

What are we evaluating in  
process evaluations?

What is an intervention?

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LONDON  
SCHOOL *of*  
HYGIENE  
& TROPICAL  
MEDICINE



# Aim of this talk

- To identify, characterise, and understand the concept of intervention in evaluation studies in health and social care.
- To distinguish between complicated and complex interventions
- To present a simple set of targets for process evaluation in research on complex interventions

# As researchers we wrestle with the problems of intervention complexity: MRC Framework shifts from study structure, to component mapping, to managing uncertainty....

Complex interventions are those that include several components

The evaluation of complex interventions is difficult because of problems of developing, identifying, documenting, and reproducing the intervention

Campbell M, et al. Framework for design and evaluation of complex interventions to improve health *BMJ* 2000; 321 :694

What makes an intervention complex?

Number of interacting components within the experimental and control interventions; number and difficulty of behaviours required by those delivering or receiving the intervention; number of groups or organisational levels targeted by the intervention; Number and variability of outcomes.

Craig P, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655.

How does the intervention interact with its context? What is the underpinning programme theory? How can diverse stakeholder perspectives be included in the research? What are the key uncertainties? How can the intervention be refined? What are the comparative resource and outcome consequences of the intervention?

Skivington K, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance *BMJ* 2021; 374 :n2061

# Definitions:

An intervention is a coherent ensemble of purposive beliefs, behaviours, practices, and artefacts that are deemed to be executable in a specific context and are believed to have predictable consequences when they are executed.

May C. Agency and implementation: understanding the embedding of healthcare innovations in practice. *Social Science & Medicine*. 2013 Feb 1;78:26-33.

Execution or implementation of interventions occurs when they are incorporated into the strategic intentions of one group of actors and translated into the everyday activities of others. The essence of implementation is collective action and collaborative work.

May C, Finch T, Rapley T. Normalization process theory. In: Nilsen P, Birken, S. (Eds) *Handbook on implementation science* 2020 May 21 (pp. 144-167). Edward Elgar Publishing.

‘An intervention is never just a thing-in-itself. Complex interventions have many moving parts, but they also have many different effects. These effects shape important aspects of the contexts in which the intervention is being evaluated’.

May C. Agency and implementation: understanding the embedding of healthcare innovations in practice. *Social Science & Medicine*. 2013 Feb 1;78:26-33.

