TITLE PAGE

Title: Clinical replicability of rehabilitation interventions in Randomized Controlled Trials reported in main journals is inadequate

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Word count: 2985

Abstract

Objective. To study if Randomized Controlled Trials (RCTs) in rehabilitation (a field where complex interventions prevail) published in main journals include all the details needed to replicate the intervention in clinical practice (clinical replicability).

Study Design and Setting. Forty-seven rehabilitation clinicians of 5 professions from 7 teams (Belgium, Italy, Malaysia, Pakistan, Poland, Puerto Rico, USA). reviewed 76 RCTs published by main rehabilitation journals exploring 14 domains chosen through consensus and piloting.

Results. The response rate was 99%. Inter-rater agreement was moderate/good. All clinicians considered unanimously 12 (16%) RCTs clinically replicable and none not replicable. At least one "absent" information was found by all participants in 60 RCTs (79%), and by a minimum of 85% in the remaining 16 (21%). Information considered to be less well described (8-19% "perfect" information) included two providers (skills, experience) and two delivery (cautions, relationships) items. The best described (50-79% "perfect") were the classic methodological items included in CONSORT (descending order: participants, materials, procedures, setting and intervention).

Conclusion. Clinical replicability must be considered in RCTs reporting, particularly for complex interventions. Classical methodological checklists like CONSORT are not enough, and also TIDieR do not cover all the requirement . This study supports the need for field-specific checklists.

Key Words. RCTs; applicability; complex interventions; rehabilitation.

What is new? This paper highlights the existing gap between research and clinics in the application of complex interventions (clinical replicability). Only 16% of RCTs are considered applicable by clinicians. Classical RCTs checklist, like CONSORT, are not sufficient for the reporting of complex interventions. In reporting checklists, a focus on clinical replicability is needed, to allow a better use by clinicians of the produced evidence.

Abbreviations.

RCTs: Randomized Controlled Trials

PRM: Physical and Rehabilitation Medicine

TIDieR: Template for intervention description and replication

REREP: Replicability Everyday rehabilitation clinical Practice

PRMp: PRM physicians

PT: physiotherapists

OT: occupational therapists

PSY: rehabilitation psychologists

OTH: others

BMJ: British Medical Journal

JAMA: Journal of the American Medical Association

NEJM: New England Journal of Medicine

Contributors

SN designed and led the study at all stages. CA and JP collected the data from all REREP Study participants. SN, CA and JP analysed the data and all the authors interpreted the data. SN drafted the work. All the authors made a critical revision of the work. All authors approved the final version, and all take responsibility for its content.

Declaration of Interest

None related to this work. SN is Chief-Editor of the European Journal of Physical and Rehabilitation Medicine and Director of Cochrane Rehabilitation; WR.F is Chief-Editor of the American Journal of Physical Medicine and Rehabilitation and President of the International Society of Physical and Rehabilitation Medicine; CK is Coordinator of Cochrane Rehabilitation; JPE and FR are in the Executive Committee of Cochrane Rehabilitation; CA and JP are part of the Headquarters of Cochrane Rehabilitation.

Acknowledgments

We acknowledge the role of all the REREP Study participants. The authors wish to acknowledge the "Royal Society Te Apārangi, New Zealand", for the support given to the study

1 Introduction

Clinical research should inform clinical practice by developing interventions that improve patient care. In this context, *applicability* (external validity or generalizability) has been defined as "the extent to which the effects observed in studies reflect the expected results of an intervention in "real-world" conditions" (1), *reproducibility* as "the replication of results by re-performing the same analysis of the same data by a different analyst" (2), and *replicability* as "the replication of results by re-performing of the experiment collecting new data" (2). These terms have been applied mainly to epidemiological and methodological research. In the present study we focus, from a clinical perspective, on a specific aspect of applicability, which we call *clinical replicability* and define as "the accurate description in published reports of clinical studies of all details needed to apply the intervention in everyday clinical practice". Clinical replicability is related to PICO elements (Patients, Interventions, Comparison, and Outcomes) (3)

Completeness of information about PICO elements, description of randomization, blinding and statistical analysis used, and the context of care, are usually ensured through the use of high-quality reporting checklists, like CONSORT for RCTs (4) or STROBE for observational trials (5). Unfortunately, while there are plenty of data on factors affecting the risk of bias, or internal validity, very few refer to applicability (1). In some clinical situations, dosage and timing could be sufficient to describe the intervention (for example in pharmacological studies), but this may not apply to complex interventions (conventionally defined as interventions with several interacting components) or interventions delivered by multi-professional teams. A checklist, the TIDieR (Template for Intervention Description and Clinical replication) (6), has been developed for all evaluative study designs to improve the reporting of interventions for replicability. A methodological guide to assess the applicability of comparative interventions studies (1) and specific checklists (7-10) have been developed, but that approach is limited to epidemiological studies.

Rehabilitation needs are steadily growing worldwide due to ageing of the population, an increase in the prevalence of non-communicable diseases, and a rise in the number of persons experiencing disability (11). For this reason, the World Health Organization is developing strategies to encourage governments to scale-up rehabilitation services worldwide (12). Physical and Rehabilitation Medicine (PRM) is the medical specialty dealing with rehabilitation and could be a good example of a field where clinical replicability can be studied. Rehabilitation in fact uses a bio-psycho-social approach (13), focuses mainly on functioning (14), and combines multiple interventions at different points in time through multi-professional and interdisciplinary team work (13). For these reasons, research in rehabilitation is particularly challenging (15).

Our hypothesis is that existing reporting checklists, including the CONSORT for non-pharmacological interventions (16) and the TIDieR (10), or those specifically developed for rehabilitation (17,18), do not address well enough the

issue of clinical replicability. To test this hypothesis, we developed the REplicability of RCTs in Everyday rehabilitation clinical Practice (REREP) Study. We asked representative expert PRM teams around the world to evaluate a sample of RCTs recently published in the main PRM journals (19,20). Our final aim was to verify if RCTs in rehabilitation include all the practical details needed of PICO elements to be able to clinically replicate the studied intervention in different clinical settings.

