Cochrane Rehabilitation

Building a bridge between research evidence and clinical practice

Presenter: A/Prof William Levack PhD
Rehabilitation Teaching & Research Unit
University of Otago, New Zealand

Trusted evidence.
Informed decisions.
Better health.

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Learning Objectives

At the conclusion of this activity, the participant will be able to:

1. Describe the roles and activities of Cochrane Rehabilitation
2. Critically read systematic reviews of RCTs, including meta-analyses
3. Critically discuss the strengths and weaknesses of the current Cochrane approach to evidence synthesis from a rehab perspective
4. Know how to get involved in or benefit from the work of Cochrane Rehabilitation

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1: Overview and origins of Cochrane Rehabilitation

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What is Cochrane?

- Global
- Independent
- Non-profit
- Network of researchers, professionals, patients, carers, and people interested in health
- Exists so that healthcare decisions get better

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A leader in evidence-based healthcare

Audit of systematic reviews found Cochrane Reviews:

- Most comprehensive reporting
- More likely to use a pre-published protocol
- More likely to report risk of bias assessment and integrate it in analysis of results
- Most consist use of appropriate statistical methods
- Most likely to be updated over time

(Page et al., 2016, PLoS Medicine)

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Rehab is a major stakeholder in Cochrane!

ARTICLE IN PRESS

ACRM American Congress of Rehabilitation Medicine

Archives of Physical Medicine and Rehabilitation

journal homepage: www.archives-pmr.org

Archives of Physical Medicine and Rehabilitation 2019;■:■■■-■■■

REVIEW ARTICLE

One in 11 Cochrane Reviews Are on Rehabilitation Interventions, According to Pragmatic Inclusion Criteria Developed by Cochrane Rehabilitation

William M.M. Levack, PhD,[a] Farooq A. Rathore, MD,[b] Joel Pollet, PT,[c] Stefano Negrini, MD[c,d]

From the [a]Rehabilitation Teaching and Research Unit, Department of Medicine, University of Otago, Wellington, New Zealand; [b]Department of Rehabilitation Medicine, PNS Shifa Hospital, DHA-II, Karachi, Pakistan; [c]IRCCS Fondazione Don Carlo Gnocchi, Milan, Italy; and [d]Clinical and Experimental Sciences Department, University of Brescia, Brescia, Italy.

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Location:

- Department of Clinical and Experimental Sciences, University of Brescia

Initial Funding:

- Care & Research Institute; Don Gnocchi, Milan

Established:

- 22 October 2016

Prof Stefano Negrini
Field Director

Cochrane Rehabilitation Executive

Stefano Negrini, MD (Italy) – Director

Carlotte Kiekens, MD (Belgium) - Coordinator

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Elena Ilieva, MD, PhD (Bulgaria) – Education Committee

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Farooq Rathore, MD (Pakistan) – LMIC Representative

Francesca Gimigliano, MD, PhD (Italy) – Communication Committee

Tracey Howe, PhD, PT (UK) – Professionals Representative

Antti Malmivaara, MD (Finland) – Methods Committee

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Cochrane Rehabilitation Advisory Board

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Am J Phys Med Rehab Pros Ortho Int

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Cochrane Organization

Review Groups: prepare & maintain Cochrane reviews

Centres: Support local Cochrane contributors, connect regions to Cochrane central

Methods Groups: development & implementation of methods used in the preparation of Cochrane reviews

Fields: Focus on dimensions of health care rather than a condition or topic; focus on knowledge translation and dissemination

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Role of Cochrane Fields: a bridge

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Cochrane Rehab Goals - Overview

1. Connect rehab stakeholders globally
2. Translate knowledge in rehab
3. Register rehab reviews
4. Educate rehab stakeholders
5. Develop rehab review methods
6. Promote Cochrane to Rehab & Rehab to Cochrane

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Search...

Cochrane News

- Students contributing to the impact of Cochrane
- Cochrane at the forefront of training in conducting systematic reviews
- Announcing Cochrane Colloquium Edinburgh 2018: a Patients Included health research conference
- Everyone is welcome! Announcing the opening of a wider world for Cochrane
- Health systems in low income countries - four new overviews

More

Latest News and Events

Elections to the Governing Board

Role and function of Cochrane Rehabilitation

Knowledge Translation: the bridging function

Cochrane Rehabilitation at 2017 ISPRM

Keep Posted

Tweets by @CochraneRehab

@CochraneRehab Retweeted

ISPRM
@ISPRM

We encourage PRM disaster responders to review the newly developed recommended humanitarian competency framework: bit.ly/2f6Eure

ISPRM r...

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2: How to read a systematic review

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What is a systematic review?

A review of research on a particular topic that follows a predetermined, replicable method for selection of studies, extraction of information, and analysis of results

- Reportable method/transparency
- Minimisation of bias
- Comprehensiveness

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Characteristics of a good systematic review

- Clearly defined review question
- Published method prior to review being conducted (see PROSPERO)
- Comprehensive search strategy to find relevant studies
- Trustworthy process for selection of studies (two indep. reviewers)
- Robust critical appraisal of study (two indep. reviewers)
- Predetermined decisions re. outcomes to extract (two indep. reviewers)
- Predetermined methods for analysis of results
- Incorporation of critical appraisal in synthesis of results
- Reporting of heterogeneity, precision and sensitivity of results
- Interpretation of clinical meaningfulness of results

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For example…

What question was asked?

PICO(T)

- Population
- Intervention
- Control/Comparison
- Outcome
- (Time of endpoint)

