

RCTs in rehabilitation research

Thorsten Meyer, William Levack, Stefano Negrini, Francesca Gimigliano, Chiara Arienti, Farooq Rathore, Antti Malmivaara

Rehabilitation sciences
| rehabilitative health services research
School of Public Health
University of Bielefeld

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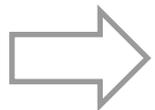
I have no actual or potential financial conflict of interest in relation to this presentation.

My present position as a professor for rehabilitation sciences is endowed by a regional pension insurance funds and different rehabilitation providers in the state of North-Rhine-Westphalia.



Background and aims

- evidence-based practice approach has strongly influenced rehabilitation research and practice
- considerable discussion on role of RCT as a tool for rehab practice / knowledge translation within rehabilitation
- no single research design can be deemed universally appropriate or effective
- discussion and resulting paper should serve as a point of departure for different motives / people engaging in Cochrane Rehab work



- a) describe and discuss pros and cons of RCTs in rehabilitation research
- b) discuss future needs for advancing methodology of effectiveness research in rehabilitation.



Characteristics of rehabilitation

PATIENTS

- Broad indications, both related to disease characteristics and aspects of functioning

PROCESS

- Specification of rehab goals is highly individual and part of the therapeutic process
- Goals of rehabilitation should be functional, including physical, activity and participation levels, they are both short-term and long-term
- Packages of interventions (complex interventions) delivered in a complex context
- “Usual care” shows high level of practice variation
- Multiple professions that ought to work in an interprofessional way (team work)
- Therapies are mostly active, i.e. work through the actions of the patient in interaction with professionals

OUTCOMES

- Multiple, functional, individual outcomes that usually unfold in longer time frames (6-12mts+), outcomes depend substantially on environmental factors beyond control of rehab

CONTEXT

- Rehab is both a medical, social and educational encounter

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In practice: homogenous diagnostic groups, usually not function-related; comorbidities or unusual pattern excluded, no orphan diseases

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It is hard to impossible to depict what can be learned (e.g. in terms of „active ingredients“);
determination of adequate control group (no care, usual care, masking/blinding)
Blinding of practitioner and patient is mostly impossible (better: outcome assessment)
Assumption of comparable contexts is difficult to sustain RCTs

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Patient as active agent is always part of the intervention, so in fact RCTs provide results of interaction between patient, intervention and professionals

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In practice: RCTs usually have a much-too-short time perspective; Insensitive outcomes when using generic instruments; individual goal achievement is difficult to measure and hardly assessed; often no primary outcome, but multiple outcomes; need of validated outcome model

Discussion

- Knowledge for rehabilitation practice has to be based on different study designs: which study design are the most valuable for which kind of clinical questions?
- RCT is mostly valuable for the evaluation of simple interventions with external ingredients and specifiable short-term outcomes
- Limitations of RCTs relate to basic characteristics of rehabilitation
- Limitations of RCTs should facilitate the development or adjustment of alternative study designs to provide useful evidence for rehabilitation practice.



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Thank you

thorsten.meyer@uni-bielefeld.de

cochrane.rehabilitation@gmail.com
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