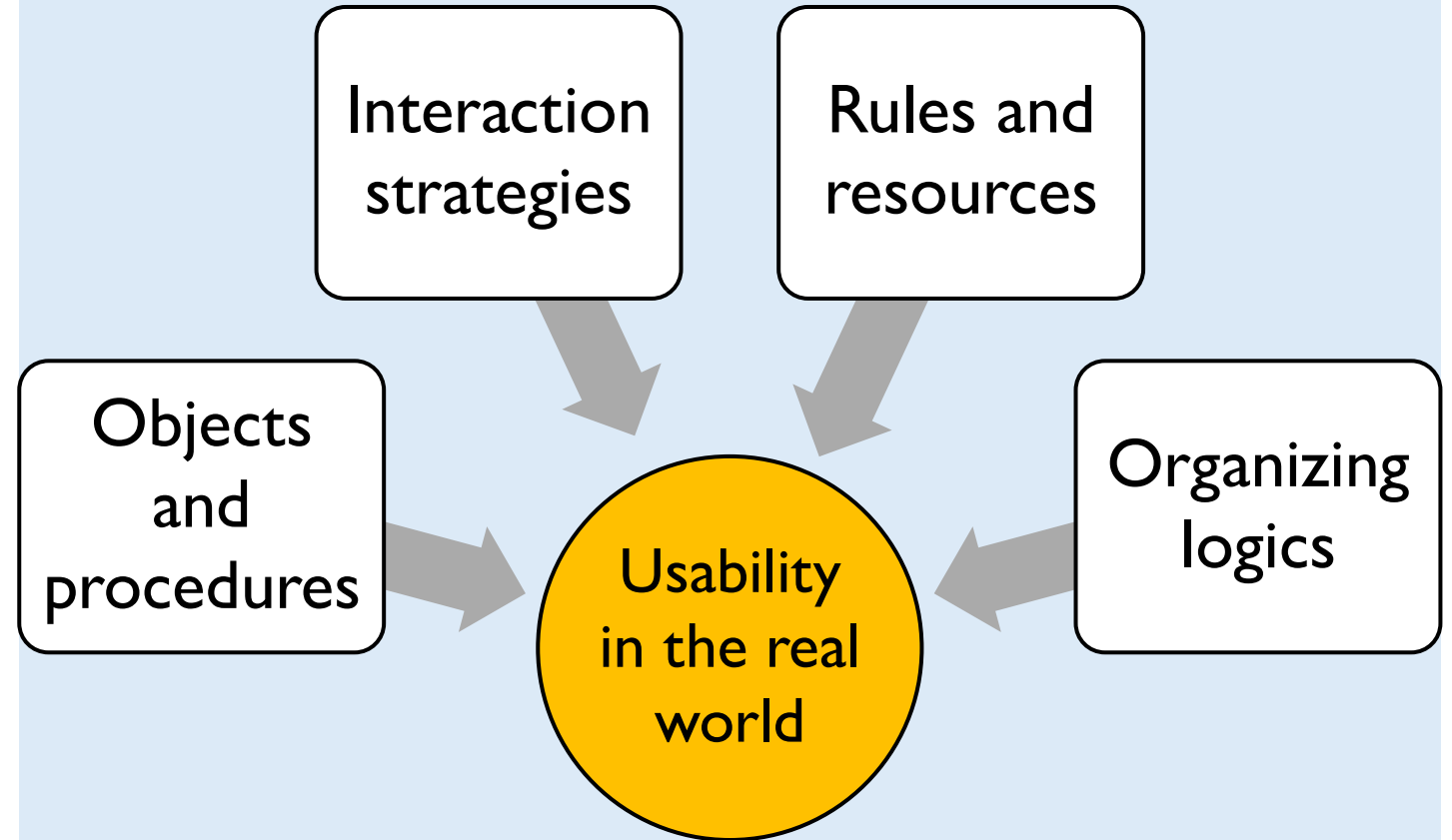
## Breaking interventions down into their elemental components

**Objects and procedures** (concrete and virtual ensembles of beliefs, behaviors, practices, are formed around objects and procedures)

**Rules and resources** (formal and informal changes in norms and roles, information and material resources, shape participants' delegated accountabilities)

**Interaction strategies** (real and virtual relations between participants are formed in ways that define their assumed capabilities)

**Organizing logics** (patterns of formal and informal agreements and values give cognitive authority to participants and assign meaning to their actions)