Look at the title, but then in the methods for more details

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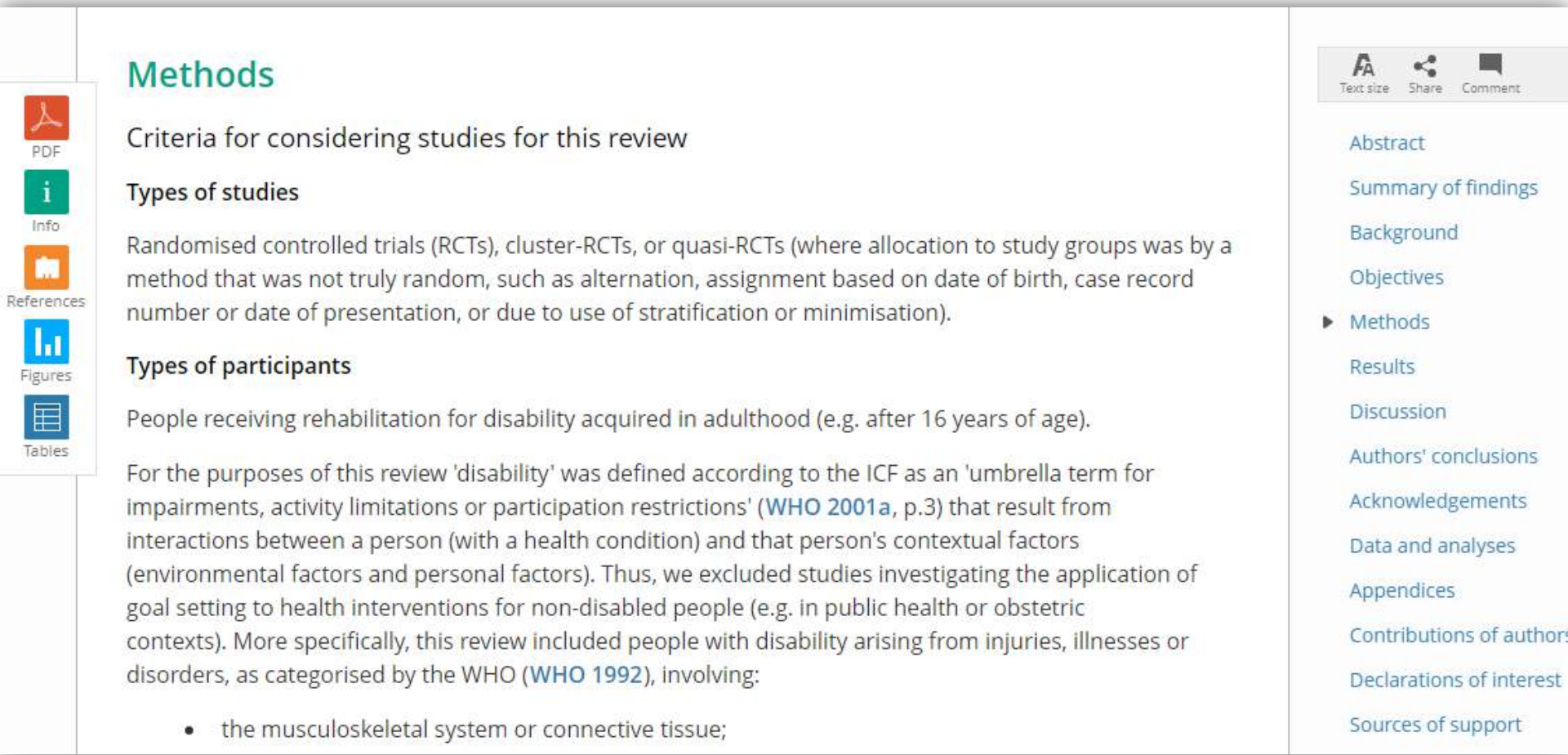
What question was asked?



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Tables

Methods

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), cluster-RCTs, or quasi-RCTs (where allocation to study groups was by a method that was not truly random, such as alternation, assignment based on date of birth, case record number or date of presentation, or due to use of stratification or minimisation).

Types of participants

People receiving rehabilitation for disability acquired in adulthood (e.g. after 16 years of age).

For the purposes of this review 'disability' was defined according to the ICF as an 'umbrella term for impairments, activity limitations or participation restrictions' (WHO 2001a, p.3) that result from interactions between a person (with a health condition) and that person's contextual factors (environmental factors and personal factors). Thus, we excluded studies investigating the application of goal setting to health interventions for non-disabled people (e.g. in public health or obstetric contexts). More specifically, this review included people with disability arising from injuries, illnesses or disorders, as categorised by the WHO (WHO 1992), involving:

- the musculoskeletal system or connective tissue;

Text size Share Comment

Abstract
Summary of findings
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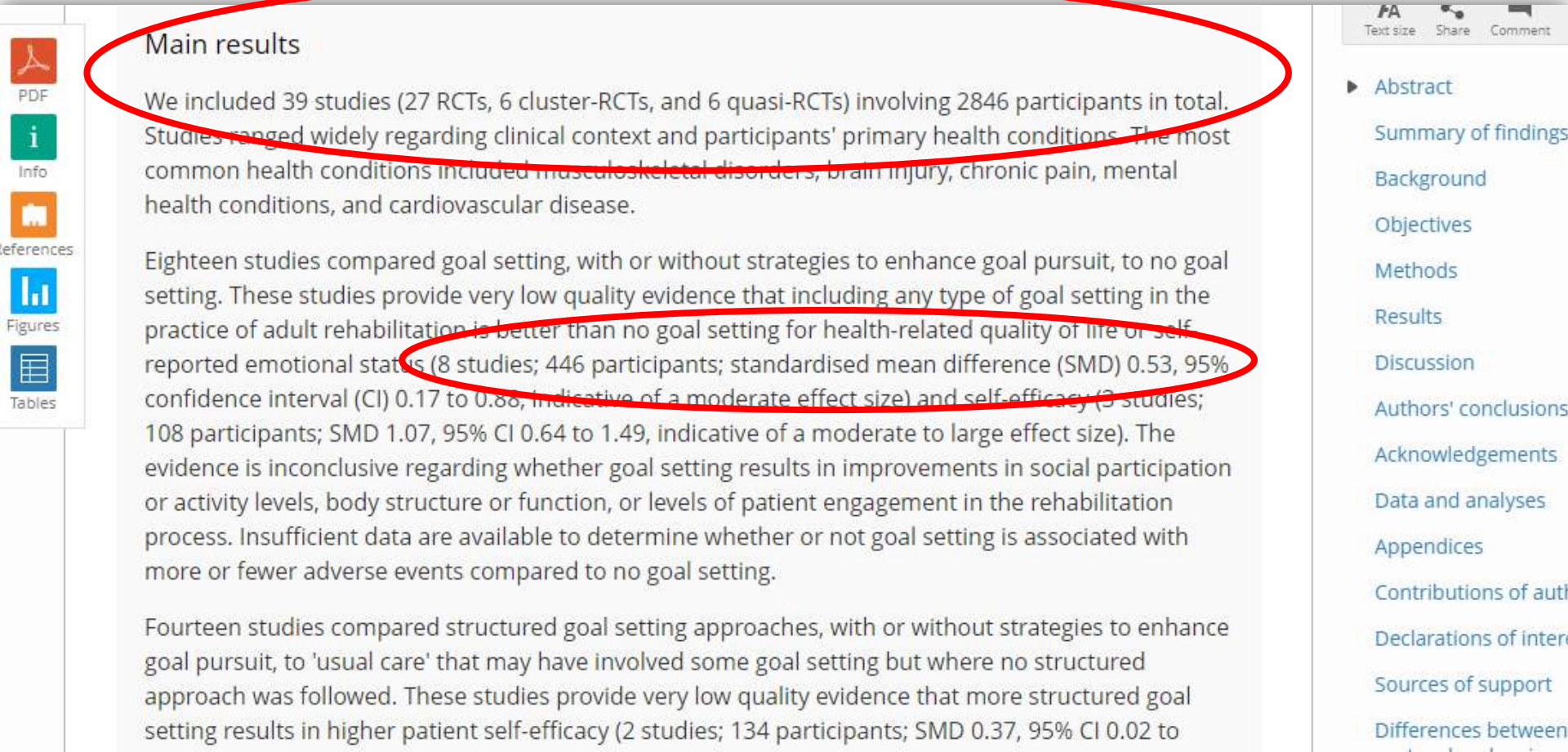
How many studies were found?

For a quick overview:

Scan the abstract

How many studies were found?



Main results

We included 39 studies (27 RCTs, 6 cluster-RCTs, and 6 quasi-RCTs) involving 2846 participants in total. Studies ranged widely regarding clinical context and participants' primary health conditions. The most common health conditions included musculoskeletal disorders, brain injury, chronic pain, mental health conditions, and cardiovascular disease.

