RCTs in rehabilitation research

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Conflict of interest

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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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.
References

- Kersten, Paula; Ellis-Hill, Caroline; McPherson, Kathryn M.; Harrington, Rachel (2010): Beyond the RCT - understanding the relationship between interventions, individuals and outcome - the example of neurological rehabilitation. Disability and Rehabilitation 32 (12), S. 1028–1034. DOI: 10.3109/09638281003775568.
Thank you

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