## Structures of action in a complex intervention: implementation of Treatment Escalation Plans at end of life

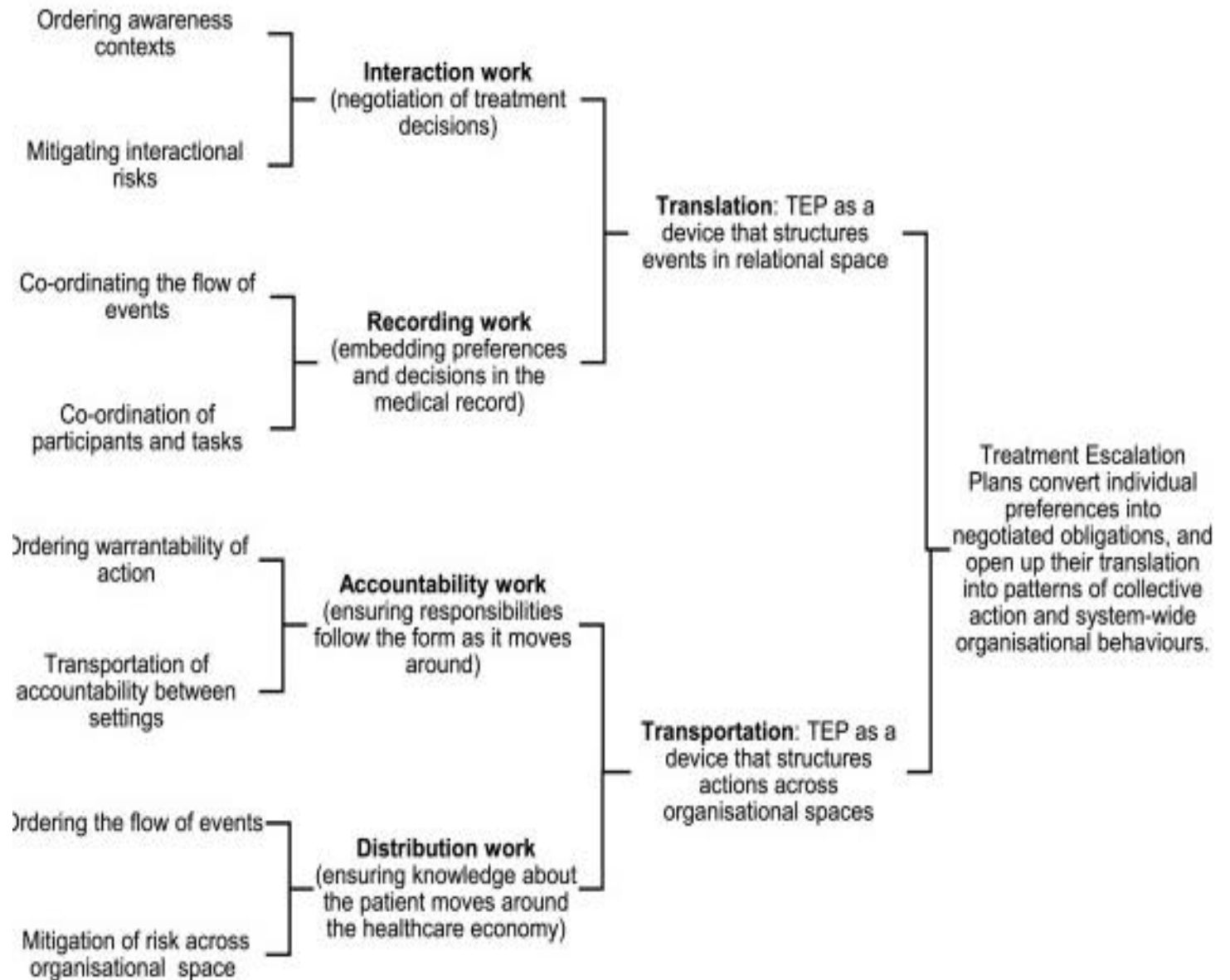
Interaction work = interaction strategies

Recording work = objects and procedures

Accountability work = rules and resources

Distribution work = organizing logics

May C, et al. Managing patient preferences and clinical responses in acute pathophysiological deterioration: What do clinicians think treatment escalation plans do?. *Social Science & Medicine*. 2020 Aug 1;258:113143.



