



MRC-NIHR Trials Methodology Research Partnership: Webinar recording

## **Use of behavioural science to increase use of core outcome sets**

*Presented, on behalf of the Health Research Board, by:*

Karen Matvienko-Sikar (University College Cork)

**20 September 2023**

The slides are available below.

For any queries, please contact [uktmn@nottingham.ac.uk](mailto:uktmn@nottingham.ac.uk)

<https://youtu.be/vsPRfrfaxG4>

# Using behavioural science to increase use of COS in trials

## BE-COS

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# Core Outcome Sets (COS)

Standardised minimum outcome set of **what** should be measured and reported in any trial of a specific health area



## Benefits of COS

Improve evidence  
synthesis

Building empirical  
bases

Reduce research  
waste

Relevant and  
meaningful to  
stakeholder priorities

Increase openness  
and transparency

Reduce bias





Health Research Board  
**TMRN**  
Trials Methodology Research Network



# COS Use

**BMJ Open** *Assessing the relevance and uptake of core outcome sets (an agreed minimum collection of outcomes to measure in research studies) in Cochrane systematic reviews: a review*

Paula R Williamson,<sup>1</sup> Ricardo de Ávila Oliveira,<sup>2</sup> Mike Clarke <sup>3</sup>, Sarah L Gorst <sup>1</sup>, Karen Hughes,<sup>1</sup> Jamie J Kirkham <sup>4</sup>, Tianjing Li,<sup>5</sup> Ian J Saldanha,<sup>6</sup> Jochen Schmitt<sup>7</sup>

7 of 100 reviews



Journal of Clinical Epidemiology 142 (2022) 19–28



ORIGINAL ARTICLE

Use of core outcome sets was low in clinical trials published in major medical journals

Karen Matvienko-Sikar<sup>a,\*</sup>, Kerry Avery<sup>b</sup>, Jane M Blazeby<sup>b</sup>, Declan Devane<sup>c,d</sup>, Susanna Dodd<sup>e</sup>, Aoife M Egan<sup>f</sup>, Sarah L Gorst<sup>e</sup>, Karen Hughes<sup>e</sup>, Pamela Jacobsen<sup>g</sup>, Jamie J Kirkham<sup>h</sup>, Jan Kottner<sup>i</sup>, Katie Mellor<sup>j</sup>, Christopher P Millward<sup>k,l</sup>, Smitaa Patel<sup>m</sup>, Fiona Quirke<sup>d,n</sup>, Ian J Saldanha<sup>o</sup>, Valerie Smith<sup>p</sup>, Caroline B Terwee<sup>q</sup>, Amber E Young<sup>r</sup>, Paula R Williamson<sup>e</sup>

