

## Development of a Core Outcome Set for Work Participation

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# INTRODUCTION

PhD research  
“Development of a core  
outcome set for work  
participation” at the  
Coronel Institute of  
Occupational health.





# TODAY'S TOPICS

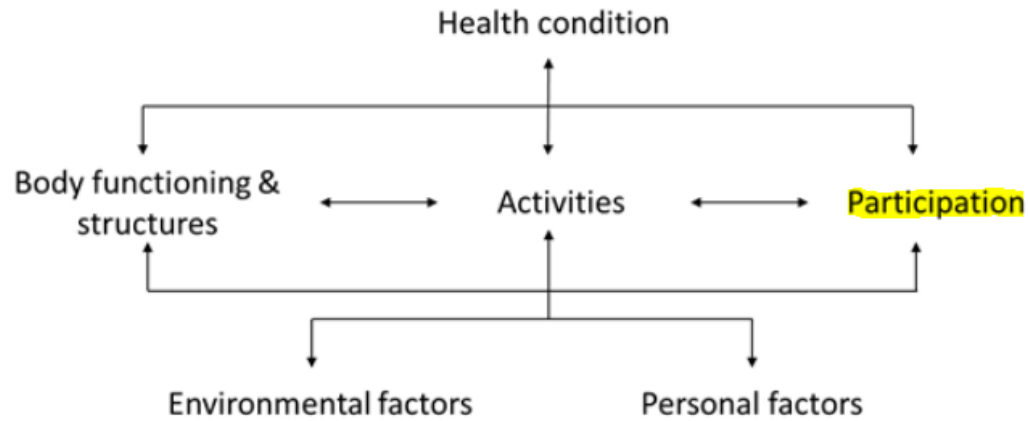
- What is the problem?
- For whom is it a problem?
- A look behind the scenes
- How do core outcome sets help?
- How are core outcome sets made?
- Ongoing work for development of COS for Work







# WHAT SHOULD WE MEASURE?



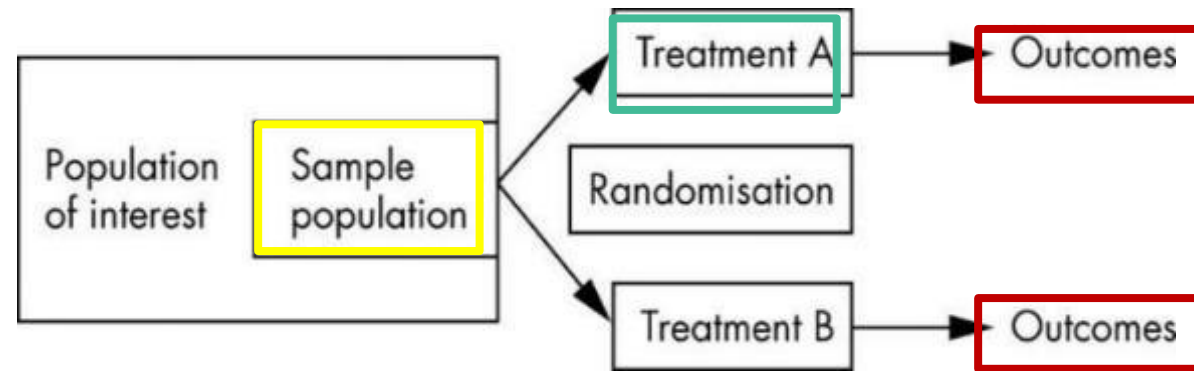
- What is important to measure (for patients, employers, social security)?
- How can we help increase (work) participation?

Mrs. Verhoeven





# DESIGN OF A RANDOMIZED CONTROLLED TRIAL (RCT)



Effectiveness of a Blended Web-Based Intervention on Return to Work for Sick-Listed Employees With Common Mental Disorders: Results of a Cluster Randomized Controlled Trial

# DESIGN OF A SYSTEMATIC REVIEW

What authors DO

Identify the issue and determine the question

Write a plan for the review  
(protocol)

