34] the Frenchay Activities Index,[35] and Modified Barthel Index;[27]

— Lower limb. The Ashworth Scale,[26] the Motricity Index,[34] the 10 meter walking Test,[36] the 6 minutes walking Test,[37] the Funcional Ambulatory Classification,[38] the Timed Up and Go Test,[39] the Walking Handicap Scale,[40] the Borg Rating of Perceived Exertion,[41] the Heart Rate, the Medical Research Council Scale,[33] the Tinetti Balance Scale,[42] and the Modified Barthel Index (Table IV).[27]

TABLE IV.—*Minimum data set assessment protocol for evaluation of upper and lower limb disabilities before and after robot-assisted training.*

	Assessment Tool
Upper Limb	Ashworth Scale
	Fugl-Meyer Assessment Scale
	Frenchay Arm Test
	Medical Research Council Scale
	Motricity Index
	Frenchay Activities Index
	Modified Barthel Index
Lower Limb	Ashworth Scale
	Motricity Index
	10 Meter Walking Test
	6 Minutes Walking Test
	Funcional Ambulatory Classification
	Timed Up and Go Test
	Walking Handicap Scale
	Borg Rating of Perceived Exertion
	Medical Research Council Scale
	Tinetti Balance Scale
	Modified Barthel Index
	Heart Rate

Discussion

This Delphi survey aimed to identify the proper evaluation tools to implement a minimum data set assessment protocol to be used in clinical practice, for outcome evaluation following robot-assisted rehabilitation. Eight clinical scales were identified for the evaluation of the upper limb and ten tools were identified for the evaluation of the lower limb, while no specific tools were identified for the evaluation of cognitive functions, leaving to the clinician the subjective evaluation that patients are able to follow simple instructions and to complete the assigned motor tasks.

Recent literature reviews on the clinical evaluation scales applied for measuring the effects of robotic rehabilitation of the upper [12] and lower [13] extremities did not report a definitive agreement on specific tools or a set of them. Sivan *et al.*[12] proposed a specific algorithm for the selection of the clinical scales included in the evaluation protocol. It is based mainly on the use of the impairment severity as selection criteria. Even if this is a reasonable choice, we have to consider that this review work showed a great variability scenario with 30 different tools found in 28 clinical trials. Furthermore, in accordance with Chen [43] who, in order to maximize the recovery of motor function after a stroke, proposed the concept of a training package related to the severity of impairment and the phase of recovery after stroke, the Sivan approach should be considered too simplistic.

The review of Geroin *et al.*[13] explored how a stereotyped motor function such as walking is assessed, which could be considered more easy to evaluate compared to the upper limb functions. It reported 45 different assessment tools in 27 clinical trials. The authors proposed three sets of tools: 1) discriminative scales, which can be used to divide the patients into homogeneous groups for experimental design; 2) evaluative scales useful to highlight the effects of treatment between the beginning and end of therapy; and 3) predictive tools able to expect a specific ability that the patient will be capable of performing.[13] Furthermore, in the national and international guidelines no specific evaluation protocol exploring all the ICF domains is proposed.

The Delphi Technique we used represents a very good methodology as it starts from an explicit clinical experience and not from conventional standards and guidelines which, excluding not randomized

clinical trials, could lose some strong information deriving from common clinical practice. Obviously, this procedure is the best choice for creating a first scientific base that could be extended to daily clinical practice and research activities. A very strong agreement (95%) was found on the inclusion of all the ICF domains. In spite of this result, in the second round we found a higher agreement only for the impairment, activities and participation levels for lower limbs, whilst for the activities and participation levels of upper extremities and for the evaluation of cognitive function, the agreement between the experts was not as strong. Actually, the number of tools proposed for the activities domain was high, and likely experts made their selection on the basis of tools' details or time saving criteria. Similarly, the proposed tools for the participation level were considered too time consuming or the numerical rating scale not informative enough.

The stroke disease resulted the most important pathology in which the experts would apply the assessment protocol. This result is not surprising in that previous experiences of the IRNRG Group produced a literature review on the use of lower limb robots in gait rehabilitation [13] of stroke patients. Actually, this bias may be related to the fact that the number of stroke patients treated by robotic devices in the rehabilitation centers involved in this survey is higher, compared to that of other neurological diseases. However, this scenario is not different from the one observed in literature where most of the robot devices are mainly applied for stroke rehabilitation.

The minimum data set assessment protocol identified in this work through the Delphi methodology could be a first step in order to broaden the agreement between clinicians and move from common clinical practice towards evidence based medicine and research activities. Future work should specifically address patients' evaluation on a large sample size, by exploring for each ICF domain the correlation between the selected clinical scales and possibly carry out a principal component analysis.

Participation and health related quality of life are distinct constructs; whereas the former refers to an individual's involvement in a real-life situation, the latter is related to the restrictions associated with a specific health condition.[44, 45] In round 2 a set of tools including also measurements of quality of life were selected to estimate participation based on their strong correlation found with scores on items that assess the participation categories of the ICF.[20]

Unfortunately, no consensus was obtained for the assessment of participation in the upper limb section. Therefore, we recommend the inclusion of a specific tool assessing this ICF domain.

Conclusions

This is the first Delphi survey related to a Robot-Assisted Rehabilitation Data Set Assessment Protocol for stroke patients. The agreement-based survey here presented allows the identification of a shared assessment protocol to be applied in the clinical practice for the evaluation of the real improvement related to robot-assisted rehabilitation of the upper and lower limbs.

Undeniably, there is no guarantee that the data set identified using this methodology could actually be the required minimum. However, it should be clear that redundancy of information may not always be considered as a negative aspect because it could play a beneficial role in favor of the immediacy of results interpretation.

Clinicians and researchers could use the results of this study to obtain a common language in robotic rehabilitation assessments. Furthermore, this protocol could be used in the future for the validation of new robotic devices and for other research purposes. Finally, in order to further improve scientific evidence on the advantages of robotic devices, randomized controlled studies with a large sample size and possibly with multicenter participation are needed and the assessment protocol proposed here should be considered beneficial to this purpose.

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