

# Are realist RCTs possible? Reflections on the INCLUSIVE trial

Dr Emily Warren

With Professors Chris Bonell and GJ Melendez-Torres

LONDON  
SCHOOL of  
HYGIENE  
& TROPICAL  
MEDICINE



RCT aims to test hypotheses about cause and effect by randomly allocating a sufficient number of people or groups to receive (or not) an intervention, following them up for an appropriate amount of time, and assessing differences at the end of the experiment

1. Randomization- minimize allocation bias and baseline differences between arms
2. Control-contemporaneous counterfactual

Often, but not always accompanied by a process evaluation which may be qual/quant/multi/mixed method

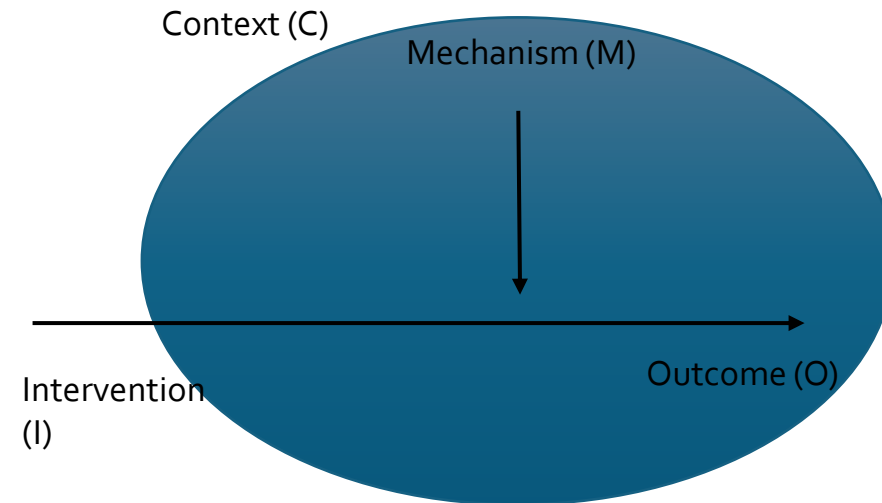
# Realist Evaluation

Situates itself in opposition to experimental interventions

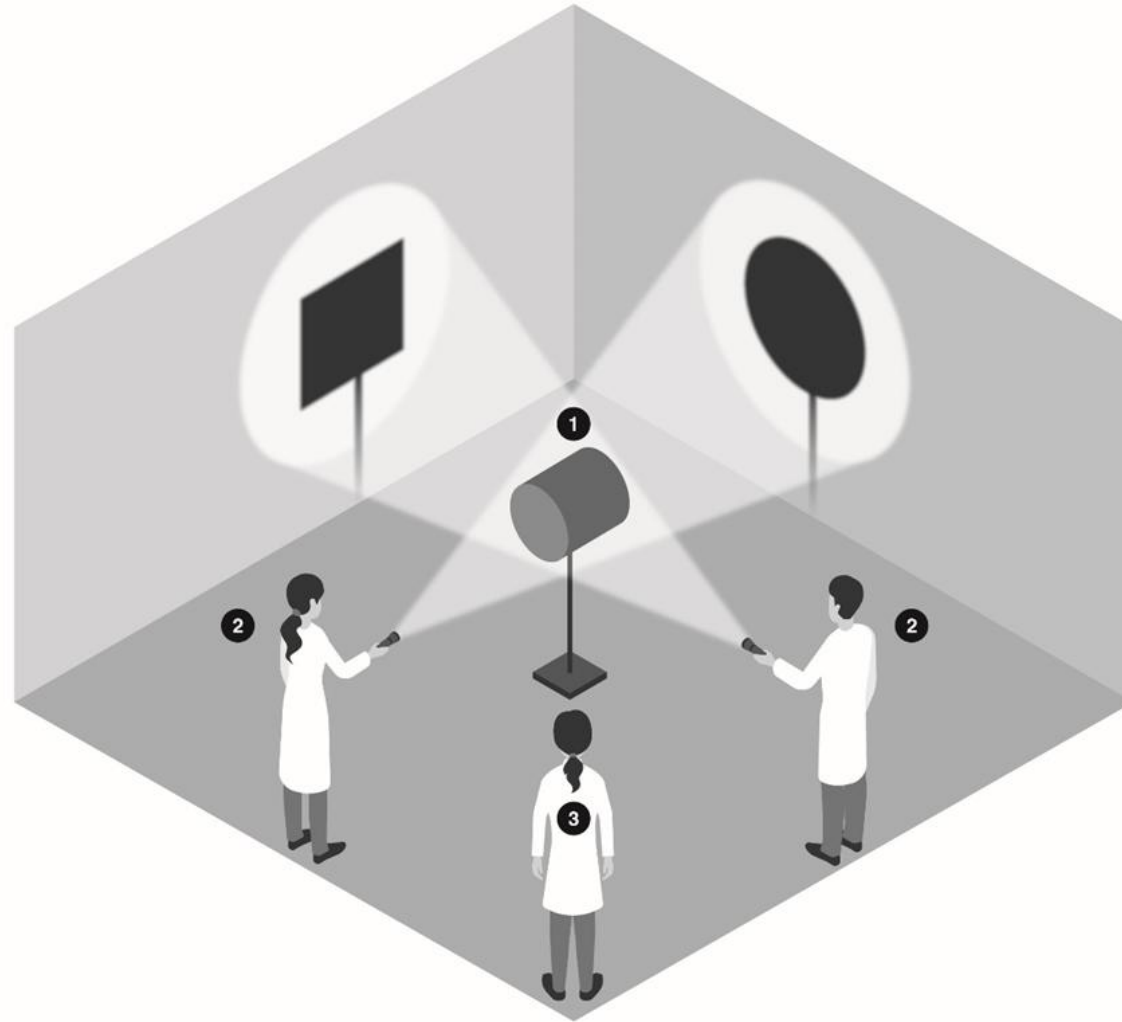
Interventions introduce resources into contexts – actors use these resources which then trigger mechanisms