Eighteen studies compared goal setting, with or without strategies to enhance goal pursuit, to no goal setting. These studies provide very low quality evidence that including any type of goal setting in the practice of adult rehabilitation is better than no goal setting for health-related quality of life or self-reported emotional status (8 studies; 446 participants; standardised mean difference (SMD) 0.53, 95% confidence interval (CI) 0.17 to 0.88, indicative of a moderate effect size) and self-efficacy (3 studies; 108 participants; SMD 1.07, 95% CI 0.64 to 1.49, indicative of a moderate to large effect size). The evidence is inconclusive regarding whether goal setting results in improvements in social participation or activity levels, body structure or function, or levels of patient engagement in the rehabilitation process. Insufficient data are available to determine whether or not goal setting is associated with more or fewer adverse events compared to no goal setting.

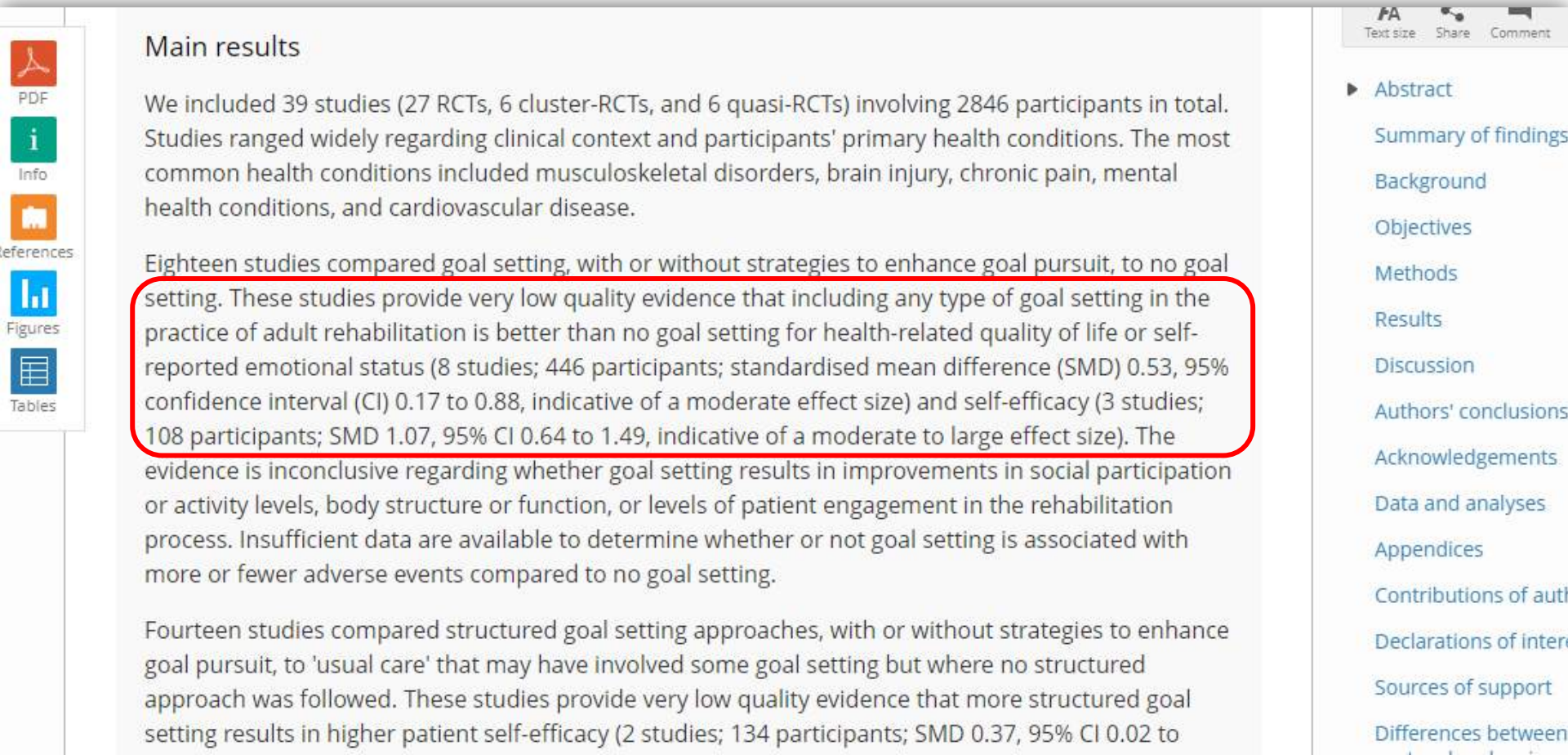
Fourteen studies compared structured goal setting approaches, with or without strategies to enhance goal pursuit, to 'usual care' that may have involved some goal setting but where no structured approach was followed. These studies provide very low quality evidence that more structured goal setting results in higher patient self-efficacy (2 studies; 134 participants; SMD 0.37, 95% CI 0.02 to

What were the main outcomes?

For a quick overview, read:

- The abstract
- The authors summary
- The lay summary

What were the main outcomes?



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Findings usually reported as:

- Risk ratios (RR) or Odds ratios (OR)
- Mean differences (MD)
- Standard mean differences (SMD)

… With 95% confidence intervals (CIs)

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Relative risk (RR) & Odds Ratio (OR)

- RR and OR are similar, but not identical
- RR compares the likelihood of an event occurs in one group (intervention) the likelihood of that event occurring in another group (control)
- A score of 1 means no difference
- Scores < 1 mean ‘less likely’
- Score > 1 mean ‘more likely’

Relative risk (RR) & Odds Ratio (OR)

Intervention group
400 out of 1000 people dead of dependent
Likelihood: 40%

Control group
450 out of 1000 people dead or dependent
Likelihood: 45%

Odds Ratio: 0.80

95% CI: 0.67 to 0.95

⇨ Five (1 to 9) people regaining independence for every 100 receiving ESD service

Langhorne et al. (2017). Early supported discharge services for people with acute stroke. *Cochrane Database of Systematic Reviews(7).*CD000443