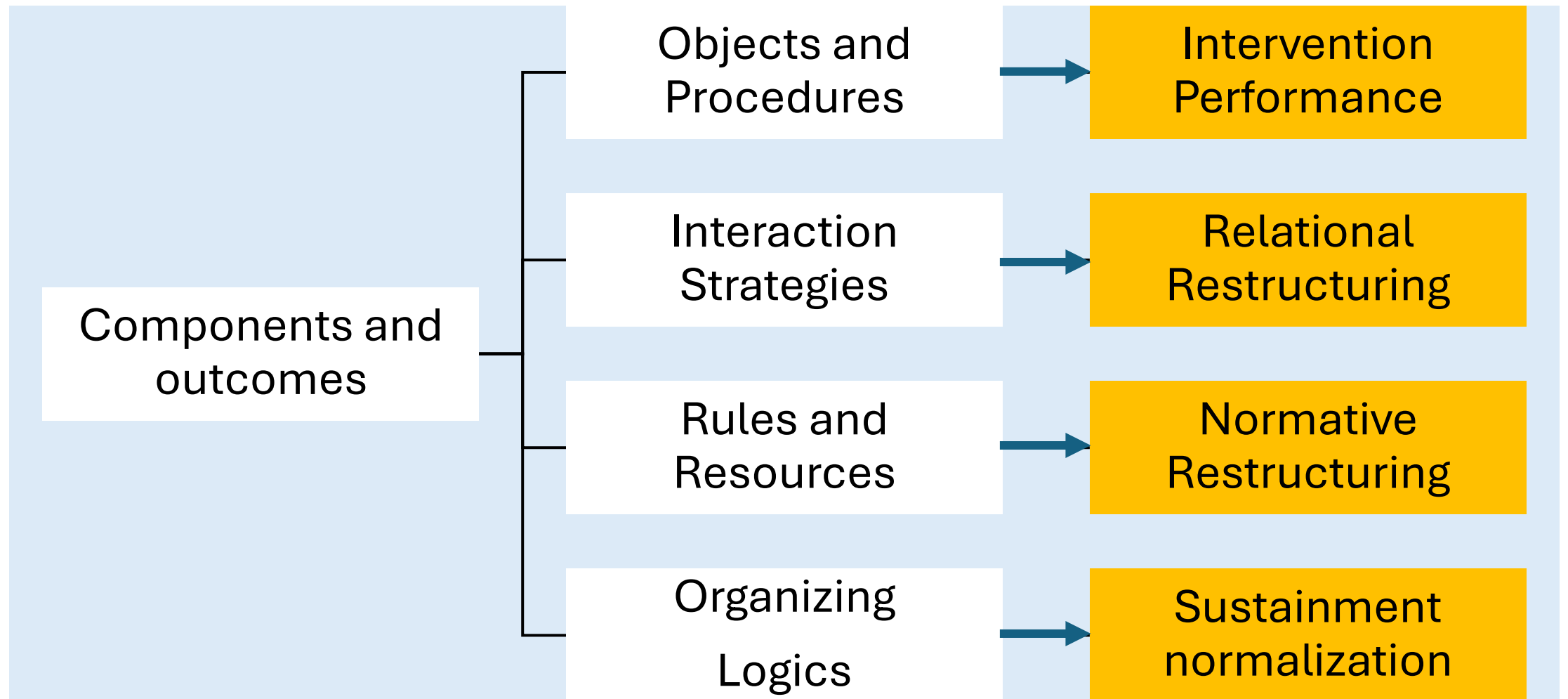
## Intervention outcomes:

May C, et al .Translational framework for implementation evaluation and research: a normalisation process theory coding manual for qualitative research and instrument development. *Implementation Science*. 2022 Feb 22;17(1):19.

<b>Intervention Performance:</b> How material practices change as the result of interventions and their components being operationalized, enacted, reproduced, over time and across settings.	<b>Relational Restructuring:</b> How working with interventions and their components changes the ways people are organized and relate to each other.
<b>Normative Restructuring:</b> How working with interventions and their components changes the norms, rules and resources that govern action.	<b>Sustainment/ Normalization:</b> How interventions and their components become incorporated/embedded in practice.



# Outcomes of intervention components in use



# Thank you!

- Want to follow up anything I've said?
- Follow/DM me on:  
@CarlRMay on X or  
carlrmay.bsky.social on  
BlueSky
- Email me:  
[carl.may@lshtm.ac.uk](mailto:carl.may@lshtm.ac.uk)

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# **What are we evaluating in process evaluations?**

## **Context and implementation**

**Tracy Finch**

## My focus.....

- What does (or can) 'context' (or 'contextualising') mean when we are undertaking process evaluation?
  - Ensuring interventions are *appropriate*
  - Ensuring interventions are *implementable*
  - Ensuring effectiveness *evaluation is 'implementable'*