2 Methods

2.1 Design

A survey of a pre-defined sample of PRM clinical expert teams chosen to be representative of the different areas of the world and clinical rehabilitation competencies.

2.2 Participants

Two authors (SN, CK), who have worldwide knowledge of the PRM community, selected a convenience group of 10 teams including professionals from the 3 different areas of the world as defined by the International Society of PRM (ISPRM): 4 from Europe, Eastern-Mediterranean & Africa, 4 from Americas (2 North, 2 Central/South), and 2 from Asia & Oceania. The rehabilitation teams had to be multi-professional; team leaders needed to have research experience but also an everyday clinical practice; team professionals had to be clinicians working in multiple clinical rehabilitation levels of care and specialties (acute, post-acute, chronic; in/out-patients; musculoskeletal, neurological, cardio-respiratory, etc). Seven teams from Belgium, Italy, Malaysia, Pakistan, Poland, Puerto Rico, and USA agreed to participate. Three teams (Argentina, Jordan and USA) did not participate for the following reasons: 1 never answered, 2 agreed but 1 had to stop for unforeseen circumstances and 1 did not submit results in due time. The final sample included 47 individual participants: 20 PRM physicians (PRMp), 12 physiotherapists (PT), 6 occupational therapists (OT), 6 rehabilitation psychologists (PSY), and 3 others (OTH), including one psychiatrist and two speech and language therapists.

2.3 Selection of published Randomized Controlled Trials

We selected all the RCTs published between January and June 2017 by the journals defined primary by the European Society of PRM (ESPRM) according to specific criteria (19,20). We included RCTs from: American Journal of Physical Medicine and Rehabilitation (PM&R), Archives of PM&R, Clinical Rehabilitation, Disability and Rehabilitation, European Journal of PRM, International Journal of Rehabilitation Research, Journal of Rehabilitation Medicine, PM&R. We excluded the online only RCTs (not yet printed), and those consisting of secondary analysis.On December 7th, 2017 we searched all these journals in PubMed using the date filter January 1st to June 30th 2017. Out of

1349 papers we found 206 RCTs. Seventy-six were included after two independent reviewers (CA, JP) checked the full papers, with a third investigator (SN) in case of disagreement for final decision. The reasons for exclusion are listed in the PRISMA diagram (Figure 1).

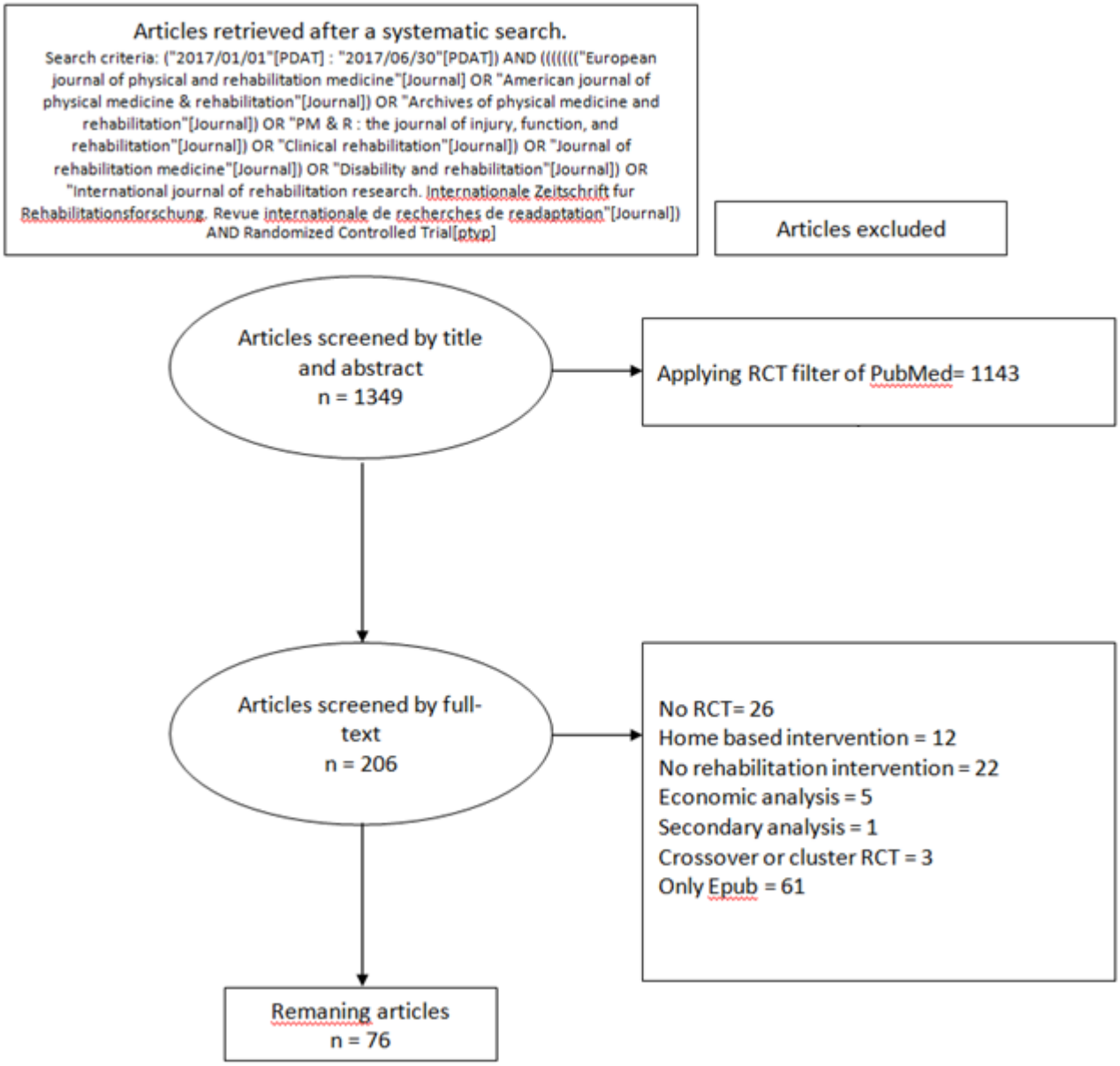

Figure 1. PRISMA diagram of RCTs selection.