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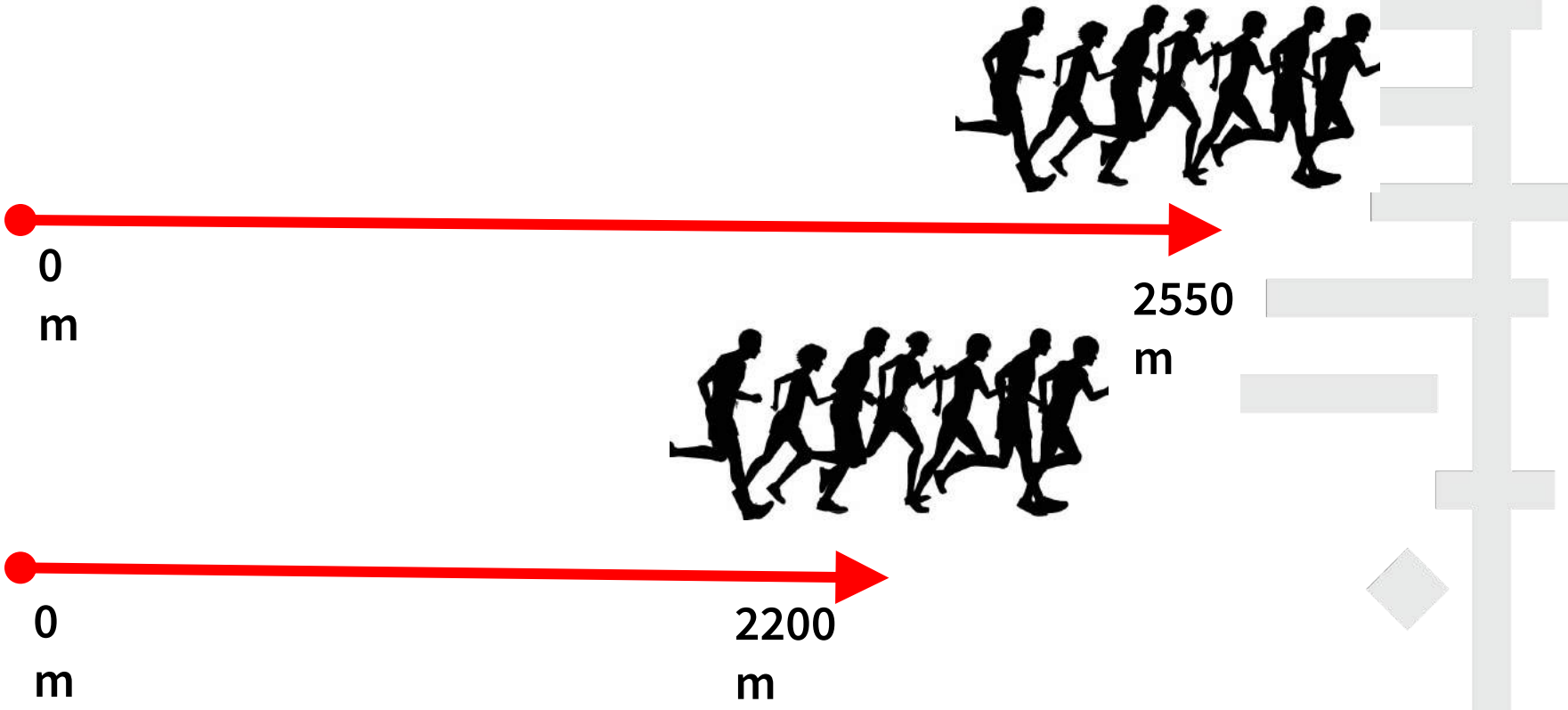
Mean difference (MD)

- Differences between the average score on the same outcome measure for two groups
- Reported in the same units as the outcome measure
- Can range over whatever scores are normal for that measure
- MD of 0 means no difference

Mean difference (MD)



Mean difference (MD)

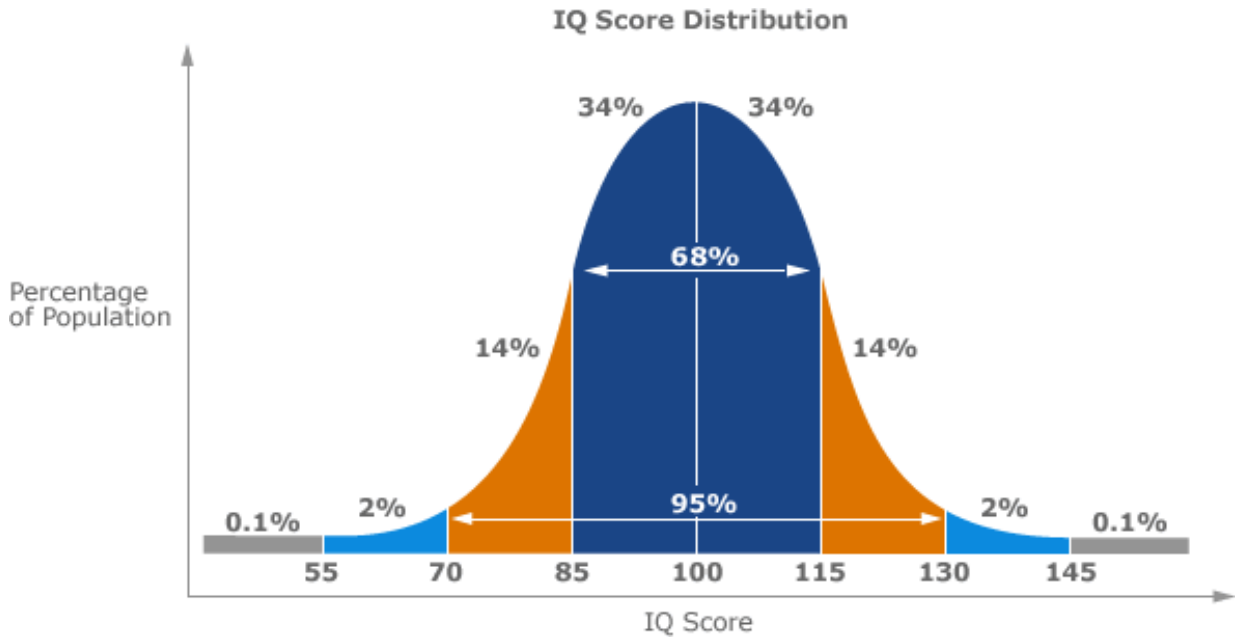
McCarthy B et al. (2015) Pulmonary rehabilitation for chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews. Issue 2:CD003793.

In relation to functional exercise capacity, the six-minute walk distance mean treatment effect was greater than the threshold of clinical significance (MD 43.93, 95% CI 32.64 to 55.21; participants = 1879; studies = 38).

Standard Mean Difference (SMD)

- Used when combining data from different measures of the same type of outcome
- E.g. pooling outcomes from several measures of quality of life:
  - SF-36
  - EuroQoL
  - WHOQOL
  - Nottingham Health Profile etc.
- Measured as a proportion of one standard deviation in score

Standard Mean Difference (SMD)



A useful way of understanding SMDs:
http://rpsychologist.com/d3/cohend/

Standard Mean Difference (SMD)

SMD = 0	No effect
SMD = 0.2	Small effect
SMD = 0.5	Moderate effect
SMD = 0.8	Large effect

Word of caution: These cut-offs are somewhat arbitrary

"this is an operation fraught with many dangers…" (Cohen, 1988)

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What were the main outcomes?