***Value of taking an iterative, theory-informed approach from the start***

# HEALTH TECHNOLOGY ASSESSMENT

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## Cognitive-behavioural therapy-based intervention to reduce fear of falling in older people: therapy development and randomised controlled trial – the Strategies for Increasing Independence, Confidence and Energy (STRIDE) study

*Steve W Parry, Claire Bamford, Vincent Deary, Tracy L Finch, Jo Gray, Claire MacDonald, Peter McMeekin, Neil J Sabin, I Nick Steen, Sue L Whitney and Elaine M McColl*

# STRIDE trial

**AIM:** Develop CBT intervention for older adults with fear of falling & evaluate effectiveness

**DESIGN:** RCT of the new CBTi vs usual care alone 415 patients randomised between CBTi plus usual care (intervention) and usual care (control group)

## RESULTS:

- Significant positive effect of intervention on reducing FoF<sup>1</sup> and anxiety/depression<sup>2</sup>
- Health Economic study found no evidence that the intervention was cost-effective

<sup>1</sup>Falls Efficacy: FES-I score at 12 months (primary outcome); <sup>2</sup>HADS at 12 mths (secondary)

# STRIDE STUDY: Process Evaluation

**AIM:** To identify, describe and explain the professional and organisational factors that **promoted or inhibited the implementation and integration of the CBTi**

**Phase 1:** CBTi development

**Phase 2:** Evaluation during trial

Methods	Source	Format
Interviews (n = 76)	Clients, caregivers, professionals, STRIDE therapists, research team members	Transcripts
Informal discussions (n = 67)  Observations (n = 34)  Meetings/ training (n = 61)	Clinics, therapy sessions, training and supervision sessions, intervention development meetings, other meetings	Field notes

RESEARCH ARTICLE

Open Access

# Making sense of a cognitive behavioural therapy intervention for fear of falling: qualitative study of intervention development

Tracy L Finch<sup>1†</sup>, Claire Bamford<sup>1†</sup>, Vincent Deary<sup>2</sup>, Neil Sabin<sup>3</sup> and Steve W Parry<sup>4</sup>

**Two domains of work** needed to develop a CBTi that made sense to stakeholders, and that could be delivered as part of an RCT:

## PSYCHOLOGISTS

Developing understanding of complexity of FoF highlighted the need for individualised rather than manualised intervention

## RESEARCH TEAM

Work done to adapt the RCT structure and process to address preliminary acceptability and feasibility concerns of the proposed CBTi



# Achieving coherence within the CBTi

R1 so I think there's a boundary issue about are we doing CBT for fear of falling,

R4 The boundary issue is key.

R1 Or **are we doing CBT for fear of falling and actual** (R4: and pain and ..) [...]

R12 ...in a sense you'll be working with them with whatever they bring, I mean it might be that you know the pain is a major factor in them not going out or whatever so I think that's a legitimate piece of work. (Intervention development meeting 15.2.2012)

## Achieving a feasible, transferable CBTi for FoF

“All of which does raise some questions about generalisability, if we were recruiting the ones who are a bit savvy and we’re giving them a lot of training [...] that **doesn’t necessarily translate into your ‘Joe Bloggs care assistant’** who is already working in a very busy ... but we’ll see, I think we have to prove it’s doable first.” (Intervention development meeting, 13.9.2011)

# Achieving coherence in RCT structures and processes: Acceptability and feasibility

## Recruiting clients:

INT: what does psychotherapy treatment mean to you?

P02: Sitting **on a couch with a shrink!**

INT: And would you then sign up for that do you think?

P02 I don't know, I don't know whether that would help me with the problems I've got.