2.4 The survey

The survey focused on the intervention and not on the control group or the outcomes. We prepared a first draft of the survey from TIDieR (Template for Intervention Description and Clinical replication) (6), CONSORT (16) and the validity items developed for Benchmarking Controlled Trials (21). After discussion among the main authors (SN, CA,

JP) a consensus on the preliminary questionnaire was reached. The draft was piloted and amended during 2 meetings with the Italian team analyzing 10 RCTs (Appendix 1). A final consensus was reached.

The Survey is included in Appendix 2 and resumed in Table1. It consists of 14 closed questions to 7 items: setting, participants, interventions, materials, procedures, providers and delivery. A 15th key question "do you have enough information to replicate the intervention in your clinics?" was added..

Questions		**Answers to be provided per each item and sub-item**		
Item	**Sub-items**	**Questionnaire**	**Categorization 1**	**Categorization 2**
Setting	Health Care Setting	Explicit information in	Perfect	Present
	Location	the "Methods" section		
Participants	Participants Features	complete information		
	Adherence	partial information	Imperfect	
Intervention		other sections of the paper		
Materials		complete information		
Procedures		partial information		
Provider	Provider	Implicit information		
	Skills	Absent	Absent	Absent
	Experience	Not applicable		
Delivery	Cautions			
	Relationships			
	Intervention Details			
	Order			
Clinical replicable?				

Table 1. Contents of the questionnaire: items, possible answers to be provided per each item, and categorization of answers used for the two analysis performed.

2.5 Data collection

The main author (SN) had a Webex meeting with all the team leaders to inform them about the details of the study. The RCTs were distributed to the team leaders who decided whether the RCT was appropriate for their clinical reality (i.e., could be considered according to their setting, even if the type of treatment was not actually provided). The team leaders distributed the RCTs in their team according to expertise and area of clinical practice. From this moment, the they did not have any role in data collection. Two authors (CA, JP) had a Webex Meeting with each team to review the survey and answer questions. They remained available for methodological questions by email and/or Skype calls. Data have been collected individually with a Survey Monkey filled in by each single clinician without any Consensus procedure into the different teams.

2.6 Data analysis

We categorized the answers according to Table1.

We looked at the rate of agreement of each pair of responders and the resulting kappa has been judged as follows: <0·2 poor, 0·2-0·39 fair, 0·4-0·59 moderate, 0·6-0·79 good, 0·8-1 very good. The reliability has been checked within each profession and for the two analysis. We considered all the RCTs that had at least 4 filled surveys (9 paired comparisons) by responders of the same profession and we included a maximum of 5 RCTs per profession, starting from those with more answers. We had 5 RCTs for PRMp (8, 8, 8, 7, 7 responders, corresponding to 28, 28, 28, 21, 21 pairs, respectively) and PT (7, 6, 6, 6, 6 responders, corresponding to 21, 15, 15, 15, 15 pairs), and 3 for PSY (5, 4, 4 responders, corresponding to 10, 6, 6 pairs) and OT (4, 4, 4 responders, corresponding to 6, 6, 6 pairs).

To look for differences in the difficulty of clinical replication, we also analyzed results per profession using the chi-square test. Since teams included all the professionals involved in the clinical replicability in each specific context, we also performed an analysis per team, with the aim to check if the studies could be applied in each clinical reality as a whole. Finally, we performed a content analysis of the last open question to identify possible future improvement of the "clinical replicability questionnaire".

2.7 Role of the funding source

The paper has been produced without an external funder. Each professional participated on a voluntary basis. The institutes of the participating teams had no role in study design, data collection, analysis, interpretation, and report writing . All the authors had full access to all data and had final responsibility for the decision to submit for publication.

3 Results

The general characteristics of the participants are reported in Tables 2 and 3, Appendix 3 includes all included RCTs listed per topic area.

	Median	Minimum	Maximum
Participants recruited by each team	8	3	13
Number of participants per professions recruited by each team	3	1	5
RCT analyzed by each team according to its clinical competences	56	33	66
RCT analyzed by each profession	12	2	74
Number of participants analyzing each single RCT	9.5	3	16

Table 2. Characteristics of participants and RCT analysis performed in the study.

	Muscoloskeletal	Neurological	Cardiological	Pneumological	Pediatric	Geriatric	Other
RCTs (number)	26	36	3	2	1	5	3
Belgium	26 (100%)	28 (78%)	0	2 (100%)	1 (100%)	5 (100%)	2 (66%)
Italy	14 (54%)	19 (53%)	2 (66%)	1 (50%)	0	2 (40%)	0
Malaysia	21 (81%)	33 (92%)	2 (66%)	0	1 (100%)	5 (100%)	1 (33%)

Pakistan	15 (58%)	6 (17%)	0	0	0	1 (20%)	0
Poland	23 (88%)	30 (83%)	3 (100%)	1 (50%)	1 (100%)	5 (100%)	3 (100%)
Puerto Rico	22 (85%)	27 (75%)	0	0	0	5 (100%)	2 (66%)
USA	3 (12%)	21 (58%)	0	1 (50%)	1 (100%)	2 (40%)	1 (33%)

Table 3. Clinical competences of included teams and RCTs analysed.