For more detailed perspective, read:

- The Summary of Findings table, then consider…
- Examining the forest plots for the main findings

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Summary of Finding Tables

Goal setting with or without strategies to enhance goal pursuit compared to no goal setting for adults with acquired disabilityparticipating in rehabilitation

Patient or population: adults with acquired disability participating in rehabilitation
Settings: inpatient, outpatient, and community-based healthcare services
Intervention: goal setting with or without strategies to enhance goal pursuit
Comparison: no goal setting

Outcomes	Illustrative comparative risks* (95% CI)		No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk			
	No goal setting	Goal setting (with or without strategiesto enhance goal pursuit)			
Health-related quality of life or self-reported emotional status Follow-up: median 11.5 weeks	The mean Physical Component Summary Scores on the Short Form-36 for the control group was **35.9 points (SD 10.1)** (out of a possible score of 0-100)[1]	The mean Physical Component Summary Scores on the Short Form-36 for the intervention group was **5.5 higher** (1.7 to 8.9 higher)[2]	446 (8 studies)	⊕◯◯◯ **very low**[3,4,5]	Higher scores indicate better outcomes. Scores estimated using a SMD of 0.54 (95% CI 0.17 to 0.88), indicative of an effect size that may range from small to large.Two additional studies with 142 participants however, reported no means or SD, but indicated that goal setting may lead to little to no difference in health-related

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Check the PICO question being answered

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Summary of Finding Tables

Check the number of studies and participants

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Summary of Finding Tables

Read the main finding

Goal setting with or without strategies to enhance goal pursuit compared to no goal setting for adults with acquired disability

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Summary of Finding Tables

Check the quality of evidence & comments

Goal setting with or without strategies to enhance goal pursuit compared to no goal setting for adults with acquired disability participating in rehabilitation

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Forest plots

Details of comparison

Analysis 1.1. Comparison 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting, Outcome 1 Health related quality of life or self-reported emotional status.

Review: Goal setting and strategies to enhance goal pursuit for adults with acquired disability participating in rehabilitation

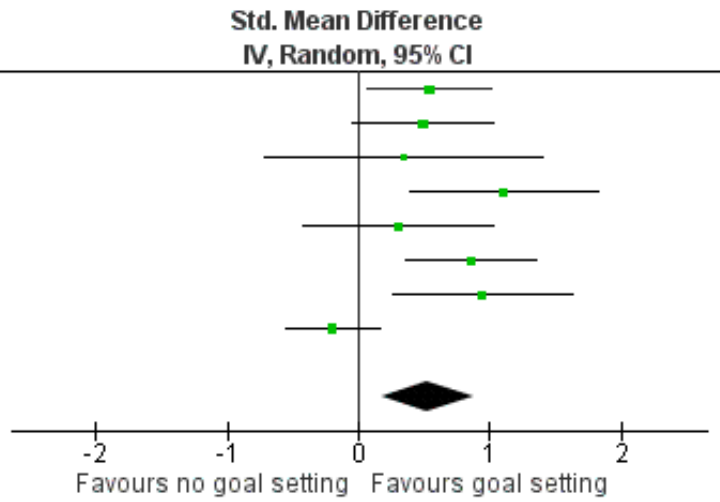
Comparison: 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting

Outcome: 1 Health related quality of life or self-reported emotional status

	Goal setting			No goal setting				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Blair 1991	-1.377	0.924	53	-1.855	0.766	26	14.7%	0.54 [0.06, 1.02]
Coote 2012	-26.2	13.3	26	-32.5	11.9	29	13.7%	0.49 [-0.04, 1.03]
Duncan 2003	-25.4	21.6	7	-33.5	22.6	7	7.2%	0.34 [-0.72, 1.40]
Evans 2002	14.46	2.73	13	11.7	2.29	26	11.0%	1.11 [0.39, 1.82]
Fredenburgh 1993	12.08	26.1	15	4.79	20.63	15	10.9%	0.30 [-0.42, 1.02]
Harwood 2012	44.8	10.4	38	35.9	10.1	31	14.4%	0.86 [0.36, 1.35]
Scott 2004	25.02	3.63	15	20.79	4.78	24	11.5%	0.95 [0.26, 1.63]
Sewell 2005	0.62	1.41	63	0.89	1.29	58	16.6%	-0.20 [-0.56, 0.16]
Total (95% CI)			**230**			**216**	**100.0%**	**0.53 [0.17, 0.88]**

Heterogeneity: Tau² = 0.16; Chi² = 20.74, df = 7 (P = 0.004); I² = 66%

Test for overall effect: Z = 2.91 (P = 0.004)



Forest plots

Names of study in analysis

Analysis 1.1. Comparison 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting, Outcome 1 Health related quality of life or self-reported emotional status.

Review: Goal setting and strategies to enhance goal pursuit for adults with acquired disability participating in rehabilitation

Comparison: 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting

Outcome: 1 Health related quality of life or self-reported emotional status

	Goal setting			No goal setting				Std. Mean Difference
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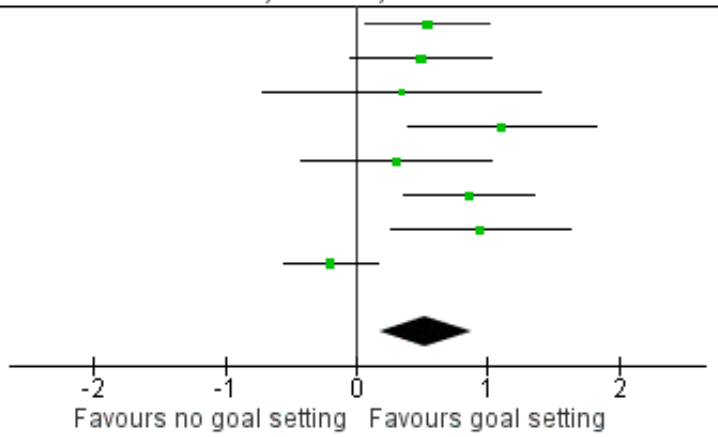

Forest plots

Data from each study for the intervention group – mean (SD) for outcome & total no. of participants

enhance goal pursuit) versus no goal
rted emotional status.

rehabilitation

Comparison: 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting

Outcome: 1 Health related quality of life or self-reported emotional status

	Goal setting			No goal setting				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
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Total (95% CI)			**230**			**216**	**100.0%**	**0.53 [0.17, 0.88]**

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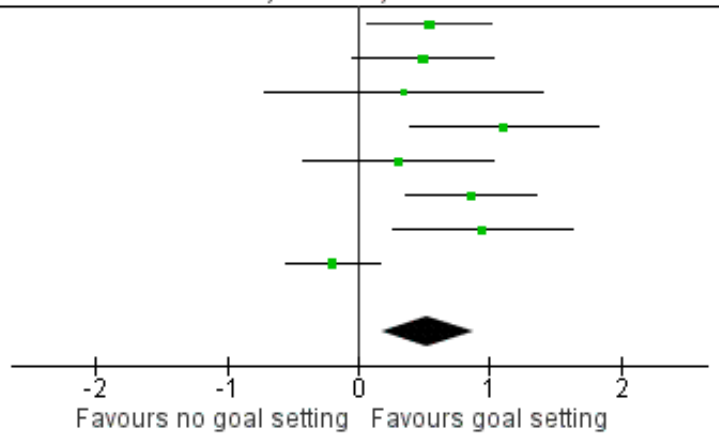

Forest plots

… and for the control

Analysis 1.1. Comparison 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting, Outcome 1 Health related quality of life or self-reported emotional status.

