

Development of a Core Outcome Set for Work Participation.

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Cochrane

Work

SURVEY OF COCHRANE WORK PARTICIPATION REVIEWS

•7 Cochrane reviews

• 82 trials

Patients with chronic medical conditions

Work participation as outcome

Hoving et al, 2018

Need for a core outcome set on work participation

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Does this intervention work?

Both practitioners and patients need to know if an intervention is effective and safe. Following the evidence-based Insurance Medicine (insuremed.cochrane.org) have a Intervention, Comparator, Outcome). To determine the effects of interventions that prevent or reduce occupa-Impact of an Intervention on a specific outcome, decision tional disability, injuries and diseases. The Cochrane makers would like to see a body of evidence formed by multiple studies. It is the purpose of systematic reviews to provide this body of evidence. However, reviewers are prevent job loss in individuals with medical conditions challenged by studies that use heterogeneous outcome interest. For example, to evaluate if training and exercise both groups aim to standardise their outcome set for prevent back pain at the workplace, researchers may refunctioning at work or the occurrence of permanent work promoting the use of evidence by those who perform tional health 'work participation' is an important outcome a prognosis of claim duration, prescribe treatment of this 'work participation' concept, but the instruments of standardisation in outcome measurement and reporting significantly hinders the synthesis of research and. consequently, hampers decision making at the expense of the best possible treatment and social care for patients. Despite the existence of a body of evidence these studies are not fully suited to answer the simple question: does this intervention work?

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Effectiveness as the main focus of Cochrane

Cochrane Work (work.cochrane.org) and Cochrane medicine (EBM) approach research questions about interventions should be structured according to PICO (Patient, and promote high quality systematic reviews about the Work Review Group produces reviews with a focus on interventions that promote return to work (RTW) or such as cancer or depression that could easily result in measurement instruments to measure similar outcomes of work disability. To make their reviews more informative, disability prevention and RTW interventions. Cochrane port sick leave resulting from back pain, reduced physical Insurance Medicine complements these endeavours by disability. For the field of insurance medicine and occupaconcept. Not only are there several outcomes related to disabling conditions, or suggest RTW interventions, ideally with evidence from systematic reviews. To this end, that measure these types of outcomes vary as well. Lack researchers of Cochrane Insurance Medicine would like to see more high-quality Cochrane systematic reviews relevant to their field.

Core outcome sets

The Core Outcome Measures in Effectiveness Trials (COMET) initiative brings together people interested in the development and application of core outcome sets (www.comet-initiative.org). A core outcome set is an agreed minimum set of outcomes that should be measured and reported in all trials in a specific health area.1,2 COMET has established methodological guidance on core outcome set development, which involves the identification and selection of outcomes that are considered 'core' (i.e. what to measure), and, in cooperation with COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) (www.cosmin.nl). that can be used to measure the core outcomes (i.e. how to measure). The Outcome Measures in Rheumatology (OMERACT) initiative has been the front runner in the field of core out-

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REPORTED OUTCOMES

1. RCTs report work related outcomes including:

Frequent:

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- Return to work/ work status
- Sick leave/ absenteeism

Less frequent:

- Functional status (Oswestry questionnaire, SF-36), health functioning
- Productivity
- Work functioning (WLQ, LIFE, Sheehan disability scale, on the job performance by HPQ)
- Work subscale (SAS work)
- Health related quality of life within return to work process (Euler 2013)





REPORTED OUTCOMES

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Used definitions for RTW:

•Partial vs. full RTW

•100% RTW

•Return to own work

•Return to adjusted work

•Workers with no RTW



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 $\bullet \mathsf{W}\mathsf{orkers}$ with no RTW

RTW is measured as:

- Event data (RTW rates)
- Time-to-event-data (time between reporting sick and RTW)
- Number of workers with 100% or no

RTW

• Varying time periods to qualify as RTW





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Follow up times:

- Directly after treatment
- 12 weeks, 3,6, 8, 9, 12, 24, 48 months
 - 100 days, 10 days etc



SURVEY CONCLUSIONS





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found in:

- Definitions
 - Sources
- Recall periods
- Time-points
- •Measurement instruments







COCHRANE REVIEWERS RECOMMENDATIONS

Implication for research:

- In order to allow better comparisons, researchers should agree on the use of outcome measures for sickness absence (van Oostrom 2009)
- We propose including a uniform assessment of job loss, job absenteeism and work functioning across trials including a long term follow-up of at least two years but preferably longer (Hoving 2014)
- Studies also needed to define what return-to-work is: return to full-time or part-time work and return to the same job or a lesser job. Finally, studies need to invest in a much longer follow-up of work-related outcomes (de Boer 2011)
- To facilitate the synthesis of evidence from various intervention studies, the occupational health field should work towards standardising and validating measures of sickness absence. (Nieuwenhuijsen 2014)

PHD CORE OUTCOME SET PROJECT

- Following the guidelines of COMET initiative
- In collaboration with

- Cochrane Work &
- **Cochrane Insurance Medicine**







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WHAT ARE CORE OUTCOME SETS?

An agreed standardised set of outcomes that should be measured and reported, as a *minimum*, in all clinical trials in specific areas of health or health care.

COMET definition

ADVANTAGES OF CORE OUTCOME SETS

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- Increases consistency across trials
- Maximise potential for trial to contribute to systematic reviews of these key outcomes
- Much more likely to measure appropriate outcomes
- Major reduction in selective reporting



COS UPTAKE

- Assessment of full uptake of Rheumatoid Arthritis core outcome sets from data in ClinicalTrials.gov
- Uptake may be influenced by introduction of regulatory guidance



Fig 2 | Percentage of trials measuring full rheumatoid arthritis core outcome set (RA COS) averaged over past 10 years. WHO=World Health Organization; ILAR=International League of Associations for Rheumatology

Kirkham et al, 2017

COCHRANE AND COMET COLLABORATION

			Contact us	Task Exchange	Training	Cochrane Library Cochran	ne.org
Cochrane		Trusted evidence.					
	Community	Informed decisions. Better health.				Search	
Review production Organizational info Help News and events							

Cochrane and COMET: working together to improve core outcome sets



Cochrane Reviews are systematic reviews of research in health care and policy, and are internationally recognized as a high-quality source of evidence for decision-making. They collate and summarize all the best available research evidence on the effects of healthcare interventions or the accuracy of diagnostic tests into a systematic review.



- COS use in alignment with Cochrane
 mission
- Cochrane Work & Cochrane Insurance
 Medicine support for COS
- Several other collaborative initiatives by Cochrane review groups
 - Cochrane Skin/ Cochrane Oral
- Collaboration is essential to prevent development of more than one COS



"Our mission is to develop and implement core outcome sets in dermatology in order to improve and standardise outcome measurement in clinical trials and to make trial evidence more useful."

- Developing clinically relevant and patient-centred sets of dermatological trial outcomes
- Improving the quality and interpretability
 of systematic reviews

 Helping researchers make a clinical difference

Cochrane

Cochrane Skin Core OUtcome Set INitiative (CS-COUSIN)



EXAMPLE COS: CHRONIC POST SURGICAL PAIN

- Rating of 56 pain features identified through a systematic review
- 2. Stakeholders rated 33 pain features
- 3. Research team and organized in core outcome domains:
 - 1. Pain intensity
 - 2. Pain interference with daily life
 - 3. Pain and physical functioning
 - 4. Temporal aspects of pain
 - 5. Pain description
 - 6. Emotional aspects of pain
 - 7. Use of pain medication
 - 8. Improvement and satisfaction with pain relief



THANK YOU FOR YOUR ATTENTION

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