The response rate was 99%. The average rate of agreement was moderate (56%) and very good (80%) for the 3 (perfect, imperfect, absent) and 2 options (present, absent) analysis, respectively. Looking at the single items, we had 5 good, 9 moderate and 1 fair average rate of agreement for the 3 options analysis and 9 very good, 5 good, and 1 moderate for the 2 options (Table 4). Due to the pairs of participants contributing to the analysis, we also checked the distribution of obtained pair of agreements as reported in Table5.

		Analysis with 3 items (perfect, imperfect, absent)	**Analysis with 2 items** (present, absent)
Total		56%	80%
Setting	Health Care Setting	54%	95%
	Location	50%	88%
Participants	Participants Features	70%	95%
	Adherence	35%	65%
Intervention		55%	84%
Materials		58%	93%
Procedures		60%	90%
Provider	Provider	43%	71%
	Skills	49%	59%
	Experience	70%	71%
Delivery	Cautions	51%	60%
	Relationships	64%	67%
	Intervention Details	57%	82%
	Order	58%	80%
Clinical replicable?		64%	100%

Table 4. Rate of agreement for each item of the questionnaire according to the two possible analysis considered. Agreement of each items was verified into each profession, and included from a minimum of 6 pairs of responders (occupational therapists and psychologists) to a maximum of 28 (Physical and Rehabilitation Medicine physicians) - see main text for details. Percentages relate to mean agreement across participant pairs.

		Analysis with 3 items					**Analysis with 2 items**				
		Poor	Fair	Moderate	Good	Very good	Poor	Fair	Moderate	Good	Very good
Total				69%	31%					44%	56%
Setting	Health Care Setting		38%	38%	6%	19%			6%	6%	88%

	Location	13%	19%	38%	25%	6%		19%	13%	69%
Participants	Participants Features	6%		38%	19%	38%		6%	6%	88%
	Adherence	13%	56%	31%		0%	6%	50%	25%	19%
Intervention		6%	50%	13%		31%		19%	25%	56%
Materials		6%	19%	44%	13%	19%		6%	13%	81%
Procedures			25%	25%	38%	13%		13%	13%	75%
Provider	Provider	13%	44%	31%	6%	6%	13%	25%	25%	38%
	Skills	6%	38%	19%	38%	0%	13%	38%	44%	6%
	Experience		25%	19%	19%	38%	13%	31%	19%	38%
Delivery	Cautions	13%	31%	25%	19%	13%	19%	44%	19%	19%
	Relationships	6%	25%	13%	31%	25%	19%	19%	38%	25%
	Intervention Details	6%	19%	44%	13%	19%		31%	13%	56%
	Order	6%	38%	13%	25%	19%	13%	13%	19%	56%
Clinical replicable?			25%	38%	6%	31%				100%

Table 5. Average of rate of agreements obtained inside each single profession with the two possible analysis.

Overall, all participants considered unanimously that 12 (16%) RCTs were clinically replicable and none not replicable. Among the others, 56 (74%) RCTs have been considered replicable and 45 (59%) not replicable by at least one complete team. Looking at the single answers to our questionnaire, no study had all the information. At least one "absent" information was found by all participants in 60 RCTs (79%), and by a minimum of 85% in the remaining 16 (21%): 2 studies (3%) had 3 participants (29% of answers) who found at least one item not "absent", 4 (5%) had 2 (20% of answers), and 11 (14%) had 1 (10% of answers).

No Item reached 80% of "perfect" answers, while 4 were below 20% (Figure 2). The topics with at least 50% of "perfect" answers included: participant's characteristics (79%), materials (65%), procedures (65%), order of interventions (63%), health care setting (63%), intervention (60%), and intervention details (59%). The answers with less than 20% included: skills (19%), cautions (14%), experience (10%), and relationships (8%). The latter 4 topics were also the only topics with more than 50% of "absent": 59%, 60%, 78%, and 80% respectively. Apart from procedures (6%), health care setting (5%) and participant's characteristics (1%), all the other topics had absent information in at least 9% of the cases.