Review: Goal setting and strategies to enhance goal pursuit for adults with acquired disability participating in rehabilitation

Comparison: 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting

Outcome: 1 Health related quality of life or self-reported emotional status

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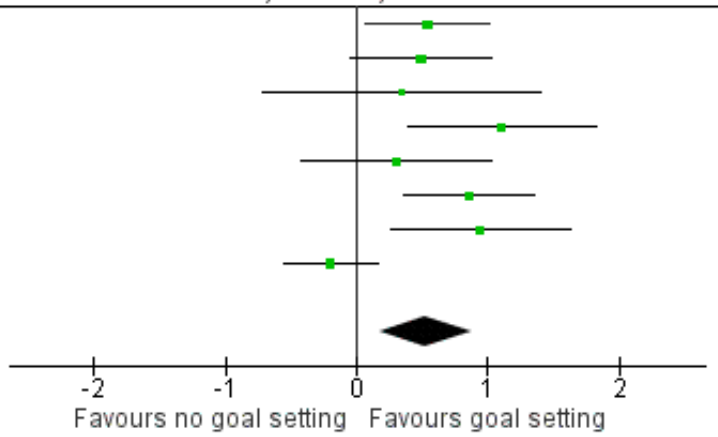

Forest plots

Total no. of people pooled in the meta-analysis in intervention and control groups

Analys **ies to enhance goal pursuit) versus no goal**
lf-reported emotional status.

Review: Goal setting and strategies to enhance goal pursuit for adults with acquired disability participating in rehabilitation

Comparison: 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting

Outcome: 1 Health related quality of life or self-reported emotional status

	Goal setting			No goal setting				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
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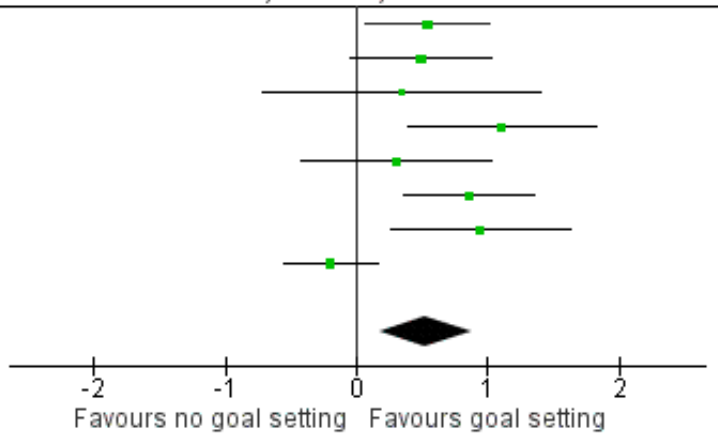

Forest plots

SMD between the intervention and control (the 'whiskers' are the 95% CI)

Analysis 1.1. Comparison 1 Goal setting (with or wit … us no goal setting, Outcome 1 Health related quality

Review: Goal setting and strategies to enhance goal pursuit for adults with acqui

Comparison: 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting

Outcome: 1 Health related quality of life or self-reported emotional status

	Goal setting			No goal setting				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
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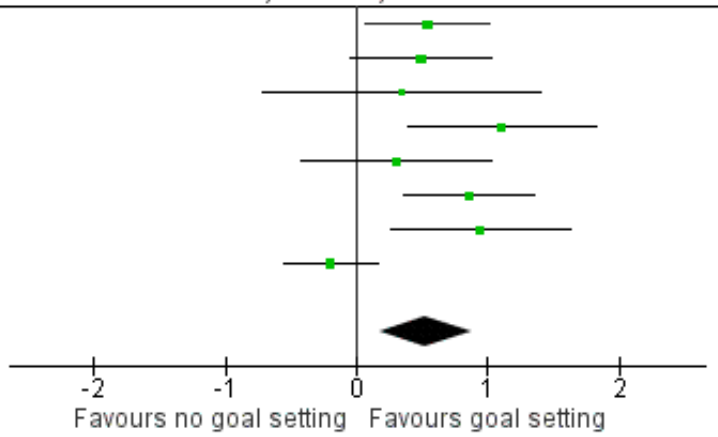

Forest plots

Line of no effect!!

Analysis 1.1. Comparison 1 Goal setting (with pursuit) versus no goal setting, Outcome 1 Health related al status.

Review: Goal setting and strategies to enhance goal pursuit for adults with acquired disability participating in rehabilitation

Comparison: 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting

Outcome: 1 Health related quality of life or self-reported emotional status

	Goal setting			No goal setting				Std. Mean Difference
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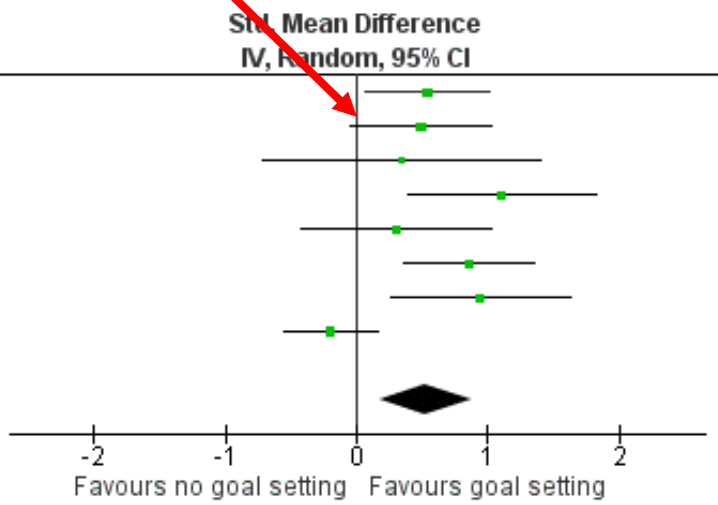

Forest plots

Poolled means and 95% CI for all studies in the meta-analysis

Analysis 1.1. Comparison 1 Goal setting … t) versus no goal setting, Outcome 1 Health rel … us.

Review: Goal setting and strategies to enhance goal pursuit for adults with acquired disability participating in rehabilitation

Comparison: 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting

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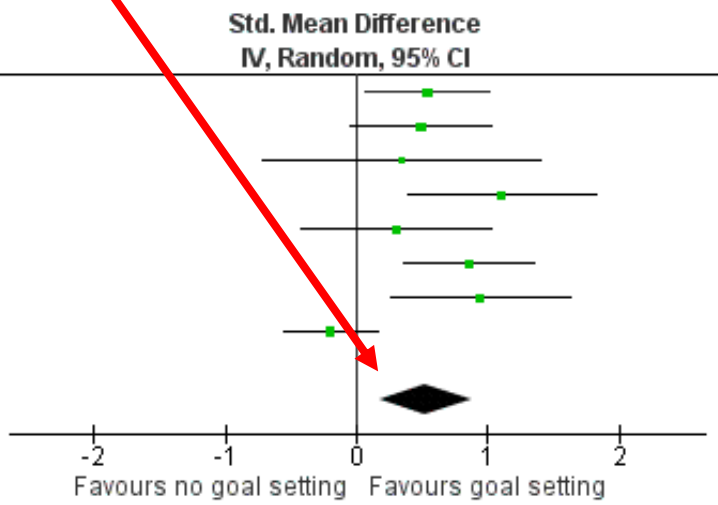

Forest plots

Same information, but numerical

Analysis 1.1. Comparison 1 Goal setting (with or without strategies to enhance goal pursuit) versus no goal setting, Outcome 1 Health related quality of life or self-reported emotional status.