Focus on demi-regularities and how context appears to enable or constrict the activation of mechanisms

Asks, 'What works for whom in what circumstances and in what respects, and how?' (Pawson and Tilley 1997, pg. 2)



# Realist ontology:



1 Ontological Realism

2 Epistemic Relativism

3 Judgemental Rationality

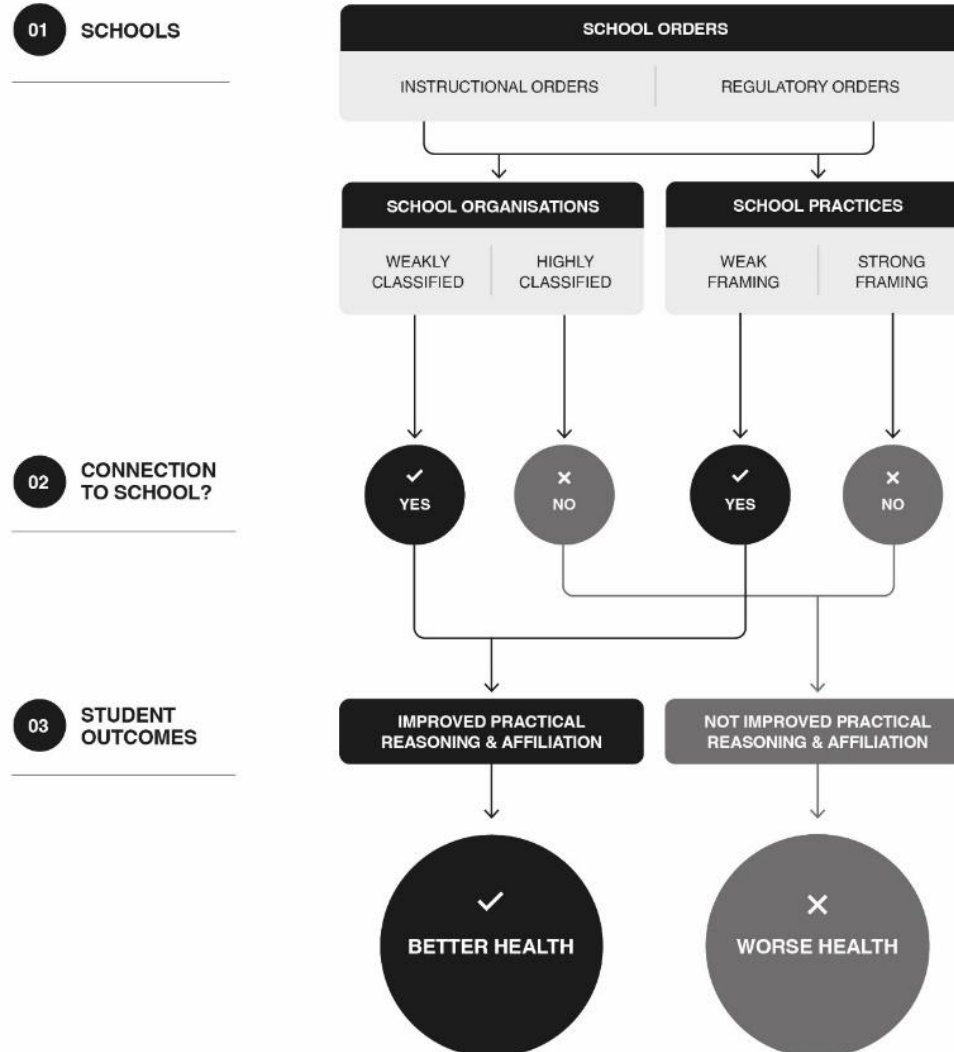
Within a realist ontology, reality is stratified into descending layers (realms)

