



Replicability of RCTs in Everyday PRM Clinics – the REREP Study

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Trusted evidence.
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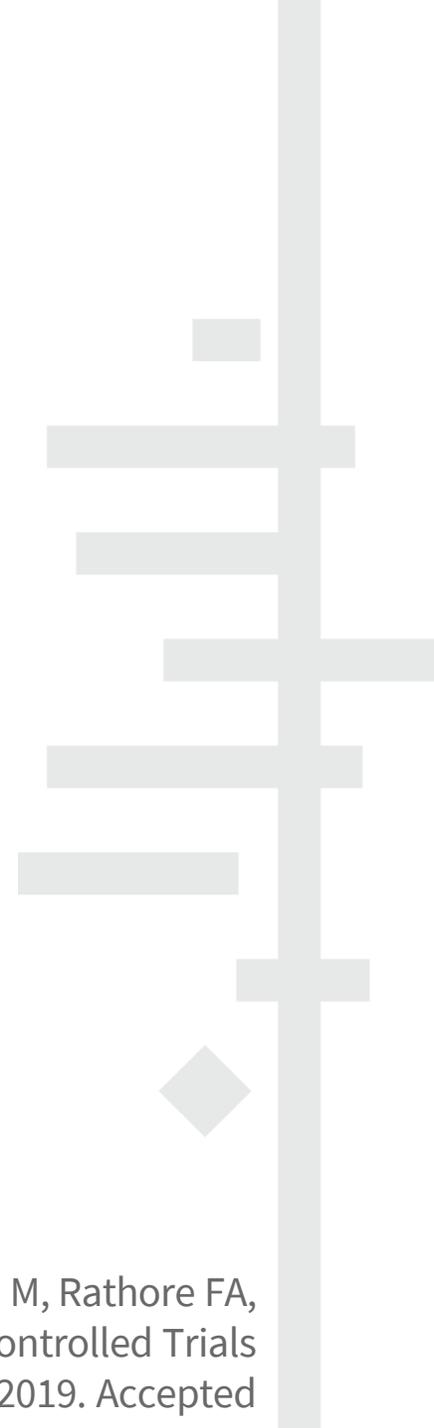
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Negrini S, Arienti C, Pollet J, Engkasan JP, Francisco GE, Frontera Roura W, Galeri S, Gworys K, Kujawa J, Mazlan M, Rathore FA, Schillebeeckx F, Kiekens C, REREP study participants. Clinical replicability of rehabilitation interventions in Randomized Controlled Trials reported in main journals was inadequate. J. Clin Epidemiol 2019. Accepted



Introduction

Human and technical factors make research in PRM challenging, but there are two sides:

- Methodological problems of research
- Application of research results in everyday PRM clinics

Material and Methods section of a research paper should contain all the information to allow replicability

Some definitions

Applicability (external validity or **generalizability**)

- The extent to which the **effects** observed in studies reflect the expected results of an intervention in “**real-world**” **conditions**

Reproducibility

- The replication of results by re-performing the same analysis of the **same data** by a **different analyst**

Replicability

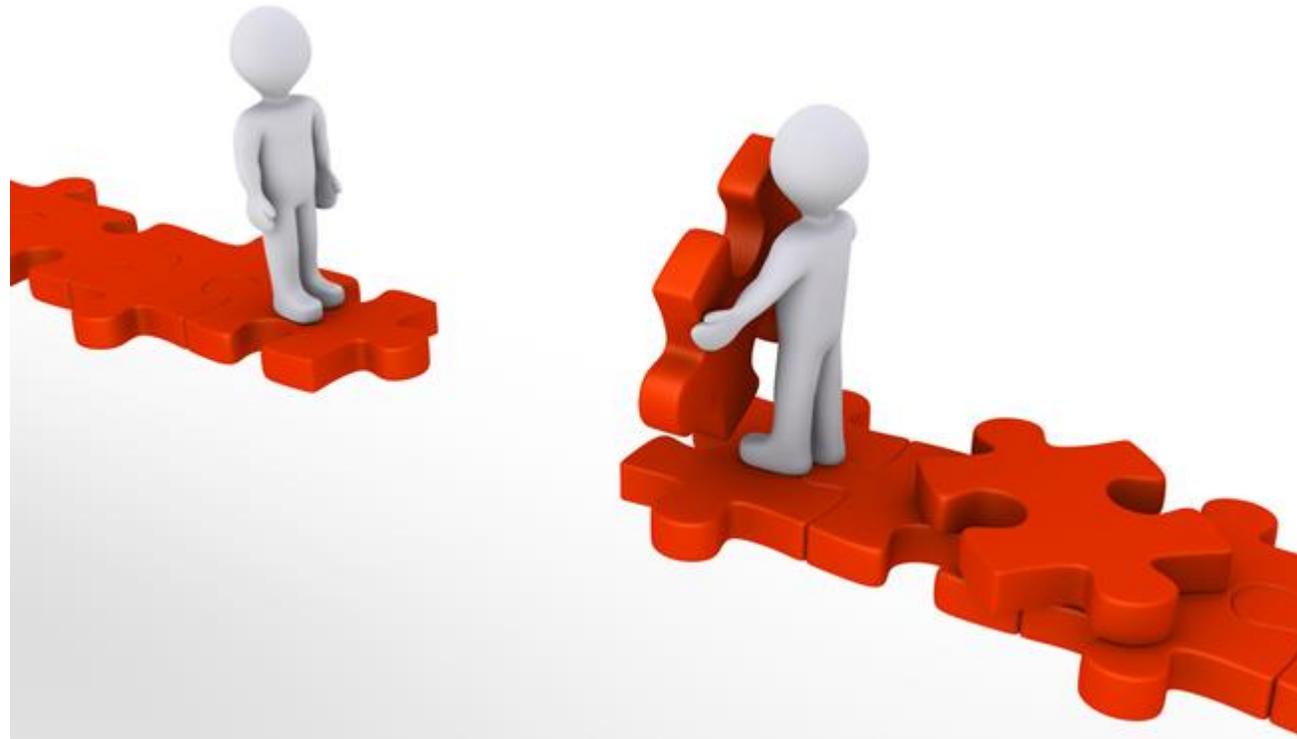
- The replication of results by **re-performing of the experiment** collecting **new data**

Clinical replicability

- The accurate description in published reports of clinical studies of all details needed to **apply the intervention in everyday clinical practice**

Question

Does Randomized Controlled Trials in rehabilitation include all **practical details** needed to be able to **replicate the intervention** in everyday clinics ?