2 of 95 trials



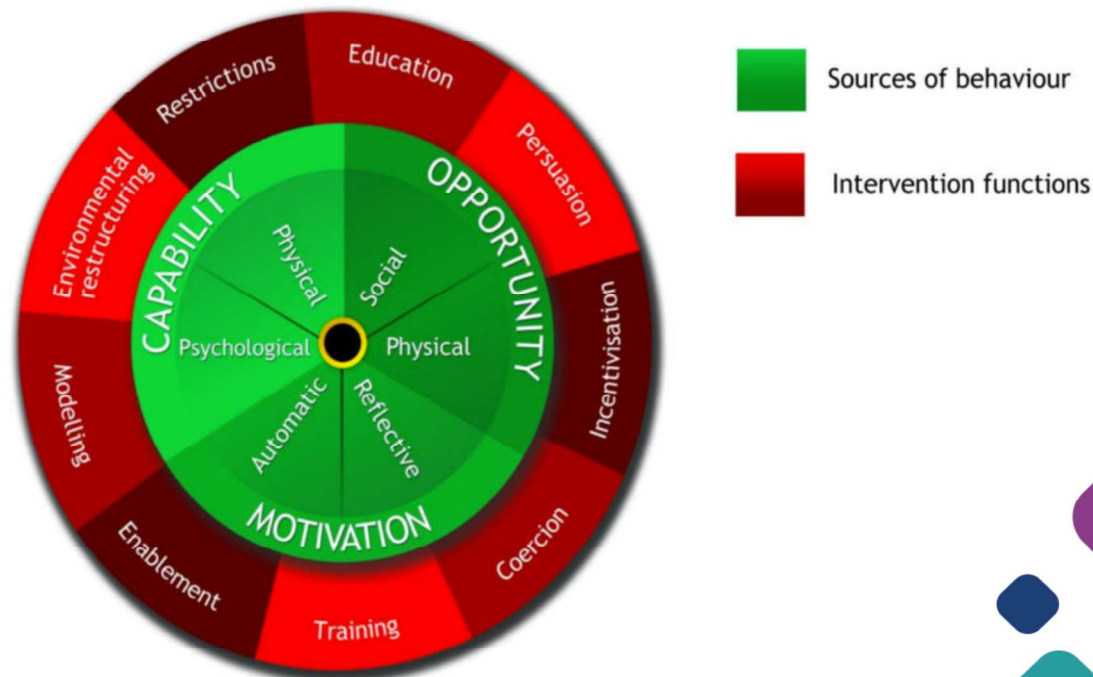
# COS Use

- COS use as a behaviour
  - Something trialists do, or not do
- Can use behavioural science approaches to address low use



# BE-COS

- Identify behavioural intervention components to potentially increase the use of COS in trials



# Methods

Components	Definition
Who	Researchers conducting trials in health areas (“Trialists”)
What	Consideration or use of a COS in design. Use of a COS in conduct and reporting of a trial in a specific health area, where a relevant COS exists
Where	Anywhere trialists design, conduct and/or report trials
When	At trial design stage. During the conduct of the trial During reporting and dissemination of trial findings
How often	When designing, conducting and reporting a trial.





# Methods

- Used existing evidence to identify barriers and facilitators to COS use in trials



Journal of Clinical Epidemiology 144 (2022) 111–120

Journal of  
Clinical  
Epidemiology

## ORIGINAL ARTICLE

In-depth qualitative interviews identified barriers and facilitators that influenced chief investigators' use of core outcome sets in randomised controlled trials

Karen L. Hughes<sup>a,\*</sup>, Paula R Williamson<sup>a</sup>, Bridget Young<sup>b</sup>

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PLOS ONE

RESEARCH ARTICLE

Assessing the impact of a research funder's recommendation to consider core outcome sets

Karen L. Hughes<sup>1,\*</sup>, Jamie J. Kirkham<sup>2</sup>, Mike Clarke<sup>3</sup>, Paula R. Williamson<sup>1</sup>

<sup>1</sup> MRC North West Hub for Trials Methodology Research, Department of Biostatistics, University of Liverpool, Liverpool, United Kingdom, <sup>2</sup> Centre for Biostatistics, Manchester Academic Health Science Centre, University of Manchester, Manchester, United Kingdom, <sup>3</sup> Centre for Public Health, Institute of Clinical Sciences, Queen's University Belfast, Royal Victoria Hospital, Belfast, United Kingdom

RESEARCH

Open Access

A survey of knowledge, perceptions and use of core outcome sets among clinical trialists



Chiara Bellucci<sup>1</sup>, Karen Hughes<sup>2</sup>, Elaine Toomey<sup>3</sup>, Paula R. Williamson<sup>4</sup> and Karen Matvienko-Sikar<sup>1\*</sup>



Journal of Clinical Epidemiology 142 (2022) 19–28

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## ORIGINAL ARTICLE

Use of core outcome sets was low in clinical trials published in major medical journals