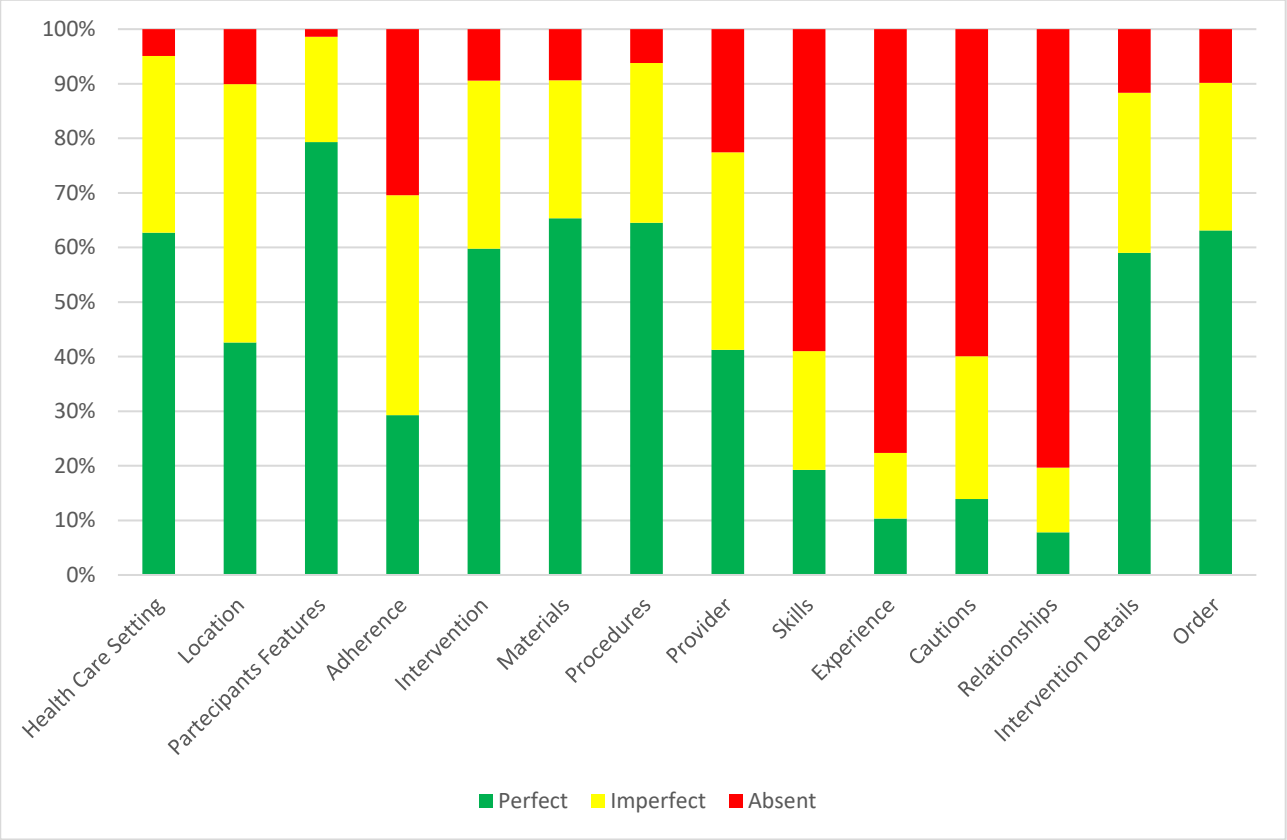

Figure 2. Answers (percentage of TRIALs) to each single item of the questionnaire. The classical methodological items present in the CONSORT checklists have the best clinical replicability, while the worst correspond to the technical description of the intervention.

There were no significant differences in the total number of answers according to profession: "perfect" ranged 36-47%, "absent" 25-30%. Looking at the single items, we did not find any difference among professions for health care setting, location, participants, adherence, provider, experience, cautions. OT showed bigger problems than all the other professionals for intervention ("absent" 22% vs a range 0-10%), materials (30% vs 8-12%), and procedures (15% vs 5-8%) ($P<0{\cdot}05$). PSY had fewer problems with intervention (0% vs 8-22%) and skills (35% vs 58-62%) ($P<0{\cdot}05$) (Figure 3).

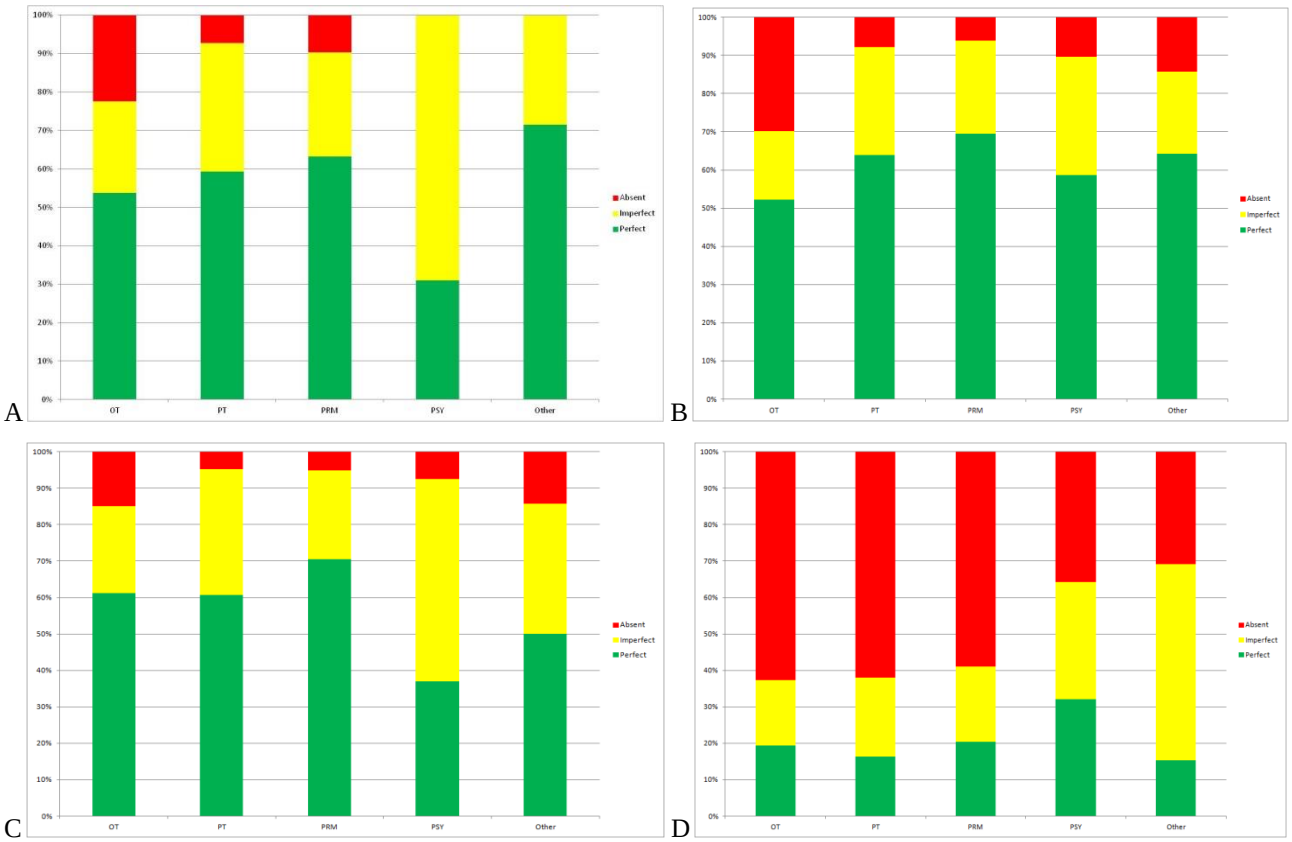

Figure 3. Answers to the questionnaire for different professionals: A. intervention; B. materials C. procedures; D. skills. Statistically significant differences from the other professionals have been shown with difficulties of OTs for intervention, materials, and procedures, while PSY showed less problems with intervention and skills. OT: Occupational Therapists (41 RCT analysed); PT: Physical Therapists (72 RCT analysed); PRMp: PRM physicians (74 RCT analysed); PSY: rehabilitation psychologists (11 RCT analysed); OTH: others (14 RCT analysed).

