



REHABILITACIÓN

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EDITORIAL

Importance of research studies in rehabilitation

La importancia de estudios de investigación en la rehabilitación

Evidence based medicine as a concept has emerged in the 90th and fairly recently reached physical and rehabilitation medicine. Controlled clinical trials are considered not only as the best support for novel type of interventions but also to critically analyze already established treatment procedures.

Thus, to enforce evidence based rehabilitation there is a need for more clinical trials in rehabilitation, although there are specific problems in doing “true” RCT, as will be discussed. There may be a choice between different models for clinical trials. It is important to notice the principle differences between studies of a specific treatment modality and of an integrated multi-professional intervention program, having different problems in the design and limitations of the interpretation of the results. As in many other clinical disciplines a number of treatment modalities are based on clinical experience rather than having a scientific base, still there may be useful and giving positive results. They may, however, in some instances be based on limited or not relevant clinical experience.

In this Editorial the aspects on research methodology and pertinent fields for research and clinical implementations will be discussed.

Aspects on research methodology

Clinical trials can be divided into quasi-experimental studies and randomized controlled trials (RCT). Studies with a quasi-experimental design may be observational studies (e.g. cohort and case–control studies). Such studies may be more useful for describing “natural” history of a condition, comparison between subgroups and different types of managements and particularly to explore risk factors and development of a particular outcome than to compare different interventions. The same strength in the conclusions cannot be reached as with a RCT.

A model to explore the preliminary feasibility and principle effects of an intervention (a pilot study) is the Single case design, where after a baseline, the changes are studied with serial observations of the patient and maybe with repeated intervention periods. This design may of value and sometimes the only possibility to study rare conditions or

when there are ethical or practical problems to get a large enough material for a study with a control group.

There may in rehabilitation research be practical problems to find a randomized control group and especially if an already established type of intervention will be studied. In such cases a study with a non-randomized control group, e.g. from another clinic, or “historical” controls has to be performed, keeping in mind and always discussing the limitations of such a study.

In designing and reporting a RCT it is important to carefully follow standardized recommendations as from CONSORT.¹ As a principle, you are advised to report the study in advance to a public trials registry as ClinicalTrials.gov. This is not only to increase the transparency but also to ensure that the initial design was followed in the study and to avoid any suspicion of fraud, which unfortunately appears in medical research, even if physical and rehabilitation medicine has been spared so far.

There are in clinical rehabilitation research definitely several limitations for a “true” RCT being double blinded. A placebo treatment unknown for both the therapist and the patient, unless there is a drug or injection treatment, can seldom be achieved, as both will usually be aware of the treatment. It is important, if principally possible, that the person and the team administrating the intervention to a “control” group have a positive attitude to that treatment, being, e.g. a conventional treatment to compare with a new modality. Of utmost importance is that there is a non-biased (blinded) assessor(s) of the different groups. Without that premise such a study would usually not be publishable. Other aspects on RCT in rehabilitation have to be taken into consideration as treatment fidelity, treatment delivery, treatment receipts and treatment enactment.² The need for sufficient large material (do always a power analyze) may require multicenter studies. Such studies are encouraged, even between nations, well aware of the practical problems to organize and harmonize such studies. The need for a long follow-up period may also be a problem but researches are encouraged to have sufficient follow-up time to demonstrate persistent effects of an intervention. There may be “outliers” worth to notice and they can give unique clinical information. Of

great importance is how the results from a clinical trial can be transformed into clinical situations. Far too often there is much too long a delay and we should try by publications, lectures and seminars to get faster and better use of new research information in clinical practice. There may be an interventionist effect by very well experienced interventionists or teams in the trial, which not without some specific education and information may be possible to reproduce in the clinic.

A good knowledge of the availability of well studied outcome measure, their psychometric properties and feasibility for the study group and the research question is necessary in clinical research. The International Classification of Functioning, Disability and Health (ICF) gives a good theoretical and conceptual basis, but does not cover all fields, as e.g. quality of life, life satisfaction and wellbeing. Still it is advisable to define the aim of the study and the instruments to be used for the outcome using ICF terms. In rehabilitation research unless only the direct effect on body function and structure is the aim of e.g. a new technical approach, outcome should usually cover wider fields as activity and if possible participation. Subjective aspects on quality of life and/or wellbeing ought, when relevant, also to be incorporated in the design of the study. There have been several recent reports and reviews on measurement of outcome in rehabilitation.^{3,4} The use of modern psychometric techniques for treating ordinal scale as Rasch methodology is recommended, and if necessary get further expert advice on this topic. That will make the outcome measurement being better scientifically based with more correct results, as also for clinical use.

Fields for prioritization of clinical research in rehabilitation

Brain plasticity is among the areas for current high interest in research as well as in clinical application. Different modalities of treatment have been tested with such an approach. However, it is necessary to base such studies on good theoretical grounds concerning the possibility for changes in brain activation. If possible, that should be studied directly in the project or having already relevant reference material that such changes would occur with a specific intervention.

The possibility for pain modulation based on physiological as well as psychological information has been given considerable interest. Studies of programs of multidisciplinary intervention for persons with persistent pain should be further encouraged. In that respect the interaction between different professionals and the fundamentals for an effective team function is of interest to study.

Among important areas for further research are different approaches for stroke and brain injury rehabilitation, as the use of new modalities effecting brain plasticity and spasticity, and also programs for improving the effect in the natural home environment (and working environment, if relevant). Then such programs need to be practically implemented. Studies of different approaches for rehabilitation of persons with long-term non-specific pain should be further performed. Even if there are problems with designing a true RCT, studies of rehabilitation interventions for persons with rare diseases should be encouraged. As a successive number of persons with disabilities from spinal cord injury, cerebral palsy, neuromuscular diseases including post polio conditions, acquired brain injuries in young age will get elderly, it is of utmost importance to understand the interrelation between aging and the "basic disability". A both research and clinical questions are how to age with a disability. What treatment modalities are pertinent in treating disability populations and how should they be supported in their daily life?

An increased research activity in rehabilitation is necessary, not at least among physicians in physical and rehabilitation medicine (PRM), even if valuable contributions are made from other rehabilitation professionals. This should be encouraged by including research training in the curriculum for trainees and by arranging for combined research and clinical appointments for PRM physicians.

References

1. Boutron I, Moher D, Altman DA, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med.* 2008;148:295–309.
2. Nelson DL, Mathiowetz V. Randomized controlled trials to investigate occupational therapy research questions. *Am J Occup Ther.* 2004;58:24–34.
3. Franchignoni Franco, editor. *Research issues in physical and rehabilitation medicine*. Pavia: Maugeri Foundation Books; 2010.
4. Küçükdeveci AA, Tennant A, Grimby G, Franchignoni F. Strategies on assessment and outcome measurements in physical and rehabilitation medicine. An educational review. *J Rehabil Med.* 2011;43:661–72.

G. Grimby

Section of Clinical Neuroscience and Rehabilitation,
Department of Neuroscience and Physiology, Sahlgrenska
Academy at University of Gothenburg, Göteborg, Sweden
E-mail address: gunnar.grimby@rehab.gu.se