- The **Empirical realm** comprised **experiences**
- The **Actual realm** comprised of **events and interactions**, regardless of whether we know about them or not
- The **Real Realm** comprised of **mechanisms** which can be active or latent; **causal potential**

## Initiating change locally in bullying and aggression through the school environment

- Ontological underpinning: realism
- Design: Cluster RCT
- Participants: 40 state-sponsored secondary schools and students in year 8 in first year of study
- Comparator: normal practice
- Primary outcomes: Bullying and victimization (GBS) and Aggressive behaviours (ESYTC)
- Secondary outcomes: QoL, health-related QoL, wellbeing, psychological problems, substance use, sexual risk behaviours, use of NHS services, contact with police, exclusions and absences and rates of staff burnout

# Theory of human functioning and school organisation

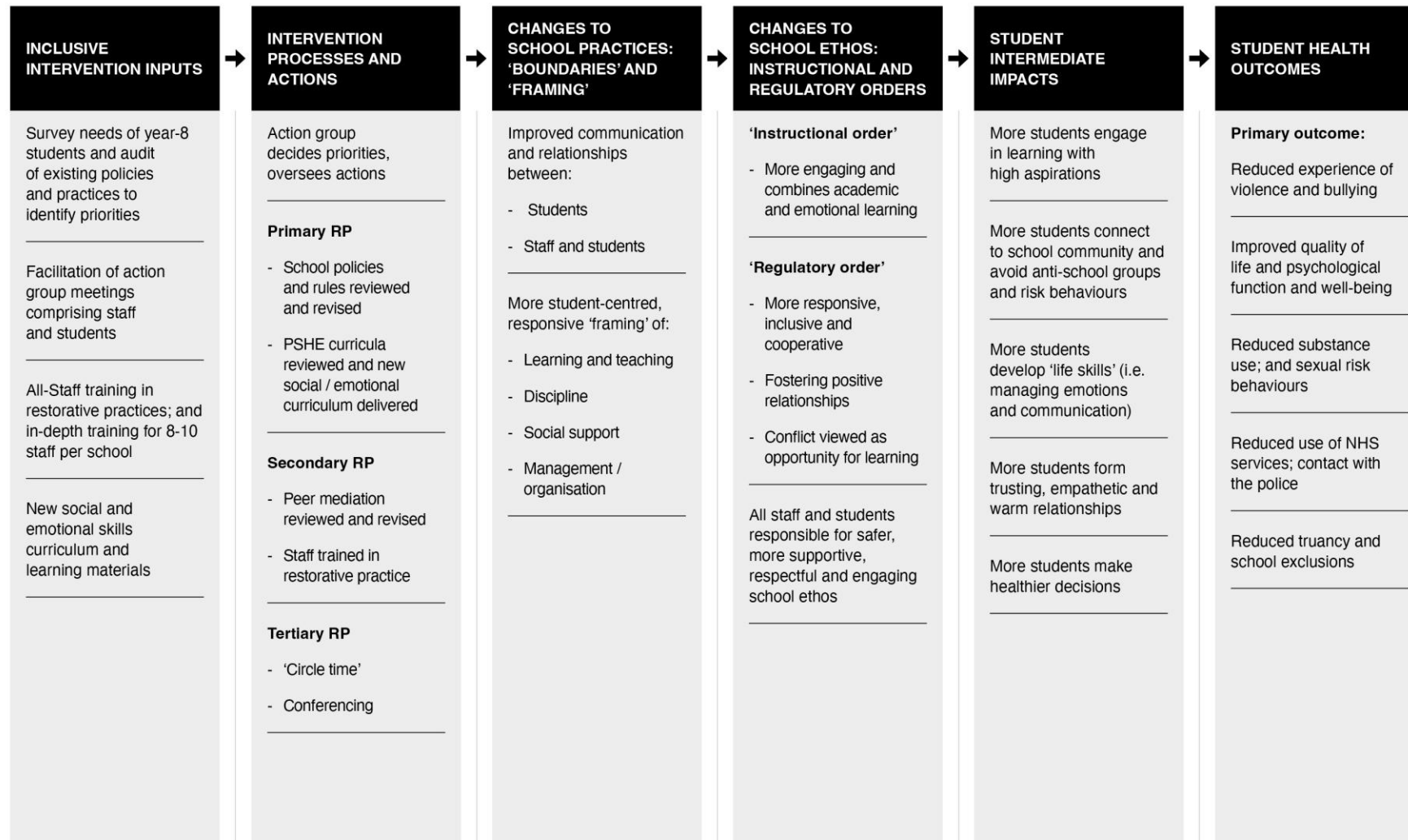


Resources provided to intervention schools:

- Manual (year 1)
- In-depth and all-staff training in restorative practice (year 1)
- SEL curricula (years 1-3)
- Data on student needs (years 1-3)
- External facilitator (years 1-2)



# Logic model



## Can we combine rigour of RCTs with the depth of a realist ontology? (Bonell 2012)

- 1) develop an a priori theory of change and CMOs;
- 2) analyse qual data to explore participant views about plausible mechanisms, paying attention to context, agency, and intervention use and theorised mechanisms, and revise the original CMOs accordingly;
- 3) test these hypotheses; and
- 4) refine mid-range theory

# Concerns about realist RCTs

## Philosophically:

- Realism and RCTs are ontologically incompatible
- RCTs are positivist and successionist

## Practically:

- Randomization and control stifle one's ability to understand how change happens