The open question did not suggest any new item for the questionnaire: we had 644 (92%) nothing is missing, 38 (5%) no answers, and 18 (3%) complaining the need to check other papers (protocol).

4 Discussion

This REREP study tested the hypothesis that the existing reporting checklists for RCT's do not solve the issue of clinical replicability in a clinical setting. In the present study, RCTs were considered not clinically replicable by as many as 31% of the expert participants. The specific areas in the methods and materials section that were rated the lowest included provider (skills and experience) and delivery items (cautions and relationships). On the contrary, best described areas were those included in the classical methodological checklists including participants characteristics, materials, procedures, health care setting, intervention, and 2 of the delivery items (order and intervention details).

The Agency for Healthcare Research and Quality developed a methods guide on "Assessing the applicability of Studies when comparing medical interventions" (1). The guide states that the applicability of a study should be judged separately for different outcomes, it depends on context and cannot be assessed with a universal rating system, and it is best reported separately from the strength of the evidence. These recommendations, however, do not apply to our results showing that clinical replicability differs from applicability. The characteristics of individual studies listed in a PICOS

framework by these guidelines are relevant. However, those characteristics have been framed from the perspective of judging studies from a methodological point of view and not from the perspective of evaluating the descriptions provided in the published reports that are needed to apply treatments in clinics. This is perhaps a subtle difference, but it is also substantial.

A study similar to ours compared RCTs to observational trials using four orthopedic surgical procedures (22). The authors considered 34 factors, grouped in 7 items: clinical characteristics of patients, setting and centre, generic items selected for all interventions, items selected for minimally invasive or computer assisted navigation procedures, blood loss and postoperative pain management protocol. These items are similar but not fully comparable to ours, due to the specific differences in setting (1) and the reduced complexity of the intervention. The lowest absolute results (<20% of prevalence of the item in the considered studies) were found for preoperative pain, deformity and comorbidities, centers' surgical volume, information provided to patients, preoperative care, protocols for thromboprophylaxis, antibiotic prophylaxis and postoperative pain management, characteristics of navigation system (open or closed), and blood loss. These results from orthopedic surgery studies confirm the problems inherent to protocol descriptions (like in rehabilitation), as well as our results for provider (skills and experience) and delivery items (cautions and relationships).

Another study (23) of knee arthroscopy used the benchmarking method, which we also considered while developing our survey (21) but approached the question from a methodological and an epidemiological perspective. The author considered 25 factors grouped in 5 items: selection of patients/population to the study, completeness of baseline data, process data, outcome data, statistical analysis. The study showed deficiencies in reporting of baseline characteristics and adherence to interventions. The same author, using the same method, looked at all RCTs published in the British Medical Journal (BMJ), the Journal of the American Medical Association (JAMA), the Lancet, and the New England Journal of Medicine (NEJM) in the first 9 months of 2017 (24) and found deficits in describing patients' path prior to randomization, health care settings, environmental factors, and co-interventions. Even though different methodologies were used, these papers confirm the deficiencies we found in some specific areas in our study.

The limitations of our study include the possible lack of representativeness of our sample of RCTs. However, there was a good correlation among the different teams from countries that are clearly different in terms of gross income, health services, culture, and rehabilitation approach and systems. In addition, the differences between different professionals' answers were small. Although our results may not be applicable to other medical specialties and/or other complex interventions, they are similar to some of the findings reported by others (1). We limited our sample of RCTs to the main PRM journals so we could study the specific competences of rehabilitation reviewers to identify clinical replicability. However, more general journals present similar problems (24). Finally, in the analysis at 3 items we had a

low agreement among responders. In our view this is not highly relevant, since the low agreement could be explained by individual different approaches to where the information should be provided in the paper.

As a group of clinicians, including three Editors-in-Chief of clinical rehabilitation journals, we felt the need to introduce in this study the concept of *clinical replicability*, defined as "the accurate description in published reports of clinical studies of all details needed to apply the intervention in everyday clinical practice". The clinical replicability could be used to identify the quality of description of PICO, which represents the main elements of the real world evidence (3) and it could allow a better applicability of the intervention in different clinical settings. Therefore, clinical replicability is not reproducibility or replicability, since it does not refer to research but to clinics. It is not applicability (external validity or generalizability), that is much wider and include methodological and conducting issues, even if it could be interpreted as the part referring to reporting. Clinical replicability is not a single reporting issue, but a concept that should inform reporting. Conceptualizing clinical replicability as an independent issue could serve epidemiologist and methodologist to better focus the needs of clinicians. A good example of a checklist developed for clinical replicability is the TIDieR (6). Although this informed part of the present study it proved to be incomplete for rehabilitation research. In our opinion, clinical replicability should be highly context specific and should inform specific checklists like those for rehabilitation (17,18).

5 Conclusions

This study shows that there are problems in the clinical replicability of published RCTs in everyday clinical practice when complex interventions as exemplified by rehabilitation interventions are tested. These problems can be identified by all rehabilitation professionals involved in the team. The areas with the least problems of clinical replicability are those generally better described by classic methodological checklists like CONSORT. Conversely, more significant problems were found in the topics related to the human factors (typical of rehabilitation, but not only) like skills, experience, and relationships. Unfortunately, also the item "cautions" revealed important problems. The results of the present study suggest the need for specific guidelines to improve clinical replicability of RCTs in rehabilitation. This specific case-study should be extended to other fields to verify the generalizability of our results.