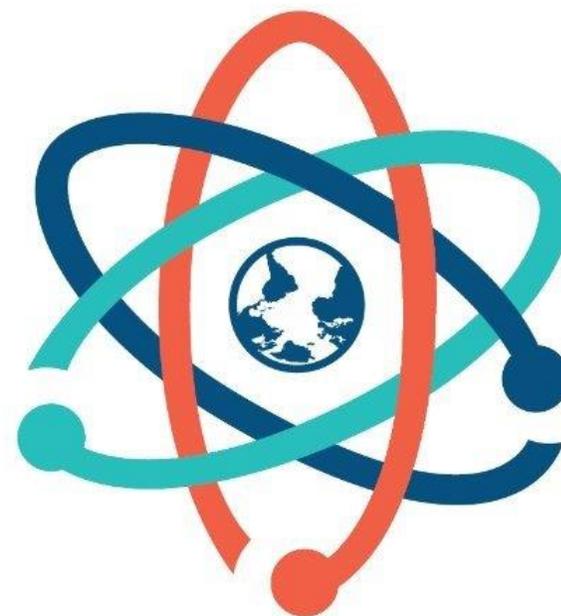




Scientific world (RCTs)

Inclusion of all RCTs published in the last 6 months of 2016 in top PRM journals (Franchignoni 2011, 2016)

- Inclusion:
 - American Journal of Physical Medicine and Rehabilitation
 - Archives of Physical Medicine and Rehabilitation
 - Clinical Rehabilitation
 - Disability and Rehabilitation
 - European Journal of Physical and Rehabilitation Medicine
 - International Journal of Rehabilitation Research
 - Journal of Rehabilitation Medicine
 - PM&R
- Exclusion: e-pub, secondary analysis





Clinical world

Clinical teams

- Different clinical PRM fields (acute, post-acute, chronic; in/out-patients; musculoskeletal, neurological, cardiorespiratory, etc)
- All rehabilitation professionals of that area in their region of the world

10 teams invited from all over the world

- Europe (Belgium, Italy, Poland)
- Americas (Argentina, Puerto Rico, 2 USA)
- Others (Jordan, Malaysia, Pakistan)

Project leader with research experience



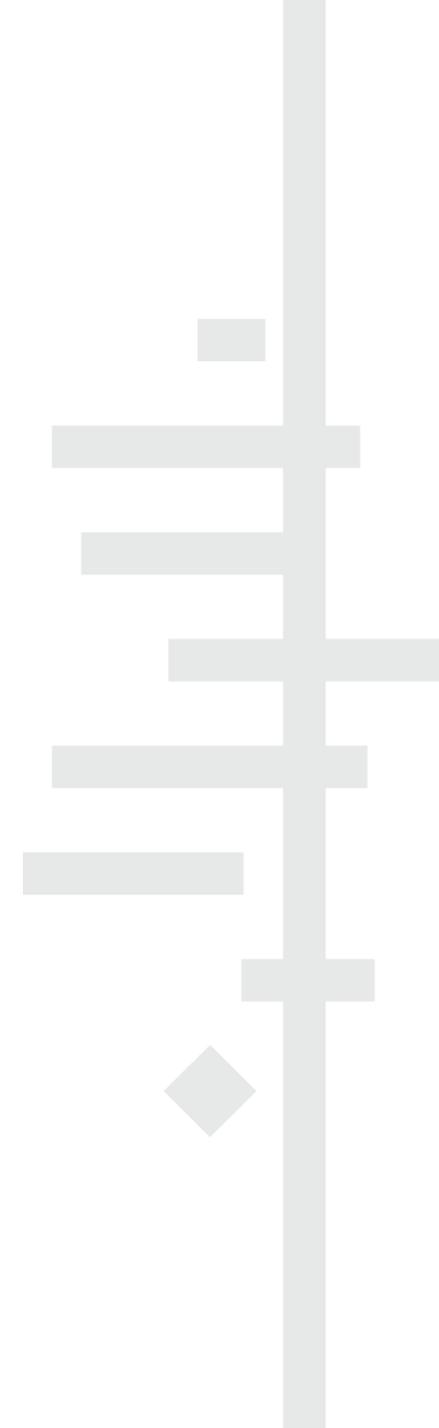
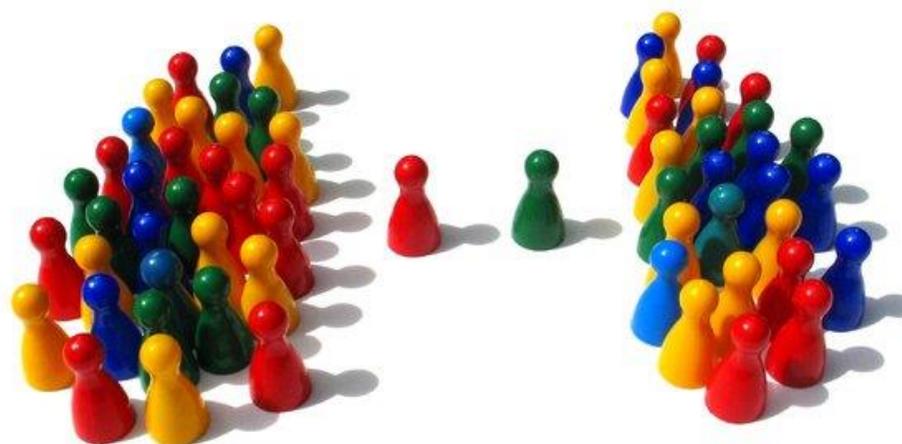
Studies and participants

Research world: 149 RCTs

- 77 included (72 not RCTs or economical/secondary analysis)

Clinical world: 10 PRM teams

- 7 included (2 did not answer, 1 dropped due to unforeseen circumstances)
- 47 individuals:
 - 20 PRM physicians (PRMp)
 - 12 physiotherapists (PT)
 - 6 occupational therapists (OT)
 - 6 rehabilitation psychologists (PSY)
 - 3 others (OTH).