- Cannot test CMOCs
- RCTs cannot assess mechanisms

# Primary and secondary outcomes

- Reduced bullying, smoking, alcohol, drugs, contact with police, psychosocial problems
- Increased belonging, mental wellbeing and quality of life
- Prespecified moderator analysis showed that:
  - Effects are not moderated by students' socioeconomic status
  - Boys and those with previous experience of being bullied or being a bully at baseline gained most benefit

Bonell, Chris, et al. "Effects of the Learning Together intervention on bullying and aggression in English secondary schools (INCLUSIVE): a cluster randomised controlled trial." *The Lancet* 392.10163 (2018): 2452-2464.

Undertook a thematic analysis to understand how implementation varied by context and found that:

- AGs were a powerful motor for change when leader was both dedicated and on the SLT
- Consistent staff engagement appeared to be crucial to improve wellbeing
- The intervention was not delivered when staff were overwhelmed or felt unsafe
- Curriculum delivered poorly

Warren, Emily, et al. "Action groups as a participative strategy for leading whole-school health promotion: Results on implementation from the INCLUSIVE trial in English secondary schools." *British Educational Research Journal* 45.5 (2019): 979-1000.

# Dimensional analysis to assess mechanisms

- **Increasing students' commitment to school community**
  - Learn others' perspective; improve relationships; initiate change in attitudes to school; increase engagement in whole school changes
- **Build healthy relationships by modelling and teaching pro-social skills**
  - Teach RP/Use RP preventatively; students learn social and emotional skills
- **De-escalate bullying and aggression amongst a core group of students**
  - Perpetrators feel empathy; perpetrators accept responsibility and punishment