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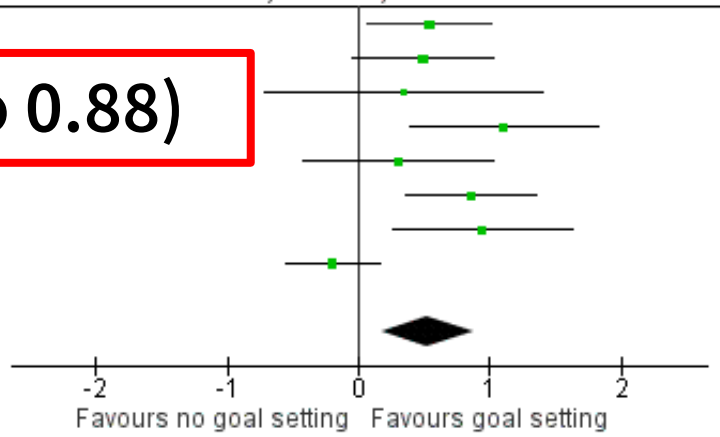

THEN…

If still interested, look for details on:

- Quality of evidence (GRADE)
- Details about the interventions
- Details about the setting
- Authors' discussion and conclusion

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Quality of evidence: GRADE

The **quality of the evidence** is a judgement about the extent to which we can be confident that the estimates of effect are correct.

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What are GRADE scores based on?

1. **Risk of bias** (how good were the study methods?)
2. **Inconsistency** (how heterogeneous were the outcomes?)
3. **Indirectness** (how closely do the included studies align with our actual clinical question?)
4. **Imprecision** (how wide are the 95% confidence intervals?)
5. **Publication bias** (can we rule out selective reporting?)

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3: Where to from here?

Some problems and ongoing work to find solutions...

Trusted evidence.
Informed decisions.
Better health.

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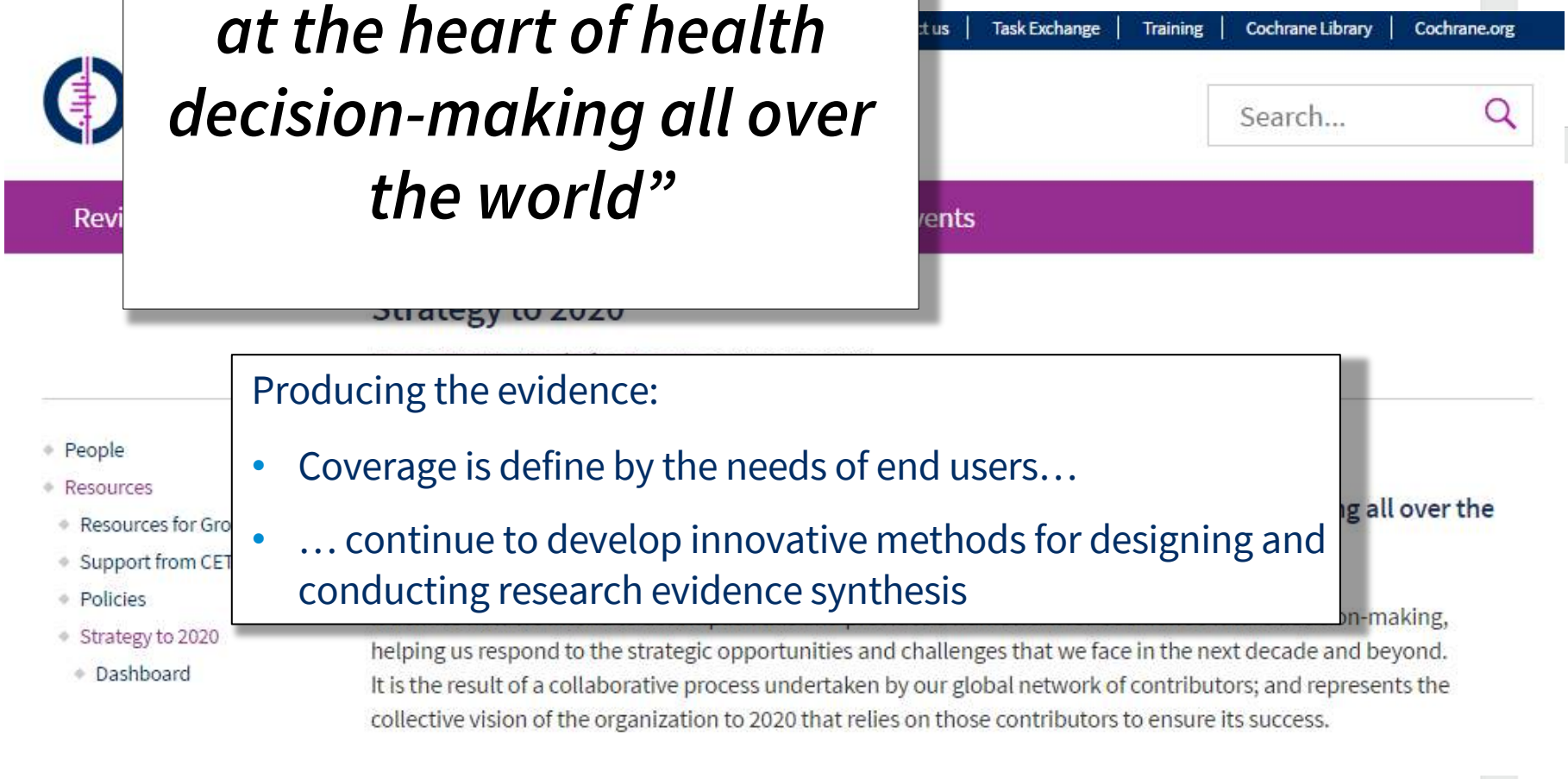
"to put Cochrane evidence at the heart of health decision-making all over the world"

Producing the evidence:

- Coverage is define by the needs of end users…
- … continue to develop innovative methods for designing and conducting research evidence synthesis



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Cochrane Reviews on TBI interventions

Scoping of reviews (Feb 2017):

- 25 reviews and protocols
  - 13 exclusive to TBI (9 reviews; 4 protocol)
  - 12 mixed brain injury, incl. stroke (10 reviews; 2 protocol)
- 9/25 reviews or protocols over 5 years out of date
- Meta-analysis attempted in only 6 reviews (incl. only 2 TBI exclusive reviews)
- Majority concluded “insufficient evidence”

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GRADE the evidence

- Risk of bias (randomisation; group allocation; ITT; other)
- Directness of evidence
- Heterogeneity
- Precision of effect estimates
- Risk of publication bias

Risk of bias

- Randomisation → Ethical and pragmatic problems of not delivering intervention
- Rehabilitation interventions usually require active involvement of patients and personnel → But blinding not possible
- Patient reported outcome measures important → But blinding not possible
- Incomplete outcome data → Problem with attrition in long term, community-based studies

Heterogenity & precision of effect estimates

Rehabilitation trials often have high heterogeneity in terms of:

- Patient population
- Person-centred interventions
- Health-care context
- Socioeconomic context
- ‘Quality’ of the therapist on effects of intervention

… All of which reduce precision of effect estimates

Other barriers to RCTs in rehabilitation

Most rehab interventions are complex (Craig et al., 2008)

- Multiple interacting components
- Behaviour challenge elements
- Individualisation of interventions

  (i.e. the 'black box' of rehabilitation)

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Other barriers to RCTs in rehabilitation

Most rehab interventions are complex (Craig et al., 2008)

… requiring many multiple RCTs to investigate ($$$ and time!)