Clinical team work

Project leader

- Is the study appropriate for your clinical reality?
- Which professionals work on the field of each RCT in your clinical reality?

Cochrane
Rehabilitation

- List of professionals with emails to be contacted

Professionals

- SurveyMonkey questionnaire



Preparation of the survey

First data
card

- TIDieR (Template for Intervention Description and Replication)
- CONSORT

Piloting

- 2 meetings with the Italian team
- Discussion of RCTs and identification of problems

Result

- Final data card for the Survey Monkey



Data collection

Webex Meeting with **project leaders** (Stefano Negrini)

- Distribution of the RCTs (Dropbox)
- Distribution of an Excel file for the answers for each RCT

1 Webex Meeting with **each team** (Chiara Arienti, Joel Pollet)

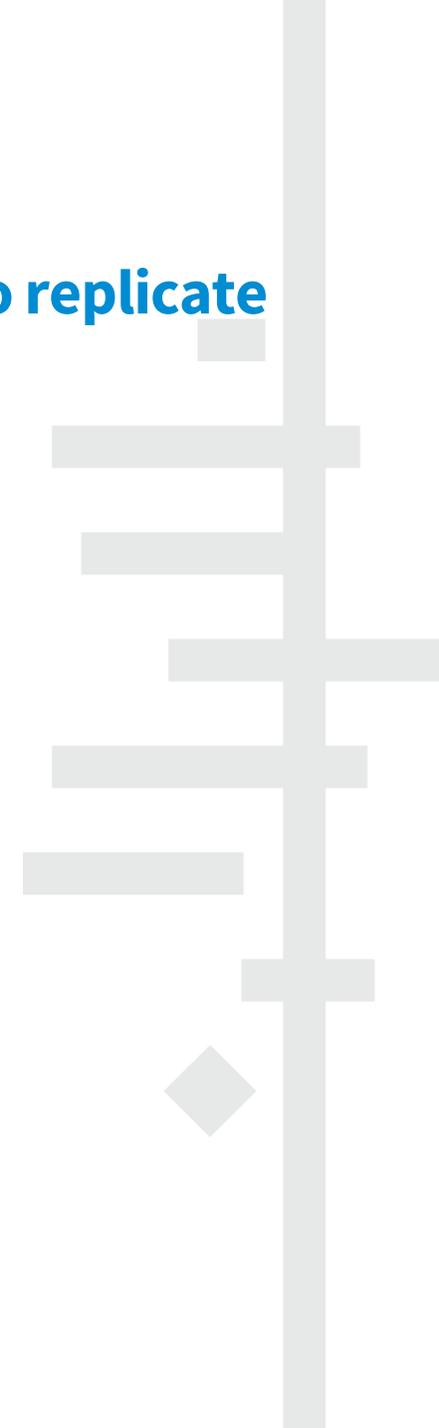
- Trial of the survey until understood the mechanisms
- Individual SurveyMonkey for each RCTs

Questions answered by email and skype calls to single participants/teams



Information on the following topics are sufficiently described to be able to replicate the experimental intervention in everyday clinics

1. Setting and places
2. Participants
3. Interventions
4. Materials
5. Procedures
6. Provider: number, skills, education, experience
7. Delivery: operator(s), team management, cautions, details and order of interventions
8. Bottom line question: Do you have enough information to replicate the intervention?



Information reported

Perfect if found in:

- “Methods” section: Complete Information
 - Partial Information

Imperfect if found in:

- “Methods” section: Partial Information
- Other sections: Complete or Partial Information)
- Implicit information

Absent

Not applicable



Statistics

Analysis in the total of answers and on single items

Percentage of agreement

- to check reliability of the questionnaire
- random stratified selection on all the RCTs that had at least 4 answers by responders of the same profession
- 5 RCTs for PRMp and PT, 3 for PSY and OT

Chi-square test

- to see if there were differences among professions in the eventual difficulty of application