	HARPER'S	MEADOWOOD	ST.ANSELM'S
<b>PROCESSES 1: INCREASED COMMITMENT</b>			
1. Learning other's perspectives	✓	✓	✓
2. Improving student/staff relationships	✗ Insufficient and inconsistent staff attendance	✓	✓
3. Participation creates new roles	✗ Lack of support for AG activities	✓	✓
4. AG participants initiate change in students' attitudes to school	✗ AG's ideas unsupported by most staff	✓	* Pro-school attitudes normalised before trial
5. Consult with student body on whole-school changes	✗ SLT rejected suggested changes	✓	✓
	↓	↓	↓
<b>PROCESSES 2: BUILDING HEALTHY RELATIONSHIPS</b>			
1. Teachers use RP to prevent misbehaviour	✗ Teachers felt RP threatened their authority and made them unsafe	✓	✗ Low levels of misbehaviour
2. Students learn social and emotional skills	✗ Neither curriculum nor RP normalised	✓	* Social and emotional skills already present before trial
	↓	↓	↓
<b>PROCESSES 3: DE-ESCALATION IN BULLYING &amp; AGGRESSION</b>			
1. Perpetrators feel empathy	✓	✓	✓
2. Perpetrators accept responsibility and except punishment	✓	✓	✓
	↓	↓	↓
<b>CONSEQUENCES</b>			
1. Decreased bullying and aggression	✗ Poor intervention fidelity	✓	✗ Low rates of bullying and aggression before trial
2. Improved mental health and wellbeing	✗ Poor intervention fidelity	✓	✓

- Assessed whether student sense of belonging at mid-line mediated intervention effects on bullying and mental health in schools that were: a) were rated 'outstanding' for leadership, b) were below the median for average levels of victimisation, and c) were above the median on a scale measuring inclusive ethos.
- In schools with the above features (but crucially not in others) belonging mediated bullying reductions
- In the strata where belonging was not a mediator, the intervention still had a significant effect on each outcome.

Melendez-Torres, G. J., et al. "Moderated mediation analyses to assess intervention mechanisms for impacts on victimisation, psycho-social problems and mental wellbeing: Evidence from the INCLUSIVE realist randomized trial." *Social Science & Medicine* 279 (2021): 113984.



# Qualitative Comparative Analysis (QCA)

## Approach:

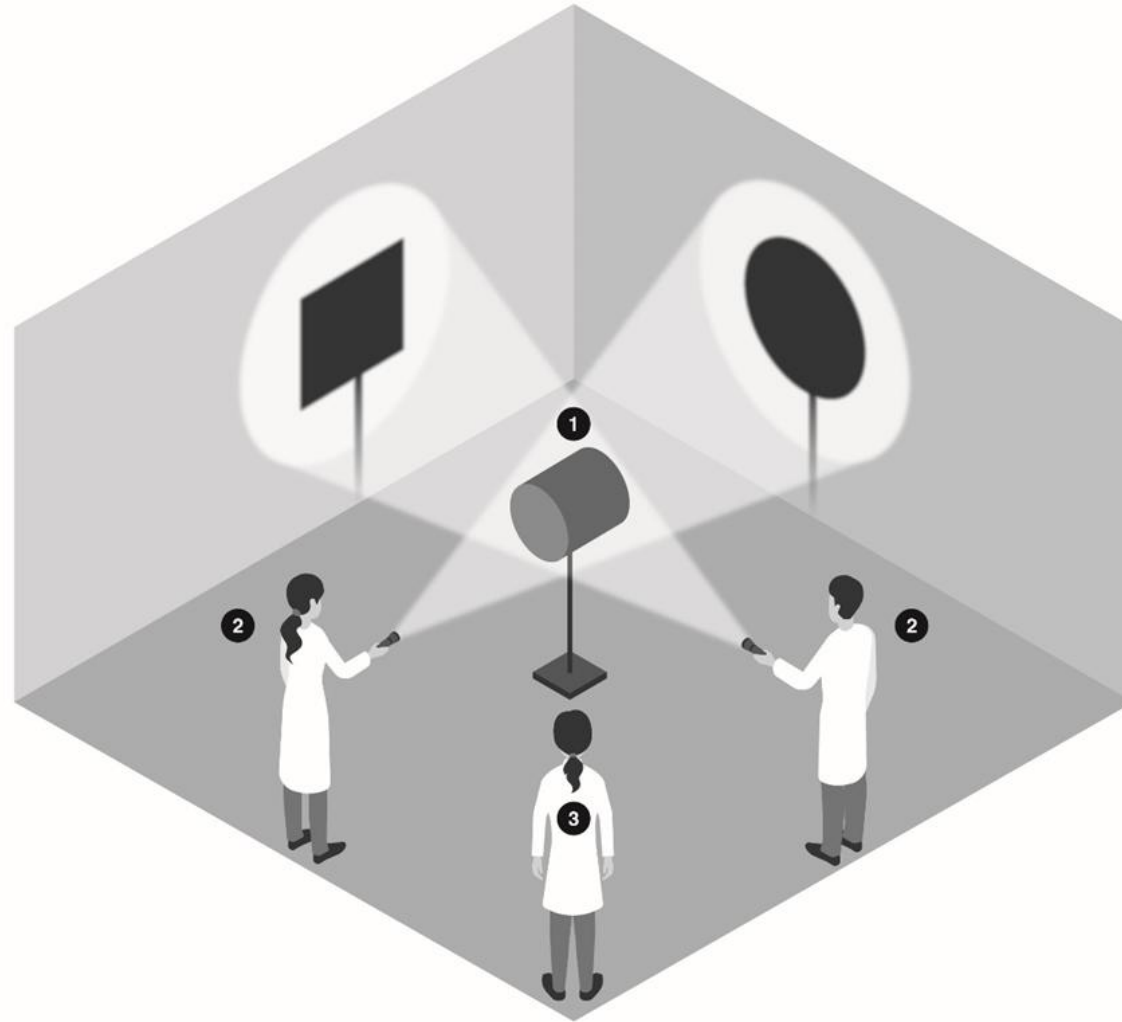
- A method and an approach meant to reveal pathways to (in)effectiveness
- Well-suited to small sample sizes and compatible with realism
- But not without disadvantages:
  - random error may make coincidental patterns appear causal
  - unable to account for confounding