Karen Matvienko-Sikar<sup>a,\*</sup>, Kerry Avery<sup>b</sup>, Jane M Blazeby<sup>b</sup>, Declan Devane<sup>c,d</sup>, Susanna Dodd<sup>e</sup>, Aoife M Egan<sup>f</sup>, Sarah L Gorst<sup>g</sup>, Karen Hughes<sup>g</sup>, Pamela Jacobsen<sup>h</sup>, Jamie J Kirkham<sup>b</sup>, Jan Kottner<sup>i</sup>, Katie Mellor<sup>j</sup>, Christopher P Millward<sup>k,l</sup>, Smitaa Patel<sup>m</sup>, Fiona Quirke<sup>d,n</sup>, Ian J Saldanha<sup>o</sup>, Valerie Smith<sup>p</sup>, Caroline B Terwee<sup>q</sup>, Amber E Young<sup>r</sup>, Paula R Williamson<sup>e</sup>

# Methods

- Coded barriers and facilitators using the COM-B framework to identify behavioural components

COM-B component	Example
Physical capability	Able to find a COS (facilitator)
Psychological capability	Knowledge about COS (barrier and facilitator)
Social opportunity	Team critiques of COS (barrier)
Physical opportunity	Measurement challenges (barrier)
Reflective motivation	Perceived COS advantages (facilitator)
Automatic motivation	Wanting to control outcomes (barrier)



# Methods

- Mapped COM-B components to intervention functions
  - ‘Broad categories of means by which an intervention can change behaviour’

Barrier/facilitator	COM-B component	Intervention Function
Knowledge about COS (barrier and facilitator)	Psychological capability	Education, Training, Enablement

- APEASE evaluation of intervention functions
  - Affordability, Practicability, Effectiveness/cost-effectiveness, Acceptability, Side-effects/safety, Equity



# Intervention Functions

Included intervention Function	Definition
Education	Increasing knowledge or understanding
Training	Imparting skills
Enablement	Increasing means/reducing barriers to increase capability (beyond training) or opportunity (beyond environmental restructuring)
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Modelling	Providing an example for people to aspire to or imitate



# Methods

- Mapping to behaviour change techniques (BCTs)
  - BCTs are irreducible, observable, and replicable active ingredients of an intervention

Barrier/facilitator	COM-B component	Intervention Function	BCT	BCT example
Knowledge about COS (barrier and facilitator)	Psychological capability	Education	Instruction on how to perform the behaviour	Workshop component on how to search for, appraise and use a COS



# Behaviour Change Techniques

Action planning

Self-monitoring of  
behaviour

Instruction on how  
to perform the  
behaviour

Information about  
antecedents

Information about  
consequences

Demonstration of  
the behaviour

Social comparison

Information about  
others' approval

Behavioural  
practice/rehearsal

Credible source

Pros and cons

Conserving mental  
resources

Identification of  
self as role model

Framing/reframing

Problem solving



# Methods

- BCT examples
  - 36 examples

BCT	BCT example
Instruction on how to perform the behaviour	Workshop component on how to search for, appraise and use a COS  Videos outlining how to search for & identify COS; how COS are developed; how to measure COS
Information about consequences	'Fact sheet' of written information on consequences/benefits of COS use  Animated video on consequences/benefits of COS use



# Methods

- Developed categories of approaches
  - Workshop, guidance, audio/visual, other

BCT	BCT example	Category
Instruction on how to perform the behaviour	Workshop component on how to search for, appraise and use a COS	Workshop
	Videos outlining how to search for & identify COS; how COS are developed; how to measure COS	Audio visual





# Conclusion

- Diverse ways to potentially increase COS use
- Next step is examining if they can increase COS use





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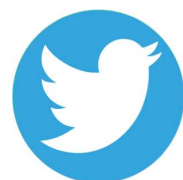
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Mike Clarke, Jamie Kirkham, Jan Kottner, Fiona  
Quirke, Ian J Saldanha, Valerie Smith, Elaine  
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Thank you!

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