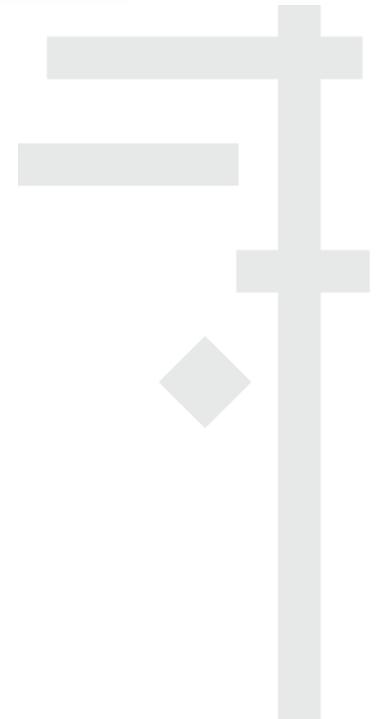
Reliability of the questionnaire

All answers in the questionnaire

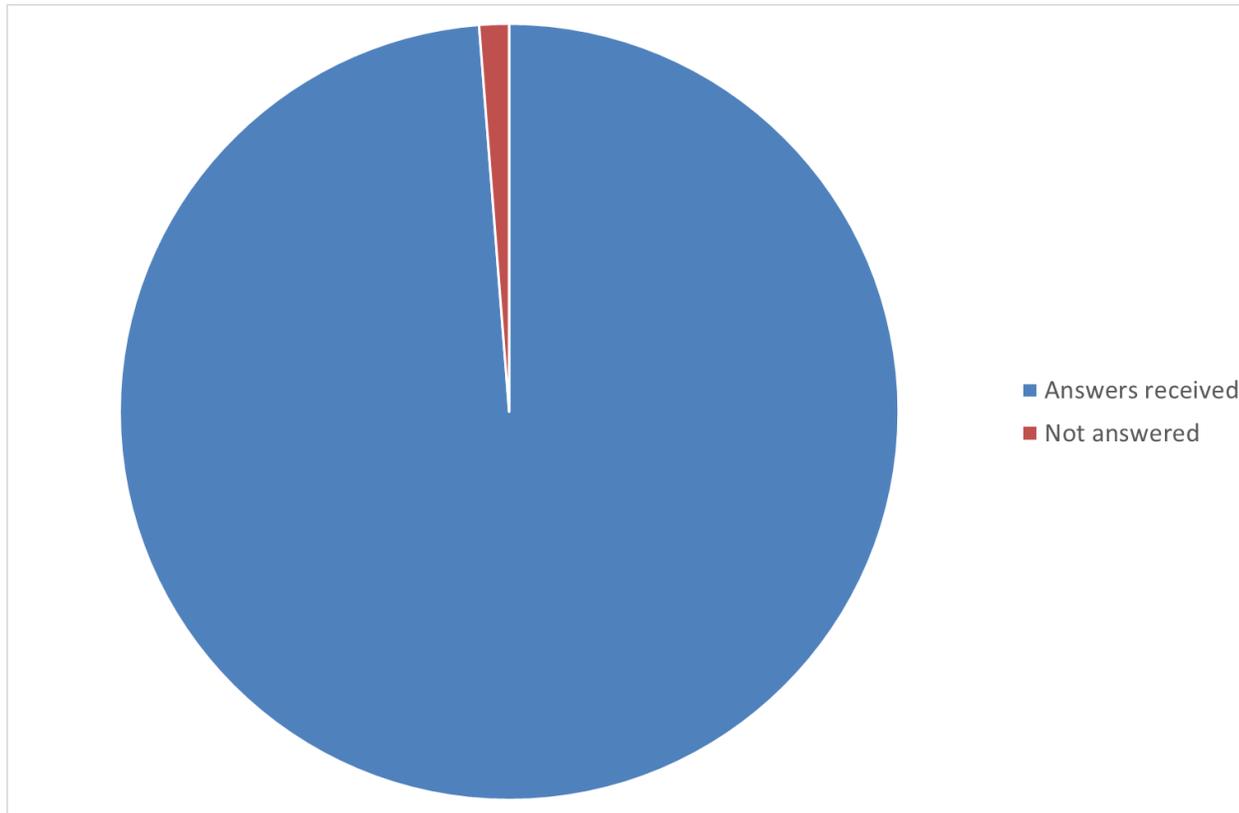
- analysis with 3 answers (perfect, imperfect, absent): Moderate (56%)
- analysis with 2 answers (present, absent): Very Good (80%)

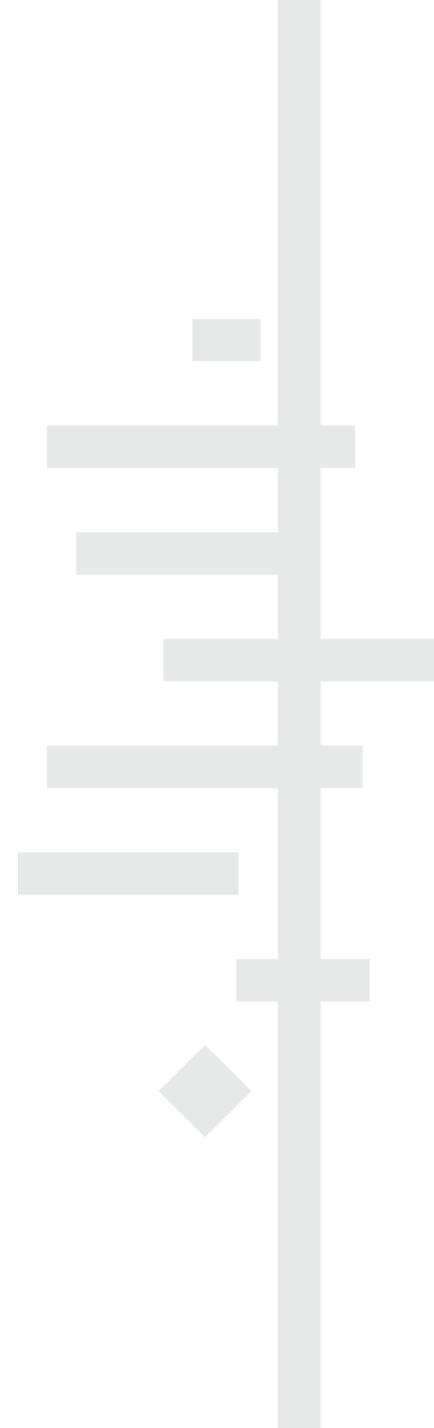
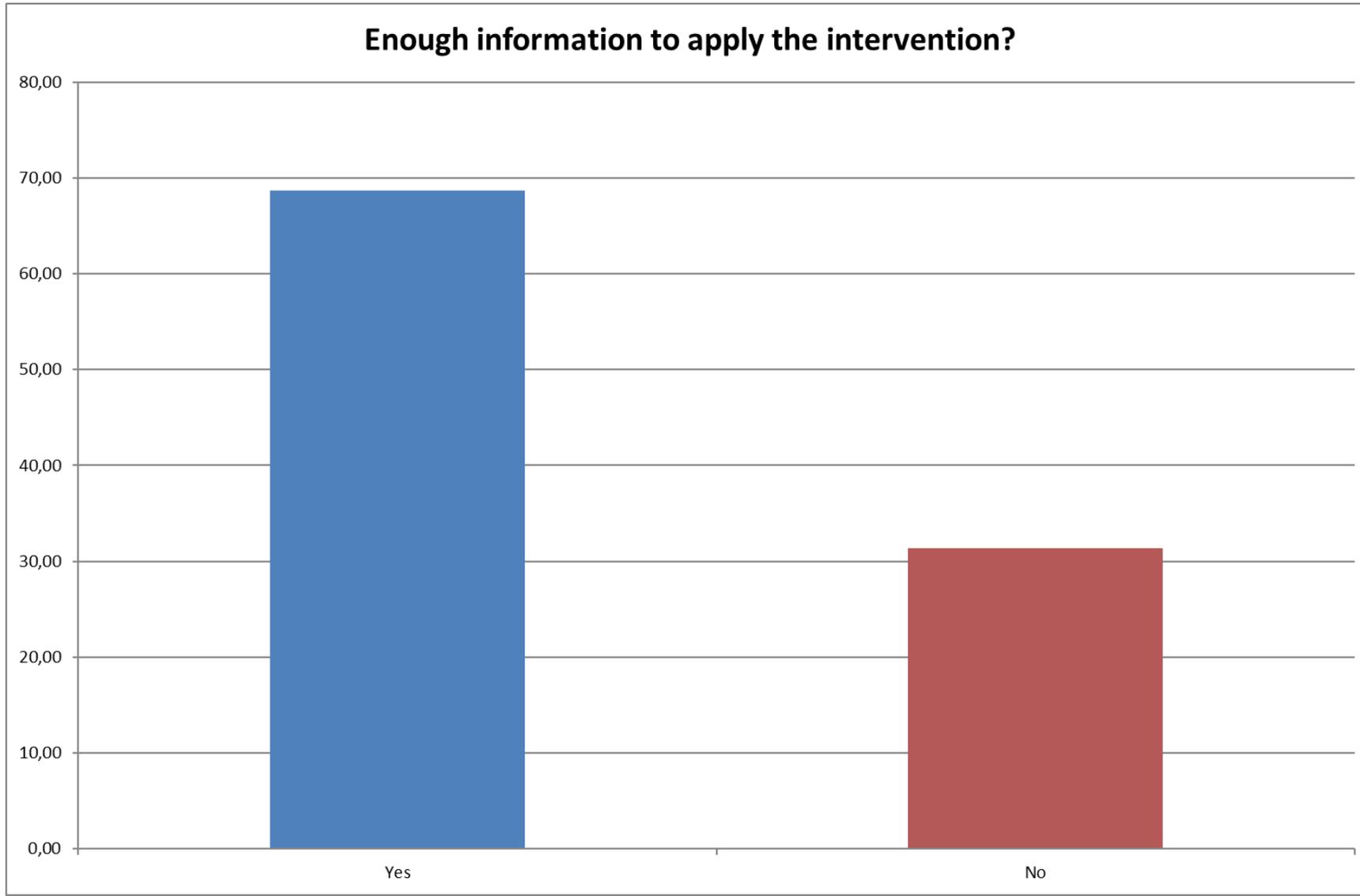
Single Items