## Findings:

- Schools did not need to activate all (or even many) mechanisms to generate a benefit
- Control schools also activated the same mechanisms (although less frequently)

# Going back to those concerns...

# Concerns about realist ontology:



1 Ontological Realism

2 Epistemic Relativism

3 Judgemental Rationality

# RCTs are positivist

## Tenet of positivism\*

Knowledge is derived from direct, sensory observation

Theoretical terms must directly equate with empirical measurements

The objective of positivism is to generate universally applicable laws

The same methods can be used in the natural and social sciences

# RCTs are positivist and successionist

Tenet of positivism*	Does this apply to trials?
Knowledge is derived from direct, sensory observation	Trials are hypothetico-deductive
Theoretical terms must directly equate with empirical measurements	True of some trials, but not all. Trials should build upon a mid-range theory
The objective of positivism is to generate universally applicable laws	Few (if any) trialists claim their work is universally generalizable but aim to provide guidance on transferability via theory
The same methods can be used in the natural and social sciences	Trials often include qualitative work and answer hermeneutical questions

# RCTs are successionist

Tenet of positivism*	Does this apply to trials?
Knowledge is derived from direct, sensory observation	No, trials are hypothetico-deductive
Theoretical terms must directly equate with empirical measurements	True of some trials but not all. Trials should build upon a mid-range theory
The objective of positivism is to generate universally applicable laws	Few (if any) trialists claim their work is universally generalizable but aim to provide guidance on transferability via theory
The same methods can be used in the natural and social sciences	No, trials can include qual data and answer hermeneutical questions
Successionist (i.e. focus on constant conjunctions)	The use of statistics proves that conjunctions are not constant

Bonell, Chris, et al. "Are randomised controlled trials positivist? Reviewing the social science and philosophy literature to assess positivist tendencies of trials of social interventions in public health and health services." *Trials* 19.1 (2018): 1-12.

- 1) Randomization and control stifle one's ability to understand how change happens
  - Randomization allows for fair comparisons and helps ensure that moderators are balanced
  - Control group gave us the means to test our theories on a comparable population
- 2) Cannot test CMOCs
  - We developed and refine CMOCs with PE data
  - Tested them using moderation, mediation, moderated mediation and QCA
- 3) RCTs cannot assess mechanisms
  - Grounded theory revealed new mechanisms
  - Moderation, mediation, QCA

# Are realist RCTs possible and useful?

INCLUSIVE showed that RCTs can be used to answer questions that are central to realist evaluation

- They can:
  - Build from, test, and refine mid-range theory
  - Unpick patterns in more nuance by being attentive to the importance of context and mechanisms
  - Help consider who and where interventions may be helpful/harmful