Search for studies

Sift and select studies

Extract data from  
the studies

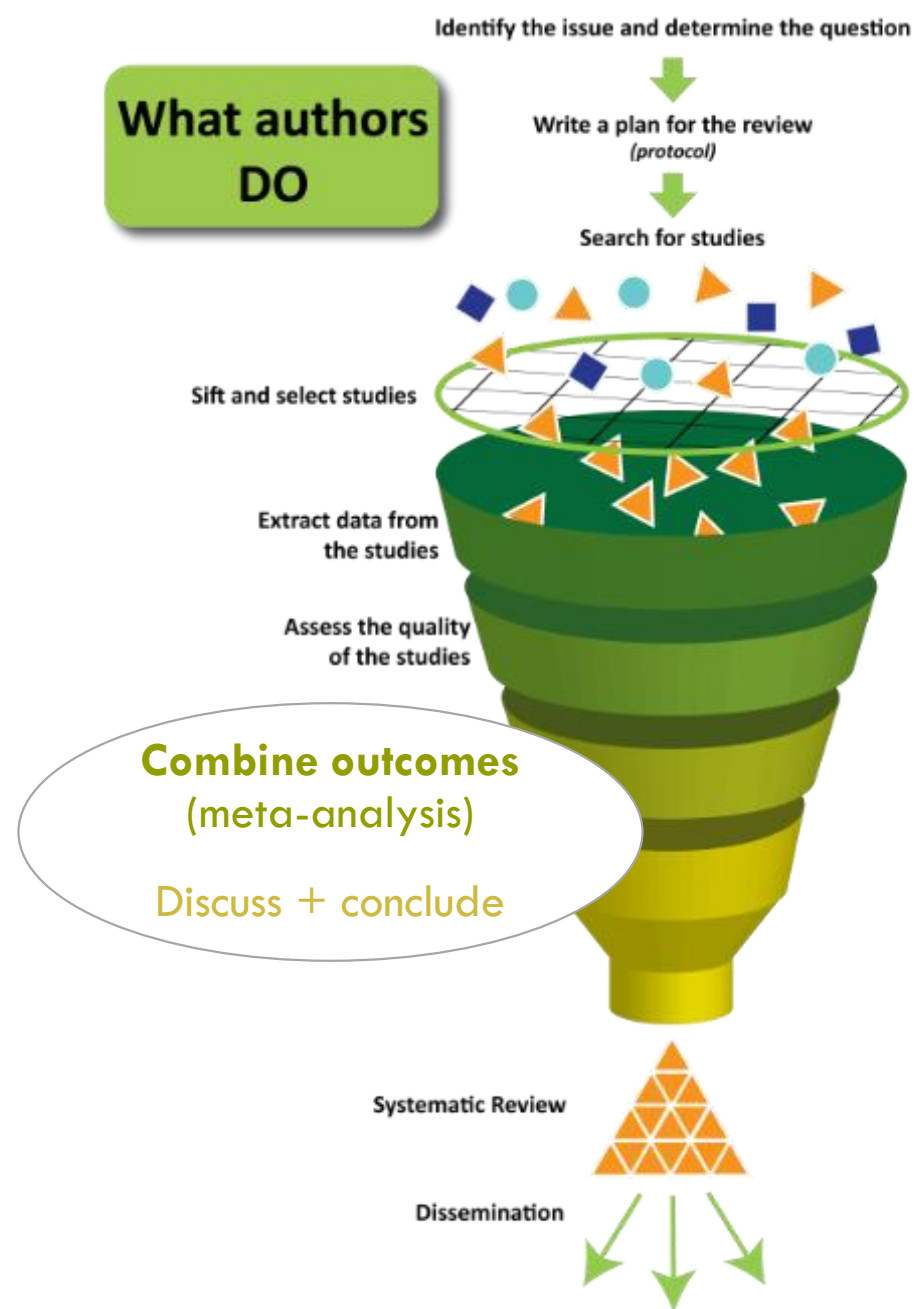
Assess the quality  
of the studies

Combine outcomes  
(meta-analysis)

Discuss + conclude

Systematic Review

Dissemination





# WHY IS IT HARD TO COMPARE RESULTS?

**Big variety in outcomes e.g. of shoulder disorders:**

- Pain
- Range of movement
- Physical functioning
- Sleep functioning
- Strength
- Radiographic results
- Dislocation
- Fracture



Measured by 319 different instruments.





# WHY IS IT HARD TO COMPARE RESULTS?

**Big variety e.g. in work outcomes:**

- Employment status
- Return to work
- Sick leave/ absenteeism
- Functional status
- Productivity
- Work functioning
- Health related quality of work-life





# WHY IS IT HARD TO COMPARE RESULTS?

## Heterogeneous definitions for return to work:

- Return to full-time, part-time work
- 100%, 75%, 50% return to work
  - Return to own work
  - Return to adjusted work
- 1 day, 1 week, 1 month, 3 months without any sick leave
  - Workers with no RTW
- End of social transfer (financial) receipt





# HOW IS INFORMATION ON OUTCOMES COLLECTED?

## How data on return to work can be obtained:

- Social security registers
  - Telephone calls
  - Clinicians reports
  - Patient's self-report
- Validated questionnaires
- Self-developed questionnaires
  - ....