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Appendix 1 Items adapted or amended from TIDieR and CONSORT checklists

TIDieR	CONSORT	Survey	
	Participants 4b Settings and locations where the data were collected	Setting	Health Care Setting
7. Type and locations			Location
	Participants 4a Eligibility criteria for participants	Participants	Features
11. How well planned/ 12. How well actual			Adherence
6. How / 9. Tailoring		Interventions	Type of treatment
3. What Materials used		Materials	Tools used
4. What Procedures / 8. When		Procedures	How to use tools and/or procedures
5. Who Provided (expertise, background and any specific training)		Providers	Provider
			Skills
			Experience
		Delivery	Cautions
			Relationships
8. How Much	Interventions 5 The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		Intervention Details
			Order of

			Interventions

Appendix 2 - the survey

The instructions for the final survey were: “The aim is to verify whether you could exactly clinical replicate the experimental intervention (not the control group) in the daily clinical practice of your structure. For this reason, please check if you can find in the paper all the needed information, either formally explicated and/or implicitly understandable. Please, focus particularly on Methods section, but look also at the whole paper. Please sign “absence of information” if you can’t get the information.”

The final survey asked if “Information on the following topics is sufficiently described to be able to clinical replicate the experimental intervention in everyday clinics”:

1. Setting
    a. Health Care Setting: Inpatient (acute/subacute) / outpatient / community etc
    b. Location: Places (gym, office, open space…)
2. Participants
    a. Features: Clinical features
    b. Adherence: Minimal adherence required
3. Interventions: Type of treatment: individual, collective, individualized in groups (with minimum and maximum number of participants)
4. Materials: *Tools used*
5. Procedures: How to use tools and/or procedures: times, setting and positions
6. Providers
    a. Provider: Operators: type and number
    b. Skills: Skills and/or: specific training needed
    c. Experience: Needed work experience to apply treatment: time and duration
7. Delivery
    a. Cautions: Cautions and/or safety procedures – Patients’ problems
    b. Relationships: Interpersonal problems management (e.g. between therapists, patients/therapist, team)
    c. Intervention Details: Interventions described in details (e.g. times, repetitions, resting time)
    d. Order of Interventions: *Order of interventions*
8. In general: do you have enough information to clinical replicate the intervention?
9. Finally free space was left to add any other reasons for eventual not clinical replicability

For each question it was asked if the information was:

1. Explicit information found in
    a. “Methods” section
        i. Complete Information
        ii. Partial Information
    b. Other section
        i. Complete Information
        ii. Partial Information
2. Implicit information (I can understand it even if not explicitly reported)
3. Absent
4. Not clinically replicable

Appendix 3. Included RCTs listed per topic area

TOPIC	REFERENCE
Cardiological	Clark IN, Baker FA, Peiris CL, Shoebridge G, Taylor NF. Participant-selected music and physical activity in older adults following cardiac rehabilitation: a randomized controlled trial. Clin Rehabil. 2017 Mar;31(3):329–39.
	Carvalho L de A, Brandao DC, Campos SL, Vidal TM de S, Remigio MI, Martins SM, et al. Noninvasive Ventilation Before Maximum Exercise Test Increases Exercise Tolerance in Subjects With Heart Failure: A Crossover Study. Arch Phys Med Rehabil. 2017 May;98(5):849–55.
	Maldonado-Martin S, Brubaker PH, Eggebeen J, Stewart KP, Kitzman DW. Association Between 6-Minute Walk Test Distance and Objective Variables of Functional Capacity After Exercise Training in Elderly Heart Failure Patients With Preserved Ejection Fraction: A Randomized Exercise Trial. Arch Phys Med Rehabil. 2017 Mar;98(3):600–3.
Geriatric	Chen M-C, Chen K-M, Chang C-L, Chang Y-H, Cheng Y-Y, Huang H-T. Elastic Band Exercises Improved Activities of Daily Living and Functional Fitness of Wheelchair-bound Older Adults with Cognitive Impairment: A Cluster Randomized Controlled Trial. Am J Phys Med Rehabil. 2016;95(11):789–99.
	Halvarsson A, Oddsson L, Franzén E, Ståhle A. Long-term effects of a progressive and specific balance-training programme with multi-task exercises for older adults with osteoporosis: a randomized controlled study. Clin Rehabil. 2016 Nov;30(11):1049–59.
	Miko I, Szerb I, Szerb A, Poor G. Effectiveness of balance training programme in reducing the frequency of falling in established osteoporotic women: a randomized controlled trial. Clin Rehabil. 2017 Feb;31(2):217–24.
	Sousa N, Mendes R, Silva A, Oliveira J. Combined exercise is more effective than aerobic exercise in the improvement of fall risk factors: a randomized controlled trial in community-dwelling older men. Clin Rehabil. 2017 Apr;31(4):478–86.
	Tseng S-Y, Hsu P-S, Lai C-L, Liao W-C, Lee M-C, Wang C-H. Effect of Two Frequencies of