## Sceptical clinicians:

“I don't know whether it's protective or not which would be my other question, is it a good thing people have a fear of falling, **if you take that fear of falling away are they going to fall** because their sense of caution has gone?” (C3)

# STRIDE: What did (NPT informed) process evaluation add?

## The Trial

Intervention more effective in  
intervention group

## The 'supporting' (sometimes invisible) work

Development of iCBT tailored to target groups  
Stakeholders' experiences and actions  
Factors affecting engagement/ participation  
Optimised trial processes  
Focus on understanding implementation of the trial

*(And even more hidden - responsive actions to keep trial afloat)*

# Normalisation process theory: a framework for developing, evaluating and implementing complex interventions

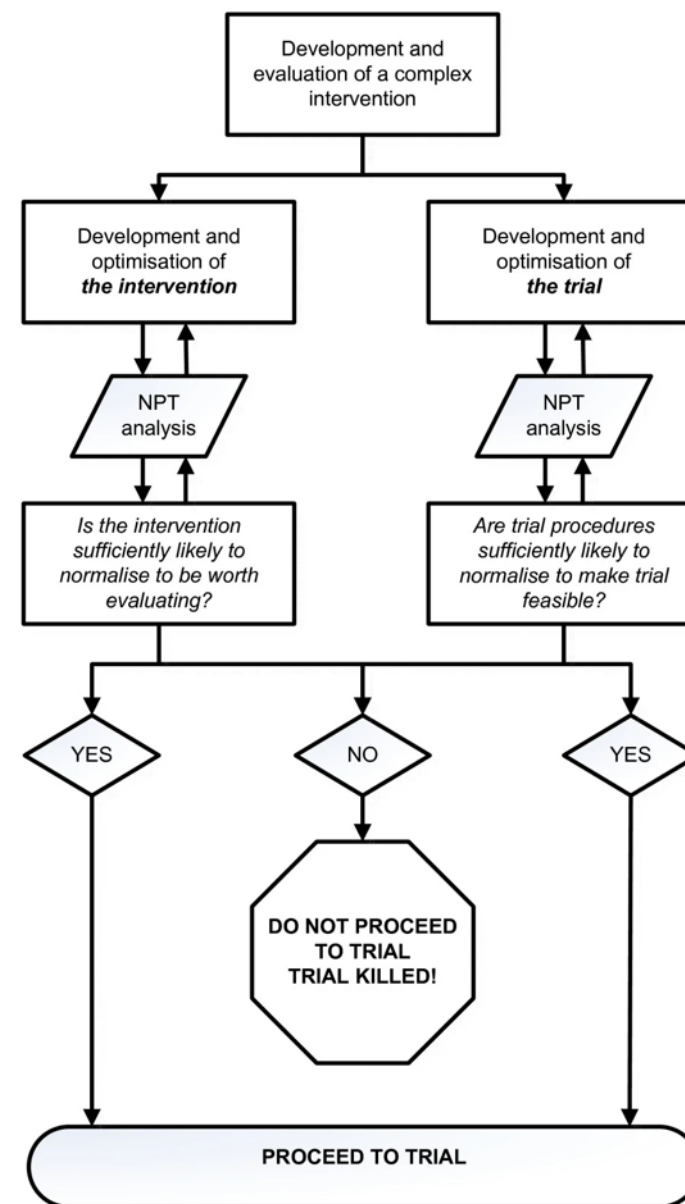
Elizabeth Murray<sup>1\*</sup>, Shaun Treweek<sup>2</sup>, Catherine Pope<sup>3</sup>, Anne MacFarlane<sup>4</sup>, Luciana Ballini<sup>5</sup>, Christopher Dowrick<sup>6</sup>, Tracy Finch<sup>7</sup>, Anne Kennedy<sup>8</sup>, Frances Mair<sup>9</sup>, Catherine O'Donnell<sup>9</sup>, Bie Nio Ong<sup>10</sup>, Tim Rapley<sup>7</sup>, Anne Rogers<sup>8</sup>, Carl May<sup>11</sup>

**NPT as 'trial killer'**

But....

**Shift our thinking – trial 'saviour'?**

From: Normalisation process theory: a framework for developing, evaluating and implementing complex interventions



Normalisation Process Theory (NPT) as a 'trial killer'. Context: All important for development, evaluation and implementation.