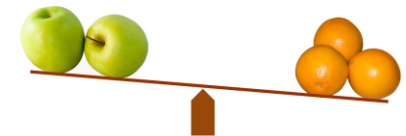




# HOW IS INFORMATION ON OUTCOMES COLLECTED?

## Selection of questionnaires used to measure productivity:

1. The Work Productivity and Activity Impairment (WPAI)
2. Social and Occupational Functioning Assessment Scale (SOFAS)
3. The Work Ability Index (WAI)
4. ...





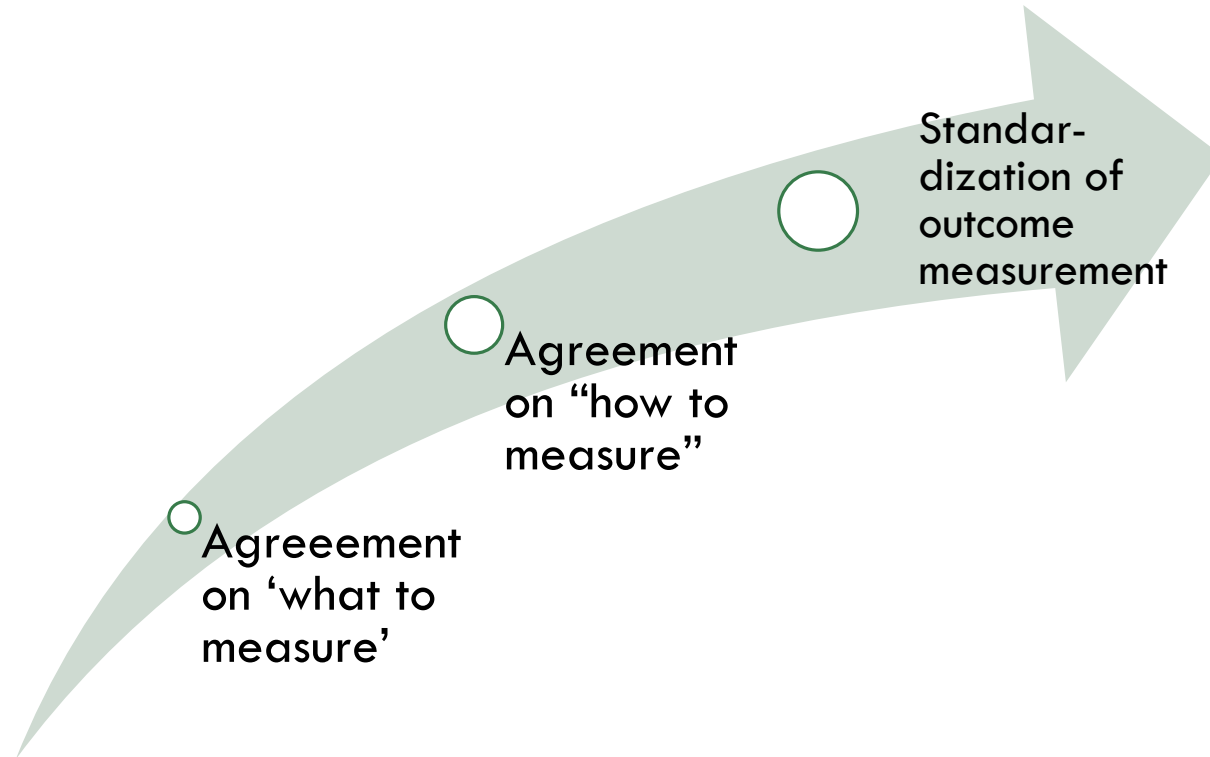
# WHAT IS A CORE OUTCOME SET AND HOW DO THEY HELP?

*"A core outcome set (COS) is an agreed standardized set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care."*





# HOW ARE CORE OUTCOME SETS MADE?



Combining, comparing studies on a large scale.

Make better informed conclusions about what works best.