… problems with intervention fidelity

… problems with selecting a comparison group

(no treatment; 'usual care'; attention control?)

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Other barriers to RCTs in rehabilitation

Sample sizes for less common conditions

- e.g. multiple sclerosis; motor neuron disease; severe TBI

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What's needed next?

Bigger, better, more RCTs?

Vs

Something else?

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The argument for bigger, better RCTs

- RCTs are absolutely the best design
- RCTs are the only way to demonstrate causality; to know if an intervention has an effect
- RCTs are need for scientific credibility in medicine

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The argument for something else

- RCTs are massively expensive
- RCTs only answer one, reductionist question – so many, many RCTs are needed to address one type of intervention
- RCTs are not possible for some conditions/interventions
- RCTs can lack generalisability
- RCTs take too long

… plus all the limitations already highlighted

Emergence of renewed interest in Non-RCT study design

N Engl J Med 2017, 377: 465-75

THE CHANGING FACE OF CLINICAL TRIALS

Jeffrey M. Drazen, M.D., David P. Harrington, Ph.D., John J.V. McMurray, M.D., James H. Ware, Ph.D., and Janet Woodcock, M.D., *Editors*

Evidence for Health Decision Making — Beyond Randomized, Controlled Trials

Thomas R. Frieden, M.D., M.P.H.

Emergence of renewed interest in Non-RCT study design

- ROBINS-I… A tool for assessment of risk of bias in non-RCT studies of intervention (Sterne et al. 2016)
- Methods for systematic review of n=1 studies (Shaffer et al. 2015)
- New methods in ‘big data’ analysis from data registries (Frieden 2017)

Survey of priorities for future work

European Journal of Physical and Rehabilitation Medicine 2017 ????;53(??):000-000
DOI: 10.23736/S1973-9087.17.04958-9

SPECIAL ARTICLE

Cochrane Rehabilitation Methodology Committee: an international survey of priorities for future work

William M. LEVACK [1] *, Thorsten MEYER [2], Stefano NEGRINI [3, 4], Antti MALMIVAARA [5, 6]

[1]Unit Rehabilitation Teaching and Research, Department of Medicine, University of Otago, Wellington, New Zealand; [2]Institute for Epidemiology, Social Medicine and Health System Research, Hannover Medical School, Hannover, Germany; [3]Department of Clinical and Experimental Sciences, University of Brescia, Brescia, Italy; [4]IRCCS Fondazione Don Gnocchi, Milan, Italy; [5]National Institute for Health & Welfare, Helsinki, Finland; [6]Finnish Medical Society Duodecim, Current Care Guidelines, Helsinki, Finland

*Corresponding author: William Levack, Rehabilitation Teaching and Research Unit, Department of Medicine, University of Otago, Mein St, Newtown, PO Box 7343, Wellington, 6242, New Zealand. E-mail: william.levack@otago.ac.nz.

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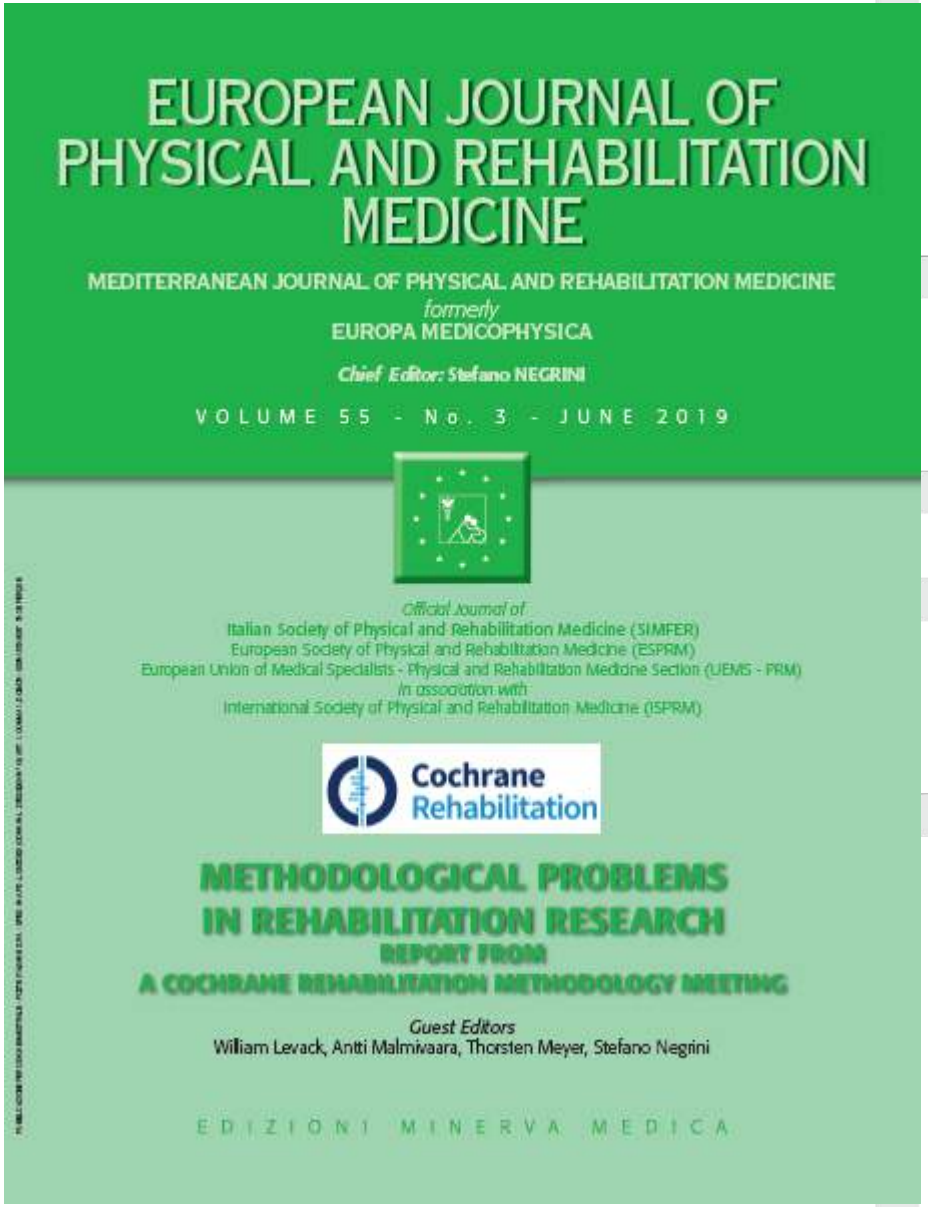
Development of methods for rehab research



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