None of the methods used here are unique to realists

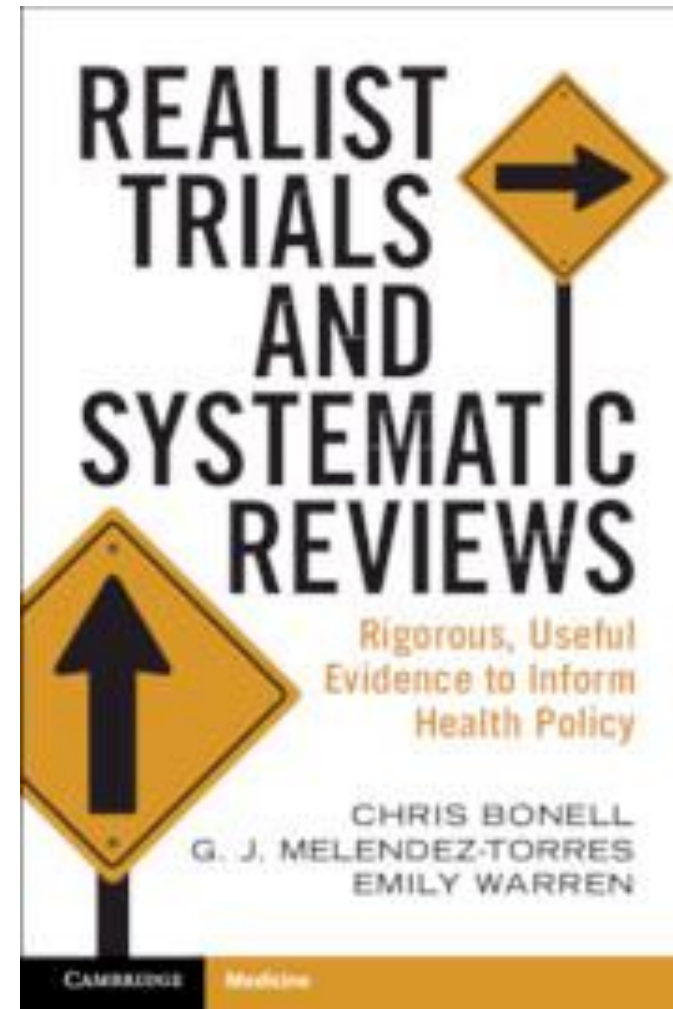


# Considerations for running a realist RCT

- 1) You need a detailed theory of change or logic model tied to a relevant mid-range theory.
- 2) The process evaluation must move beyond feasibility, fidelity, and acceptability to explore mechanisms and their contextual contingencies
- 3) Analyses should be planned that allow you to explore what worked for whom (outcome evaluation); under what conditions (moderator analyses and moderated mediation analyses); and how (fidelity assessment, grounded theory, QCA)

Thank you!

Our new book is  
now available!



# Selected references

- Bonell, C., et al., *Realist randomised controlled trials: a new approach to evaluating complex public health interventions*. Social science & medicine, 2012. **75**(12): p. 2299-2306.
- Bonell, C., et al., *Effects of the Learning Together intervention on bullying and aggression in English secondary schools (INCLUSIVE): a cluster randomised controlled trial*. The Lancet, 2018. **392**(10163): p. 2452-2464.
- Markham, W.A. and P. Aveyard, *A new theory of health promoting schools based on human functioning, school organisation and pedagogic practice*. Social science & medicine, 2003. **56**(6): p. 1209-1220.
- Willis, P.E. and P. Willis, *Learning to labor: How working class kids get working class jobs*. 1981: Columbia University Press.
- Jamal, F., et al., *The school environment and student health: a systematic review and meta-ethnography of qualitative research*. BMC Public Health, 2013. **13**(1): p. 798.
- Bonell, C., et al., *Initiating change locally in bullying and aggression through the school environment (INCLUSIVE): study protocol for a cluster randomised controlled trial*. Trials, 2014. **15**(1): p. 1.
- Moore, G.F., et al., *Process evaluation of complex interventions: Medical Research Council guidance*. bmj, 2015. **350**: p. h1258.
- Van Belle, S., et al., *Can 'realist' randomized controlled trials be genuinely realist?* Trials, 2016.
- Marchal, B., et al., *Realist RCTs of complex interventions—an oxymoron*. Social Science & Medicine, 2013. **94**: p. 124-128.
- Warren, E., et al., *Action groups as a participative strategy for leading whole-school health promotion: Results on implementation from the INCLUSIVE trial in English secondary schools*. British Educational Research Journal, 2019.
- Warren, E., et al., *Using qualitative research to explore intervention mechanisms: findings from the trial of the Learning Together whole-school health intervention*. Trials, 2020. **21**(1): p. 1-14.
- Bonell, C., et al., *Examining intervention mechanisms of action using mediation analysis within a randomised trial of a whole-school health intervention*. J Epidemiol Community Health, 2019. **73**(5): p. 455-464.
- Melendez-Torres, G., et al., *Moderated mediation analyses to assess intervention mechanisms for impacts on victimisation, psycho-social problems and mental wellbeing: evidence from the INCLUSIVE realist randomized trial*. Social Science & Medicine, 2021: p. 113984.
- Warren, E., G.J. Melendez-Torres, and C. Bonell, *Using fuzzy set qualitative comparative analysis (fsQCA) to explore the causal pathways to reduced bullying victimization in a whole-school intervention: results from a cluster randomized controlled trial*. Journal of School Violence (under review), 2021.
- Pawson, R. and N. Tilley, *Realistic evaluation*. 1997: Sage.
- Sayer, A., *Realism and social science*. 1999: Sage.
- Befani, B., S. Ledermann, and F. Sager, *Realistic evaluation and QCA: conceptual parallels and an empirical application*. Evaluation, 2007. **13**(2): p. 171-192.
- Oliver, C., *Critical realist grounded theory: A new approach for social work research*. British Journal of Social Work, 2012. **42**(2): p. 371-387.
- Hanckel, B., et al., *The use of Qualitative Comparative Analysis (QCA) to address causality in complex systems: a systematic review of research on public health interventions*. BMC public health, 2021. **21**(1): p. 1-22.