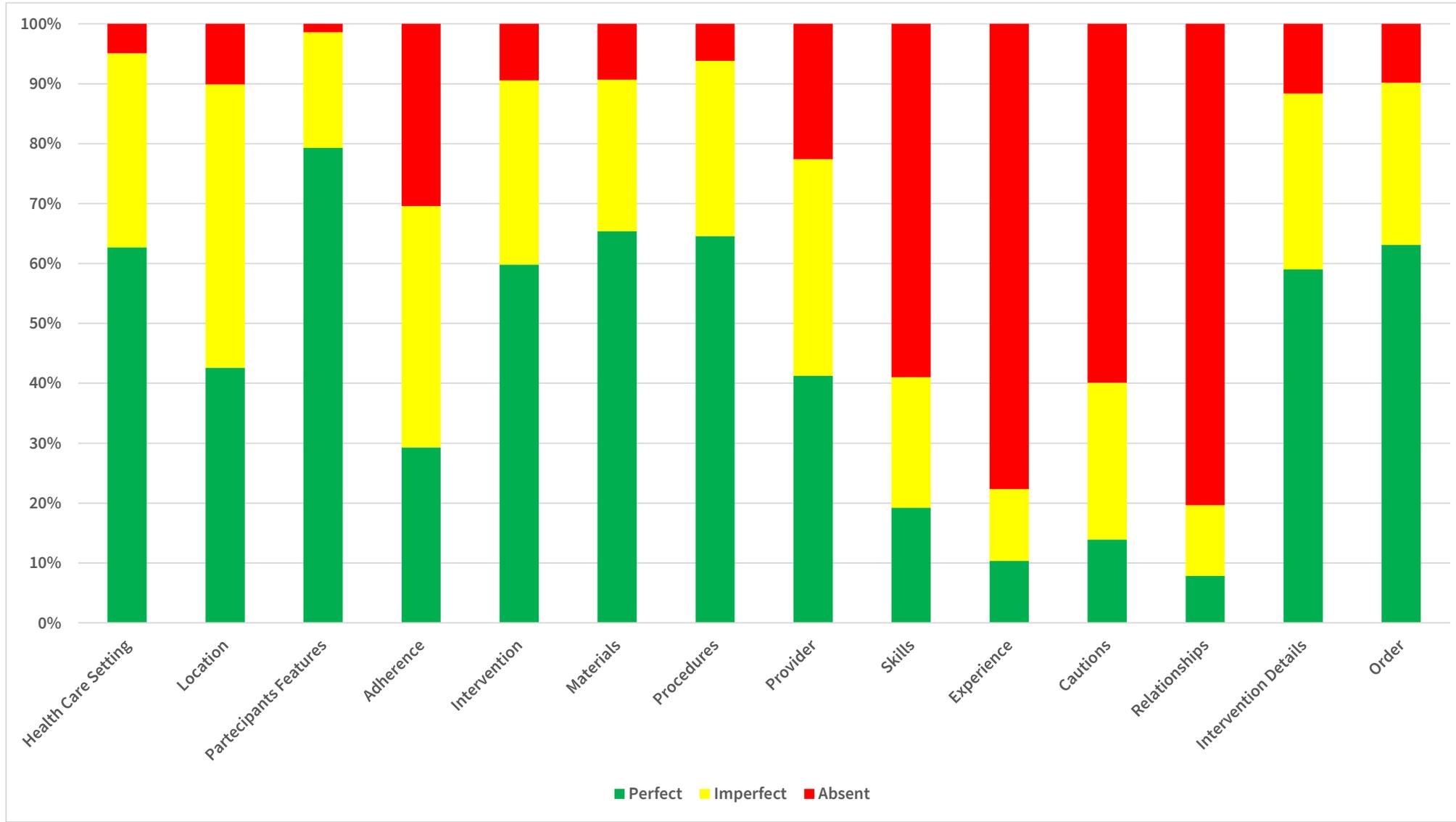
- analysis with 3 answers (perfect, imperfect, absent): 5 Good, 9 Moderate and 1 Fair
- analysis with 2 answers (present, absent): 9 Very Good, 5 Good, and 1 Moderate