	Whole-Body Vibration Training on Balance and Flexibility of the Elderly: A Randomized Controlled Trial. Am J Phys Med Rehabil. 2016;95(10):730–7.
Muscoloskeletal	Albornoz-Cabello M, Maya-Martin J, Dominguez-Maldonado G, Espejo-Antunez L, Heredia-Rizo AM. Effect of interferential current therapy on pain perception and disability level in subjects with chronic low back pain: a randomized controlled trial. Clin Rehabil. 2017 Feb;31(2):242–9.
	Andersen LN, Juul-Kristensen B, Sørensen TL, Herborg LG, Roessler KK, Søgaard K. Longer term follow-up on effects of Tailored Physical Activity or Chronic Pain Self-Management Programme on return-to-work: A randomized controlled trial. J Rehabil Med. 2016 Nov 11;48(10):887–92.
	Artz N, Dixon S, Wylde V, Marques E, Beswick AD, Lenguerrand E, et al. Comparison of group-based outpatient physiotherapy with usual care after total knee replacement: a feasibility study for a randomized controlled trial. Clin Rehabil. 2017 Apr;31(4):487–99.
	Bayon-Calatayud M, Benavente-Valdepeñas AM, Del Prado Vazquez-Muñoz M. Mirror therapy for distal radial fractures: A pilot randomized controlled study. J Rehabil Med. 2016 Oct 12;48(9):829–32.
	Capan N, Esmaeilzadeh S, Oral A, Basoglu C, Karan A, Sindel D. Radial Extracorporeal Shock Wave Therapy Is Not More Effective Than Placebo in the Management of Lateral Epicondylitis: A Double-Blind, Randomized, Placebo-Controlled Trial. Am J Phys Med Rehabil. 2016;95(7):495–506.
	Dissanayaka TD, Pallegama RW, Suraweera HJ, Johnson MI, Kariyawasam AP. Comparison of the Effectiveness of Transcutaneous Electrical Nerve Stimulation and Interferential Therapy on the Upper Trapezius in Myofascial Pain Syndrome: A Randomized Controlled Study. Am J Phys Med Rehabil. 2016;95(9):663–72.
	Eid MAM, Aly SM, El-Shamy SM. Effect of Electromyographic Biofeedback Training on Pain, Quadriceps Muscle Strength, and Functional Ability in Juvenile Rheumatoid Arthritis. Am J Phys Med Rehabil. 2016;95(12):921–30.

	Emilson C, Demmelmaier I, Bergman S, Lindberg P, Denison E, Asenlof P. A 10-year follow-up of tailored behavioural treatment and exercise-based physiotherapy for persistent musculoskeletal pain. Clin Rehabil. 2017 Feb;31(2):186–96.
	Ferragut-Garcias A, Plaza-Manzano G, Rodriguez-Blanco C, Velasco-Roldan O, Pecos-Martin D, Oliva-Pascual-Vaca J, et al. Effectiveness of a Treatment Involving Soft Tissue Techniques and/or Neural Mobilization Techniques in the Management of Tension-Type Headache: A Randomized Controlled Trial. Arch Phys Med Rehabil. 2017 Feb;98(2):211-219.e2.
	Fleckenstein J, Friton M, Himmelreich H, Banzer W. Effect of a Single Administration of Focused Extracorporeal Shock Wave in the Relief of Delayed-Onset Muscle Soreness: Results of a Partially Blinded Randomized Controlled Trial. Arch Phys Med Rehabil. 2017 May;98(5):923–30.
	Franco KM, Franco YDS, Oliveira NB de, Miyamoto GC, Santos MO, Liebano RE, et al. Is Interferential Current Before Pilates Exercises More Effective Than Placebo in Patients With Chronic Nonspecific Low Back Pain?: A Randomized Controlled Trial. Arch Phys Med Rehabil. 2017 Feb;98(2):320–8.
	Guo Y-H, Kuan T-S, Chen K-L, Lien W-C, Hsieh P-C, Hsieh I-C, et al. Comparison Between Steroid and 2 Different Sites of Botulinum Toxin Injection in the Treatment of Lateral Epicondylalgia: A Randomized, Double-Blind, Active Drug-Controlled Pilot Study. Arch Phys Med Rehabil. 2017 Jan;98(1):36–42.
	Jorgensen PB, Bogh SB, Kierkegaard S, Sorensen H, Odgaard A, Soballe K, et al. The efficacy of early initiated, supervised, progressive resistance training compared to unsupervised, home-based exercise after unicompartmental knee arthroplasty: a single-blinded randomized controlled trial. Clin Rehabil. 2017 Jan;31(1):61–70.
	Lahtinen A, Leppilahti J, Vahanikkila H, Harmainen S, Koistinen P, Rissanen P, et al. Costs after hip fracture in independently living patients: a randomised comparison of three rehabilitation modalities. Clin Rehabil. 2017 May;31(5):672–85.
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	Moustafa IM, Diab AA, Harrison DE. The effect of normalizing the sagittal cervical configuration on dizziness, neck pain, and cervicocephalic kinesthetic sensibility: a 1-year randomized controlled study. Eur J Phys Rehabil Med. 2017 Feb;53(1):57–71.
	O'Halloran PD, Shields N, Blackstock F, Wintle E, Taylor NF. Motivational interviewing increases physical activity and self-efficacy in people living in the community after hip fracture: a randomized controlled trial. Clin Rehabil. 2016 Nov;30(11):1108–19.
	Pistone EM, Laudani L, Camillieri G, Di Cagno A, Tomassi G, Macaluso A, et al. Effects of early whole-body vibration treatment on knee neuromuscular function and postural control after anterior cruciate ligament reconstruction: A randomized controlled trial. J Rehabil Med. 2016 Nov 11;48(10):880–6.
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	Wang P, Yang L, Liu C, Wei X, Yang X, Zhou Y, et al. Effects of Whole Body Vibration Exercise associated with Quadriceps Resistance Exercise on functioning and quality of life in patients with knee osteoarthritis: a randomized controlled trial. Clin Rehabil. 2016 Nov;30(11):1074–87.
Neurological	Ada L, Foongchomcheay A, Langhammer B, Preston E, Stanton R, Robinson J, et al. Lap-tray and triangular sling are no more effective than a hemi-sling in preventing shoulder subluxation in those at risk early after stroke: a randomized trial. Eur J Phys Rehabil Med. 2017 Feb;53(1):41–8.
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Other	El-Shamy SM, Abdelaal AAM. WalkAide Efficacy on Gait and Energy Expenditure in Children with Hemiplegic Cerebral Palsy: A Randomized Controlled Trial. Am J Phys Med Rehabil. 2016;95(9):629–38.

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