DEBATE

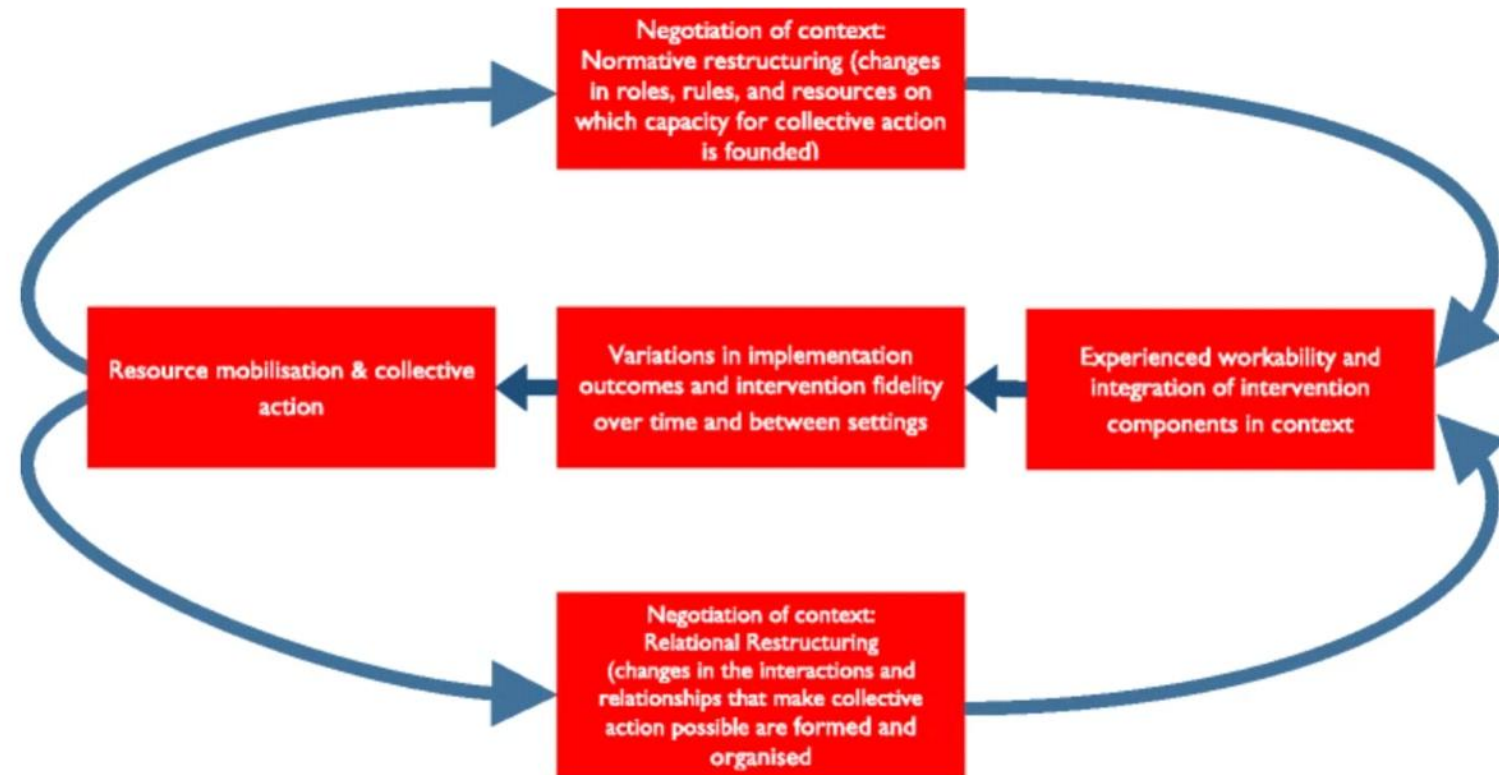
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# Implementation, context and complexity

Carl R. May<sup>1,2,3\*</sup>, Mark Johnson<sup>2,4</sup> and Tracy Finch<sup>5</sup>

Concept
Collective action
Context
Coupling
Elasticity
Emergence
Normative restructuring
Plasticity
Relational restructuring



**Thank you for listening 😊**