# Selected references (cont'd)

- Baron, R.M. and D.A. Kenny, *The moderator–mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations*. Journal of personality and social psychology, 1986. **51**(6): p. 1173.
- Sawyer, M.G., et al., *School-based prevention of depression: a randomised controlled study of the beyondblue schools research initiative*. Journal of Child Psychology and Psychiatry, 2010. **51**(2): p. 199-209.
- Shackleton, N., et al., *A new measure of unhealthy school environments and its implications for critical assessments of health promotion in schools*. Critical public health, 2017. **27**(2): p. 248-262.
- Wiggins, M., et al., *Health outcomes of youth development programme in England: prospective matched comparison study*. Bmj, 2009. **339**: p. b2534.
- Schatzman, L., *Dimensional analysis: Outline in preciform*. Unpublished manuscript. University of California, San Francisco, 1980.
- Schatzman, L., *Dimensional analysis: Notes on an alternative approach to the grounding of theory in qualitative research*. Social organization and social process: Essays in honor of Anselm Strauss, 1991: p. 303-314.
- Green, J. and N. Thorogood, *Qualitative methods for health research*. 2013: Sage.
- Pearce, W. and S. Raman, *The new randomised controlled trials (RCT) movement in public policy: challenges of epistemic governance*. Policy sciences, 2014. **47**(4): p. 387-402.
- Rowe, M. and C. Oltmann, *Randomised controlled trials in educational research: Ontological and epistemological limitations*. African Journal of Health Professions Education, 2016. **8**(1): p. 6-8.
- Hinds, K. and K. Dickson, *Realist synthesis: a critique and an alternative*. Journal of Critical Realism, 2021. **20**(1): p. 1-17.
- Bonell, C., et al., *Are randomised controlled trials positivist? Reviewing the social science and philosophy literature to assess positivist tendencies of trials of social interventions in public health and health services*. Trials, 2018. **19**(1): p. 238.
- Bonell, C., et al., *Realist trials and the testing of context-mechanism-outcome configurations: a response to Van Belle et al*. Trials, 2016. **17**(1): p. 478.
- Perez, C.C., *Invisible women: Exposing data bias in a world designed for men*. 2019: Random House.
- Segawa, E., et al., *Evaluation of the effects of the Aban Aya Youth Project in reducing violence among African American adolescent males using latent class growth mixture modeling techniques*. Evaluation review, 2005. **29**(2): p. 128-148.
- Saarento, S., A.J. Boulton, and C. Salmivalli, *Reducing bullying and victimization: Student-and classroom-level mechanisms of change*. Journal of abnormal child psychology, 2015. **43**(1): p. 61-76.
- Merton, R.K., *On sociological theories of the middle range [1949]*. 1949: na.
- Manzano, A., *The craft of interviewing in realist evaluation*. Evaluation, 2016. **22**(3): p. 342-360.
- Bhaskar, R., *The possibility of naturalism: A philosophical critique of the contemporary human sciences*. 2014: Routledge.
- Jamal, F., et al., *The three stages of building and testing mid-level theories in a realist RCT: a theoretical and methodological case-example*. Trials, 2015. **16**(1): p. 1.