Rate of answers: 98.77%



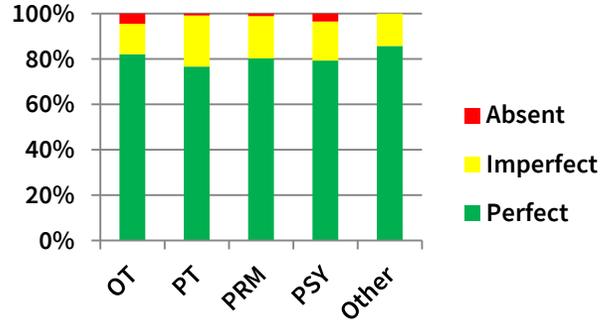




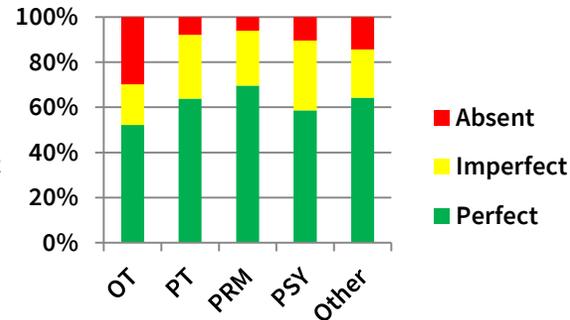


Areas well covered

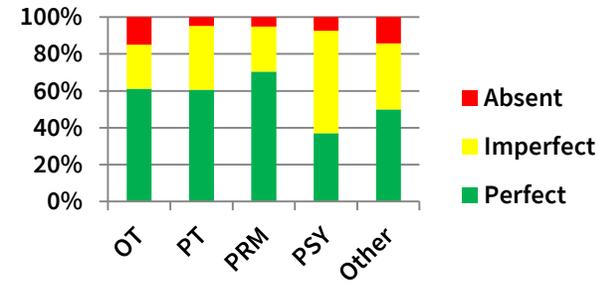
Participant Features



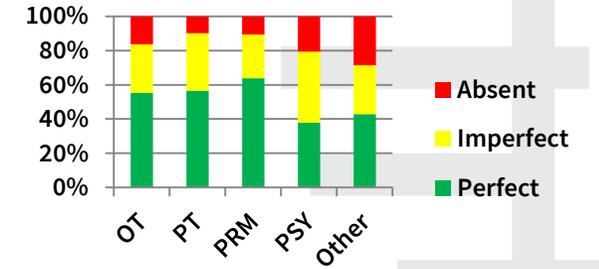
Materials



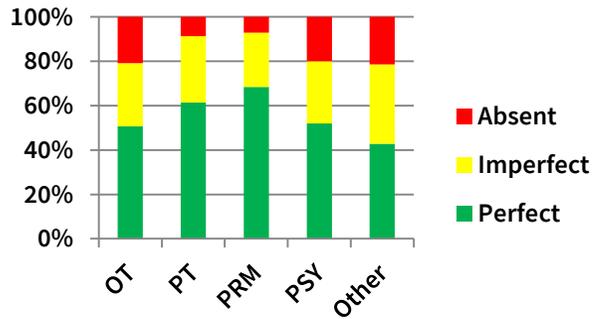
Procedures



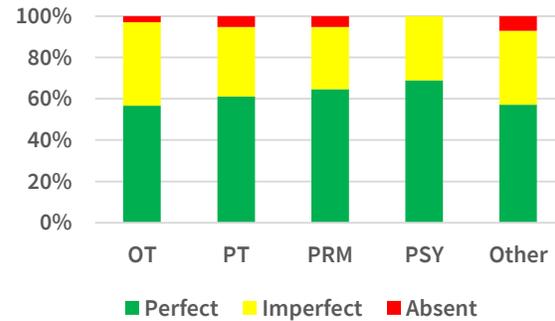
Intervention Details



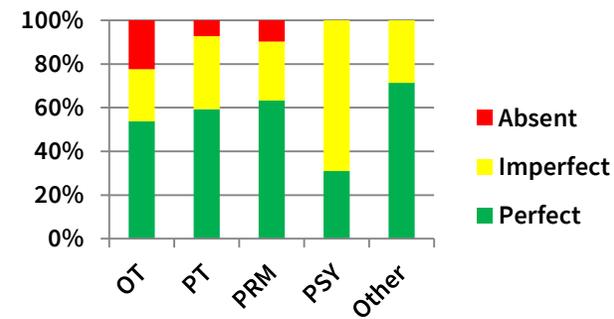
Order



Health Care Setting



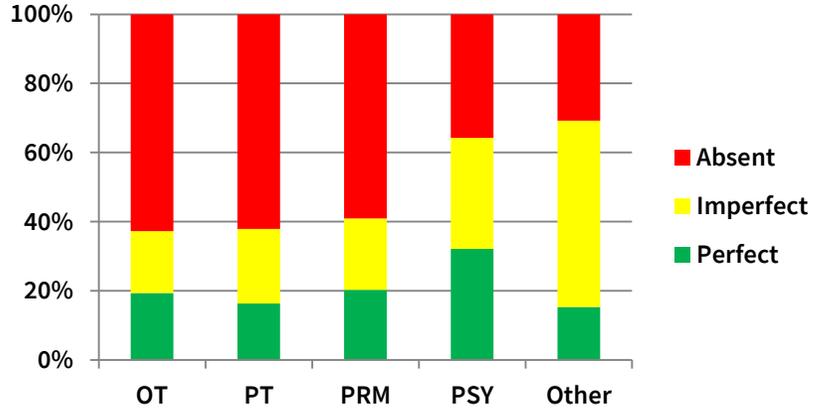
Intervention



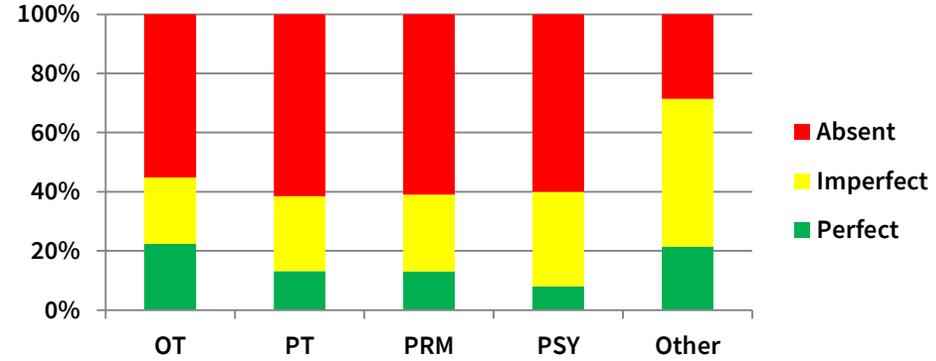


Areas badly covered

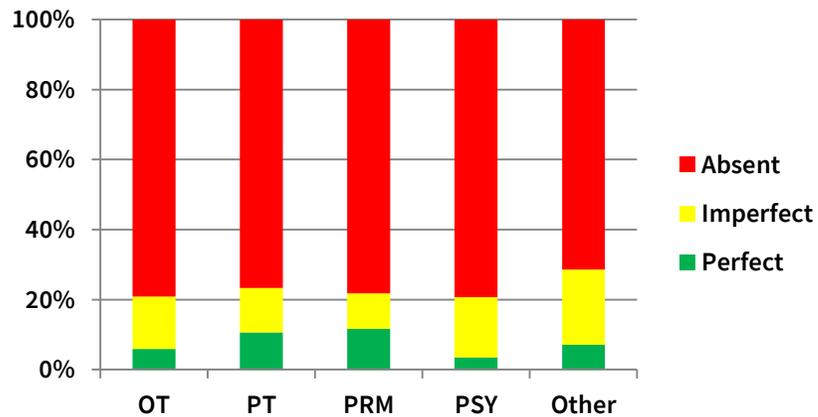
Skills



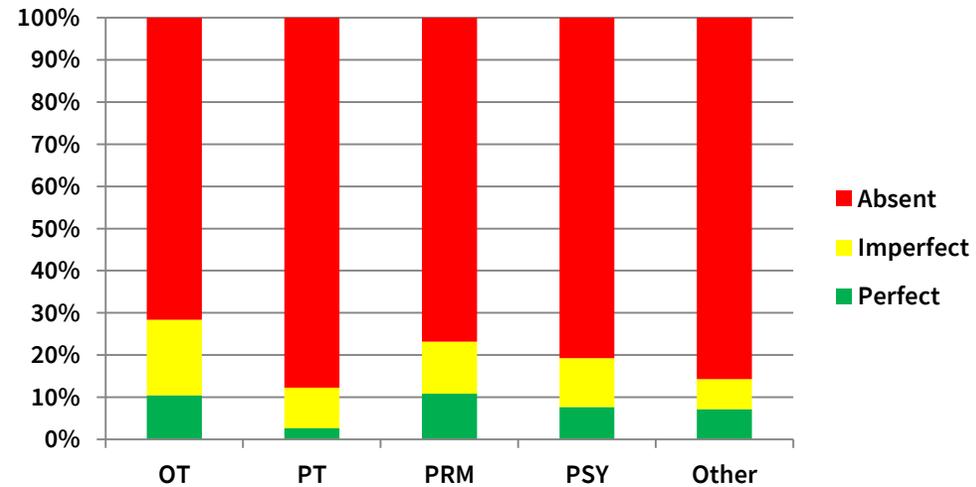