# ADVANTAGES OF CORE OUTCOME SETS

- ✓ Much more likely to measure appropriate outcomes
- ✓ Major reduction in selective reporting
- ✓ Contribution for systematic reviews, policy/guideline development





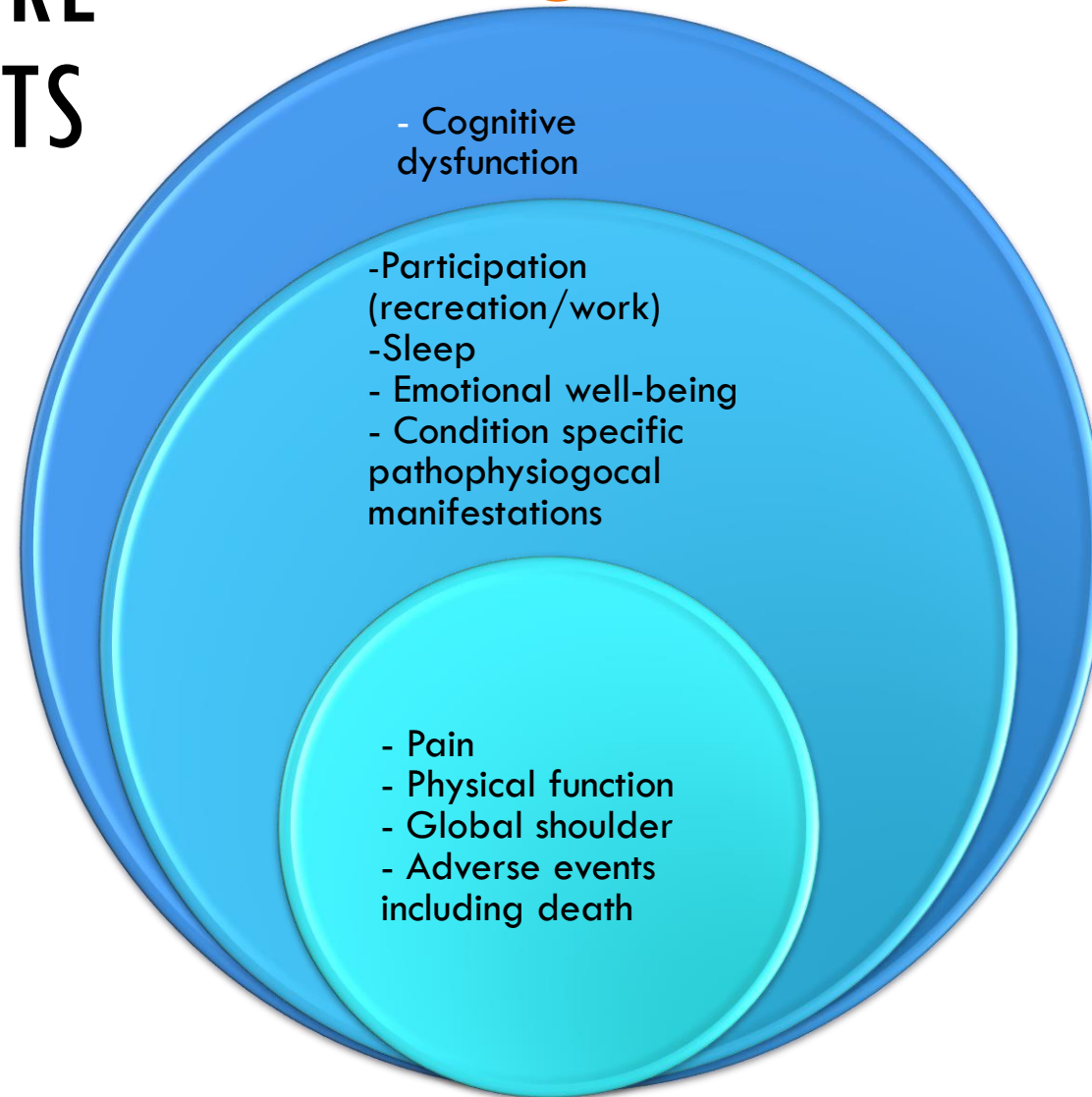
# HOW ARE CORE OUTCOME SETS MADE?