Cautions



Experience



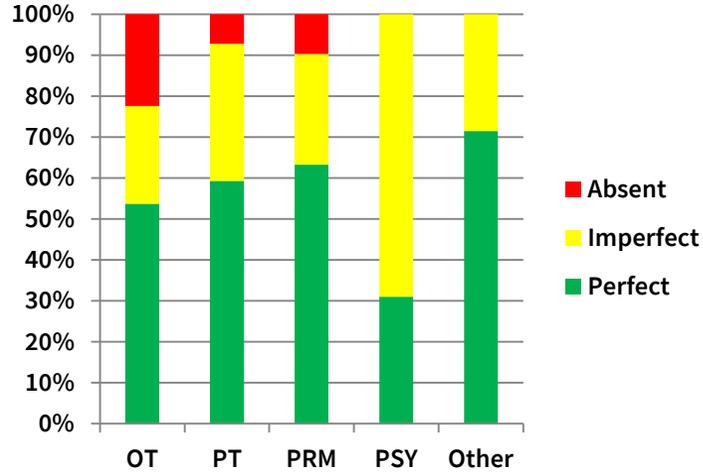
Relationships



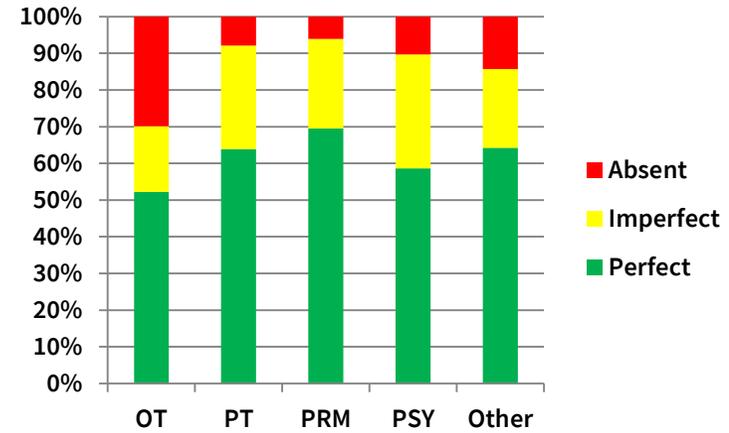


Increased problems of Occupational Therapists

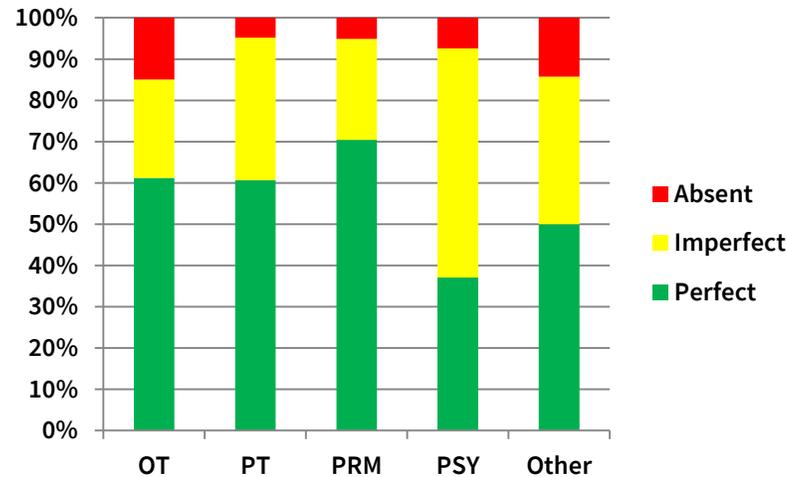
Intervention



Materials



Procedures

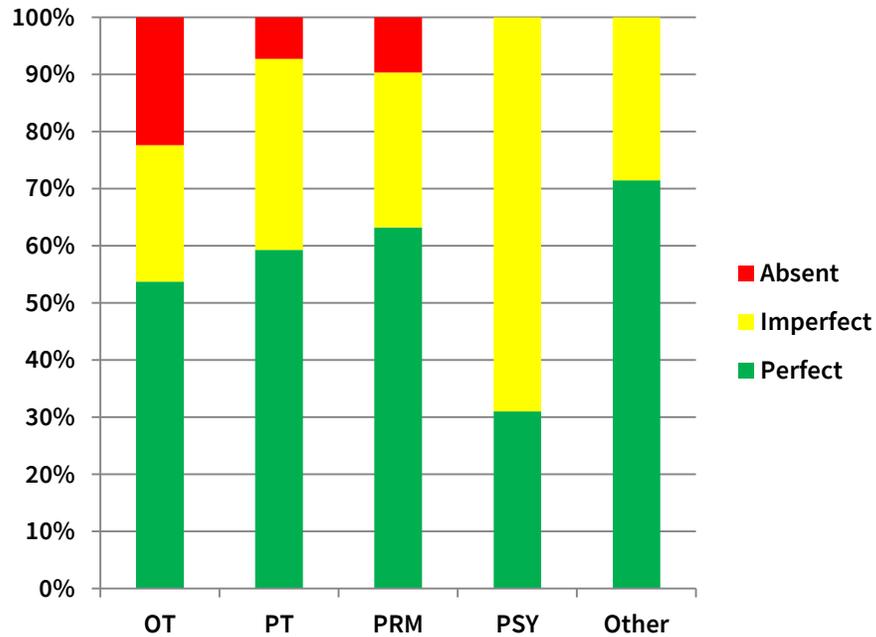



 OCCUPATIONAL
 THERAPY

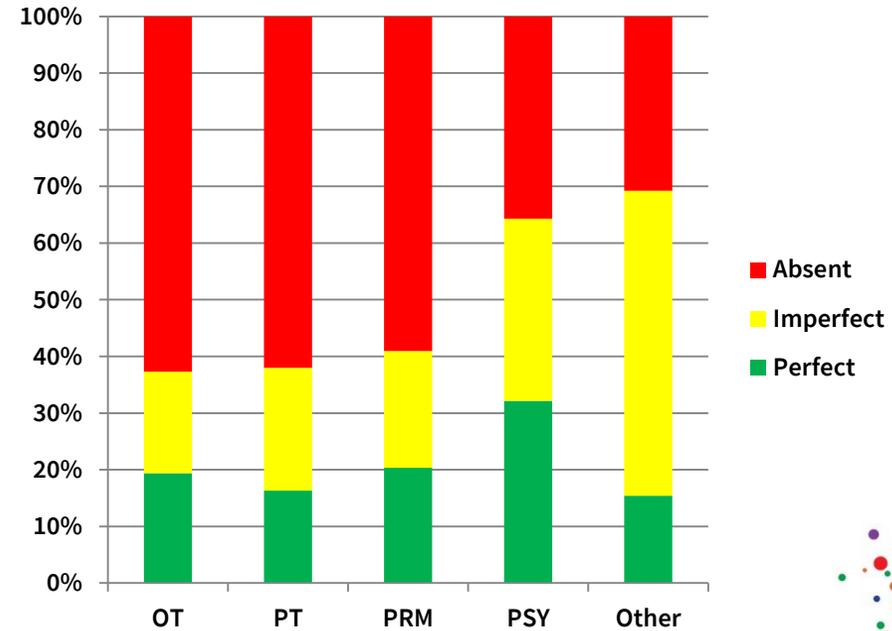


Reduced problems for Psychologists

Intervention



Skills





There are **problems in the applicability of RCTs results** in clinics in PRM.

These problems are spread among all professions

There are **differences according to rehabilitation professions**, but in general results are very close

The areas with the **lowest problems** of applicability are those generally better described by **classical methodological** checklists like CONSORT and include: Participants Features, Materials, Procedures, Order, Health Care Setting, Intervention, and Intervention Details.

We found the **biggest issues in the topics related to the human factors** typical of rehabilitation: Skills, Experience, and Relationships

Cautions revealed important problems

These results seems to suggest the need for specific **guidelines to improve applicability** in clinics of RCTs in PRM.





Thank you!

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