## **Example: Core outcome set for shoulder disorders**

1. Establish the extent of the problem:
  - Analysis of 409 studies: 32 outcome domains, 319 instruments
2. Several rounds of international consensus: shoulder trial experts, clinicians and patients



# HOW ARE CORE OUTCOME SETS MADE?



Outer circle:  
Research

Middle circle:  
Important,  
but optional

Inner circle:  
Compulsary



# COS FOR WORK COLLABORATIONS

- In collaboration with  
Cochrane Insurance Medicine,  
Cochrane Work and UK Centre for  
Musculoskeletal Health and Work
- Following the guidelines of  
COMET initiative





# AIM OF COS FOR WORK

- A core outcome set for work participation for any health problem
- For authors of effectiveness studies and systematic reviews
- For workers with a health problem or people aiming to gain paid work
  - For vocational and clinical/medical studies





# ONGOING WORK ON COS FOR WORK

## 1. A framework for work participation outcomes

- How can many different types of outcomes be grouped?
- A conceptual classification which will be used as a frame of reference for further development of the core outcome set.



# ONGOING WORK ON COS FOR WORK

## **2. A systematic review on how work outcomes are measured in medical and vocational RCTs**

- How are work participation currently measured?
- Analysis of used work participation outcomes and measurement methods on global scale and across disciplines.



# ONGOING WORK ON COS FOR WORK

## 2. A systematic review on how work outcomes are measured in medical and vocational RCTs

**Inclusion criteria:** RCTs, economic evaluations, vocational or medical aim, any health problem, published between 2014- 2019

**Process:** 20 028 RCTs found, 10 022 abstracts screened, 723 full texts screened, 286 used for analysis.

### **Outcomes categorization:**

1. Employment status
2. Absence from paid work
3. At work productivity loss
4. Employability



# ONGOING WORK ON COS FOR WORK

## **3. A survey amongst authors or RCTs and Cochrane systematic reviewers**

- How do researchers decide which outcomes to use?
- What are their experiences with various measurement methods?
- Which barriers and facilitators do they see for the development and implementation of COS for Work?



# THANK YOU FOR YOUR ATTENTION

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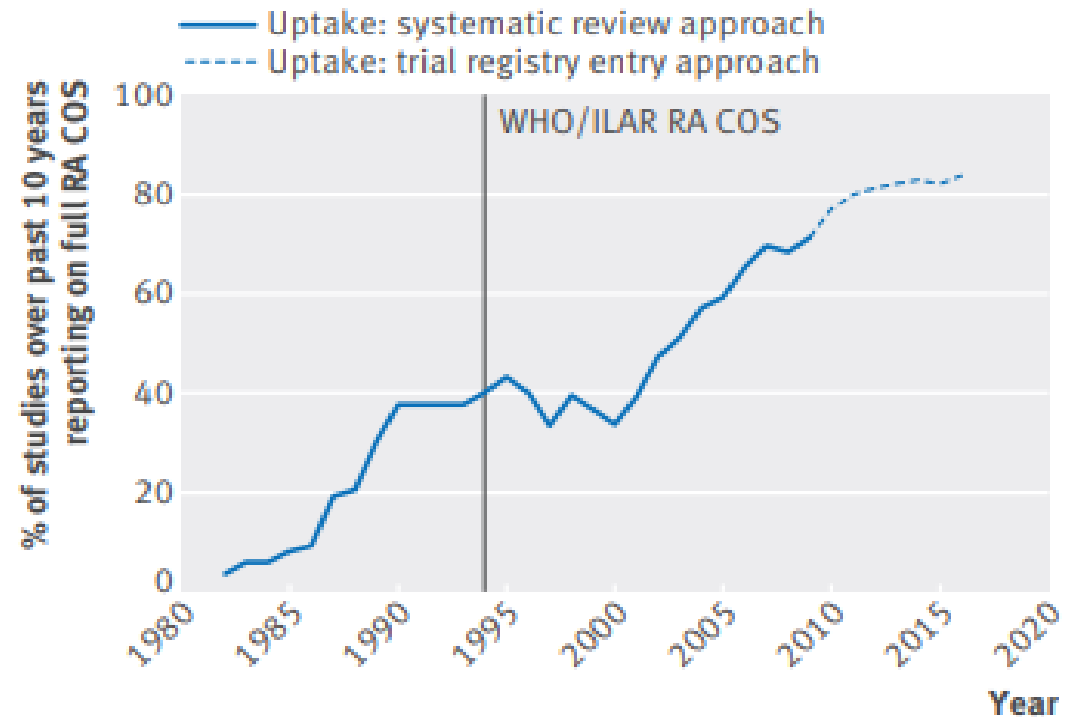
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# COS UPTAKE

- 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